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#ЗАНАМИБУДУЩЕЕ

Совет молодых ученых и специалистов
«Техноспецназ Росстандарта»

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COST EFFECTIVENESS OF LEGAL METROLOGY IN UZBEKISTAN AND APPLICATION OF ARTIFICIAL INTELLIGENCE TO MEDICAL DEVICES PERFORMANCE PREDICTION

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Abstract

In today's developing world a large number of different modern medical devices are used for diagnosis, treatment and prevention of diseases. In meantime safety and reliability of medical devices are becoming more emphasized as the time passes.

The aim of this study is to analyze application capability of artificial intelligence to medical devices performance prediction and to present the results of implementation of legal metrology framework.

The study was based upon 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 show that the legal metrology framework is implemented effectively in Uzbekistan and it leads to a significant increase in the accuracy of medical devices. However highly recommended to apply artificial intelligence systems to medical device performance prediction in order to early detection of the degree of inconsistency of the medical devices.

Fault prediction of medical devices enables more effective maintenance strategies thus enhancing cost-effectiveness and decreasing the down time of equipment. This in turn leads to a more efficient healthcare system capable of facing challenges of the society.

Keywords: *legal metrology, medical devices, accuracy, artificial intelligence, performance prediction*

1. Introduction

Today, there are over 2 million different kinds of medical devices on the world market, categorized into more than 7000 generic devices groups [1]. 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 [2].

Medical devices, as such, have to be overseen and regulated at all phases of their lifespan, from ideation phase to utilization in healthcare institutions [3]. 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.

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 (MDD90/385/EEC and 93/42/EEC) [4, 5] to the Medical Device Regulations (MDR2017/745 and 2017/746) [6, 7]. The new MDRs entered into force in 2017 and replaced the previous MDDs [6, 7].

In the United States of America (USA), the Food and Drug Administration (FDA) is the responsible institution for regulating medical devices [8]. 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 [9]. China Food and Drug Administration (CFDA) oversees medical devices and ensures their safety and effectiveness, and protects human health and life in China [10]. This responsibility is taken by Pharmaceuticals and Medical Devices Agency (PMDA) in Japan [11]. 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 [12–18], Portugal [19], Serbia [20] and Saudi Arabia [21] are already implementing these practices. A paper by Badnjevic et al., [3] revises all PMS strategies laid out by national and international guidelines and proposes the best solution that could be used as a reference standard.

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 [22]. 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) [23] and the State Center of Expertise and Standardization of Medicines, Medical Devices, and Medical Equipment (SCESMMDME) of The Ministry of Health [24].

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 [25]. This decree was developed based on the learning experience of Moldova [26], Russia [27], Belarus [28], Ukraine [29], Kirgizia [30], and Kazakhstan [31] and comparison between their laws and decrees related to list of measuring and testing devices that are subject to metrological control. 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).

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.

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 1 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 [32].

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 1).

Table 1. 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.

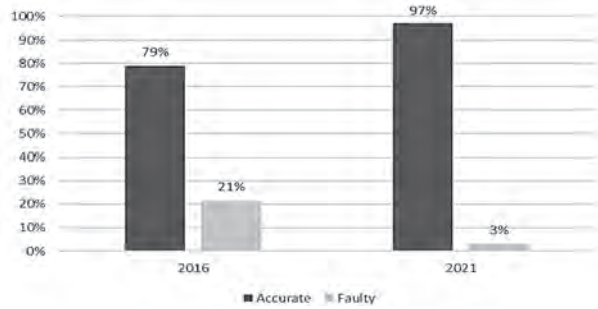

Fig. 1. Increase in the accuracy of medical devices between 2016 and 2021

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 Figure 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 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 2 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.

Table 2. Improvement in the accuracy of each inspected medical device in 2021 compared to 2016

Purposed Medical Device	The percentage of inspected medical devices in 2016, X_1 (%)	The percentage of inspected medical devices in 2021, X_2 (%)	Percent point, (%)	2016		2021		Percent point, Y_1 (%)
				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

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.

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 (Figure 2).

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.

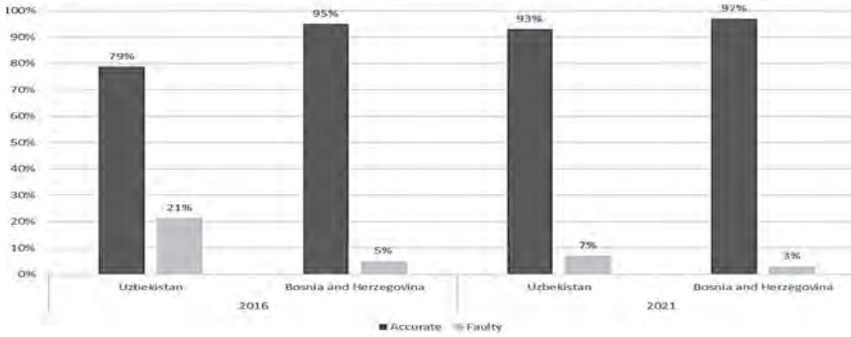

Fig. 2. Improvement in the accuracy and performance of medical devices in Bosnia and Herzegovina and Uzbekistan

The data collected during annual performance inspections regarding the visual state of the device, electrical safety and performance is digitized [33] 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. It means that these digitalized data allows to apply performance prediction of medical devices.

Based on existent data highly recommended to develop performance prediction model by using artificial intelligence (AI).

AI covers digital methods, ranging from computer vision to deep learning techniques, which model intelligent behavior without human intervention. It has been applied to many areas of medicine, especially to aid the detection and prevention of disease. In respect to traditional computer programming, AI methods emulate the decision-making process of humans.

In order to implement AI to the medical device performance prediction, medical devices inspection information will be used and it's block diagram is given in figure 3. Mainly medical devices inspection consists of 3 charts:

a) visual inspection — cleanliness, labeling/marking, casing and part integrity, manufacturer, type, serial number;

b) assaying — main voltage, protective earth resistance, connection to the patient;

c) determination of metrological characteristics — measured values depending medical devices functions and it's accuracy.

In the block diagramm medical devices inspection information will be used as an input layer ($X_{1,...Z}$) and data which is processed by expert system will be used as an output layer.

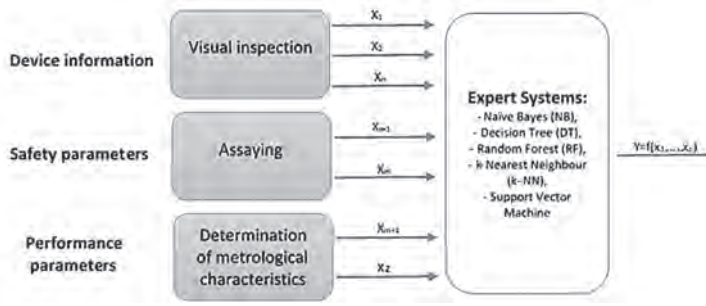

Fig. 3. Block diagram for the application of AI to MD performance prediction

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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29. Decree of the Cabinet Ministry of the Republic of Ukraine June 4, 2015 N 374 "On approval of the list of categories of measuring equipment subject to periodic verification".

30. Decree of the Government of the Republic of Kyrgyz September 27, 2012 N 664 "On measures to implement the Law of the Kyrgyz Republic "On ensuring the uniformity of measurements".

31. Decree of the Ministry of Health of the Republic of Kazakhstan November 24, 2009 N 765 "On approval of the List of medical equipment, which is a means of measurement".

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