

Original Article

A Key Point in Medical Measurements: Device Calibration and Knowledge Level of Healthcare Professionals

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Abstract

Objective: This study was conducted to determine the level of knowledge of healthcare professionals regarding calibration and their ability to consider device calibration for medical measurements.

Methods: Purposive sampling method was used in this cross-sectional descriptive study. The study sample comprised 541 healthcare professionals. The data were collected using personal information form and 'Medical Device Calibration Information Form'.

Results: 72.2% of participants did not receive training on calibration, 40.5% indicated that they had no information about the presence of uncalibrated equipment in their units, and 14.3% reported uncalibrated devices in their units. Total knowledge scores of female participants or those at the age of 35 and older, and doctors or laborants were determined to be significantly higher than the other participants ($p < 0.05$).

Conclusions: It was determined that healthcare professionals had a low level of knowledge about calibration, used non-calibrated medical devices, and did not receive training on calibration. It is recommended that calibration should be introduced as a subject in both the university curriculum and in-service training programs for healthcare professionals.

Key Words: Health and safety, Quality healthcare, Quality assurance, Patient satisfaction, Patient safety

Introduction

Human power and technological, medical devices are used together in providing healthcare services. There has been an increase in the number and variety of medical measurement devices in healthcare along with the currently developing technology. These devices have become even more important in the diagnosis and treatment process. This has resulted in the creation of concepts such as reaching standards, patient safety, quality, and calibration (Sahin, Muldur and Guler, 2003; Ozgules, Aksay and Orhan, 2015).

According to the International Organization for Standardization calibration is the set of operations that establish, under specified conditions, the relationship between values indicated by a measuring instrument, a measuring

system or values represented by a material measure, and the corresponding known values of a measurand (International Organization for Standardization, 1993).

Accuracy and reliability of all measurements would be doubtful if the instruments used were not calibrated. Calibration ensures that a measuring instrument displays an accurate and reliable value of the quantity being measured (United Nations Industrial Development Organization (UNIDO), 2006).

Calibration is the process of reporting measurement results by comparing the reference measurement device, which is ascertained to its accuracy, with another measurement device whose accuracy cannot be ascertained. Calibration is not an adjustment operation,

maintenance or the repair of a device (Persson, 2014; Turkish Standards Institution, 2017).

The importance of calibration has been increasing in devices used in healthcare (Sahin, Muldur and Guler, 2003; Songur, 2013). Since the World Health Organization (WHO) considers medical calibration measurements as part of quality health care, it publishes guidelines for standard practice and seeks to ensure that health care providers focus on the issue (Sezdi and Altay Gunes, 2017).

Faulty measurements by medical devices may result in misdiagnosis and false treatment, leading to an increase in medical costs and a threat to patients' lives (Aytekin, Cevlik and Emerk, 2009; Kurutkan, Akaytay and Mete, 2014). For instance, the use of non-calibrated medical devices such as blood pressure monitors (sphygmomanometer), thermometers and glucometers lead to uncertainty in the accuracy and reliability of their measurements (United Nations Industrial Development Organization (UNIDO), 2006). Moreover, calibrated weight and height measurement devices should be used in obesity treatment, as its treatment is based on height and weight measurements (Sen, 2016).

Calibration, which refers to the proof of the reliability of a measurement device, directly affects the quality of patient care and efficiency in healthcare services (Tuna, 2011; Persson, 2014). Thus, medical calibration services are priority issues that need to be considered both regarding legal and social responsibility as well as the quality of health services. It is also a requirement for quality certificate that contained within 'Health Quality Standards' of Ministry of Health, Republic of Turkey. But especially important for patient safety (Kirsac, 2015; Turkish Standards Institution, 2017).

A large number of medical devices require periodic maintenance and calibration (Sahin, Muldur and Guler, 2003; Cable, 2005). Measurement devices should be calibrated when first delivered, or after each repair, adjustment, and maintenance, or in the pre-determined periods or upon any doubt about their measurement results. If the device has been dropped or hit or damaged after calibration, or if its calibration period has passed, it should be re-calibrated (Turkish Standards Institution, 2017). For devices that are being relocated but are not mobile and require to be installed and fixed, re-

testing, checking, and calibration are necessary (Ozgules, Aksay and Orhan, 2015).

It is the responsibility of the user, namely the healthcare professionals, to follow the device calibrations, especially after environmental changes. The calibration awareness and practices of healthcare professionals are of great importance for avoiding medical errors that may arise due to incorrect measurements. However, there have been no studies to determine the level of knowledge of healthcare professionals regarding calibration. Therefore, the present study was conducted to determine the level of knowledge and behavior of service providers in the healthcare industry regarding medical device calibration services.

Method

Study Design : This study was conducted in a cross-sectional descriptive design to determine the level of knowledge of healthcare professionals regarding calibration and their ability to consider device calibration for medical measurements. These medical devices are consist of clinical devices (digital thermometer, glucometer, sphygmomanometer, defibrillator, electrocardiograph device patient monitors), in vitro devices (automatic pipet, complete blood count, sediment control) and the other medical devices (ultrasound, X-ray devices).

Setting and sample : The study was performed in a university hospital located in the eastern part of Turkey and accreditation works were conducted.

The health centre has a working quality management system. All part of this health centre has some national and international quality certificates.

These certificates are ISO 9001, ISO 14001, ISO 18001 and Health Quality Certificate given by Ministry of Health, Republic of Turkey. And also hospital does not have international accreditation. Shortly hospital certified but not accredited. It was carried out in the period from 16 June to 16 September 2017. The study was conducted in the hospital's internal medicine, surgical, pediatric, obstetric, laboratory, and emergency departments, as well as in oral and dental health units.

The study consisted of nurses, doctors, laborants, midwives and dentists working in university hospitals. The purposive sampling method was

used for sample selection. The research data were collected in intensive care units, oral and dental health units, emergency units and laboratories wherein many medical technological devices were used where calibration was more important.

Moreover, data were also collected from pediatric and surgical units with a higher likelihood of drop-hitting for devices. The study sample consisted of 625 healthcare professionals working in the units mentioned above. Among these, 84 subjects, who were absent or refused to participate in the study or did not complete the questionnaire, were not included in the study.

Thus, the study was completed with the participation of 541 healthcare professionals who fully and correctly completed the survey.

Data Collection : The data were collected using a face-to-face interview technique through the 'Medical Device Calibration Information Form' developed by the researchers and the personal information form asking about the socio-demographic characteristics of healthcare professionals.

The Medical Device Calibration Information Form consisted of two parts including 23 questions. The first part consisted of 8 questions designed to obtain general information and behavior of healthcare professionals about calibration (taking into account device calibration, checking calibration document, requesting calibration, and receiving training).

The second part consisted of 15 questions aiming to measure the level of knowledge of healthcare professionals regarding calibration and asking about the definition of calibration, units responsible for device determination and follow up, the frequency of required device calibration, equipment to be calibrated, and conditions and reasons for calibration. Healthcare professionals received 1 point for each correct answer and 0 points for each incorrect answer, and then the mean score for their knowledge level on calibration was calculated (min: 0 max: 15).

The draft questionnaire was sent to seven biomedical engineers and five EOQ Quality specialists for their expert opinion, and then

necessary arrangements were made on the form in line with their expert opinions. Finally, a pilot study was conducted on a group of healthcare professionals with 50 people to examine the

clarity of the questionnaire. No problems were encountered in the pilot study, and the survey form was finalized.

Data Analysis : The SPSS 21.0 Version package program was used to evaluate the data. The frequency, percentage, mean, and standard deviation from descriptive statistics, t-test and ANOVA test from independent groups and Bonferroni test from multiple comparison tests were used in the data analysis. The findings obtained were interpreted at 95% confidence interval at a significance level of 0.05.

Ethical considerations: Before starting the research, an ethical approval and relevant written permissions were obtained from the Committees of Scientific Research and Publication Ethics at İnönü University and the health institutions in which the survey was conducted. Written approvals were obtained from the participants after they read the written approval form containing information on the purpose of the study. The researchers interviewed participants individually to avoid interactions among them. There was no conflict of interest between the researchers and participants, referring to no risk of material / moral damage to each other.

No master list of participants was kept in order to ensure confidentiality. Thus, no one knows or will know who did or did not participate and no one knows what was reported.

Results

The mean age of participants was 31.6 ± 6.9 years (min:19, max:54), their mean professional experience was 8.6 ± 7.4 years (min:1, max:34), and the mean working experience in their currently employed unit was 4.1 ± 4.5 years (min:1, max:30). Moreover, among the participants, 34.5% were at the age range of 19-27 years, 65.2% were women, 51% and 24.9% had bachelor and post-graduate degrees, respectively, and 46.5% were working in internal medicine units. Most of them were nurses (73.9%), and 8.6% of nurses were working as chief or trainer nurses (Table 1).

Table 1. Some Sociodemographic Characteristics of Healthcare Professionals

Characteristics	n	%
Age		
19-27	190	34.5
28-34	184	33.4
35 and upper	177	32.1
Gender		
Female	359	65.2
Male	192	34.8
Occupation		
Nurse	407	73.9
Doctor	93	16.9
Dentist	18	3.3
Laborant	17	3.1
Midwife	16	2.9
Educational Status		
High School/Associate Degree	135	24.1
Bachelor degree	279	51.0
Graduate degree	137	24.9
Working Unit		
Units of internal medicine	256	46.5
Surgical units	136	24.7
Pediatric units	70	12.7
Emergency services	31	5.6
Oral and dental health unit	21	3.8
Gynecological and obstetric units	20	3.6
Laboratories	17	3.1
Total	482	100

Table 2. Healthcare Professionals' Behaviors Related to Medical Device Calibration

	Yes		No	
	n	%	n	%
Receive training in calibration	153	27.8	398	72.2
Place emphasis on calibration	300	54.4	251	45.6
Request for calibration	271	49.2	280	50.8
Take calibration results into account	488	88.6	63	11.4
Check calibration certificate of a new device	359	65.2	192	34.8
Control device calibration	324	58.8	227	41,2
Use of non-calibrated device	185	33.6	366	66.4
Non-calibrated device in the unit *	79	14.3	249	45.2

* 223 people (40.5%) stated that they did not know.

Table 3. Comparison of Total Knowledge Score of Healthcare Professionals on Calibration by Some Variables

	n	$\bar{X}\pm Sd$	Statistical analysis	p
Gender*				
Female	359	8.8±1.9	t: 2.29	0.022
Male	192	8.4±2.2		
Age**				
19-27	190	8.2±2.2	F:15.87	0.000
28-34	184	8.6±1.9		
35 and upper	177	9.3±1.8		
Occupation**				
Nurse	407	8.6±2.0	F:3.032	0.017
Doctor	93	9.1±2.2		
Dentist	18	8.3±1.8		
Laborant	17	9.9±1.1		
Midwife	16	8.4±1.5		
Working Unit**				
Units of internal medicine	256	8.7±1.9	F:2.318	0.032
Surgical units	136	8.7±1.9		
Pediatric units	70	8.8±2.1		
Emergency services	31	7.8±3.2		
Oral and dental health unit	21	8.6±1.8		
Gynecological & obstetric units	20	8.3±2.0		
Laboratories	17	9.9±1.1		
Educational Status**				
High School/Associate Degree	135	8.7±2.4	F:0.030	0.970
Bachelor degree	279	8.7±2.1		
Graduate degree	137	8.7±2.0		
Calibration training*				
Yes	153	8.9±2.0	t: 1.303	0.193
No	398	8.6±2.0		
Non-calibrated device use*				
Yes	185	8.1±2.2	t: -5.164	0.000
No	366	9.0±1.9		

* t-test was applied.** ANOVA test was applied.

Among the participants, 72.2% did not receive training on calibration, 54.4% gave due importance to calibration, and 49.2% requested calibration for a device. Moreover, 88.6% reported that they controlled the result of calibration in medical device use, but only 65.2% and 58.8% reported that they controlled the calibration certificate of a new device and routinely checked the calibration in medical device use, respectively. Among those (n=324) who reported that they controlled calibration for medical devices, 69.4% (n = 225), 25.7% (n=83) and 4.9% (n=16) stated that they controlled it through a checking device label, barcode, and certificate, respectively. Participants were asked about their use of non-calibrated equipment, and 66.4% reported that they would not use a non-calibrated device. As reasons for not-using a non-calibrated device, 65.5% (n = 238) stated that the device would not produce correct results, 23.5% (n = 86) stated that the device would not be reliable, and 8.2% (n = 30) stated that the device would not function properly.

Among the participants, 92.4% stated that devices were required to be calibrated, while 96.7% reported that calibration influenced the diagnosis and the treatment process. Moreover, 40.5% indicated that they had no information about the presence of uncalibrated equipment in their units, and 14.3% reported uncalibrated devices in their units. The mean score on the level of knowledge of the participants regarding calibration was determined as 8.71 ± 2.0 (min: 2 max: 14). It was determined that females, over 35 years old, doctors and laborants received significantly higher total scores on the level of knowledge about calibration. The relationship between the total knowledge score and the currently employed unit and the use of non-calibrated medical devices was found to be statistically significant ($p < 0.05$). (Table 3)

It was found that the lowest and highest total scores on the level of knowledge about calibration were received by those with a high school diploma and a post-graduate degree, respectively. However, this difference was statistically insignificant. Moreover, the relationship between calibration training and total knowledge score was also statistically insignificant ($p > 0.05$).

Discussion

Scientific and technological developments significantly affect healthcare, and high

technology medical devices are used intensively in hospitals. Periodical maintenance, repair, and calibration of the devices used in providing efficient and high-quality service have become prominent. Failure to comply with these rules may yield erroneous results (Coskun and Comlekci, 2011; Mishra *et al.*, 2013).

In the context of patient safety, deaths may occur due to incorrect measurements by devices. To avoid such situations with devastating effects, it is necessary to calibrate all measurement devices used in hospitals and consider their calibration results (Kurutkan, Akaytay and Mete, 2014). According to this study, all participants reported that calibration was necessary, and it had substantial effects on diagnosis and treatment. A previous study that investigated the level of knowledge of healthcare professionals regarding calibration indicated that the vast majority of participants claimed to have information about the importance of calibration in medical devices (Ozcan and Yurdakos, 2016).

Accurate and reliable results without damage to patients are possible by calibrating these devices at regular intervals (Gulec *et al.*, 2009). It was found that 14.3% of the participants reported an un-calibrated device in their units, and 40.5% had no knowledge on the calibration of medical devices they used. These conclusions can be interpreted as the result of not giving priority to the accreditation works of health institutions in the developing countries. This may increase the risk of use of uncalibrated devices in the developing nations.

It is important to calibrate equipment both before and after their use to obtain best measurement results, and accordingly make correct decisions (Persson, 2014). Similarly, a new device must be calibrated before its first use to ensure its accuracy. In the present study, however, only 65.2% of the participants reported to checking the calibration certificate of devices for their first use. Calibration is required after some environmental changes in addition to the initial use of the device and at specific intervals (Cable, 2005; Turkish Standards Institution, 2017). Moreover, nearly half of the participants (41.2%) reported that they did not consider calibrations in the routine use of devices. The medical devices being exposed to drop, hit or damage are the most likely to produce faulty measurements, posing a risk to patients.

Medical technology management in hospitals is being implemented by biomedical engineering departments. In this respect, a biomedical unit must be found in hospitals to carry out better calibration services (Ozgulles, Aksay and Orhan, 2015). Similarly, 92.2% of the participants reported that a biomedical unit should be established in hospitals. However, the fact that the bio-medical unit is not the only responsible department for monitoring and follow-up of medical devices should be considered and the device users, who play an important role regarding this, should also be held accountable.

Although device calibration is not a difficult or expensive procedure, 33.6% of the participants reportedly used non-calibrated medical devices (Rouse and Marshall, 2001). This situation can be interpreted as a faulty medical measurement and threat to patient safety. Rouse and Marshall (2001) examined the sphygmomanometers used routinely ($n = 1462$) and found that 9.2% of them made measurement errors. Similarly, some different study results suggest that sphygmomanometers as the most commonly used devices in medical practice make faulty measurements at various ratios (McVicker, 2001; Sahin, Muldur and Guler, 2003; Sen, 2016). Sezdi (2010) calibrated some medical devices in different units of a hospital and accordingly found that 26.6% of defibrillators, 21.4% of ECG devices, and about half of patient monitors made faulty measurements (Sezdi, 2010). There are similar studies at literature that have made faulty measurements (Waugh *et al.*, 2002; Mishra *et al.*, 2013). The World Health Organization reported in 2005 that more than half of the medical devices in developing countries were not properly functional (Kirsac, 2015). Faulty measurements can lead to improper processing, which may have potentially serious consequences.

Only 27.8% of the participants reported having training on the calibration of medical devices. Kirsac determined that 20.3% of nurses, 19.7% of doctors and 38.5% of other healthcare personnel received training on the calibration of medical devices (Kirsac, 2015). These results corroborate our findings. However, this indicates that the rate of healthcare professionals receiving such training on the subject is very low. Considering that the present study was conducted in a non-accredited health center, the low rate of medical personnel with calibration training

suggests that more attention should be given to the subject.

The mean score of the level of knowledge on calibration received by participant healthcare professionals was determined as 8.71 ± 2.0 . Although there is no reference in related studies, the highest score of 15 taken from the scale indicates a low mean score of healthcare professionals. The study conducted by Sezdi and Altay Gunes it was reported that while nurses have a certain knowledge background on calibration measurements, this level of knowledge is not sufficient (Sezdi and Altay Gunes, 2017). The low level of knowledge of healthcare professionals about calibration may be due to the low rate of having relevant training activities (27.8%), and the fact that calibration is not included in the training curriculum.

The total knowledge score of the healthcare professionals, who were older than 35 years, was significantly higher than those in other age groups. This situation can be explained by the increase in occupational working years and professional experience together with the increase in their ages.

The difference between the mean scores of the level of knowledge on calibration received by healthcare professionals according to their profession types was found to be statistically significant. Bonferroni test suggested that this difference was because of the doctor and laborant group. The participant dentists, midwives, and nurses were found to have lower total knowledge scores. Similarly, another study determined the knowledge levels of nurses to be lower than that of doctors and technicians (Kirsac, 2015). This result may be because nurses consider calibration as the duty of chief nurse.

Ozcan and Yurdakos conducted a study with 202 healthcare professionals, including physicians, midwives/nurses and health technicians, and found that the level of consciousness in medical device calibration was significantly higher in polyclinic workers than other groups (Ozcan and Yurdakoş, 2016). The present study determined that the difference between the total knowledge scores of the participants according to their currently employed units was statistically significant.

The personnel working in the laboratory and the emergency services received the highest and lowest mean knowledge scores, respectively.

Bonferroni test suggested that this difference was because of the people working in laboratory and emergency units. It can be asserted that the low knowledge scores in emergency service workers may be due to the high patient intensity and workload in this unit.

The relationship between the total knowledge score and the use of non-calibrated medical devices was statistically significant ($p < 0.05$). This also shows the effect of having knowledge of calibration on behavioral change and can be considered as a sign that the problem can be solved by increasing awareness in device users. It was determined that participants with high school diplomas and post-graduate degrees received the lowest and highest total knowledge scores, respectively; however, this difference was statistically insignificant. This situation demonstrates that the lack of knowledge on calibration applies to health professionals at all levels of education. Therefore, it is possible to infer that there is a lack of necessary emphasis on calibration in the curriculum of most schools, from health vocational schools to post-graduate education. The knowledge scores of participants who received calibration training were determined to be higher than those without such training, but the difference between the groups was statistically insignificant. Although the difference between the groups is not significant, the higher scores in the participants with calibration training reveals the necessity of training for healthcare professionals.

Limitations: The greatest limitation of this study is was conducted only one hospital. It is a single-centre experience. The study results may be different in accredited health institutions and organizations. Moreover, this study was planned and implemented as a cross-sectional type study. Although the relationship between some variables was determined, the causal relations were not explained.

Conclusion: As a result of the study, it was determined that healthcare professionals had low levels of knowledge about calibration and most of them used non-calibrated medical devices and did not receive training on calibration.

Necessary training activities should be provided at adequate levels to ensure that all healthcare personnel, particularly nurses, have sufficient knowledge of calibration. Moreover, the inclusion of calibration and its importance in the curriculum will be useful in raising the level of

awareness of healthcare professionals. General and on-site unit-based training should be mandatory in the annual training plans of health institutions. Further extensive studies on the subject are recommended to gain new insights into this issue.

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