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Abstract

Background: The safety and reliability of medical devices are becoming more emphasized as time passes. Crisis situations such as COVID-19 have shown the negative effects that can be brought upon by a lack of medical device surveillance mechanisms.
Objectives: The aim of this study is to present the results of the implementation of the legal metrology framework conducted by joint efforts of the State Center of Expertise and Standardization of Medicines, Medical Devices, and Medical Equipment and the Uzbek National Institute of Metrology.
Methods: The study was based on the data collected from annual performance inspections in all healthcare institutions in the period from 2016 to 2021 for 37 types of medical devices. Data envelopment analysis was used to derive conclusions and the results were compared with results from Bosnia and Herzegovina.

Results: Results indicate that the implementation of legal metrology the framework leads to a significant increase in the accuracy of medical devices hence leading to increased reliability and patient safety in diagnostic and therapeutic processes.
Conclusions: Fault prediction of medical devices enables more effective maintenance strategies thus enhancing cost-effectiveness and decreasing the downtime of equipment. This in turn leads to a more efficient healthcare system capable of facing challenges of the society.

Keywords (separated by '-')	Legal metrology - Medical devices - Accuracy - Healthcare system

Implementation of Legal Metrology Framework for Medical Devices to Healthcare Sector in the Republic of Uzbekistan

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1 Introduction

Crisis situations like COVID-19 always point out bottlenecks in the sector in which they occur. Emergency authorization of medical devices during the COVID-19 pandemic has shown a great need for dedicating a significant degree of attention to the entire healthcare

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sector and the operations within with an emphasis on medical devices [1]. Besides skilled healthcare professionals, medical devices are a key component ensuring functionality of the healthcare system [2]. Today, there are over 2 million different kinds of medical devices on the world market, categorized into more than 7000 generic devices groups [3]. More than 90% of diagnoses and treatments made by medical professionals are based on the results of analysis using medical devices, and the remaining 10% are based on other diagnostic methods such as direct physical examination and anamnesis. Since the measurements made by medical devices are used for diagnosis, prevention, monitoring of diseases, and life support, they pose a potential risk to the patient's life [4].

Medical devices, as such, have to be overseen and regulated at all phases of their lifespan, from ideation phase to utilization in healthcare institutions [5]. Rapid progress in the healthcare systems in recent years has been brought upon by the emergence of biomedical engineering and significant advancements in digital technologies. This rapid growth in both interest and volume of modern medical devices developed and produced each day has made policy makers more aware of adverse events that can occur if the devices are not overseen in a proper way [5]. Hence, medical device oversight while the devices are operating on the market has become more stringent in the past years and enforced by the relevant directives. The European Union and the US Food and Drug Administration have developed databases containing information regarding adverse events caused by medical device malfunction or failure. The Manufacturer User Facility Database (MAUDE) contains reports regarding medical device-associated adverse events and device recalls reported by manufacturers, importers and device user facilities and voluntary reporters such as health care professionals, patients and consumers [6]. European database on medical devices (EUDAMED) is one of the key mechanisms for implementation of new rules on medical devices [7]. It provides the public with evidence-based representation of the lifecycle of medical devices used on the market of the European Union. It integrates a variety of electronic systems that collate and process information regarding medical devices and manufacturers. Hence, it enhances the transparency and coordination of activities related to medical devices between different EU member states.

Legislation on medical devices in the European Union (EU) is managed by the European Commission in close cooperation with Health Authorities of the member states. Medical devices manufacturers must have CE Marking, comply with international standards and EU legislation in order to place the certain device on the EU market. The EU legislation has been in a transition period from the Medical Devices Directives (MDD 90/385/EEC and 93/42/EEC) [8, 9] to the Medical Device Regulations (MDR 2017/745 and 2017/746) [10, 11]. The new MDRs entered into force in 2017 and replaced the previous MDDs [10, 11].

In the United States of America (USA), the Food and Drug Administration (FDA) is the responsible institution for regulating medical devices [12]. In Australia, the responsible body for regulating medicine and medical devices is The Therapeutic Goods Administration (TGA) which is part of the Australian Government Department of Health and Ageing [13]. China Food and Drug Administration (CFDA) oversees medical devices and ensures their safety and effectiveness, and protects human health and life in China [14]. This responsibility is taken by Pharmaceuticals and Medical Devices Agency (PMDA) in Japan [15]. In terms of scope, all of the aforementioned documents cover the same,

they all require premarket evaluation of medical devices, and they mention post-market surveillance. However, the methodology of post-market surveillance is quite variable amongst the aforementioned guidelines and there is a large discrepancy on the market [5]. Countries worldwide have initiated efforts and constructed guidelines for medical device surveillance. Best practices of MD surveillance are those that are evidence-based and Bosnia and Herzegovina [16–22], Portugal [23], Serbia [24] and Saudi Arabia [25] are already implementing these practices. A paper by Badnjevic et al. [5] revises all PMS strategies laid out by national and international guidelines and proposes the best solution that could be used as a reference standard. Evidence-based medical device performance assessment is founded on metrology principles with an aim of ensuring traceability of measurements and treatments made by medical devices. Metrology is the science of measurement process ensuring that measurement meets specified degrees of both accuracy and precision.

Metrology institutes from all over the world have different infrastructure and experience in the field of measurements in healthcare. The most influential metrology institutes in the world, that regulate subject areas such as bioscience and health, medical devices, diagnostics, standard reference materials, biomedical optics sections and medical devices metrology and standards are NIST (National Institute of Standards and Technology) [26] from USA, LNE (Laboratoire national de métrologie et d'essais) [27] from France and PTB (The Physikalisch-Technische Bundesanstalt) [28] from Germany. In Spain, Portugal, Saudi Arabia, Republic of Serbia, Bosnia and Herzegovina [5], and the Chezch Republic medical measurement devices are subject to legal metrology and metrological inspection carried out periodically. These inspections are carried out either by metrology organizations or accredited inspection laboratories and the results of inspection are entered in a single registry. This approach allows for continuous monitoring of medical devices, assessment of their performance, and identification of potential risks and their prevention [29].

In Uzbekistan, the demand for healthcare increased dramatically in the last years because of the rising prevalence of preventable, non-communicable diseases and the suboptimal use of healthcare resources [31]. Along with it, the field of legal metrology for medical devices advanced as well. For example, e-metrology online platform has been created and it has been used since the beginning of 2021. The two main organizations taking responsibility for medical device performance inspection according to metrological characteristics of measurands are the Uzbek National Institute of Metrology (UzNIM) [32] and the State Center of Expertise and Standardization of Medicines, Medical Devices, and Medical Equipment.

(SCESMMDME) of The Ministry of Health. The Institute of Metrology [33] has the following functions:

(a) implementation of a unified state policy in the field of metrology, ensuring the uniformity and reliability of measurements in assigned regions and by types of measurements;
(b) storage and maintenance at an appropriate level of high-precision initial and exemplary measuring instruments;
(c) development of the national metrological service;

(d) improvement of existing methods and means of measurement of the highest accuracy, standardization of methods and means of measurement, control and testing;
(e) organization of work on state tests in order to approve the type of measuring instruments;
(f) organization of work on metrological certification, verification, and calibration of measuring instruments [32].

The main objectives of SCESMMDME include the following activities:

(a) organization and implementation of quality control by the state;
(b) registration and permitting the use of local and foreign drugs, medical measurement devices, and medical equipment;
(c) coordination of activities and management of institutions and organizations engaged in the examination, standardization, certification of pharmaceutical and medical products;
(d) metrological control of medical measurement devices;
(e) conducting examinations, laboratory and clinical trials, as well as approval of regulatory documents [33].

In cooperation with these two organizations, a list of medical devices with measuring function has been developed and registered by the Ministry of Justice of the Republic of Uzbekistan on August 22, 2017, under No. 2916 [34]. This decree was developed based on the learning experience of Moldova [35], Russia [36], Belarus [37], Ukraine [38], Kirgizia [39], and Kazakhstan [40] and comparison between their laws and decrees related to list of measuring and testing devices that are subject to metrological control. According to the decree, a total of 32 measuring medical devices and 5 testing medical devices are subject to metrological control. For the 37 medical devices included in the legal metrology framework, there are 11 different measurement and testing functions. For the purpose of this study, the devices that share the same measurement or testing function are grouped and presented as a single device, and those are: Electroencephalograph (EEG), Electrocardiograph (ECG, including holter, cardio monitor), Pulse oximeter, Sphygmomanometer, Electromyograph, Exoencephalograph, Rheographs (including Rheoanalyzers), Ultrasound diagnostic device, hematological analyzer, biochemical analyzer, and physiotherapy equipment (including low frequency therapy devices, ultra high frequency therapy devices, ultrasound therapy devices). After the introduction of these devices into the legal metrology of Uzbekistan, there was a firm foundation for carrying out metrological control once a year by two responsible organizations based on decree No2916 [34].

As there is a significant discrepancy, and lack of overall harmonization of procedures for post-market surveillance of medical devices, it is of high importance to develop traceable methods that show significant results in decreasing the rate of faulty medical devices. Such method was developed by the UzNIM and SCESMMDME and the results of this method, along with the impact on the state of the medical device performance in healthcare institutions in Uzbekistan is presented in this study.

2 Methods and Materials

According to the Uzbek legal metrology framework, medical device performance inspections are conducted annually. In this study, data was collected on the territory of Uzbekistan during the period of January 1, 2016 to December 31, 2021. The methodology according to which the devices were inspected, along with the permissible deviations is shown in Table 1.

Table 1. Description of monitored parameters, maximum allowed error limits and reference guidelines.

Medical device under test	Parameters that are monitored	Maximum allowed error limit	Guidelines
Electroencephalograph (EEG)	Relative error of calibration error (amplitude calibrator and time stamp calibrator) signal	±2%	O‘zDSt 8.089:2020 State system for ensuring the uniformity of measurements of the Republic of Uzbekistan electroencephalographs, electroencephaloscopes and electroencephalo-analyzer Verification procedure
	Measurement range and relative error of amplitude and time parameters of EEG signals	7–15%	
	Level of internal noise brought to the entrance	2%	
	Relative error of signal spectral composition	1,5–4 μV Frequency-≤10%, Amplitude- ≤15%	
Pulse oximeter	Voltage measurement error	±10% (±15%)	O‘z DSt 8.091:2020 State system for ensuring the uniformity of measurements of the Republic of Uzbekistan. Patient monitors. Methods and means of verification
	Time measurement error	±10%	
	Internal noise voltage applied to the input	≤25 μV	
	Amplitude-frequency description (AChT-AChX) unevenness	From—10% to 5%	
	Heart rate range and measurement error	Based on user manual	
	Pressure measurement error	Based on user manual	

(*continued*)

Table 1. (*continued*)

Medical device under test	Parameters that are monitored	Maximum allowed error limit	Guidelines
	SpO2 oxygen saturation measurement error	Based on user manual	
	Temperature measurement error	Based on user manual	
Sphygmomanometer	Hermeticity of the pneumo-system of pressure gauges	From 2 mmHg/impulse to 3 mmHg/impulse	O‘zDSt 8.090:2020 State system for ensuring the uniformity of measurements of the Republic of Uzbekistan. Arterial pressure meters non-invasive mechanical, semi-automatic and automatic. Methods and means of verification
	Electrical resistance of the insulation	More than 20 MΩ	
	Electrical strength of the insulation	–	
	Pressure measurement error	± 3 mmHg	
Electrocardiograph (ECG, including holter, cardio monitor)	Measurement range and relative error of amplitude and time parameters of signals	Based on standard forms of signal and ± 3%	O‘zDSt 8.086:2019 State system for ensuring the uniformity of measurements of the Republic of Uzbekistan. Electrocardiographers, electrocardioscopes and electrocardio analyzers. Methods and means of verification
	Voltage measurement error	± 10% (± 15%)	
	Time interval measurement error	± 10%	
	Calibration voltage error	± 5%	
	Internal noise voltage applied to the input	Less than 25 μV	
	Shifting of signals between channels	Less than 1 mm	
	Range of input voltages	Based on user manual	
	Amplitude-frequency description (AChT-AChX) unevenness	Based on user manual	
	Time constant	Based on user manual	

(*continued*)

Table 1. (*continued*)

Medical device under test	Parameters that are monitored	Maximum allowed error limit	Guidelines
	Heart rate range and measurement error	± 5%	
	ST segment level measurement error	± 25 μV	
Electromyograph	Bioelectric activity of muscle and nerve structures	Based on user manual	QU 15.92:2018 Methods and means of verification of electromyograph
Exoencephalograph	Functional parameters based on the geometric dimensions of the examined internal anatomical structures of the patient's body organs and tissues, the size of the fetus, the cardiovascular system, the speed of blood flow in the vessels, the parameters of the structure of the brain and the principle of ultrasound examination	Based on user manual	QU 15.92:2018 Methods and means of exoencephalograph
Rheographs (including Rheoanalyzers)	Muscle impedance, electrical resistance of the blood system and tissues	Based on user manual	QU 15–350:2016 Methods and means of rheographs (including rheoanalyzers)
Ultrasound diagnostic device	Resting zone	±10 mm (for all sensors), ± 3 mm (for linier sensor)	O'z DSt 8.085:2019 State system for ensuring the uniformity of measurements of the Republic of Uzbekistan. Medical ultrasonic diagnostic echo pulse scanning systems with doppler function. Methods and means of verification
	Measurements in vertical direction, distance measurement	± 1 mm	
	Measurements in horizontal direction, distance measurement	± 2 mm	

(*continued*)

Table 1. (*continued*)

Medical device under test	Parameters that are monitored	Maximum allowed error limit	Guidelines
	Axial and lateral solutions	At least 4 targets from each group of phantom targets should be clearly imaged without distortion	
	Width of the focal zone	At least 8 targets should be clearly imaged without distortion	
	Sensitivity (maximum depth of ultrasound penetration)	Based on user manual	
	Gray scale and dynamic range to be reflected	–	
Hematological analyzer	Relative error of Hematological analyzer (Blood test, hematological analysis (analysis) parameters)	Based on user manual	ГОСТ 8.627–2013 Interstate Standart. Hematological analyzer. Means of verification
Biochemical analyzer	Relative error of biochemical analyzers	Based on user manual	O‘z DSt 8.045:2015 State system for ensuring the uniformity of Measurements of the Republic of Uzbekistan. Bio-chemical analyzers methods and means of verification
	Mean square error of optical density measurement results	Based on user manual	
Physiotherapy equipment (including low frequency therapy devices, ultra high frequency therapy devices, ultrasound therapy devices)	Output parameters of low-frequency therapeutic devices	Based on user manual	QU 15.93:2018 Methods and means of verification of physiotherapy equipment

Table 1 shows that methods which are used for the verification of medical devices in Uzbekistan fits at some points with the methods which are used for the verification of medical devices in Bosnia and Herzegovina [41–49].

The data from 2016 to 2021 was collected manually based on the reports of UzNIM and SCESMMDME while the data for 2021 was retrieved from the e-metrology platform.

In order to analyze the results of implementation of the legal metrology framework, a total number of medical devices was identified and all reports corresponding to those devices were reviewed. Table 2 presents the data regarding inspected and non-inspected medical devices in healthcare institutions.

The inspected medical devices were further classified into two categories, accurate (A) where measured output of the device is within maximum permissible error for all measurement points and faulty (F) where measured output of the device is outside the permissible error limit for the inspected device.

Data envelopment analysis (DEA) is a helpful nonparametric method in operations research for performance evaluation by measuring the efficiency scores of the decision-making units (DMUs). The fundamentals of DEA are based on a nonparametric approach that solves the problem of determining the efficiency of various DMUs according to how inputs are converted into outputs [42].

Two inputs and one output were chosen:

X1—percentage of medical devices that were carried out metrological control in 2016.

X2—percentage of medical devices that were carried out metrological control in 2021.

Y1—percentage of increase of accurate medical devices, where applicable.

3 Results and Discussion

When comparing the ratios of inspected and non-inspected medical devices in the first year of implementation of annual performance inspections and 2021, the results indicate a substantial improvement and a 71% increase in the percentage of inspected devices accompanied with the same reduction in non-inspected devices (Table 2.).

Table 2. Percentage of inspected and non-inspected medical devices

Year	2016 (%)	2021 (%)
Inspected medical devices	15	86
Non-inspected medical devices	85	14

The fraction of non-inspected medical devices decreased significantly when comparing 2016 and 2021. In 2016, the fraction of non-inspected medical devices decreased from 75 to 14% while the fraction of inspected devices increased accordingly from 15 to 86%. The estimated figures for 2016 and 2021 indicate that this trend will continue, and all medical devices will be covered by metrological control in the upcoming years.

An important aspect to consider, both regardless and with respect to the number of inspected devices is the ratio of accurate and faulty devices. As indicated in Fig. 1, in 2016, almost 21.3% of inspected medical devices were faulty, while 78.7% of them were accurate. In 2021, 7.4% of inspected medical devices were faulty, while 92.6% of them

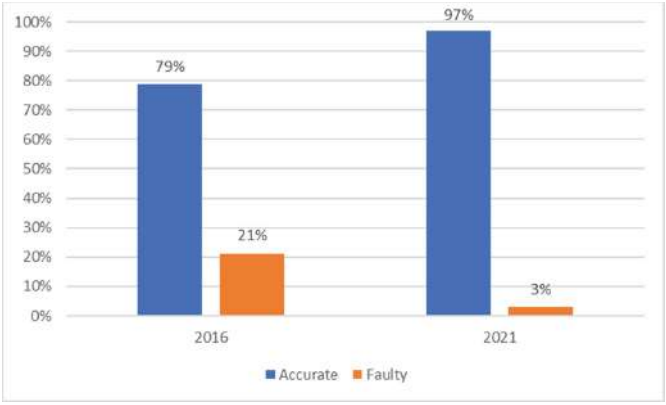

Fig. 1. Increase in the accuracy of medical devices between 2016 and 2021.

were accurate. This shows a substantial increase in the safety and performance reliability of medical devices due to the implementation of the legal metrology framework.

Table 3 illustrates key findings of metrological control of medical devices after the 6 year implementation of the legal metrology framework. The most significant improvement in the number of devices subjected to metrological control was observed in electromyography devices, where an 84% point increase is observed. On the other hand, the fraction of pulse oximeter devices subjected to metrological control has experienced the lowest increase of 41%. The reason for the low percent increase observed with pulse oximeters is the fact that they have been incorporated in legal metrology in 2020 while other devices were incorporated much earlier. A factor that has to be taken into consideration is the import rate, which significantly affected the rate of metrological inspection of electromyography devices, where a significant increase in their metrological inspection rates was observed in accordance with their increased presence on the market.

The fraction of accurate electromyograph, exoencephalograph, and rheograph devices inspected in 2021. Is 100%, as indicated in Table 3. In comparison with 2016, metrological inspection of these devices indicates a 21%, 18% and 19% increase in the percentage of accurate devices respectively. This emphasizes the positive effect that regular metrological control has.

When observing all of the medical devices encompassed under the legal metrology framework in Uzbekistan, the percentage of accurate medical devices has increased from 69 to 93% over the course of 6 years, while the overall percentage of inspected devices increased from 15 to 86% over the same time period.

To emphasize the results, the discussion focuses only on the medical devices exhibiting the highest and lowest increase in the percentage of inspected devices in the period of 6 years. The highest increase is observed in physiotherapy equipment while the lowest increase is observed in sphygmomanometers.

Figure 2 shows that in 2016 faulty physiotherapy equipment had the highest rate of faulty devices and in 2021, that decreased significantly. The percentage of faulty devices was lowered by 24%.

Table 3. Improvement in the accuracy of each inspected medical device in 2021 com- pared to 2016

Purposed medical device	The percentage of inspected medical devices in 2016, X1 (%)	The percentage of inspected medical devices in 2021, X2 (%)	Percent point, (%)	2016		2021		Percent point, Y1 (%)
				X (%)	✓ (%)	X (%)	✓ (%)	
EEG	23	89	76	23	77	2	98	21
ECG	17	92	75	25	75	6	94	19
Pulse oximeter	0	41	41	0	0	39	61	0
Sphygmomanometer	21	85	64	24	76	8	92	16
Electromyograph	7	91	84	21	79	0	100	21
Exoencephalograph	11	93	82	18	82	0	100	18
Rheographs	14	87	73	19	81	0	100	19
Ultrasound diagnostic device	19	90	71	25	75	9	91	16
Hematological analyzer	22	94	72	22	78	1	99	21
Biochemical analyzer	20	95	75	23	77	4	96	19
Physiotherapy equipment	15	86	71	35	65	11	89	24
Average:	15	86	71	21	69	7	93	17

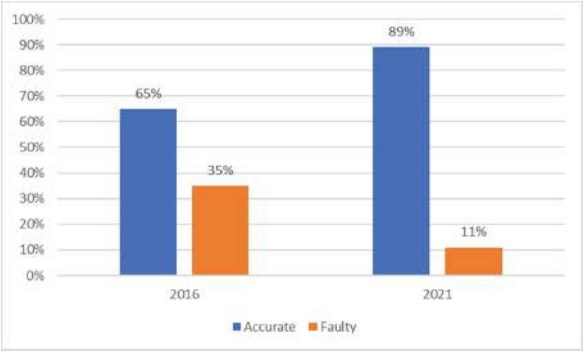

Fig. 2. Improvement in the accuracy and performance of Physiotherapy equipment in 2021 compared to 2016.

The main factor for such kind of increase is the widespread use of physiotherapy equipment, and the high interest in their performance inspection in order to ensure high quality treatment for patients.

Figure 3 shows an increase in accuracy and performance of sphygmomanometers that is the lowest one among the inspected medical devices. In general, this result is also satisfactory, because in 2016, the percentage of accurate sphygmomanometers was 76% and it went up to 92% in 2021. However, considering the high utilization of these devices in regular medical practice, the 16% increase is expected to improve in the following years.

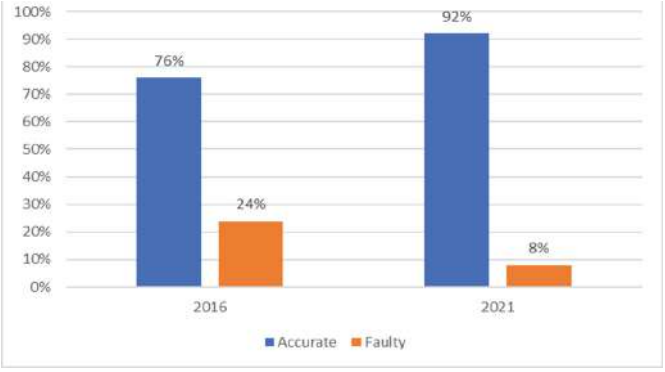

Fig. 3. Improvement in the accuracy and performance of Sphygmomanometer in

During the analysis process of metrological control of Sphygmomanometers, the fact that many healthcare institutions still use mercury sphygmomanometers and low-quality electronic sphygmomanometers was taken into consideration. Hence, the accuracy drawbacks were expected. However, in order to ensure safety and accurate treatment of all patients, UzNIM and SCESMMDME should give more attention to strengthening the metrological control of the Sphygmomanometer and make adjustments to the verification procedure.

In order to emphasize the significance of this methodology, the results achieved in Uzbekistan are compared with the results achieved in Bosnia and Herzegovina. The results of implementation of the legal metrology framework in these two countries are comparable due to the fact that the guidelines for performance evaluation have the same permissible error limits. When considering all medical devices, the accuracy was significantly higher in Bosnia and Herzegovina in the initial year, hence the implementation of legal metrology framework did not result in a large increase in the percentage of accurate devices (Fig. 4.)

The percent increase in the accuracy of physiotherapy equipment due to implementation of the legal metrology framework in physiotherapy equipment is more significant in Uzbekistan in comparison with Bosnia and Herzegovina (Fig. 5.). The reason for this is the same as for all medical devices, the better initial state of the equipment in healthcare institutions.

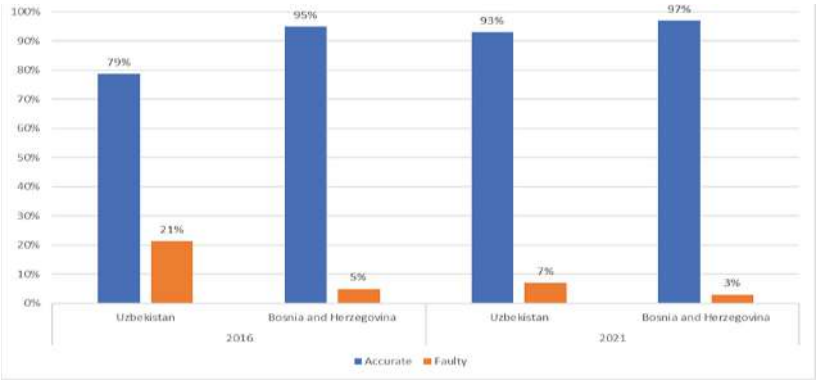

Fig. 4. Improvement in the accuracy and performance of medical devices in Bosnia and Herzegovina and Uzbekistan

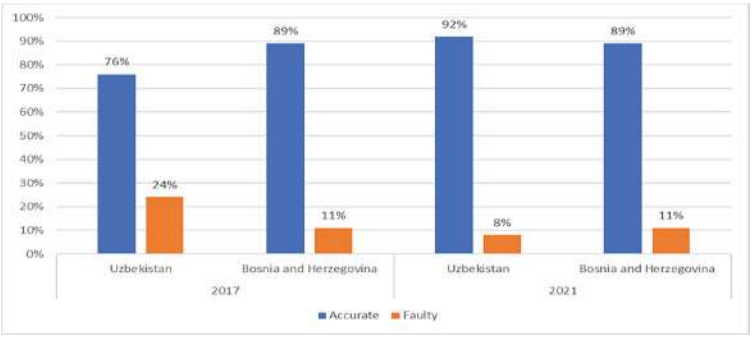

Fig. 5. Improvement in the accuracy and performance of physiotherapy equipment in Bosnia and Herzegovina and Uzbekistan

The percent increase in the accuracy of sphygmomanometers due to implementation of the legal metrology framework in physiotherapy equipment is more significant in Uzbekistan in comparison with Bosnia and Herzegovina (Fig. 6). However, the implementation of the legal metrology framework has resulted in higher accuracy of sphygmomanometers in Uzbekistan in 2021 when compared with the accuracy of these medical devices in Bosnia and Herzegovina.

The statistical analysis shows that the market coverage of medical devices is directly proportional to their higher accuracy since most prominently used medical devices are the ones whose performance is most vital for healthcare workers. Additionally, increased import rate of medical devices consequently leads to a conclusion that old and faulty medical devices are decommissioned to use new medical devices. The most crucial point is that every hospital, clinic and diagnostic center should understand decommissioning impacts to increase the accuracy and reliability of medical devices.

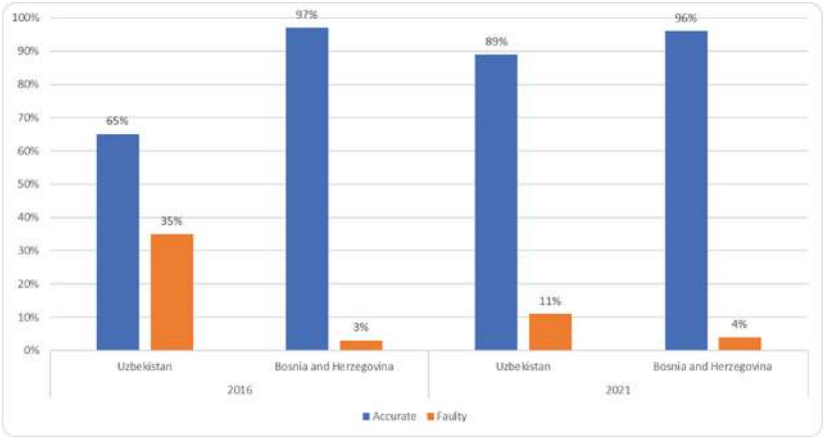

Fig. 6. Improvement in the accuracy and performance of blood pressure monitors (sphygmomanometers) in Bosnia and Herzegovina and Uzbekistan

The data collected during annual performance inspections regarding the visual state of the device, electrical safety and performance is digitized [42] to maximize its usefulness. As this data is collected in a standardized manner, it ensures traceability of measurements made by medical devices and the best usefulness of data is derived by using it for predictive modeling of device behavior to implement the best possible maintenance strategies [43]. Performance predictions for several medical devices were done using artificial intelligence based on the data collected during annual performance inspections in Bosnia and Herzegovina [52–87].

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4 Conclusion

Legal norms in the field of medical metrology in the Republic of Uzbekistan are aimed at protecting the rights and legitimate interests of citizens and are regulated by the Uzbek Agency for Technical Regulation. Annual metrological inspection of medical devices serves to ensure continuous quality of diagnoses and treatments given to patients and human health and well-being.

The results of this study, which is the first of this kind for Uzbekistan, shows that effective implementation of the legal metrology framework for medical measurement devices has the potential to prevent possible errors in the use of medical devices. In comparison between the results of case studies which were carried out in Bosnia and Herzegovina, the results of this study suggest similar trends as the results of research carried out in Uzbekistan. Hence, it can be concluded that the proposed methodology is indeed effective.

In addition to providing health benefits for all patients and healthcare workers, implementation of the legal metrology framework leads to an increase in cost-effectiveness of maintenance systems and makes planning of maintenance possible. Future endeavors will be devoted towards development of artificial intelligence based algorithms for performance prediction of medical devices thus resulting in predictive maintenance

infrastructure that will significantly contribute to both cost-effectiveness and accuracy of diagnostic processes in healthcare.

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