

IMPACT OF APPLYING INTERNATIONAL QUALITY STANDARDS ON MEDICAL EQUIPMENT IN SAUDI ARABIA

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ABSTRACT

With the great development that, modern medical technology is witnessing today, medical devices and equipment have become a basic pillar of any healthcare system in the world and cannot be dispensed with, so we find competition between the major companies that manufacture medical devices and equipment resulting in a huge variety of complex modern medical technologies. These medical devices and equipment require high accuracy in manufacturing and packaging in addition to operation, maintenance, and follow-up, because any error in any of the previous stages will have bad consequences for the patients and the health system, there are many accidents that have led to some deaths. Therefore, we find that many medical device producers and medical companies in addition to health service providers seek to find systems and protocols to reduce accidents resulting from medical devices. As a result, many systems have recently appeared that seek to protect from the dangers of medical devices and equipment. This research aims to conduct a study of the effects of international standards on the safety of medical devices and equipment and reduce their risks. By counting the international standards in force in the Kingdom of Saudi Arabia that are applied by the Saudi Food and Drug Authority, making questionnaires, and distributing them to health service providers and regulatory bodies for medical devices and equipment, considering the data, these data will be analysed and evaluated the effectiveness of quality systems and standards in maintaining Effectiveness and quality of medical devices and equipment. The study will include governmental and private health services sectors.

KEYWORDS

Medical devices, standards, safety, regulatory affairs, questionnaires

1. INTRODUCTION

Globally, "medical devices or medical equipment and medical supplies" means everything that is used in the medical field and the field of healthcare provision, from wound patches to major devices such as medical imaging devices, biometric devices of various types, and prosthetic and alternative devices such as prosthetics and others [1]. No one can deny that medical devices and equipment contribute mainly to helping doctors and medical specialists to perform their duties and greatly facilitate their work. We find that doctors rely very heavily on medical devices and equipment for diagnosis and conducting examinations and treatment at other times, examples of this are very many, and due to the great importance of medical devices and equipment, many companies and factories have tended to compete in the design, manufacture and development of medical devices and equipment in addition to medical supplies, Therefore, we find the multiplicity and abundance in the companies that manufacture and develop medical devices in

competition and remarkable diversity, which led to the flooding of the medical field with many medical devices and equipment of various kinds, if we take only as a model of blood pressure measuring devices, we will find a large number of them in one store not to mention the other markets [2]. It is known that commercial interference in any field makes it vulnerable to many issues such as commercial fraud, greed, and low quality. To avoid falling into such problems and protect consumers and the health field, governments seek to create laws that work to regulate medical devices, equipment and supplies through global and local standards aimed at protecting consumers [3]. As we find that the World Health Organization (WHO) pays very great attention to this position, and we find that governments have worked to establish institutions and bodies such as food and drug agencies and standards and metrology bodies that operate according to international regulations, laws and standards aimed at regulating medical devices, equipment, and medical supplies [4]. The WHO is working with their partners to achieve medical device nomenclature uniformity, which will have the substantial influence on the patient safety. This is especially crucial for detecting negative event recalls and reports [5, 6]. All medical apparatus on the market at the enactment time of the pre-amendment devices—were divided into three categories by the FDA under the 1976 Medical Device Amendments (MDA, P.L. 94-295). The three classes—Class I, Class II, and Class III—were defined by Congress based on the risk the devices posed to patients (low, moderate, and high, respectively). The type of regulatory regulations that must be followed by a manufacturer is determined by device categorization. The regulatory requirements for each class are discussed in greater depth below. Unless exempted by law, general controls apply to all three classes of FDA-regulated medical devices, and controls at this level are the only ones that apply to Class I devices. Premarket notice, device listing, establishment registration, and good manufacturing practice standards are examples of broad controls[7]. Under present law, Devices in class I are those for which there are no specific control are sufficient to offer reasonable assurance of the device's safety and effectiveness. Devices in Class II represent a patient's moderate risk, and they may include novel apparatus for that knowledge or controls are available to decrease or mitigate risk. Although most devices of Class II are passed through the premarket notification process, a handful are exempt [8]. Class III devices are highly-regulated 'high risk' medical device—e.g., pacemakers and heart valves—approved by the FDA. The clinical effectiveness of a gadget is a good predictor of its performance. Technical functions, in addition to clinical effectiveness, may be included in performance.

Every device was created with a specific purpose in mind. When a device produces the effect anticipated by the maker in relation to the medical condition, it is considered clinically effective. An alert feature, for example, may not directly contribute to therapeutic effectiveness but may be valuable in other ways [9]. Furthermore, performance is easier to objectively evaluate and quantify than therapeutic effectiveness. Safety and performance are inextricably intertwined. As a result, medical device safety and performance are frequently addressed in tandem. The preceding section emphasizes a medical device's inherent danger. The medical device producer is responsible for demonstrating that all potential risks connected with the product have been identified and effectively handled [10].

The regulatory authority's job is to make sure the manufacturer has followed the risk management procedure and met all other regulatory requirements. Regulations contain terms that are legally binding and hence have limited meanings. Vendors, merchants, manufacturers, and distributors, for example, all have exact definitions in rules, and their definitions change between countries [11,12]. Different countries use distinct words for post-market surveillance, which have the different implications. The Task force of Global Harmonization which is working to introduce various terminologies currently. In this Guide, the phrase "post-market surveillance" refers to all the monitoring efforts, including the in use medical apparatus vigilance system [13]. Post-market testing, rather than pre-market testing, is the most important control point for medical devices.

Post-market testing, rather than pre-market testing, is the most important control point for medical devices. Medical Device Authority (MDA)'s two complementary strategy of Adverse Incident and Vigilance reporting Scheme make this a considerable activity. The Agency supports incident reporting via direct electronic means. The database of Agency's allows for trend analysis and can detect underreported sectors and geographic locations. Over the previous five years, the MDA has implemented a sequence of the measures to enhance rates of reporting, which have resulted in a 12 percent annual rise in reports and is depicted in Figure 1. The reporting system enables the Agency to keep track of the device's safety and take corrective action as needed.

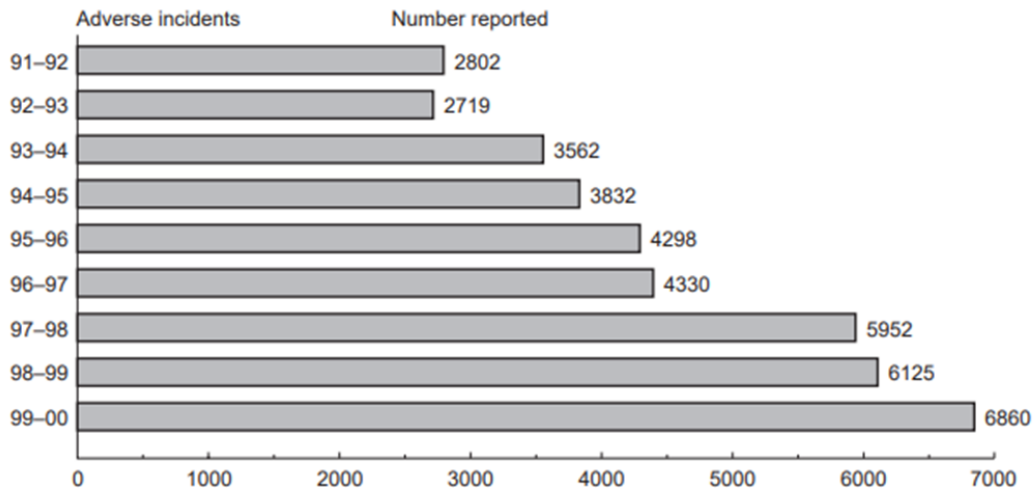


Figure 1: The number of adverse incident reports over the period 1991 to 2000

When an event is reported, the MDA's professional team investigates it in collaboration with the hospital and the manufacturer. By identifying the fundamental cause of device-related events and conveying the users and manufacturers issues, MDA can prevent recurrence. Figure 2 depicts the causes of bad occurrences reported in the previous year. MDA conducted the more serious incidences investigations in-depth throughout that time.

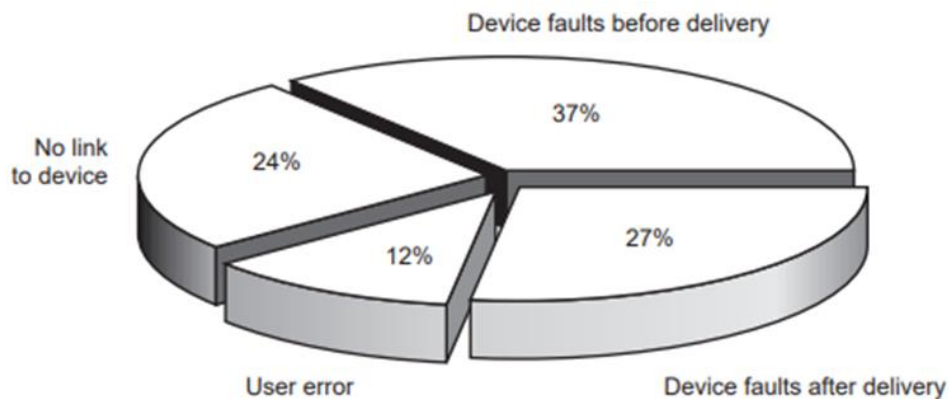


Figure 2: The causes of adverse incidents reported during April 1999 to March 2000

Some investigations result in the dissemination of safety recommendations. MDA issued 8 Advice Notices, 36 Safety Notices and eight Device Alerts, last year. Safety and Hazard Notices require receivers to take urgent action. Manufacturer actions are occasionally reinforced through Safety Notices. Figure 3 depicts the findings of the investigations. In 149 incidents, the Agency

oversaw device recalls or repairs and provided advise on how to use devices safely or improve training of staff [14]. Every device carries a level of risk and may cause issues in various situations. Many flaws medical apparatus is not detectable until for the long period the product has been on the market. An implantable device, for example, could fail in an unexpected way now of the implantation; the dereliction could be due to factors that are specific to certain patients. The present-day approach for the safety of device is to predict the likelihood of a gadget becoming a hazard, posing a risk of injury or death. The risk assessment is a term used to describe this estimate [15].

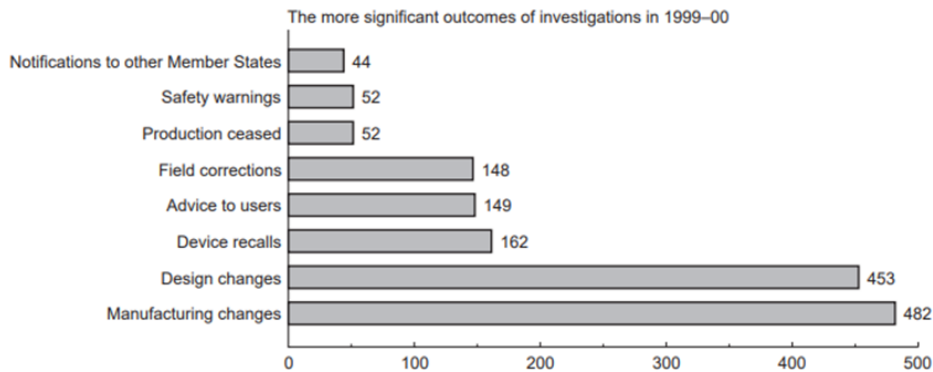


Figure 3: The more significant outcomes of investigations during 1999 to 2000

The benefit/ risk nature of medical devices is highlighted in this remark. As a result, the focus is to increase benefit while minimizing risk [16]. The risk management method is also used by medical device manufacturers. The International Organization for Standardization (ISO) has published a document (ISO 14971:2000) that provides framework for manufacturers for risk management in medical device design, development, manufacturing, and post-sale monitoring, including risk analysis, risk control and risk evaluation [17]. The first three phases of a medical device's life span are normally managed by the manufacturer, as indicated in Figure 4. Distributors, Importers, merchants, and manufacturers (who trade their medical device) are all considered vendors. The User is usually a health-care professional, although it could also be one of the patients [18]. The Public/Patient and the Government, along with these three types of people who are directly associated with the various medical devices' phases, are also essential interested parties. The ultimate benefactor of the medical apparatus is public, and they are also the users of over-the-counter gadgets [19, 20].



Figure 4: Persons who directly manage the different phases of medical devices

The most crucial component in ensuring all these stakeholders' collaboration is a thorough and shared grasp of the issues. Communication and mutual education may effectively achieve shared understanding and accountability. This can be accomplished efficiently by involving all stakeholders in the development of a process which ensures performance and safety of the medical devices.

2. MATERIALS AND METHODS

With extremely advanced, computerized hospital devices to basic wooden tongue extensor muscles, healthcare systems cover the gamut. Regulations reflect public policy by encapsulating society's expectations for just how facilities and systems should operate. Regulators, whose create and regulate, have the authority to determine policy in the interest of the public and are eventually publicly accountable. Standardization helps to society's critical services, such as environment and health, while somehow encouraging durability and sound regulatory behavior. the International Organization for Standardization (ISO), the International Telecommunication Unionid the International Electrotechnical Commission (IEC) are three international organizations that develop International Standards (ITU). International Standards (rather than state or global criteria) have become increasingly important in the trade process, maintaining a fair playing field for exporting and guaranteeing that imports fulfil internationally recognized safety and performance standards [21-27].

The purpose of this research is to find the impact of applying international quality standards on medical devices and equipment in consumer protection. The main pipeline of the research methodology is divided into four main parts targeted population, design of questionnaire, data evaluation and summary of results as shown in figure 5.

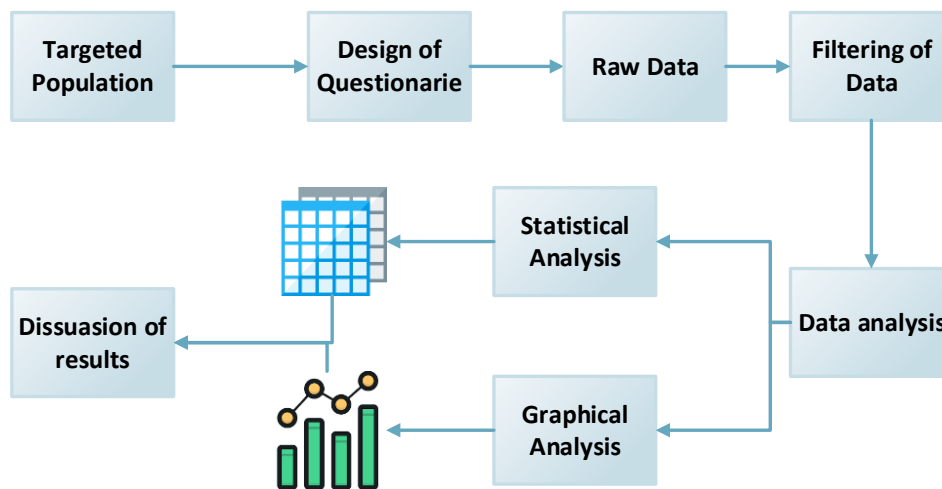


Figure 5. Block diagram of the proposed method

To start the analysis for the research topic we must define the group or population which are targeted in this research domain. The targeted population is the staff, specialists, workers, doctors' nurses of the hospital hence everyone working in the hospital is part of the system as well part of the survey of this research. The number of samples of this study is 300 which means 300 subjects participated in this survey. After the selection of target group, the most important step is the design of the questionnaires of the survey. The backbone of this survey is that we must pin pout the effect of ISO on the hospital effectiveness and efficiency in terms of safety as well equipment's management. After quality research a set of 14 questions in main part and five questions related to their gender, profession, organization, age and working experience are added to the final draft. Next step is to analyze the collected data using SPSS software. Finally, conclusions are derived from the charts and tables.

2.1. Dataset

Data of this study is in the form of responses to the questions asked in the questionnaire of survey. There were 300 responses from different subjects who are related different fields of medical and organizations hence this data is covers large group of people. The set of questions were shared to the subjects using the google form where they can fill the options and their response is automatically recorded and saved in from of the excel sheet. The questionnaires were designed in a way that it is divided in to four parameters which further consists of different questions. The first parameter checks the impact of ISO on the safety which consists of three questions further, 2nd parameter checks the impact of ISO on the medial devices, surgical implants and equipment testing, sterilization and safety which contains six questions, third parameter checks the impact of ISO on the terminologies used it consists of two questions and the last parameter checks the impact of ISO for the compatibility and interoperability which consists of three questions. The general structure of the questionnaire is shown in the figure 6. After the collection of 300 responses the final data set sheet is exported and further filtered to shape the data and remove any unknown entry.

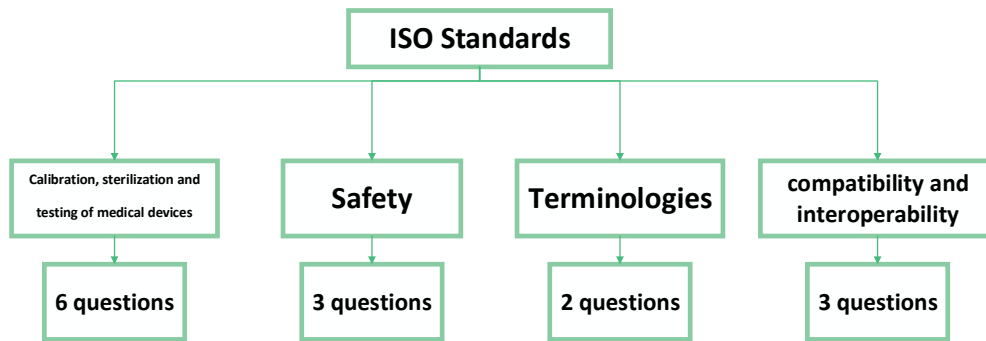


Figure 6. Framework followed in questionnaire

The total number of participants in this survey is 300 of which there were 226 males and 74 females, and it can be observed that there are more males as compared to females as shown in figure 7 male ratio is 75.3% and the female's ratio is 24.7% which reflects the workforce in healthcare sector. The survey was conducted among employees of public and private hospitals, healthcare agencies in across Saudi Arabia to cover large number of organizations and major cities. This ensures the accuracy of results by covering diversity of different locations which can sometime effect results.

hospitals. The goal of the questions of this parameter is to check the impact of ISO standards on the safety of patients, effectiveness of health practices risk management, and medical device safe disposal after life cycle completion. The response from the participants on these three questions shows that approximately 80% strongly agree that these standards of ISO have great significance in the safety parameters as shown in the pie charts, frequency tables, and bar charts in figure 8 to figure 12.

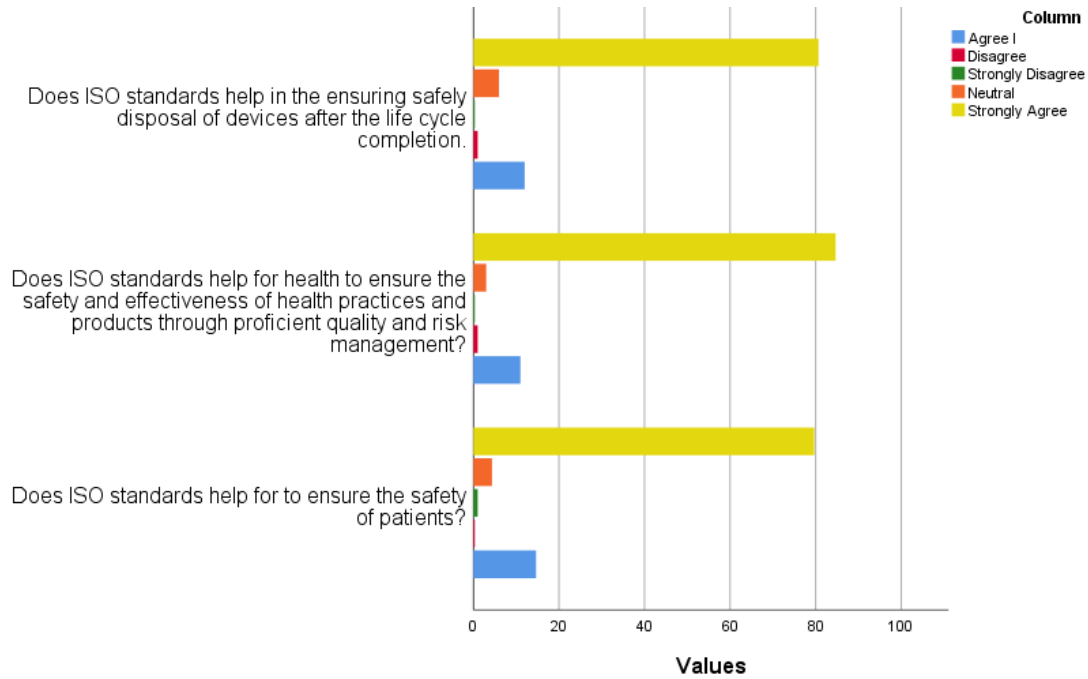


Figure 9. Bar chart for the summary of the safety parameters response

The second parameter of this study measures the specified role of ISO standards on the calibration, sterilization, and testing of medical devices. The goal of the questions of this parameter is to check the impact of ISO standards on the Clinical laboratory testing and in vitro diagnostic test systems, biological and clinical evaluation of the medical device, calibration of medical devices, sterilization processes of healthcare products standardization in oral healthcare, safety, and effectiveness of the surgical implant. The response from the participants to these six questions shows that approximately 80% strongly agree that these standards of ISO have great significance in the medical devices, equipment, and surgical implant handling as shown in the pie charts, frequency tables, and bar charts in the figures 4.10 to figure 4.15. Table 4.7 to 4.12 summarizes the frequencies and percentages for each question and each category separately.

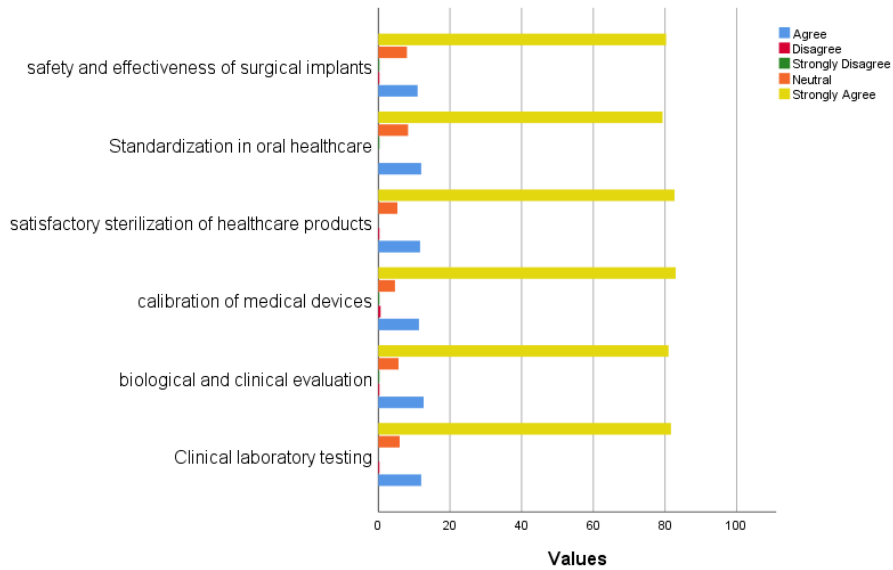


Figure 10. Bar chart for the summary of calibration, sterilization, and testing of medical devices

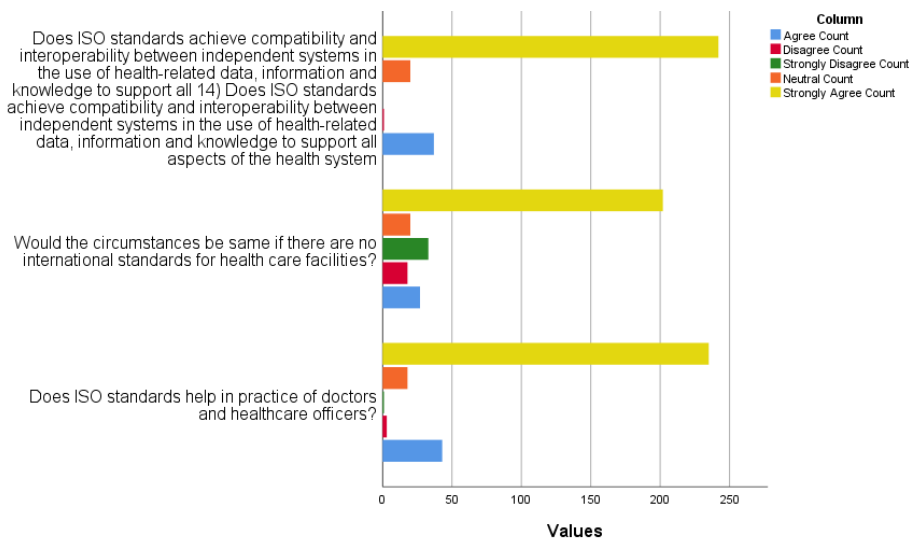


Figure 11. Bar chart of compatibility and interoperability parameter

In this study the compatibility and interoperability parameters measure the role of ISO standards in the practice of doctors and healthcare officers and health care data handling. It can be observed from the table 4.13 to 4.15 shows the frequency statistics that 78.3% of people strongly agree that it has significant impact on practice of doctors and 80.7% of people strongly agree that ISO standards achieve compatibility and interoperability between independent systems in the use of health-related data, information and knowledge to support all aspects of the health system. This analysis is also presented in pie chart and bar chart which clearly shows that strongly agree response is more significant all figures.

In this study the terminologies parameters measure the role of ISO standards develop uniform terminology, classification, terminology, nomenclature, and management practices and metrics covering non-clinical operations. It can be observed from the tables 4.16 to 4.17 shows the frequency statistics that 83.3 % in question 1 and 77% in question 2 people strongly agree that

ISO standard have great influence on the nomenclature management to handle the safety issues of the healthcare system. This analysis is also presented in pie chart and bar chart which clearly shows that strongly agree response is more significant all figures.

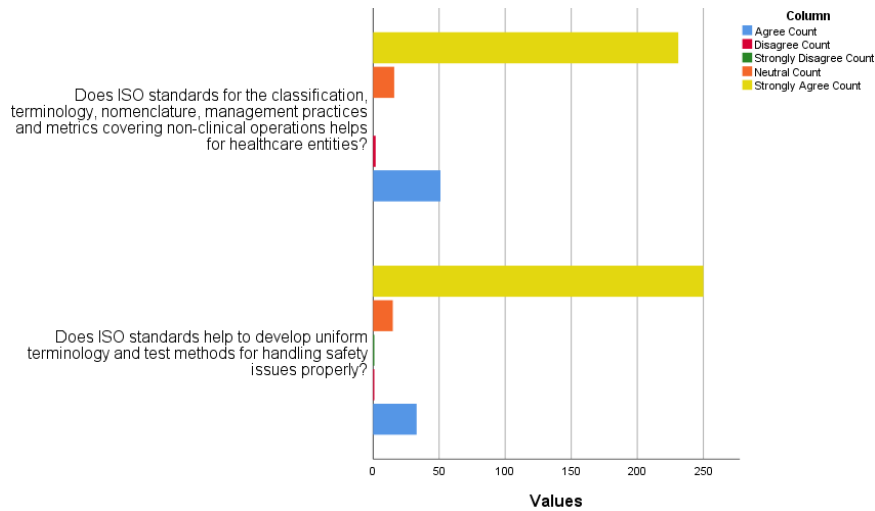


Figure 12. Pie Chart of terminologies parameter

2.3. Discussion

In this study researchers conducted a thorough survey in different health care services, hospitals, and organizations to get the response of targeted population about the ISO standards role in hospitals quality of care and safety of patients. Therefore, a set of 14 questions which are dependent upon four basic parameters to measure the effectiveness of ISO standards in hospitals were arranged. Total 300 people responded to this survey and their responses were saved in excel sheets via google form. After suitable formatting of the collected data final dataset is analysed in the SPSS software for further processing. In SPSS descriptive analysis (min, max, median, mode, range and sum) and graphical analysis done. In All the bar charts and pie charts approximately 80% people strongly agree that ISO play an important role in the safety, calibration, sterilization, testing of medical devices, surgical implants and equipment, medical devices terminologies and nomenclature management and compatibility and interoperability. Table 1 shows the descriptive analysis summary of all 14 questions of the survey. Mode is the measure of the central tendency of the data. It can be observed that the mode for all questions is 5 as it is the value for strongly agree which is the most occurring value hence the most people agreed on the strongly agree response. To measure the variability of the data range is measured which tells the data spread from lowest to highest for almost ten questions range value is 4 and four questions range value is 3. The median for all questions is 5 which means half of the values are above and half are below this value for all the responses to the survey.

Table 1: Summary of Descriptive statistics for all parameters

Statistics								
Questions	N		Media n	Mode	Ran ge	Min	M ax	Sum
	Valid	Mi ssi ng						
Does ISO standards help for to ensure the safety of patients?	300	0	5.00	5	4	1	5	1415
Does ISO standards help in practice of doctors and healthcare officers?	300	0	5.00	5	4	1	5	1408
Would the circumstances be same if there are no international standards for health care facilities?	300	0	5.00	5	4	1	5	1247
Does ISO standards help for health to ensure the safety and effectiveness of health practices and products through proficient quality and risk management?	300	0	5.00	5	4	1	5	1436
Does ISO standards help for Clinical laboratory testing and in vitro diagnostic test system?	300	0	5.00	5	3	2	5	1425
Does ISO play role in biological and clinical evaluation of medical devices?	300	0	5.00	5	4	1	5	1421
Does ISO play role in the calibration of medical devices and equipment?	300	0	5.00	5	4	1	5	1428
Does ISO standards help in ensuring for sterilization processes, sterilizing equipment, washer disinfectors and ancillary products used to ensure the satisfactory sterilization of healthcare products?	300	0	5.00	5	3	2	5	1430
Does ISO standards help to develop uniform terminology and test methods for handling safety issues properly?	300	0	5.00	5	4	1	5	1430
Does ISO help for Standardization in oral healthcare includes terminology, methods of test and specifications applicable to materials, instruments, appliances and equipment used in all branches of dentistry?	300	0	5.00	5	4	1	5	1410
Does the ISO standards for specifications and test methods for the safety and effectiveness of surgical implants that are inserted into the body for diagnostic or therapeutic purposes are helpful?	300	0	5.00	5	4	1	5	1412
Does ISO standards help in the ensuring safely disposal of devices after the life cycle completion.	300	0	5.00	5	4	1	5	1415
Does ISO standards for the classification, terminology, nomenclature, management practices and metrics covering non-clinical operations helps for healthcare entities?	300	0	5.00	5	3	2	5	1411
Does ISO standards achieve compatibility and interoperability between independent systems in the use of health-related data, information and knowledge to support all aspects of the health system	300	0	5.00	5	3	2	5	1420

Establishing guidelines for activities is the most common way to quality management in healthcare. Public health is a critical quality problem for health improvement and maintaining quality of life; nevertheless, a search of existing medical quality standards for citations to health programs turned up few hits. To assure the quality of support rendered in this region, standards for public health in hospitals are required. ISO (International Organization for Standardization) is a non-profit organization that creates standards to maintain the safety, quality, and effectiveness of services and products provided by any organization.

Because of the intensive quality healthcare, technical and functional standardization and procedures in health research and medical centres have become critical. The ISO working group, the International Classification for Standards (ICS), and the British Standards Institution have all produced several quality standards [28-30]. The organizations mentioned have established highly strict technical requirements for medical treatments and surgeries. The application of ISO provides a basic transition plan for integrating all functions engaged in comprehensive medical services to provide better treatment to patients [31-35].

This study focused on the role of ISO in the safety and efficiency of medical devices in hospitals. The data was collected from different organizations in terms of survey questionnaire, which was later analysed in SPSS, such research is not conducted in the Saudi in the past papers regarding the impact of ISO standards. There are some papers in terms of quality of services in hospitals such as in [36] Ali Al Mansour et.al conducted a study for exploring the employee's perceptions at level of managers regarding the process of Joint Commission International (JCI) accreditation and their significant role on patient's quality care in hospitals of Saudi Arabia. The planning phase of the JCI certification process was thought to be the simplest. Establishing and maintaining improvements that clearly improve patient quality and safety of care after certification was deemed more challenging. Institutions must implement methods to guarantee that advances in care persist beyond the certification term while planning for certification. In [37] Abdullah AlKhenizan et.al. assessed the program of developing accreditation of CBAHI (the Central Board for Accreditation of Healthcare Institutions) regarding the regulations of the Central Board for Accreditation of Healthcare Institutions to acknowledge the ways to improve the standards of CBAHI. The stated standards ISQua accreditation principles were used to undertake a qualitative evaluation and analysis of CBAHI standards. According to the findings. CBAHI standards will need to be significantly modified to fulfil ISQua principles.

3. CONCLUSIONS

Patients' and health professionals' safety and health are protected by international standards. Authorities can have them as a technological foundation for healthcare policy, ensuring that their citizens get the treatment they deserve. Standards are a harmonizing factor for healthcare organizations, helping to enhance the efficacy of medical care throughout regions. Standards also make it easier for producers to develop reliable and safe goods. Ensure that everyone has access to efficient and cheap healthcare is a major priority for the healthcare providers and government alike. This implies that the organizations and individuals involved must be capable of providing what patients require. Health professionals can deliver the finest care possible if there are standards in place for medical services. Healthcare systems range from surgical instruments to life-support equipment and are used in the detection, prevention, and therapy of medical problems. ISO specifies the requirements for a medical device-specific quality management process. The benchmark was recently updated with enhancements that widen its potential application to all participating organizations in the life cycle of healthcare equipment, enable maximum regulatory orientation, and put a higher emphasis on post-market monitoring, such as complaint management, infrastructural facilities, and risk assessment. The Targets of the United Nations place a premium on human health and well-being. The standards of ISO help to achieve

this significant milestone in a variety of ways, including ensuring that the gadgets and goods we need to be healthy or recuperate from sickness function properly. There really are ISO requirements for telehealth delivery of services, for instance, that ensure optimal, high-quality remote medical help while protecting a client's data. Guidelines can also help manage the effect of light from technological devices on our bodies, which has been found in recent research to have a negative impact on sleep. Hence this study conducted a questionnaire-based survey in which ISO standards in different aspects are assessed. The proposed method used the response of 300 subjects based on the 14 questions on ISO standards. This method evaluated the collected data on SPSS software using the descriptive analysis and graphical analysis. The presented tables and charts in results sections demonstrated that in all responses of the questions almost 80% people strongly agree that ISO standards play important role in the medical devices' safety, sterilization, testing, calibration, nomenclature, and efficiency. The study will play important role for the policy makers in improving health care services in terms of ISO standards. The limitation of this study is that there must be more parameters to in depth measurement of the ISO standards. In future study a detailed survey with larger dataset should be conducted for improving the results.

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