Addis Ababa University

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Assessment of the Current Status of Post-Market Surveillance of Medical Devices, its Regulatory Challenges and Future Perspective in Ethiopia

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A Thesis Submitted to the Department of Pharmaceutics and Social Pharmacy, School of Pharmacy, Addis Ababa University in Partial Fulfillment of the Requirements for the Degree of Master of Science in Regulatory Affairs (Medicine Regulation Track)

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This is to certify that the thesis prepared by Meaza Giragn entitled: *Assessment of the Current Status of Post-Market Surveillance of Medical Devices, its Regulatory Challenges and Future Perspective in Ethiopia* and submitted in partial fulfillment of the requirements for the degree of Master of Science in Regulatory Affairs (Medicine Regulation Track) complies with the regulations of the University and meets the accepted standard with respect to originality and quality.

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Abstract

Background: Beside their significance in improving the diagnosis and intervention of disease, medical devices (MD) have the potential for adverse events, hazards, or malfunctions with serious consequences for patients and users. In Ethiopia, post-market surveillance (PMS) of medical devices does not get enough attention, despite the fact that it plays a crucial role in protecting the patient by ensuring the continued quality, safety, and effectiveness of the MDs in use.

Objective: To assess the current status of post-market safety surveillance of medical devices, its regulatory challenges, and future perspectives in Ethiopia.

Methods: An explanatory sequential mixed method design approach was followed i.e. the quantitative data was first collected and analyzed, and then the qualitative data was collected and analyzed based on the quantitative result. Data was collected using a checklist adapted from Word Health Organization (WHO) and Global Harmonization Task Force (GHTF) guidelines, and interview guide questions were used to identify the regulatory challenges and proposed strategies associated with poor implementation of the PMS of MD.

Results: The current practice of PMS of MDs at the National Regulatory Authority and importers is in its infancy stage. Major regulatory challenges in the implementation of PMS for MD include: a mix-up of the regulatory structure of MDs and medicines, resource constraints, a lack of awareness, and poor collaboration between stakeholders. Poor implementation results in: patient exposure to unsafe, ineffective, and low-quality MDs; loss of trust in healthcare professionals and National Regulatory Authority (NRA); and economic failure for the country. Separating MD regulation; capacity building for the NRA; creating awareness among all responsible stakeholders; developing an adverse event reporting system for MD; and engaging stakeholders in ensuring patient safety are all recommended improvement strategies.

Conclusion: The current practice of PMS of MDs at regulatory authority and MAHs, two key essential players are at infancy stages. Most of the regulatory requirements utilized to implement were either not present or just existed on paper. In general, to create a robust and effective post-market surveillance system for MDs, it requires ongoing, continuous work.

Keywords: Medical Device Regulation, Post Market Safety Surveillance, Patient Safety, Adverse Event

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List of Abbreviations/Acronyms/

AEs	Adverse Events
EFDA	Ethiopian Food and Drug Authority
EC	European Commission
EU	European Union
GHTF	Global Harmonization Task Force
IMDRF	International Medical Device Regulatory Forum
KI	Key Informant
MHRA	Medicines and Healthcare Products Regulatory Agency
MD	Medical device
NMRA	National Medicine Regulatory Authority
NRA	National Regulatory Authority
PIP	Poly Implant Prostheses
PMS	Post Market Surveillance
PMCF	Post Market Clinical Follow up
PV	Pharmacovigillance
RA	Regulatory Authority
SF	Substandard/ Falsified
UK	United Kingdom
US	United States
WHO	World Health Organization

1. Introduction

1.1 Background

Through time, therapeutic interventions with medical devices (MDs) have become increasingly and widely used in the health care system (Kramer *et al.*, 2014). Its application is diverse, from simple routine medical procedures like bandaging a sprained ankle, diagnosing HIV/AIDS, to highly complicated procedures like implanting an artificial hip and breast implants. Such health technologies are also used to diagnose illness, monitor treatments, assist disabled persons, or intervene and treat illnesses, both acute and chronic cases (World Health Organization, 2017).

The Global Harmonization Task Force (GHTF) defines "medical device" as any instrument, apparatus, implement, machine, appliance, implant, *in vitro* reagent or calibrator, software, material, or other similar or related article intended by the manufacturer to be used alone or in combination for human beings for one or more of the specific purpose(s) of diagnosis, prevention, monitoring, treatment, alleviation, or compensation for an injury or investigation; replacement, modification, or support of the anatomy or of a physiological process; or supporting or sustaining life; or control of conception or disinfection of medical devices; or providing information by means of *in vitro* examination of specimens derived from the human body; and which does not achieve its primary intended action in or on the human body by pharmacological, immunological, or metabolic means; and which may be assisted in its primary intended action in or on the human body (GHTF, 2012).

Beside its significance in improving the diagnosis and intervention of diseases, medical devices have a potential for adverse events (AE), hazards, or malfunctions with serious consequences for patients and users (Kramer *et al.*, 2013); post-market surveillance (PMS) plays a crucial role in protecting the patient by ensuring the continued safety and effectiveness of the medical device in use (Lamph, 2012). PMS encompasses all monitoring activities such as device performance monitoring, problem identification, AE reporting, alerts, recalls, and medical device corrective action (Fig 1). PMS activities can be both proactive and reactive, with proactive activities relating to market control such as batch release testing and establishment inspection. And reactive activities cover the medical device vigilance system, which is based on the collection of post market data received from spontaneous reporting of complaints and incidents (Altayyar,

2016). This MD vigilance program's primary goal is to improve the health and safety of users, patients, and others by lowering the likelihood that AEs will occur again. To this end, reported AEs are evaluated; information that could be used to prevent or lessen the effects of AE is disseminated; the devices are modified; or the MD is taken off the market (Rogers, 2019)**.**

The presence of a well-structured vigilance system is the backbone of a robust regulatory framework to ensure the quality and promote the safe use of MDs, and the information gained from the PMS is useful for harm prevention, product improvement, the development of standards, and regulatory refinement (Altayyar, 2016; Shukla *et al.*, 2020).

Figure 1: Post market surveillance activities of medical devices (WHO Forum, 2017)

1.2 Statement of the problem

Medical device regulation is required throughout its life to protect the public's health from poor quality and ineffective (unsafe) medical devices. It is naturally true that MD can fail, and the failure rate will depend on its lifetime (Ertkjern and Babic, 2014). But sometimes , the failure rate may not be because of its life time rather, it can be resulted due to manufacturing defects, poor product design, misleading labeling, confusing instructions, storage conditions, duration of storage, warehouse environment, transportation, installation, servicing, patient sensitivity, user training and also practices (WHO, 2017; Maisel, 2004). Since, pre-market approval system for medical device does not have enough clinical data it needs continuous monitoring during its use (WHO, 2003).

Until the 1980s, i.e., since there was a compulsion to draft regulatory policies on MDs to assess their quality, safety, and performance, there were limited MD regulation and regulatory control systems, and poor quality and unsafe devices were not managed properly (Gupta, 2016). Most of the problems of medical devices wouldn't be identified until widespread (extensive) market experience is gained. For example, an implantable device may fail in a manner that was not predictable at the time of implantation (WHO, 2003).

A medical device hazard is a potential source of harm that is caused by the inherent risk of medical treatment, device failure, device malfunction, and device use. On the other hand, it has been suggested that the frequency and consequences of hazards resulting from MD use might far exceed those resulting from device failure. There are many reasons for device-related hazards to be higher, among which are: using the devices in ways that were not anticipated, device use that is inconsistent with the user's expectations about the device's operation; and the use environment, such as work load and mental load (Altayyar, 2016). Today, the health care system requires quality standards and accreditation, but without proper medical device management (regulation), it is nothing (Altayyar, 2016). Due to their unique challenges like user variability, the technological complexity, and the permanent nature of some implants, medical device is more difficult than medicine in ensuring their safety and effectiveness (Pane *et al.*, 2017).

The other sources of MD in this region are donations from developed countries. Even though they have many benefits, such as improving the efficiency of health facilities, saving money on purchasing new equipment, and making some diagnoses or therapies available to patients, they

also have many drawbacks that go beyond their necessity, such as the donation of outdated or near-outdated products, a lack of proper documentation regarding the source of the product, a lack of evidence to support safety, quality, and performance, and non-functional, outmoded equipment (WHO, 2017).

The regulation of medical device is still at infancy stage in many developing countries, where regulatory controls are not yet well established to prevent the importation or use of sub-standard devices (Lamph, 2012). In 2017, a study conducted showed that all African countries, except Sahrawi Republic have National Medicines Regulatory Authorities (NMRA), but even if there is a progressive improvement in regulatory capacity, particularly in quality control and PMS, pharmacovigilance (PV) and clinical trials oversight, any of NMRA could not undertake the full range of regulatory functions including Ethiopia (Ndomondo-sigonda, Miot and Naidoo, 2017).

In Ethiopia, medical device regulation mandate is given for the national regulatory authority called Ethiopian Food and Drug Authority (EFDA) by the proclamation of 1112/19. (Saidi and Douglas, 2016) Importers have agreed during registration to have PMS plan to do entirely on market safety surveillance, i.e., to report AE, malfunction, and risks associated with MDs. (EFDA, 2022) At the health facility level, there are a number of problems associated with medical devices, but there is a lack of knowledge on how to manage them. On the other hand, there is no adverse event reporting system specific to MDs, and there is also a lack of awareness about whom to report and how to report. Because of these factors, patients continued to be harmed. On the other hand, the regulatory authority has been mandated to enforce other stakeholder's implementation, but it is difficult to make sure the enforcement mechanism has been applied.

In our country, the pharmacovigilance system and ADR reporting practices associated with medicine have been studied better than those of medical devices, even if it is not enough. (Barry *et al.*, 2020; Nadew, Michael Beyene and Beza, 2020)Whereas, until now, there have been no data or studies done about PMS of medical devices and its practice, this study tried to fill this gap.

To the best of the investigator's knowledge, there has not been any previous study that assessed PMS of medical devices and its regulatory challenges.

1.3. Significance of the study

In our country, even though there is not enough data to show the current status of the substandard and ineffective MDs on the market, that doesn’t mean that there is no cases. The medical device's safety should be monitored and controlled throughout its lifetime, especially after entering the market and being used by the patient; this is done by implementing a post-market surveillance system. This study tries to assess the current status of the PMS program and also tries to explore what kinds of challenges hinder the regulatory practices, which will be an input for the government, especially for the NRA, to take action or to review the policy or vigilance strategies. It may also create an initiative by the authority for effective implementation of the PMS program.

This study will act as a starting point for future studies on PMS-vigilance of medical devices in Ethiopia because no previous research has been done in this nation

2. Literature Review

2.1 Medical Device Performance and Its Adverse Events

The presence of thousands of different types of MDs in the market makes the regulatory control of medical devices complicated since the risks associated with each medical device differs with each type. There is no medical device without any risk (absolutely safe), even those classified as "low risk" or "class I" are still capable of killing and injuring patients when misused (WHO, 2016).

A device is clinically effective when it produces the effect intended by the manufacturer relative to the medical condition. Clinical effectiveness is a good indicator of device performance. Performance, however, may include technical functions in addition to clinical effectiveness. For example, an alarm feature may not directly contribute to clinical effectiveness but would serve other useful purposes. Furthermore, it is easier to measure objectively and quantify performance than clinical effectiveness. Performance is closely linked to safety. For example, a blood collection syringe with a blunt needle would perform badly for collecting blood and could inflict injury. A patient monitor that does not perform well could pose serious clinical safety problems to the patient; therefore, safety and performance of MDs are normally considered together (WHO, 2016).

Even though medical devices give opportunities of better qualities for diagnosis and intervention of disease (Kramer *et al.*, 2013), in the health care system with the help of technological advancements, such as drug–device combination products, automation and wireless technology, and advanced clinical application of devices (Fouretier and Bertram, 2014), it will bring predictable as well as unforeseen risks, which in some circumstances, may lead to immediate life-threatening consequences (Kramer *et al.*, 2014).

French health products agency reported that Poly implants prostheses (PIP), the third biggest global supplier of breast implant made implants with substandard and non-authorized material not fit for humans which causes 7,500 of PIP implants rupturing and 3,000 results in undesirable side effect – mainly inflammation. Since 2003, in UK about 65000 people have received metal on metal hip implant, of which around 49000 have gotten problems (Ertkjern and Babic, 2014).

One study done in China in 2012 showed that within a year more than 180,000 suspicious medical device adverse events were reported, of which 13% resulted in serious injury and 0.06% led to death.

Most (71%) of the ADR cases were reported by medical institutions, while 22% were reported by distributors, 3% were reported by manufacturers and 5% were reported by individuals (Kramer *et al.*, 2014). In 2017, statistical analysis done in Australia revealed that, TGA (Therapeutic Good Act), the Australia's medicine and medical device regulatory Authority, received about 5370 adverse event report associated with MDs, in which most of the report made by sponsors (authorized representatives), i.e., 4604 (84.9% of all reports) and when we see the report made by health professionals, 101 (2% of the total) and 102 (2.1% of the total) are made by doctors and nurses respectively (TGA Administration, 2017).

2.2. Classification System of Medical Devices

Regulatory controls should be proportional to the level of risk associated with a MD. The level of regulatory control should increase with the degree of risk, taking account of the benefits offered by the use of the device. As a result, MDs must be classified based on their risk to patients and users. The classification of medical devices depends on several factors, such as the duration of device contact with the body, the degree of invasiveness, whether the device delivers medicines or energy to the patient, whether they are intended to have a biological effect on the patient, and local versus systemic effects (GHTF, 2005). Different countries' regulatory authorities have different risk classification systems for different groups of devices (Lamph, 2012). In the United States, medical devices are categorized as class I, II, or III based on the potential risks of the device. Class I devices present the lowest risk to patients, whereas Class II and III medical devices present significant enough risks that they require a premarket notification application to the FDA (Sastry, 2014). On the other hand, the European Union classifies medical devices into three classes, with Class II being subdivided into IIa and IIb (WHO, 2003).

Ethiopia uses a globally accepted practice approach for the classification of MDs, i.e., a risk-based approach, and applies different conformity assessment techniques to each class. Article 19(1) of the Food and Medicine Administration's proclamation 1112/2019 states that the rigor of regulatory assessment of medicines and medical devices must be commensurate with the product

type, nature, and potential risk to human health. Based on this, MDs are classified into Classes I, II, III, and IV, with Class I being the devices with the lowest risk and Class IV being the devices with the highest risk (EFDA, 2022).

2.3. Global Medical Device Regulation

Due to increasing societal pressure, the global medical device regulation revolution begins in different countries with different time. In US, the report of 10,000 injuries from medical devices, and more than 200 septic second trimester abortion and 11 maternal deaths due to the dalkon shield intrauterine devices made the medical device regulation to be evolved in 1970s. Whereas, medical device directives in the European Union (EU) were adopted in the 1990s, prior to this legislation, different nations had different regulatory processes (Wylie, 2016).

Relative to medicine and vaccine, the regulation of MD is less advanced. The formal regulation of medical devices began in the mid-1990 (Altayyar, 2016). After several years of starting formal regulation of medical device, in 2007, WHO introduced the new regulation of medical devices, by implementing World Health Assembly Resolution 60.29, which encourages the announcement of national or regional guidelines for good manufacturing and regulatory practices and establishment of surveillance systems and other measures, targeting at ensuring quality, safety and performance of medical devices (Saidi and Douglas, 2016). Around the world, the regulation of medical device varies from one country to other with respect to their development. It ranges from comprehensive to none (Lamph, 2012). Many countries have neither the financial resources nor the technical expertise to transition successfully from unregulated market to a comprehensive medical devices regulation, in which the fund, people, technologies and facilities are the main inputs for government policy objectives and priorities (WHO, 2003).

In 1993, to combat these regulatory differences, countries with advanced medical device regulation and a voluntary international group (US, EU countries, Japan, Canada, and Australia) established the so-called Global Harmonization Task Force (GHTF), now called the International Medical Device Regulatory Forum (IMDRF). The primary goal of IMDRF is to develop the standardization of medical device regulations across the world in regard to safety, performance and quality of medical devices (Lissel *et al.*, 2016).

2.4. Medical Device Regulation in Africa

The majority of MDs are manufactured in developed countries, where they are built based on the demand and resources available in high-income countries and do not encounter the challenges found in less developed countries like Africa. Therefore, it is vital to develop MDs that are specifically designed to address these challenges in order to improve African patients' access to medical care. On the other hand, since the medical device regulatory process in many African countries is not well defined, they rely on clearance from the European Medicines Agency or the U.S. Food and Drug Administration (FDA). Even though these regulatory processes are stringent and have excellent safety standards, they are not designed to meet the needs and safety issues present in Africa (Hubner *et al.*, 2021).

In addition to improving access to safe, effective, and high-quality healthcare and medical devices, international organizations such as WHO and IMDRF are dedicated to developing guidelines and have made an effort to promote the harmonization of regulatory standards for medical devices regulatory processes by making information freely available and accessible, as well as by providing support to countries where poor or no regulation exists. Despite all these efforts, only a few African countries have established a regulatory system. According to a 2017 World Health Organization (WHO) report, 40% of the countries in the African region have no medical device regulations, 32% have some regulation, and the remaining 28% lack any data. These indicate that, in this region, patients are exposed to lower-quality medical devices and have limited access to health care technology (Lissel *et al.*, 2016; WHO, 2017).

The prevalence and economic cost of substandard medications and medical devices increase the necessity of medical device regulation. In 2017, a WHO report showed that, the approximate failure rate of substandard and falsified (SF) medical products in low- and middle-income countries was 10.5%, which translates to an economic loss of around $30.5 billion in medical expenditures (WHO, 2017). The SF products may be assembled from inferior-quality components or, worse yet, from fake parts that could contain toxic materials. SF medical devices pose a significant health risk to both patients and healthcare providers that could result in injury, permanent disability, or even death (WHO, 2010). On the other hand, the increase in substandard medications and medical devices implies the presence of poor medicine and medical device regulation, which would have a negative impact on consumer trust in the health care system,

health professionals, the supply chain, and genuine suppliers of medicines and medical devices (Glass, 2014). Reports of SF medical devices have emerged from all over the world, Falsified condoms, contact lenses, catheters, syringes, and needles have been reported from Africa, Asia, and Europe (WHO, 2017). Strong medical device regulation is therefore an important and needed step toward achieving higher quality and more affordable medical care for countries already working within tight economic constraints (WHO, 2017).

2.5. Post Market Surveillance of Medical Devices

Since 1976, when medical device regulation became a concern in the United States, all medical devices (low and high risk) have had to go through the 510(k) clearance process, which means that in the premarket approval process of medical devices, only one controlled trial is required rather than multiple randomized controlled trials, which are required for new medicine approval. In this approval system, the manufacturer was only required to demonstrate a device was substantially equivalent to another device already on the market. Because of this insecurity in medical device regulation, complications with Poly Implant Prothese (PIP) for breast implants and Metal on Metal (MoM) hip implants increased. In addition to this, the study of medical device recalls and the device-regulation process reveals the increasing nature of the problems. On the other hand, in a study done from 2007 to 2011, the number of recalls for moderate- or high-risk devices more than doubled. Furthermore, many recalled medical devices in the United States were cleared using a less stringent process known as 510(k), or even something even more problematic. EU countries have used the same approval system and had the same problem as the US. From 2006 to 2010, the UK regulator, the MHRA, issued 2,124 manufacturer field safety notices, an increase of 1,220 percent over this five-year period. Above all these, the more concerning part is that many problems with medical devices went unnoticed, making it difficult to know the magnitude of the problem. All of these factors contributed to the 510(k) clearance method being replaced with an integrated pre-market and post-market regulatory framework that effectively provides a reasonable assurance of safety and effectiveness throughout the device life cycle (Heneghan and Thompson, 2012).

Effective vigilance and post-market surveillance programs are two ways to find SF medical products early on. Regulatory authorities should set up systems that make it possible and desirable to report medical devices that are considered suspicious and they should also respond

to such reports. Strengthening capacity among regulatory authorities to respond transparently, consistently, and proportionately and also working with stakeholders, including law enforcement and the judiciary, will help to ensure that serious cases of falsification are dealt with in a manner commensurate with the risk to public health and also maintain confidence in health systems (WHO, 2017).

2.6. Regulatory Challenges of Post- Market Surveillance of Medical Device

According to the 2020 study, many African countries face a number of challenges in ensuring medical device safety surveillance, including: insufficient staff numbers in each national authority; an imbalance between pre-market approval and post-market surveillance, with more emphasis placed on pre-market activities; and the neglect of post-market surveillance due to a lack of funds to conduct related activities. On the other hand, the medical device regulation was mixed; for example, in Tanzania, the regulatory system is not robust enough to guarantee medical device safety, effectiveness, and quality as inspection of manufacturing facilities is done and the approach applied is based on the pharmaceutical regulatory framework (Dusabe, 2020). The other major challenge in ensuring medical device safety is the lack of adequate training for the responsible stakeholders. In 2022, the study done in London indicates that since the level of training given by the manufacturer is poor and inconsistent, clinicians are often faced with unfamiliar devices during a procedure. Only 12% of medical device users get specific device training (Tase *et al.*, 2022).

When we come to our country, Ethiopia, since the practice of regulating medical devices is elementary; there is an inadequate framework for post-market safety surveillance of medical devices and an adverse event reporting system for medical devices for manufacturers, importers, user facilities, and healthcare professionals that can be implemented on the ground. Even though data on the consequences of medical device failure is limited, this does not mean that there is no problem or that no adverse event is associated with the medical devices.

Cases like these all indicate that premarket evaluation alone is not enough to ensure the continued quality and safety of a medical device. Rather, an active post-market surveillance vigilance system is as important as and a mandatory part of regulatory control of a medical device.

2.7. Conceptual Framework of the Study

The following conceptual framework has been created based on the literature review, WHO guidelines. The variables influencing the full implementation of post-market surveillance of medical devices are taken into consideration when creating the conceptual framework. (Figure 2)

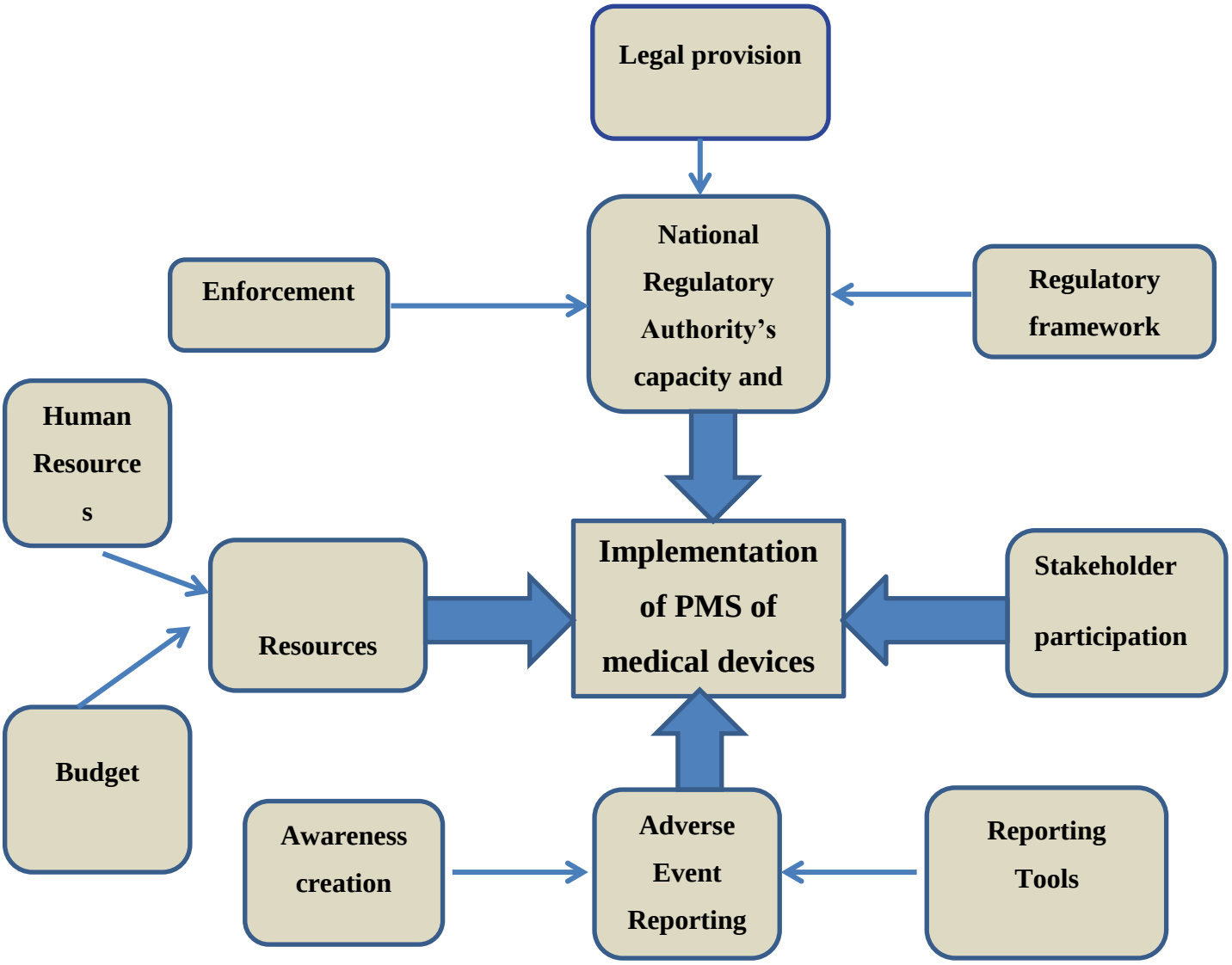

Figure 2: Conceptual frameworks for qualitative study

3. Objectives of the study

3.1 General objective

To assess the current status of post market safety surveillance of medical devices, its regulatory challenges and future perspectives in Ethiopia

3.2. Specific objectives

- ✓ To assess the current practice of post market safety surveillance system of medical devices
- ✓ To identify the challenges in full implementation of the post market surveillance of medical devices
- ✓ To explore the future perspectives of post marketing surveillance system of medical devices

4. Methods

4.1. Study area and Period

The study was conducted with different stakeholders, mainly in the EFDA and also with selected importers of medical devices found in Addis Ababa. Addis Ababa is the capital and the largest city in Ethiopia. The reason for selecting the study area to be in Addis Ababa is that as a country, most large companies that import essential and lifesaving medical devices are present here in this capital city, so it will be representative of those found in the other regions of the country. In Addis Ababa, there are about 580 legally registered private medicine and medical device importers, of which 41 are medical device-only importers. EFDA is the NRA mandated by Proclamation 1112/2019 to ensure the medical device's safety, quality, and performance. The study was conducted from February to May 2022.

4.2 Study design

An explanatory sequential mixed method design approach was followed i.e. the quantitative data was first collected and analyzed, and then the qualitative data was collected and analyzed based on the quantitative result. The current practice of post-market surveillance of medical devices was assessed with quantitative study methods, and the challenges associated with poor implementation of post-market surveillance of medical devices and its future perspectives were explored with ground theory of qualitative study design.

4.3 Study population and Subjects

The study population includes all EFDA staff working in different units and managers who is working in different importers and are legally registered by EFDA. The study subjects were selected respondents from EFDA who are directly related to the regulation of MDs and authorized representatives or importers of MDs that are currently active and that are legally registered by EFDA.

4.4 Sampling and recruitment

In this study, for the quantitative part, according to EFDA's database, the total number of MAHs (importers) of MDs found in Addis Ababa that were registered as medicine and medical device importers was 580. Of these, 208 were new, i.e., having less than one year of experience, and 372 having more than two years of experience. Based on the study selection criteria, i.e., importers having an experience of two years or more were included, but, during the study period, we found that more than three-fourths of the companies didn't actually import the MDs, but rather they only imported medicines. In addition, some of these companies either didn't start to import or imported single items and worked only on the local market despite the availability of an import license. For the above reasons, only about 67 importers have been actively working. Again, some importers did not volunteer to participate in the study for undisclosed reasons. Therefore, the final sample size for the importer was 52 volunteer companies.

For the qualitative study, key informants were purposefully selected to recruit participants from EFDA, particularly those focal persons who have experience in the area of regulation of medical devices, such as in the approval process of MDs, inspection of MDs, and PMS of MDs. In addition, health care professionals who have been working in different importers as technical managers or regulatory affairs officers and have a minimum of two years' experience in that position were selected. The number of participants for the interview was determined based on the saturation of ideas.

4.5. Eligibility Criteria

4.5.1 Inclusion Criteria

- Staff of EFDA working on MD regulation and well experienced i.e. having five year and more experience in the position;
- Staff of local legal representatives/importers of MD working as managers(technical, deputy, general) , and also sales and service manager and having two and more than two years' experience in the position; and

- Local legal representatives/importers of MDs registered in EFDA and having an experience of two years and more.
- Biomedical engineers/pharmacists who have been working at higher hospitals and having five and more years' experience.

4.5.2 Exclusion Criteria

- EFDA staff who were not directly working on MDs regulatory unit;
- Local legal representatives/importers of MDs registered in EFDA and having less than two year experience; and
- Local legal representatives/importers not imported MDs
- Biomedical engineers/pharmacists working at higher facilities and having less than five years' experience

4.6 Data collection and management

4.6.1. Data collection instrument and procedure

For the quantitative part, the checklist was adapted from WHO guideline (WHO, 2020), GHTF (GHTF, 2006) and from different studies done before (Nkansah, *et al*., 2018). The data was collected by the investigators by asking key personnel working in the pharmacovigilance unit at EFDA and the technical managers, sales and service managers and regulatory affairs officers of importers. Observation and evidence-based document review were done for the validation of verbal communication. For the qualitative part, the data was collected using semi-structured interview guide questions in which the investigator conducted in-depth interviews with each participant to gather relevant and detailed information. The interview was done in the local federal language (Amharic), and the interview was conducted for an average of 25 to 40 minutes for each participant. During the interview, the investigator used a tape recorder and field notes.

4. 7. Data Analysis

The checklist data was entered into an Excel sheet, and descriptive statistics such as percentages of each result were calculated. The findings were primarily presented in the form of frequency tables. The qualitative thematic analysis mainly followed a deductive approach. The analysis was started with predetermined codes to the data set and then finds quotes that fit those codes from the row data set (text from the interviews). The codes used in this approach were created from concepts drawn from the literature. Those issues not captured in the deductive analysis or those not fit with themes used in the deductive approach were coded inductively in which themes were generated by looking at patterns from the data set. The codes were revised, and similar codes were grouped into themes. As the process continued, new themes emerged, and groups of related themes (sub-themes) were placed together under larger ones.

4.8. Data Quality Assurance

For quantitative study, to ensure the consistency and quality of the data collection tool, a pretest was done in the target population. About five companies participated, and based on the results, some ambiguous sentences were deleted and improvements were made. Then, before starting data analysis, the data was checked for its completeness and given an appropriate code

For the qualitative study of the interview guide questions, the investigator had taken online training on collecting interview data and peer review was done before starting the data collection. Then, about three pilot interviews were conducted to assess the interview guide's questions' significance to the study's aims and research questions. And these pilot interviews resulted in small changes and amendments to the interview guide, such as the addition of more probing questions and the removal of ambiguous and leading questions. Before starting the data analysis, the interview result was back-translated to compare translations with the original text for quality and accuracy and to evaluate the equivalence of meaning between the source and target texts.

4.9 Ethical Considerations

Ethical approval was obtained from the ethics review committee of the School of Pharmacy, Addis Ababa University (ERB/SOP/309/13/2021). An official letter was written from the Department of Pharmaceutics and Social Pharmacy. Informed consent was obtained from study participants to confirm their willingness for participation after explaining the purpose of the study and its benefit. They were assured of the confidentiality of their identities in the study. There was no personal identifier in the data collection format. The data collection tools did not include any information that could lead to the identification of a specific study respondent, such as the respondent's name. The collected data was not accessed by any third party. The collected information was presented in aggregate form in a way that makes identifying a particular participant impossible.

4.10. Operational Definitions

Legal Local Representatives: Any natural or legal person established within a country or jurisdiction who has received a written mandate from the manufacturer to act on their behalf for specified tasks with regard to their obligations under that country or jurisdiction's legislation (WHO, 2020)

Importer: Any natural or legal person in the supply chain who is the first in a supply chain to make a MD, manufactured in another country or jurisdiction, available in the country or jurisdiction where it is to be marketed (WHO, 2020).

National regulatory authority: A government body or other entity that exercises a legal right to control the use or sale of medical devices within its jurisdiction, and that may take enforcement action to ensure that medical products marketed within its jurisdiction comply with legal requirements(WHO, 2020)

Post market surveillance: Systematic process (activities) to collect and analyze experience (information) gained from medical devices that have been placed on the market (WHO, 2020).

User: The person, either professional or lay, who uses a medical device. The patient may be the user (WHO, 2020).

Malfunction: A failure of a device to perform in accordance with its intended purpose when used in accordance with the manufacturer's instructions (GHTF, 2006b)

Incident/Adverse Event: Malfunction or deterioration in the safety, quality or performance of a device made available on the market, any inadequacy in the information supplied by the manufacturer and undesirable side-effects (WHO, 2020).

Use error: User action or lack of user action while using the medical device that leads to a different result than that intended by the manufacturer or expected by the user. (WHO, 2020)

4.11. Researcher's Position and Reflectivity

Currently, the researcher is a pharmacist by profession working in health office and doing her Master's degree in Regulatory Affairs (Medicine regulation track). The researcher didn't work at NRA and health facilities including hospitals. As a result, KIs from the study organizations were free to give their view freely.

The researcher only took a course entitled research method which covered an introductory aspect on qualitative research design and methods as part of fulfilling the Master's program. To minimize its impact on the overall research design, the researcher had extensively explored online qualitative study design training including analysis and presentation which enabled familiarize herself with the concept of qualitative research. In addition, interview guide question development, translation, back translation, coding, and theme development were done under the supervision of advisors. In the process of data collection, the researcher assessed interview guides used and amends some of the irrelevant and vague questions which enable to revise and modify the interview guide.

The researcher is a female and Amharic speaker, which also had an impact on data collection, created a common ground for some to discuss freely in interviews.

5. Results

5.1 Quantitative Findings

5.1.1 The study organization and socio demographic characteristics of respondents

In this study, a total of 52 importers of MDs were assessed; their work experiences ranged from 2 years to more than 20 years. Of those, 62% had more than five years of work experience. They imported different types of medical devices, including diagnostic, therapeutic (treatment), and life-sustaining (support) devices. Regarding the respondents' professions, the majority of them were pharmacy professionals and biomedical engineers (52% and 36%, respectively). Their responsibilities were different in different organizations, and the majority of the respondents, i.e., 46%, were technical managers. More than half of the study participants have bachelor's degrees. (Table 1)

Table 1 (Socio demographic characteristics of the respondents)

Variable	Categories	(N, %)
Profession	Pharmacist	27 (52%)
	Biomedical engineer	19 (36%)
	Laboratory Technologist	3 (6%)
	Medical doctor	1 (2%)
	Other profession	2 (4%)
Level of education	Diploma	1 (2%)
	Degree	35 (67%)
	MSc/MPH	15 (29%)
	MD	1 (2%)
Current position	General Manager	13 (25%)
	Technical Manager	24 (46%)
	Regulatory Affairs	3 (6%)
	Sales and service manager	12 (23%)
Work experience	2 to 5 years	27 (52%)
	More than 5 years	25 (48%)

5.1.2 Current practices of post market surveillance of medical devices in MAHs/Importers

Of the total, i.e., 52 MD importers, 71% had a PMS plan, which is one of the criteria as a component of technical documentation inquired about by the regulatory authority during market authorization. Of these, i.e., companies with PMS plan, 26 (70%) of the companies that import higher-risk medical devices have post-market clinical follow-up (PMCF) plans. During the study period, since there is a lack of sufficient documented evidence, it is difficult to get complete information. More than half of the importers of MD had positive responses for human resources. But only 10 (19%) of them had budgets. About 40 (77% of all importers) supplied five-year PMS data to the regulatory body during the market authorization of their product (Table 2).

Table 2 Current status of post market surveillance plan and available resources in study companies (N=52)

No	Characteristics		Response (N, %)	
			Yes	**No**
1	presence of PMS plan for medical devices that it imports to the country		37 (71%)	15(29%)
2	The scope of the PMS plan for medical devices using a risk-based approach		26 (70%)	11 (30%)
3	PMS plan has post market clinical follow up plan (PMCF) especially for higher risk medical devices		26 (70%)	11 (30%)
4	Available resources for PMS activities of medical devices	Human resource	28 (54%)	24 (46%)
		Budget	10 (19%)	42 (81%)
5	Submission of PMS data (less than five year data) during registration/market authorization of the devices		40 (77%)	12 (23%)
6	The PMS plan has a clear and well described data collection methods		18 (48%)	19 (52%)

As shown in Table 3 below, all MD importers possessed the list of MDs that they imported to the country, and also those that were distributed or sold to the users. This indicates that it is easy to trace the medical device that had a problem or safety issue. Of these, 71% of them used serial numbers as a unique identification number. Regarding the implementation status, even if 18% of importers (from 37 importers having a PMS plan) have implemented it according to the plan, they do not have enough documented evidence. Only 11 (21%) of importers had experience collecting safety data surveillance on the MDs that they imported; of these, only 7 of them had documented evidence. Of the 52 importers that were assessed, only 4 (8%) had experience receiving complaints regularly, and 21 (40%) had never received any complaints associated with the medical device that they imported.

Even if it doesn't contain enough information for medical device adverse event reporting, 73% of the importers have responded "yes" to using reporting methods like email and paper-based

formats, but none of them know about the presence of data-based systems and free calls for adverse event reporting.

Table 3 Current practice of importers in post market safety surveillance of medical devices (N=52)

Ser. no	Characteristics		Responses (N, %)	
			Yes	**No**
1	Medical devices list which it imports		52 (100%)	0 (0%)
2	Document of medical devices that it sales /distributes to User		52 (100%)	0 (0%)
3	Unique identification number (code) of MD that it distributed to the users		37 (71%)	15 (29%)
4	Implementation of the PMS activities according to the plan		7 (19%)	30 (81%)
5	Experience of collection of safety data surveillance of medical devices that it imports		11 (21%)	41 (79%)
6	Experience of receiving compliant of medical devices from users (in the last two years)	Regularly	4 (8%)	
		Sometimes	27 (52%)	
		Never	21 (40%)	
7	Categorizing, analyzing and verifying the collected Feedback.		15 (29%)	37 (71%)
8	Experience of manufacturer in the root cause analysis of an adverse event that you report.		25 (48%)	27 (52%)
9	Risk management plan for the adverse event/malfunction associated with medical devices		20 (54%)	17 (46%)
10	Experience of taking an action following the investigation of the complaint (adverse event)		15 (29%)	37 (71%)
11	Presence of formal medical device adverse event /malfunction reporting method		38 (73%)	14 (27%)
12	System of distributing feedback information to the user after making risk based analysis of the compliant,		28 (54%)	24 (46%)
13	Prepare a post market surveillance (PMS) training program for its staff		10 (19%)	42 (81%)
14	Participated in any PMS training prepared by NRA		0 (0%)	52 (100%)
15	Prepared/given short term training for the user about the MD that it sold?		36 (69%)	16 (31%)
16	Calibrate, provide maintenance according to the operation and service manual		43 (83%)	9 (17%)
17	Monitoring and evaluation platform for its PMS program		0 (0%)	52 (100%)

More than 50% of respondents in this study were aware that adverse events and malfunctions associated with MDs that could result in patient illness or death should be reported to the EFDA and the manufacturer. Additionally, 81% of respondents were aware of their reporting obligations (see Table 4).

Table 4 Awareness / perception of health care professionals (working in Importers of MDs) in the reporting of adverse event associated with medical devices (N= 52)

Sr. no	**Variables**	**Response (N, %)**		
		Yes	**No**	**I don't know**
1	Medical device use could be linked to patient illness or death.	28(54%)	12(23%)	12(23%)
2	Adverse event associated with MDs should be reported to EFDA/ manufacturer	34(65%)	13(25%)	5(10%)
3	Importers are responsible in reporting of AEs associated with MDs to EFDA	42(81%)	8(15%)	2(4%)
4	EFDA promote reporting mechanism for AE/ malfunction associated with MDs to your Organization	20(38%)	25(48%)	7(14%)
5	EFDA has an experience of controlling or monitoring of your organization in the post market surveillance of medical devices	12(23%)	19(37%)	21(40%)

5.1.3. The current practice of post-market surveillance of medical devices in the National Regulatory Authority

The study results showed that the National Regulatory Authority (NRA), i.e., EFDA, has statutory provisions, such as national policy, legislation, that give it the authority to direct the PMS of MDs. Additionally, the results showed that the NRA's existing organizational structure has a PV center, which is mixed with PV of medicines but not active and with many gaps. On the other hand, there was no PMS plan with a clear objective and timeline that targeted prioritizing high-risk medical devices.

Actually, there was no periodic activity of collecting safety data; rather, it was initiated in response to compliant reports from either local legal representatives or users. But, once there was a problem identified and reported, the NRA would take action, starting with a recall to withdrawal from the market. And the NRA does not oversee and supervise the local legal representatives in compliance with the obligation. Even though there is no standardized adverse event or malfunction reporting format specific for medical devices, the format created for medicines is still used (Table 5).

Table 5 The current status of the National Regulatory Authority in the practice of post-market surveillance of medical

Ser. no	Indicators	Findings		
		Yes	No	Remark
1	Existence of a statutory provision (national policy, legislation, and regulation) for PMS of MDs	√		
2	The legislation gives the mandate to the NRA to guide post market surveillance of MD	√		
3	The legislation defines PMS of MD	√		
4	Existence of organizational structure for PMS program/ PMS center	√		
5	Existence of human resource with adequate number, skill and (knowledge) experience for PMS of MDs in the unit		√	Currently there is no Delegated personnel
6	Existence of regular financial budget for the PMS of MDs program or activities		√	
7	Existence of concrete plans to carry out PMS activities with clear objective and time line		√	Still not approved and not Implemented
8	Existence of PMS plan/ program targeted to prioritized MDs (risk based)such as high risk MDs		√	Still not approved and not Implemented
9	Existence of guide line for implementation of PMS of MDs	√		
10	Existence of written SOPs and Tools for the implementation of PMS of MDs based on the plan		√	On plan
11	Existence of any mechanisms (e.g., coordination, task group, intelligence) for coordination of key stakeholders		√	
12	Existence of means of communication with legal local representatives/importers, user and with other regulatory authorities		√	Most frequently during the process of market authorization. Not for safety issue of MD
13	Does the NRA regulate and control importers in compliance of the requirement in protecting the public health		√	
14	Existence of risk management and communication and enforcement system		√	
15	Experiences of collection of safety data surveillance of MDs that are being present in the market		√	There is no planned and periodic activity that the authority done by itself
16	Experience of receiving safety data report (complaints, problems linked with MDs) from importers, health care professionals, and users in the last two years	√		
17	Existence of evidence-based decision-making practice through the use of PMS data (e.g. regulatory actions taken against poor quality MDs) Withdrawal from the list of marketed MD Recall Quarantine Disposal Financial penalties and Prosecution Warning letter	√		On some products E.g. Condom, gloves, syringes
18	Existence of training program on reporting and management of AE of MD to the staff of PMS unit in the NRA, Authorized representatives/MAH/, health care professionals and users		√	There is no functional unit in the Authority that is dedicated to manage this
19	Existence of AE of MD reporting methods for authorized representatives and health care professionals and user	√		Hard copy Email Free call i.e. 8482
20	Does the organization has monitoring and evaluation platform for its PMS program (documented evidence)		√	

5.2. Qualitative Findings

5.2.1. Socio-demographic characteristics of Key Informants

A total of 12 Key Informants were interviewed, of which 5 of them were from EFDA, 5 from Importers and 2 of them from health facility (one from specialized, and one from general hospital).The detailed socio-demographic information was described in the following (Table 6).

Table 6. Socio-demographic characteristic of Key Informants

Se.no	Variable	Category	N (%)
1	Gender	M	10 (83%)
		F	2 (17%)
2	Age group	< 30	2 (17%)
		30-40	9 (75%)
		>40	1 (8%)
3	Profession	Pharmacist	5 (42%)
		Biomedical engineer	7 (58%)
4	Level of education	MSc	4 (33%)
		B pharm, BSc	8 (67%)
5	Current position	Medical device facility inspector	2 (18%)
		Medical device registration and licensing expert	1 (8%)
		Pharmacovigillance and clinical trial expert	1 (8%)
		Directorate director at EFDA	1 (8%)
		Managers(General, Deputy, technical) and also sales and service manager	5 (42%)
		Pharmacy head	1 (8%)
		Bio med. Technologist	1 (8%)
6	Work experience	5-10Years	9 (75%)
		>10 years	3 (25%)
7	Work organization	EFDA	5 (42%)
		Importers	5 (42%)
		Health facilities(Hospitals)	2 (16%)

5.2.2. Key informants' perspectives and experiences on the regulatory challenge of implementing post-market safety surveillance of medical devices

The findings of key informants' perceptions and experiences about the difficulties in implementing post-market surveillance of MDs and their improvement strategies were analyzed using a thematic analysis approach. This resulted in four major themes, namely, EFDA's current system's capabilities; challenges to the implementation of post-market safety surveillance of medical devices; the effects of inadequate implementation; and improvement strategies/future perspectives

I. The capacity of current system of EFDA

Similar to other developing nations, our nation's post-market safety surveillance of medical devices regulatory system is very weak. Even if there were a number of patient safety problems or complaints associated with the medical devices, there was little experience managing and monitoring them. The key informants (KIs) expressed the current EFDA system's capability in controlling and monitoring marketed medical devices from various perspectives. The majority of participants were evaluated and labeled as not capacitated, which was seen in terms of structure, resources, and communication. The current mixed structure of medicine and medical device regulation makes the device does not get adequate attention. This is because the majority of professionals that are present in the structure are pharmacists. In terms of resources, the current system of the EFDA has a scarcity of skilled and adequate human power to perform or implement the PMS of medical devices. On the other hand, there are no ways for communicating about medical device-related patient safety issues with other stakeholders, ranging from MAHs and importers to lower-level health care professionals and the general public. One of the communication methods is the AE reporting system. As of now, no AE reporting system has been established for medical devices, so no report on a medical device-related safety issue has been done. One of the key informants expressed as

"… *EFDA focuses more on medicine, even during inspection time, they only inspect medicine rather than both medicine and medical devices. In my opinion, they do not have enough and adequate human power with adequate knowledge for PMS of MDs. And in terms of communication, there is no information sharing mechanism or even no publication on their*

website about medical device related issues. Generally, the system is not adequate to invite the stakeholders." [p 3, 5 years, importer]

The other participant also described as

"... I do not think that the current system of the EFDA has the capacity to control and monitor the marketed medical devices. This is because primarily the medical device and medicine regulation systems are in the same directorate and the composition of the staff is not appropriate, i.e., most of them are pharmacists and no biomedical engineers are included. This lengthens the regulatory process, especially for MDs. "And also, the mixed structure of medicine and medical device regulation makes it difficult." [P 7, 6 years, importer]

All stakeholders, including the EFDA, give more attention to the pre-market approval stage. Even after the importer gets licensing and registers its device, no one will monitor the safety and performance of the device. And also, the system is open and exposed to introducing any similar fake devices once it is approved by the sample. This is corroborated more by the one KI

"...I think the EFDA has strong regulatory premarket approval system compared to the east African countries. This means it gives more focus on pre-market stage control. On the other hand, the importers also try to fulfill the requirements at this stage. Then after, they only focus on their business."[p 8, 13 years, importer]

II. Limitations to the implementation of PMS program of medical devices

The other major theme was characteristics that limit the PMS program's implementation in medical devices. The key informants described many factors with regard to the limitation of the implementation of PMS for medical devices, namely, inadequacy of legal provision; mix-up of the program (Medicine and Medical Devices Regulatory Directorate); lack of resources; lack of awareness; lack of adequate skills; lack of coordination and collaboration between stakeholders; and lack of technology.

a. Inadequacy of legal provision

According to certain key informants (KIs), one of the problems that restrict the implementation of PMS in medical device is the legal framework's inadequacy. The legal framework is crucial to

the implementation and enforcing the law for monitoring of marketed medical devices. Participants in the interview stated that, while there is a proclamation granting the NRA to control and monitor medical devices, there is no enforcement mechanism for implementation. One of the problems that restrict the implementation of PMS in medical devices, according to certain KIs, is the legal system's inadequacy. One of the participants summarizes the above statements as:

"…currently there is no problem with the proclamation. It gives clear mandate to Regulatory authority to control and monitor the medical devices starting from design of medical device up to its disposal, contrary to this, there is no enforcement mechanism for implementation. [p 1, 8 years, NRA]

b. Mix up of the program

The majority of participants stated that the primary barrier to the implementation of PMS for MD is the mix up of the regulatory structures for medicines and medical devices at each regulatory control unit, particularly the mix-up of the program of pharmacovigilance for medicines and post-market surveillance for medical devices. One of the KI described as

"…The main factor behind this limitation is the merger of the directorate, i.e., both medicine and medical devices are managed in one unit and also the improper allocation of professionals, i.e., pharmacy professionals for both, which makes the medical devices not to get suitable and appropriate attention and also there is not even AE reporting format for medical devices which results in failure in the program" [P 9, 7 years, importer]

c. Lack of resources

Most of the KIs interviewed described resource constraints as the main challenge for full implementation of PMS in medical devices. They grouped resource constraints as being related to human resources and budget. Assigning suitable human resources is essential at every stage of medical device regulation, from the EFDA to the lower health facilities. Even if a large number of medical devices are imported into the country either through procurement or donation from industrialized nations, their management and proper usage are challenging without a sufficient

number of skilled and adequate human resources. And the KIs' described scarcity of human power is the main reason for the PMS for MD not to be implemented as required.

"...It is impossible to get relevant human resource in medical device regulation program especially in PMS of MD. Even if there is department called pharmacovigilance and clinical trial unit which is given the mandate to both medicine and MD under product safety directorate, the assigned professionals are all pharmacists in which they only focus on medicine and have inadequate knowledge about medical device PMS program. Contrary to this, no medical device professionals are assigned to the unit, because of this the pharmacovigilance (PMS) program of MD is inactive or almost at zero level. [P12, 10 years, NRA]

The assignment of an appropriate budget will facilitate every process in the work; this is also true for PMS in medical device. On this regard, there is no allocated budget for the implementation of this program; it makes the implementation of the program difficult. One of the KI described the budget constraint as follows.

"…there is no budget allocated for medical device post market surveillance program by the NRA. Rather, when there is complaint or reported problems by the users or market authorization holders, we make post market safety surveillance in some selected devices like condom, different kits (malaria kits, HIV kits), and gloves and so on, with the help of fundraising companies such as NGO's donation. This makes it difficult to do the PMS regularly as needed. [P 2, 8 years, NRA]

d. Lack of awareness and knowledge

The KIs stated that lack of awareness is the greatest obstacle to effective implementation. There is a significant knowledge gap across all levels of healthcare professionals as well as among the general public. Even though EFDA's top managers have mostly changed their perspectives in the previous few years, there is still considerable awareness gap, which prevents the implementation of a post-market safety surveillance program for medical devices. In some health care professional, there are difficulties in differentiation of medical devices itself and its associated consequences like adverse events to the patient. Furthermore, the presence of insufficient skill and knowledge among health facility staff means that the number of nonfunctional medical devices present in health facilities, particularly hospitals, is high; some of them would be easily

managed, but there are also medical devices that are malfunctioning but still being used, causing patients to spend a lot of time in the hospital or worsening their illnesses, which can lead to death. The MAHs/importers of medical devices, on the other hand, have a limited understanding of the post-market safety surveillance of medical devices and only focus on the "aftermarket services" they promised during the agreed-upon warranty period with the customers at the time of purchase. The primary goal of aftermarket services is exclusively business, i.e., the sustainability of the business rather than patient safety. They are unconcerned about the patient's medical device issue.

One of the participants expressed this.

"…Once the importers or distributers sell the device to the facility, since they do not have the awareness of the safety surveillance, they do not totally monitor the safety and performance of the device and some of them are not even willing to do maintenance. When we see at health facility level, the number of equipment that are stored as nonfunctional is high, whereas they can be maintained and be functional with small spare parts. But, since the awareness is very low and also absence of appropriate professionals at the facility level make it difficult and lead to loss of high cost."[P 10, 8 years, Health facility]

Another participant also described the issue as

"… The main challenges to apply the PMS of medical devices is the presence of huge awareness gap within all stakeholders who are responsible in the supply chain of medical devices starting from EFDA's staff, local agents, and customers. Even when there is desire by the manufacturers to report Periodic Safety Update Report (PSUR) by their local agents, there is reluctance of handling this process by EFDA. [P 6, 13 years, NRA]

e. Lack of coordination and collaboration between stakeholders

The KIs who participated in this study described that the collaboration of all stakeholders involved in the supply chain of medical devices is necessary for post-market surveillance of medical devices to be successful; failure to do so will result in program failure. This is supported by the following KI's idea

"…most of the time, we meet with EFDA either during the registration time for the new product or during the inspection period, even the inspection is focused on medicine only" [P 9, 7 years, importer]

f. Lack of Technology

As Ethiopia is a developing country, we do not have adequate technologies in many areas. This is also true in the health care system, especially in the regulation of medical devices as they are fabricated and imported from other developed countries. Each medical device should be allowed to enter the country after multiple inspections. To do this, it needs advanced technologies, including lab equipment, which is not available in our country. As a result, multiple falsified and outdated medical devices are allowed to enter our country and be marketed to users, and after marketing, we are unable to control or monitor the product due to a lack of adequate lab technologies and skilled manpower, resulting in the patient being exposed to these falsified devices. This is supported by the following statement

"… At the premarket stage, it is illegal to approve medical devices only by reviewing documents, since documents can be fabricated. But, because of our country's incapacity to approve the medical device effectiveness, and quality using laboratory tests, we accept without doing this. Most of the time, this is done believing the international manufacturers are practicing international legal agreements. This weak premarket approval system subsequently poses a problem to the patients after marketing." [P 1, 8 years, NRA]

III. The impact of inadequate implementation

a. Impact on patient and health care professionals

Poor implementation of post-market safety surveillance of medical devices in one country means the devices that are marketed and used by patients and healthcare professionals are not controlled and monitored. This means we are not sure about the safety and performance of the medical devices. Because of this uncertainty about the safety and performance of medical devices, the patient will be exposed to unsafe medical devices, which can result in severe adverse events and even death. On the other hand, there is an increase in drug resistance bacteria which is because of inappropriate result of the diagnosis, e.g., TB. Sometimes, wrong diagnostic will result in false positive which force the patient to start medication for false TB diagnosis; The patient may then

through time be exposed to new TB bacteria from the treatment center and the new TB infection will develop resistance for the drugs There will be also increased transmission of diseases, cleaners and nurses working in hospitals also exposed to easily transmitted diseases, e.g., HIV, Hepatitis virus and so on because of the quality problem of protecting materials. There are also near-expired or outdated devices on the market and in health care facilities that put patients at risk of death. These cause health care professionals to lose confidence in their services. One of the participants strongly describes this as

"... After premarket approval, the system is open to allow introduction of falsified medical devices, and also no monitoring post-market which has impact on the transmission of diseases to increase" [P 6, 13 years, NRA]

The other participant working in health facility added that

"... If I knew the medical device that I used in the patient treatment or diagnostics has quality problem, I will not be confident in my work and I will always be in fear" [P 11, 8 years, Health facility]

On the other hand, KIs clarified the impact of the exemption rule used in emergency situations, stating that because certain of the requirements that must be met in a normal circumstance will not be required, it is challenging to ensure the quality of the devices. Because of this, it affects both the patient and the person operating the equipment greatly. Additionally, the devices that are donated and imported into the nation are of worse quality than anticipated. One participant from importer remarked

"... Medical devices that were appropriate for this treatment during the COVID period were permitted to enter without meeting the requirement, i.e., having several defects (with exemption rule). Even while it has the benefit of meeting demand, when put to use it will fail quickly, failing to serve the manufacturer's original purpose. All of these result in the device not functioning as intended, and the majority of COVID patients in the ICU died as a result." [P 3, 5 years, importer]

b. Impact on regulatory authority

The EFDA is the sole regulatory authority in the country, and the PMS of medical device is the main regulatory function and mandate given by the legislation. However, failing to follow the legislation's requirements will have its own consequence. One of the KI explained as follow

"…One consequence of not implementing PMS of MD on the Authority itself is it will lose its trust from other stakeholders that are responsible in the supply chain of the medical devices including health care professionals, importers, distributers and local agents. And also it will lose its trust from the public who are aware."[P 7, 6 years, importer]

*An*other participant from the RA explained from maturity level perspective, where, it is given by WHO to its members of National Regulatory Authority based on their effectiveness of their regulatory system

"…Since EFDA is the sole regulatory authority in the country, the only thing that NRA loses by not fully implementing this PMS of medical device is decreasing its 'maturity level' " [p 12, 8 years, NRA]

c. Impact on country economy

Lack of an efficient post-market surveillance program for medical devices will have a significant impact on the country's economy. This is due to the fact that, as a third-world nation, the majority of our medical devices were imported using loans obtained from developed nations to pay for them. And if this imported equipment is not used for the intended purpose specified by the manufacturer, many of them will fail and have to be discarded. This implies that patients would not get appropriate care, which also means leaving the diseases to worsen and, finally, increasing deaths. Then, we will still require other MDs, making us reliant on loans and unable to stand on our own. And then, the country's economy is always dependent.

"…I think most medical equipment found in governmental higher health facilities were being out of service with the need of small spare parts but no one wants to solve the problem rather they will be thrown in the garbage and new ones will be procured, which result in the loss of millions of dollars. When this happens to all other health facilities, it will have an impact on the country's economy" [*P 9, 7 years, importer*]

IV. Improvement strategies and Future perspectives

The KIs proposed certain strategies for the improvement of the weak practices of post-market surveillance of medical devices, which include: splitting the structure of medicine and medical device regulation; creating awareness and increasing knowledge starting from the staff of EFDA to all stakeholders who are responsible for the management of medical devices; creating serious coordination within responsible stakeholders; and establishing an efficient regulatory body.

a. Reorganizing the current structure of medical device regulation

The majority of KIs noted that the current system of medical device regulation is mixed with the medicine regulation program, which makes regulation of medical devices more difficult, i.e., the regulatory plan and action taken are based on the medicine regulatory concept, especially in the product safety unit. This is because there were no procedures, or SOPs used to implement its PMS program (assessing the medical device's safety, quality, and performance that are present in the market or used by patients), and beside this, the professionals assigned were all pharmacists, who were responsible for medicine only. On the other hand, medical devices do not have assigned professionals. Due to the aforementioned reasons, it is necessary to restructure the regulatory system for medicines and medical devices. To do this, the programs for the two types of broadly regulated items must be separated, and each must be governed by its own set of regulations, protocols, and SOPs. Additionally, they assign their own qualified and trained specialists to each program. One of the participants from the EFDA, described as

"… to improve the regulatory program, the separation of medicine and medical device regulation must be the first initiative, then making a team with adequate skill and knowledge of this medical device PMS process, so they will prepare guidelines, SOPs, and procedures, which are used to implement the program and also the team has responsibilities of awareness creation, AE reporting system to be implemented, and also doing analysis of these reported problems and timely action to be taken. In addition to these, it has responsibilities of modifying the guidelines based on the result obtained."[P6, 13 years, NRA]

The other participant from the MAHs recommends

"…restructuring the current system of regulation program of medical devices at EFDA is essential and should be done. After that, pilot program should be implemented by participating all stakeholders who are responsible" [P3, 5 years, importer]

b. Increasing of Knowledge and awareness

The other key technique for successful implementation of post-market safety surveillance of medical devices that the KIs described is raising awareness and increasing knowledge among all stakeholders. Since the majority of healthcare professionals have awareness gap of the necessity of post-market surveillance, it will be challenging to achieve. There are many methods of creating awareness and increasing understanding of the PMS of MD among healthcare professionals. One of these is preparing continuous training for each stakeholder. Following the development of the PMS program unit in the medical devices regulation directorate, the EFDA, as the regulatory authority, must allocate budget for staff skill and education. And this skilled and well educated staff will train and give awareness to the responsible stakeholders. The MAHs, /importers, and healthcare professionals working in the health facilities should also be committed to responding to the changes. The other method of increasing knowledge and awareness is by sharing experiences with other countries that have already implemented and been successful, especially countries that are at the same level of development in terms of resources and economic development, to learn how to tackle the challenges and become effective.

This is supported by the KI from regulatory authority

"...awareness should be created through the organization of continuous training after the medical device regulation program is separated from medicine, not only for the staffs working in the post-market surveillance program but also for all staffs working at the programs of medical device regulation." [P 1, 8 years, NRA]

''…since one of the reasons behind poor implementation of PMS of MD is lack of awareness within all stakeholders, it is important to create awareness through preparing panel discussion'' [P 10, 8 years, Health facility]

KIs also noted that increasing the knowledge of healthcare professionals on reporting adverse events from medical devices is important. These adverse events include any problem that occurs on a patient and causes harm to the patient that is associated with the medical devices used, as well as malfunctions of medical devices that occur even when they are not used on patients. This can be done first through the training of healthcare professionals and then by encouraging them to make AE reporting a regular part of their daily routine work. On the other side, the key issue is the lack of a suitable AE reporting format, i.e., no reporting format was established for medical devices, and the currently available format is based on medicines, so it is challenging to use because it lacks information related to medical devices. So, in relation to giving training on AE reporting, it is essential to prepare an appropriate reporting format first. In addition to the paper-based reporting format, it is necessary to prepare an online and database-based reporting system for medical devices.

"… In our country, most health care professionals are aware of reporting of medicine related adverse events only, even if, it is not effective as expected. On the other hand, when we see medical devices related adverse event reporting culture, it is at zero level, i.e., not starting at all this is because of lack of awareness within the professionals and also absence of appropriate format. So, it must be the first work." [P 9, 7 years, importer]

The KIs also stated that the long-term strategy to tackle the challenges in the implementation of post-market surveillance of medical devices is integrating the general medical device regulation program into the curriculum of education. One of the participants stated as follows:

"...Since medical devices have an impact on patient treatment and diagnosis that is equal to that of medicine, and because they have different regulatory science, they need to be controlled and examined independently. So, as a curriculum of regulatory affairs for medicine and food track implemented in MSc program, it must be true for medical devices" [P 6, 13 years, NRA]

c. Coordination and collaboration of stakeholders

According to KIs, in order for post-market safety surveillance of medical devices to be successful, all stakeholders must play significant roles and fulfill the obligations placed on them. Every stakeholder must be committed and knowledgeable. The regulatory authority must set up its system as well as manage and enforce other stakeholders in accordance with the established

regulations and guidelines. Making information distribution channels between stakeholders is one strategy, i.e., there should be ways of communication between responsible stakeholders, including RA, MAHs/importers, health care professionals at each level of health facilities , educational institutions and also ministry of health. While stakeholders, such as importers, should stop business-oriented practices and instead prioritize patient safety first. This is accomplished by accepting accountability for the devices they imported as well as by maintaining communication with the end users. They must monitor the devices' performance and safety until the point at which they are disposed of. Health care professionals working in health facilities should also be active in monitoring the devices they use for patient diagnosis and treatment, i.e., for each problem that occurs on patients, it is critical to determine whether or not it is related to the devices used and to take appropriate action. Also, be active in the monitoring of malfunctioned medical devices present in their unit of work and in reporting them to responsible bodies. One of the KI described as

"… The system most importers followed, i.e., business-oriented aim should be changed to patient safety objective. They should be responsible for each device that they imported is safe and effective until it is disposed, and any problem that happened should be reported not only to their supplier but also to EFDA to take responsible action. On the other hand, the healthcare professionals should be responsible to the device they used."[P5, 13 years, importer]

The other participant also described as

"*…post-market surveillance of medical devices is not the responsibilities of one entity; rather it needs coordination of all stakeholders who are responsible in the medical device supply chain. In our country, since health care service is controlled by MOH, it is not possible to enforce health care professional rather only through encouraging reporting any problem associated with medical devices used; whereas it is possible to enforce the importers to report the problems linked to their product to EFDA in addition to their suppliers"* [*P 2, 8 years NRA*]

d. Establishment of an efficient regulatory system and capacity

The EFDA is a major player in the implementation of post-market safety surveillance of medical devices. As the KIs stated, for the post-market safety surveillance of medical devices to be effective, the EFDA should be capacitated in its regulatory system in terms of the legal

framework, human resources, budget, reporting tools, and others. The first and main requirement is to develop a PMS of MD-specific policies, regulation, guidelines, and SOPs, which are used to enforce and monitor the responsible stakeholders in the implementation of the program. The EFDA should also have skilled and adequate human resources for effective management of the program. As RA, it is expected that more initiation is needed and that the stakeholders will follow. This would be done through skilled human power. Budget is also an essential requirement, so EFDA should allocate enough budget specific to this program. One of the participants explained it as

"... If the existing implementation needs to be improved, the EFDA is the key player. However, it is unable to manage and monitor on the current state so it should capacitate its regulatory system, which would enable to improve the management of stakeholders in the assurance of patient safety. "[P 12, 13 years, NRA]

6. Discussion

This study tried to assess the current practice of post-market safety surveillance of medical devices among importers and in the NRA. It also tried to explore the regulatory challenges that have limited its full implementation and its improvement strategies. The quantitative and qualitative analysis results showed that the current practice of post-market surveillance of medical devices in our country is at the preliminary stage, and there have been many regulatory obstacles to fully implement the medical device PMS system.

Every manufacturer and importer of medical devices should submit a post-market surveillance plan for their products marketed to the user and patient. The PMS plan should have a different approach and scope based on its type and risk class (WHO, 2020). Despite this requirement, since most developing countries have weak regulatory functions, it is difficult to control and monitor the devices' safety and performance through the coordination of their local legal representatives (Dusabe, 2020). In this study, the findings show that there is a significant gap between the plan and its implementation, i.e., more than 70% of Importers had a PMS plan, which was expected to be implemented, but when we saw the implementation status, it was only 18%, implying that most importers prepared the PMS plan solely to meet the criteria requested during the market authorization process rather than to inquire about patient safety.

Importers should collect the safety data surveillance either through themselves based on the risk of medical devices or receiving adverse event report from the health care professionals and user, then analyzing and giving feed back to the user is mandatory, but, only less than 25% of Importers had experiences with collecting safety data surveillance, which is done at the initiative of the supplier or manufacturer, during which there was a safety problem in other supplied countries even though there was no full documentation. On the other hand, it was possible to say they didn’t have experience of receiving any AE associated with medical devices from healthcare professionals and users (4 out of 52 importers). Even though 58% of them gave positive response for action taking and gave feedback for the received complaints, it was not as much since the received complaints were almost none. Furthermore, the results showed that only 8% of adverse events and malfunctions in medical device were acknowledged and resolved, despite the fact that the problem was massive. These all demonstrate that, first, the importers have only communicate with their suppliers / manufacturers of the medical devices they

imported; in contrast, they have limited channels of communication with the NRA as well as with their end users regarding safety issues with medical devices. The second and most important indicator of these findings is that post-market surveillance of medical devices, particularly the adverse event reporting system, is not given as much attention.

The national regulatory authority in one country is the primary and sole responsible body for controlling and monitoring medical device safety by developing, implementing, and enforcing the regulations, guidelines, and SOPs that must be followed and implemented so that other stakeholders (such as importers, health care professionals working in various health facilities, and users) comply. This study demonstrated that, as in other developing countries with weak medical device regulation (Dusabe, 2020), there is a huge gap in the implementation of post-market surveillance of medical devices in this country. The regulatory authority follow a reactive mode, i.e., they take action based on the problems or complaints reported either by the user or healthcare professionals. This meant that any adverse events that occurred on the patient or medical device malfunctions would not be assessed and reported unless healthcare professionals or users reported them. On the other hand, there was less reporting experience from the importers to the NRA.

This is contrary to the result obtained in India and Australia, where the Indian Pharmacopoeia Commission, which is the national coordinating center, received about 1931 adverse event reports within four years, mostly from MAHs (Shukla *et al.*, 2020), in Australia, where most adverse events (85%) were reported by the authorized representatives (TGA Administration, 2017).

Beside this, even if more than 50% of them have knowledge of adverse events associated with medical devices, there has been less reporting experience from the importers to the NRA. This is because 65% of the importers didn't know it was reportable, and more than 80% of them do not understand their obligation. From the study, we understand that, there was awareness and knowledge gap among importers, because of this, there was no experience in reporting any problem. A study done in Saudi Arabia, shows that, even though over 66% of respondents had experienced technical or usage errors related to medical devices, the majority of them, i.e., 78%, have never reported these adverse events, both to avoid legal liability consequences that could be traced back to them and also because of their lack of knowledge about the existence of specific

legislation for adverse events of medical devices (Alsohime *et al.*, 2019). The other study done in resource-limited settings also presented the finding that, since there was underreporting of the poor quality of MDs and IVDs, patients living there were exposed to them. (Mori et al., 2014) This indicates that there was a significant lack of awareness among health care professionals regarding the goal of adverse event or malfunction reporting of medical devices.

The quantitative result obtained also indicated, at the EFDA, lack of resources like human resources and the failure to allocate funding for this program are two of the main reasons why the post-market surveillance for medical devices has not been put into action. As a result, RA has been forced to delay taking action on the ad hoc reported adverse event. This delay in taking action means the problem is continuing and would also harm the public, which is an indication of failures in one's responsible organization.

Training program is one way of creating awareness and also strengthening the program of post market surveillance of medical devices and adverse event reporting system and the regulatory authority is mandated (WHO, 2020). But the study result indicated that there was absence of a training program regarding post market surveillance of medical device from the NRA, which contributed to the gap in knowledge and awareness created among health care professionals working in the regulation of medical devices; the NRA has not yet organized any training for its staff or the other responsible stakeholders. On the other hand, some importers (19%) reported that when they procured or imported new devices, their manufacturers/suppliers had arranged training for their staff, but the EFDA had not sent out any offers for training. Similar result obtained in UK and also in African countries. The study done in UK, demonstrated that the level of training is not as needed as even if it is used to reduce device related risk. Only 12% of training were device specific training and around 60% of the training were manufacturer initiative (Tase *et al.*, 2022). In African countries the study done demonstrated that most trainings gained from their suppliers especially on regulation of condom (Dusabe, 2020). In our country, there was not adequate educational training program regarding medical device regulation, particularly post-market safety surveillance of MD, and the number of existing medical device professionals including biomedical engineers, are insufficient. So, it is better to strengthen in capacity and quality the existing professionals through training and also by sharing experience with other countries that have successfully implemented this regulatory activity. So,

preparing a continued training program should be mandatory. Due to a lack of training in this program, health care professionals working in each step of the medical device regulation, from the main responsible body EFDA to lower level health facilities, were not aware and would lack sufficient skill and knowledge in assessment, identifying and taking the necessary action, as well as patient monitoring for those in the treatment and diagnosis with the medical devices. So, at this point, we can say that it was difficult to ensure the safety and performance of medical devices that are on the market and are used by patients and health care professionals. This finding is supported by a study conducted in India, which recommends that the country's educational curriculum for health care should include post-market surveillance of medical devices and their adverse event reporting as one subject in the postgraduate program, as well as training should be a criteria for doctors during license renewal (Saifuddin,*et al*., 2022).

The qualitative analysis result revealed that one of the major challenge stated was the mix-up of the programs of medicine and medical device regulation, especially the post-market safety surveillance of medical devices and the pharmacovigilance unit of medicine in the EFDA. This program mix-up causes medical devices to be ignored for two reasons: first, most of the professionals assigned are pharmacists, so they focus on medicine; and second, they all adhere to the medicine regulation concept rather than the medical device. The same result was obtained in the study done in countries found in two different scenarios: Tanzania, where the medical device regulation was not robust since the medicine regulatory framework was followed (Dusabe, 2020), and in studies conducted in developed countries with well-developed medical device regulation (the United States, the European Union, and Japan), indicating that the mix-up of the medicine and medical device regulatory frameworks was a challenge in the development and evolution of medical device regulation (Altenstette, 2012).

The other factor described was lack of adequate and skilled human power at each regulatory control step of medical device. Human power is the main and one of determinant for the policy and objective to be implemented. The study found that the NRA lacked sufficient and trained human resources, which prevented the legislation from being put into effect on a practical level. In addition, it was noted that a major problem to the program's effectiveness was a lack of funding. This result also supported by the study done in 2020, in ten Africa countries including Ethiopia, which showed that none of the countries have specific medical device regulation or

regulatory body as that of developed countries, in which established regulatory frameworks are broad in their approach to regulation, encompassing many types of product, however they have divisions and trained personnel for the regulation of medical devices specifically. Where as in developing countries even though the regulations are presented broadly to cover medicines, foods, cosmetics, and related substances, they likely lack the resources and a critical mass of skilled personnel to focus solely on the regulation of medical devices (Saidi and Douglas, 2020).

Lack of technology was also stated as one of the challenges in the implementation of post-market safety surveillance of medical devices. Since medical devices are becoming more advanced in technology, the regulatory system should also be more advanced starting from premarket approval to its post-market surveillance system. The same result obtained from the study done in UK (Pane, Katia M.C. Verhamme, *et al.*, 2020). Otherwise, confirming the quality, safety, and performance of medical devices would be more difficult, which result in patient to be exposed to risk.

The above all result were supported by the study findings done in Africa, which stated that insufficient number of staff, neglecting PMS of MD due to lack of funding, mix up of the medicine and medical device program and also the absence of regulatory framework of its own were challenges in implementing of PMS of MD in most African countries (Dusabe, 2020).

The qualitative analysis result also demonstrated the impact of not fully implementing the PMS of MD in the health care system. Not implementing the PMS of MD in one country means deciding that the patient and users of medical devices will be exposed to unsafe, ineffective, and poorly performing medical devices, which will mean the patient will stay in the hospital for a long time, i.e., the diseases will be exacerbated, and even death will occur. This result is supported by the study done in Africa, (McNerney and Peeling, 2015) This also results in a loss of trust by patients and the public in healthcare professionals, medical device importers and the NRA, and this finally makes the healthcare system fail. This result was also exacerbated during an emergency situation in which even the premarket requirements couldn’t be fulfilled, which means the device that was entered into the country under the exemption rule was not assured of the safety and quality of medical devices. A similar finding was found in a study done in Bosnia, which showed that mechanical ventilators that were marketed during COVID time without being

tested have been proven faulty in clinical settings, and today, lawsuits are being filed in many countries against those responsible for the deaths of many patients. The consequence was high in countries with no PMS program (Badnjević, A., Pokvić, L.G., Deumić, A. and Bećirović, 2022). The other study done in the US concluded that medical device failure and recall would affect all the key participants in the medical device supply chain, but patients and end-user customers tend to be the worst affected by medical device malfunctions (Thirumalai, S. and Sinha, 2011).

The other effect of poor PMS implementation in MD, as described by key informants, was on the country's economy. As our country is classified as a "third world" (developing country), most life-saving and other medical devices used for treatment and diagnosis purposes are imported from other developed countries, and the fund that is used to import these devices is again sourced from these developed countries (with loan), so if we do not use these imported devices based on the manufacturer's intended use as ordered on the labeling and also if we do not calibrate, adjust, and maintain them timely, we would lose many medical devices before reaching the end of their life cycle; this also makes us need other medical devices, which are also with other loaned funds, and when this happens all the time, the country would lose millions of dollars and also would not be free from loan Finally, the country's economy will be weakened. This suggestion is supported by the WHO report made in 2017, In low- and middle-income countries with lax medical device regulations, the distribution of substandard and low-quality medical devices would increase, resulting in large economic losses (World Health Organization, 2017).

The findings of the qualitative analysis suggested strategies for enhancing the current post-market safety surveillance: separating the medicine and medical device regulatory structures and stand on their own; following that, organizing a working group of senior expertise and finally, organizing and delegating its dedicated professionals to this unit; the dedicated professionals would then prepare the SOPs or procedures based on the guidelines. . The second strategy stated by the KIs is to coordinate and collaborate with the responsible stakeholders by preparing a panel discussion. This also indicated in the study done in US (Mehran *et al.*, 2004), building a collaboration among regulators, clinician investigators and manufacturers is essential for successful implementation of post-market surveillance of medical devices.

The other major strategy indicated was adapting an adverse event reporting system specific to medical devices, which is done through continuous training and mentoring by the newly formed

medical device directorate, especially the PMS unit at the EFDA. This result is supported by the study done in US, (Pane, Katia M C Verhamme, *et al.*, 2020), and in India to address the problem of quality issues with medical devices, it is appropriate to engage all responsible stakeholders in compliant reporting through the provision of tools and the preparation of educational materials for health care professionals at the health facility level (Saifuddin PK, 2022).

Even though it was difficult to fully implement the post-market surveillance program for medical devices, it is still possible to uphold and establish a strong regulatory system by creating an efficient regulatory authority through the development of human resources and economic ability, the cooperation and coordination of stakeholders, the development of a medical device-specific adverse event reporting system, and the advancement of laboratory technology.

7. Strengths and Limitations

7.1 strengths

One of the main strengths of this study is that it attempted to show the practice of PMS of MD in the regulatory Authority and Importers which are the main key player in the medical device regulation.

The other strength of this study is, it tried to use mixed study design, i.e., quantitative and qualitative in which more relevant information were gathered. The qualitative study design attempted to explore the data which are difficult to address in the quantitative study, which includes the challenges that hinder in the implementation of PMS of MD and also possible strategies to fully implement it.

On the other hand, since, this area of study is new and preliminary for our country; it will be a base for other researchers who want to study on this regard.

7.2. Limitations

Despite the fact that the study made an effort to demonstrate the current practice of post-market surveillance of medical devices among the major key players, namely, the regulatory authority and importers, it did not address the healthcare professionals' practice, awareness, and behavior in the adverse event reporting of medical devices used in their workplaces, i.e., at the facility level, which is one of the key elements of post-market safety surveillance. Due to time and financial constraints, the study was unable to do this. The other major limitation of this study is due to the presence of limited number of literature and even the presented articles published were not recent, make the study analysis to be difficult

8. Conclusions

This study generally demonstrated that the current practice of PMS of MDs at regulatory authority and importers is at infancy stages. Most of the regulatory requirements utilized to implement were either not present or just existed on paper only.

The full implementation of post-market surveillance of medical devices is, restricted by a number of problems, including the existing system, a lack of adequate and qualified human resources, a budgetary restriction, a lack of technology, and a lack of coordination and collaboration amongst stakeholders.

The lack of robust post-market surveillance of MD in the country had a negative impact on the healthcare system in several scenarios: the patient would be exposed to counterfeit or substandard medical devices; there would be a loss of trust in healthcare professionals and on NRA; there would also be a significant impact on the country's economy; all of this would affect the overall quality of care. Besides, the study also proposes some possible strategies to address the problems: the first strategy is creating awareness, creating Adverse Event reporting system, integrating the PMS of MD into the healthcare system, capacitating the RA with adequate and skilled human power, allocating budget, preparing guidelines and also procedures and SOP.

In general, creating a robust and effective post-market surveillance system for medical devices is not a one-time task; rather, it is a progressive task through time. So, for its effectiveness, it needs the active participation and commitment of all responsible stakeholders. This study suggests that, to fully implement the PMS system for MD, challenges should be combatted as much as possible.

9. Recommendations

Based on the study findings, critical analysis of thematic contents, and the conclusions made, the following recommendations are forwarded to the respective stakeholders.

Recommendation for the National Regulatory Authority

- It is important to restructure the existing system, i.e., separating the two broad regulated items (medical device from medicine) and making each to stand by its own.
- Updating the existing PMS policy and also making it adequate and responsive
- The separated medical device directorate should be equipped with adequate and skilled human power and allocate budget
- Awareness should be created within the staff and also to all responsible stakeholders through training and experience sharing
- Creating active Adverse Event reporting system starting from the RA to the lower health facilities
- Making strong collaboration and coordination with responsive stakeholders
- Establishing advanced laboratory with high technology which help in testing
- All stakeholders starting from NRA, medical device importers, educational institutions, healthcare professionals at health facilities should be committed for the change.
- There should be active and responsive policy and regulation on the medical devices which are imported by donation

Recommendation for the Importers

- The importers should develop concern about patient safety rather than business orientation only
- They should have to create ways of communication with the health facilities on the effectiveness and performance of medical devices
- Strengthening the department of PMS of MD through allocating budget and assigning skilled personnel to the place

Recommendation for Higher Education Institutions

- Strengthen the existing curriculum specific to medical device regulation for biomedical engineers
- Should work coordinately with responsible stack holders i.e. with EFDA, MOH, and also with other Non-governmental organizations
- Sharing information from foreign universities having a good experience and taking a sample curriculum that has been successfully implemented

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11. Annex

Annex 1

ADDIS ABBABA UNIVERSITY

College of health science

School of pharmacy

Department of pharmaceutics and social pharmacy

Respondent's profession_____

Respondent position_____

Year of work experience_____

Se.no	Indicators	Result		
		Yes	No	Finding
Legal mandate/statutory provision				
1.	Existence of a statutory provision (national policy, legislation, and regulation) for post-marketing surveillance of medical devices			
2.	Does the legislation give the mandate to the NRA to guide post market surveillance of medical devices			
3.	Does the legislation define post market surveillance of medical devices			
4.	Existence of organizational structure for post-marketing surveillance program/post market surveillance center			
i. Resources				
5.	Existence of human resource with adequate number, skill and (knowledge)experience for post market surveillance of medical devices in the unit			
6.	4. Existence of regular financial budget for the post-marketing surveillance of medical devices program or activities			
7.	Existence of concrete plans to carry out post-marketing surveillance activities with clear objective and time line			
8.	Existence of post-marketing surveillance plan/ program targeted to prioritized medical devices (risk based)such as high risk medical devices			
9.	Existence of guide line for implementation of post market surveillance of medical devices			
10.	Existence of written SOPs and Tools for the implementation of post-marketing surveillance of medical devices based on the plan			

I. Check lists for regulatory authority for assessment of Current status of post market surveillance of medical devices program

	i. Practices			
11.	Existence of any mechanisms (e.g., coordination, task group, intelligence) for coordination of key stakeholders			
12.	Existence of means of communication with legal local representatives/importers, user and with other regulatory authorities Receipt of incident reporting/adverse or events/malfunctioning of medical devices/complaints offering of feed back			
13.	Does the NRA regulate and control legal local representatives/ MAH in compliance of the requirement in protecting the public health			
14.	Existence of risk management and communication and enforcement system			
15.	Experiences of collection of safety data surveillance of medical devices that are being present in the market			
16.	Experience of receiving safety data report(complaints, problems linked with medical devices) from importers, health care professionals, and users in the last two years			
17.	Existence of evidence-based decision-making practice through the use of post marketing surveillance data (e.g. regulatory actions taken against poor quality medical devices) ✓ Withdrawal from the list of marketed MD ✓ Recall ✓ Quarantine ✓ Disposal ✓ Financial penalties and ✓ Prosecution ✓ Warning letter			
18.	Existence of training program on reporting and management of adverse event of MD to the staff of PMS unit in the NRA Authorized representatives/MAH/health care professionals and Users			
19.	Existence of adverse event of medical device reporting methods for authorized representatives and health care professionals and users ✓ Data based ✓ Hard copy ✓ Software /application ✓ E mail ✓ Free call			
20.	Does the organization has monitoring and evaluation platform for its PMS program (documented evidence)			

I. Check List for the Market Authorization Holders /Importers

Assessment of the practice of importers in the post market safety surveillance of medical devices

Name (code) of the organization_____

Year of starting work_____

Profession of the respondent_____

Position of the respondent_____

Year of experience_____

Se .no	Items to be measured		Result		
Part I General					
			Yes	**No**	**Remark**
1.	Does your organization have a plan of post market safety surveillance for medical devices that it imports to the country?				
2.	Does the post market surveillance plan has its scope in which prioritizing based on risk based approach				
3.	Does your post market surveillance has an objective i.e. what to achieve at the end of PMS of each medical device				
4.	Does the post market surveillance plan has post market clinical follow up plan (PMCF)				
5.	Does the PMS plan have role and responsibilities at each stage				
6.	Does your organization has available resources for post market surveillance activities of medical devices				
		a. Human resource			
		b. Budget			
		c. Infrastructure			
7.	Does your organization submit post market surveillance data(less than five year data) during registration/market authorization of the device in the country?				
8.	Does the PMS plan has a clear and well described data collection method (step by step)				
Part II current practice					
9.	Does the organization have medical devices list in which it import				
10.	Does the manufacturer have document of medical devices that it sales /distributed to the user				

11.	Does the organization use unique identification number(code) for MD that it distribute to the users			
12.	Does the organization implement the post market surveillance activities according to the plan (is there any evidence e.g. documented evidence)			
13.	Does your organization have an experience of collection of safety data surveillance of medical devices that it imports? see documented evidence 1)regularly 2)sometimes 3)never			
14.	Does your organization have an experience of receiving any compliant of therapeutic medical devices from users(in the last two years)			
15.	Does the organization categorized, analyzed and verified the collected feedback since the complaints can identify quality, safety and performance Issues that are of high risk and therefore might require immediate action to protect public health and safety.			
16.	Does the manufacturer has an experience of the rout cause analysis of an adverse event that you report, by establishing a methodology for determining the causes, then determining all probable causes and likelihoods for each cause (i.e., the probability that the cause contributed to the adverse event or incident); and the evidence for reported causes and likelihoods.			
17.	Does the importer have risk management plan for the adverse event/ malfunction associated with medical devices which is reported by users?			
18.	Does your organization have an experience of taking an action following the investigation of the complaint(adverse event) which is reported by users/ what type of action do you take **a)** Repair, modification, adjustment, relabeling, destruction, or **b)** inspection (including patient monitoring) of a product without its physical removal to some other location			
19.	Does your organization have legal medical device adverse event/malfunction reporting method(Email, data base, format, any other)			
20.	Does your organization have the system of distributing feedback information to the user after making risk based analysis of the compliant, for protecting the patient from similar repeated cases.			
21.	Does the organization prepare a PMS training program for its staff			
22.	Does the organization have been participated in any PMS training prepared by NRA			
23.	Does the organization prepared/given short term training for the user about the MD that it sold? (documented evidence)			
24.	Does the organization calibrate, provide maintenance according to the operation and service manual that the manufacturer prepared to the medical devices that it sold to the user (documented evidence)			
25.	Does the organization has monitoring and evaluation platform for its PMS program (documented evidence)			
26.	Do you think that medical device associated patient illness or death occurs? 1 Yes 2. No 3. I do not know			

27.	Do you think that adverse event associated with medical devices should be reported to EFDA/ manufacturer of that devices in which repeated patient illness will not occur 1 Yes 2. No 3. I do not know			
28.	Do you think that importers of medical devices are responsible in reporting of adverse events associated with medical devices to EFDA that they received from users/health institutions 1 Yes 2. No 3. I do not know			
29.	Does EFDA promote reporting mechanism for Adverse Event (AE)/ malfunction associated with medical devices to your organization 1 Yes 2. No 3. I do not know			
30.	Does EFDA has an experience of controlling or monitoring of your organization in the post market surveillance of medical devices 1.Regularly 2.Sometimes 3.Never			
31.	Do you think that the current system of EFDA for regulation of medical devices has the capacity to control marketed medical devices 1. Yes 2. No 3. I do not know			

II. Interview questions on regulatory challenges associated with implementation of post market safety surveillance of medical devices

Part I General

a. Code of the interviewee_____

b. Age_____

c. Sex: male_____ female_____

d. Profession of the interviewee_____

e. Level of education_____

f. Name of the current working unit_____

g. Current position in the unit_____

h. Year of work experience in the position_____

Part II. The experience and perception of senior staffs/Key Informants of EFDA on regulatory challenges/factors affecting implementation of post market surveillance of medical devices

1. What do you think on the necessity of implementing post market safety surveillance of medical devices? Explain it.
2. What do you think that the current system of EFMHACA/EFDA has the capacity to control marketed (in used) medical devices? elaborate it, probe in terms of

a. legal framework such as (Policy/legal provision, regulation, guideline)

b. System/structure

c. Resources

d. Information communication method with other stack holders(e.g. PMS tools)

3. What do you think the reasons (factors) behind for not implementing of post market safety surveillance of medical devices in Ethiopia? Explain it

   Probe: - Law, regulation, guideline; top management commitment; awareness; trained personnel, coordination and communication b/n stakeholders

4. What do you think the influence of not having post market safety surveillance program of medical devices on: probe

a. The health care system

b. Country economy

5. How to improve the existing practice and future perspective of post market surveillance of medical devices in Ethiopia?

6. What to be expected from the stack holders in the creation of effective post market safety surveillance of medical devices program in Ethiopia?

a. Regulatory Authority

b. Authorized representatives/MAH

c. Health care professionals

d. Other interested parties e.g. Universities

Annex 2

አዲስ አበባ ዩኒቨርሲቲ

ጤና ሳይንስ ኮሌጅ

የፋርማሲ ት/ቤት

የፋርማሲዉቲክስና ሶሻል ፋርማሲ ትምህርት ክፍል

<u>የቃለ መጠይቅ ፎርም</u>

<u>መግቢያ</u>

እኔ_____ በአዲስ አበባ ዩኒቨርስቲ ጤና ሳይንስ ኮሌጅ ፋርማሲ ት/ቤት በፋርማሲዉቲክስና ሶሻል ፋርማሲትምህርት ክፍል

በድህረ ምረቃ ፕሮግራም የሁለተኛ ዲግሪ (ማስተርስ) ተማሪ ስሆን የመመረቂያ ፅሁፌን **"የህክምና መሳሪያዎች ከገበያ በኋላ ደህንነት**

ክትትል፣ የቁጥጥር ተግዳሮቶች እና የወደፊት እይታ በኢትዮጵያ" ላይ እየሰራሁ እገኛለሁ። የዚህ ጥናት ዋና አላማ ከህክምና መሳሪያዎች ደህንነት ጋር በተያያዘ ሊቀረፉ የሚችሉ ችግሮችን ለይቶ በማውጣት በሀገሪቱ ውስጥ የተሻለ ህክምና መሳሪያዎች ደህንነት ክትትል ስርአት እንዲለብት ለማድረግ ነው፡፡ ስለሆነም ይህንን አርዕስት በተመለከተ መረጃ ለመሰብሰብ ይጠቅም ዘንድ ከታች የሚገኘውን ቃለመጠይቅና ቼክሊስት አዘጋጅቻለው፡፡በዚህ ጥናት በመሳተፍዎ በእርስዎ ጤና፣ አካልና ስነልቦና ላይ የሚደርስ ምንም አይነት ጉዳት አይኖርም፡፡ የእርስዎ ተሳትፎ ግን በሀገሪቱ ለሚተገበረው ትክክለኛ "የህክምና መሳሪያዎች ደህንነት ክትትል ስርአት መሻሻል ይረዳል፡፡ ጥናቱ ሙሉበሙሉ በፈቃደኝነት ላይ የተመሰረተ ሲሆን ከእርስዎ የሚገኘው መረጃ በሚስጢር የሚያዝ ይሆናል፡፡ መረጃ በሚሰበሰብበትም ጊዜ የእርስዎን ስምም ሆነ እርስዎን ሊያመለክቱ የሚችሉ ነገሮች አይካተቱም፡፡ በጥናቱ የመሳተፍ ወይም ያለመሳተፍ የእርስዎ ምርጫ ሲሆን በጥናቱ መሃል (ቃለ ምጠይቅ ጊዜ) አቋርጠው የመውጣት መብትዎም የተጠበቀ ነው፡፡ ለቃለ መጠይቁ የሚሰጧቸው ምላሾች ሁሉ በሚስጥር የተጠበቁ ሲሆኑ ከጥናት አድራጊው ውጪ ማንም ሰው የሰጡትን መረጃ ሊያገኘው አይችልም፡፡መረጃ ሙሉ በሙሉ ለመመዝገብ ይቻል ዘንድ በቃል-መጠይቁ ጊዜ የድምፅ መቅጃ መሳሪያ እና ናት መያዝ ያስፈልጋል፡፡ የእርስዎ ሀቀኛ የሆነ መልስ ለፅሁፌ እውነተኛነት እና በስኬት መጠናቀቅ ትልቅ ሚና ስላለው እንዲተባበሩኝ በትህትና እጠይቃለው፡፡ ቃለ መጠይቁ ከ25-40 ደቂቃ የሚፈጅ ሲሆን በመረጡት ቦታና ግዜ ሊካሄድ ይችላል፡፡ በመቀጠልም እርስዎ ፈቃደኛ ከሆኑ መጀመር እንችላለን፡፡

ከድህረ ገበያው የህክምና መሳሪያዎች ክትትል ትግበራ ጋር በተያያዙ የቁጥጥር ተግዳሮቶች ላይ የቃለ መጠይቅ ጥያቄዎች

1. መለያ ኮድ: _____

2. ቃለ መጠይቁ ያደረገው ስም:_____

3. የቃለ መጠይቁ ቀን:_____

4. ቃለ መጠይቁ የተደረገበት ቦታ:_____

ክፍል 1: የቃለ መጠይቅ ተሳታፊው አጠቃላይ መግለጫዎች

1. ፆታ፡ ሀ. ወንድ ለ. ሴት

2. እድሜ: (በአመት)_____

3. የሙያ መስክ: _____

4. የትምህርት ደረጃ:_____

5. አሁን ያሉበት የስራ መደብ:_____

6. የስራ ልምድ (በአመት)_____

ክፍል 2: ጥናቱን የተመለከቱ ጥያቄዎች

1. የሕክምና መሣሪያዎችን ከገበያ በኋላ የደህንነት ክትትልን መተግበር አስፈላጊ ስለመሆኑ ምን ያስባሉ? አስረዱት።
2. አሁን ያለው EFDA ስርዓት ለገበያ የሚቀርቡ (ያገለገሉ) የህክምና መሳሪያዎችን የመቆጣጠር አቅም አለው ብለው ያስባሉ።

ሀ. የሕግ ማዕቀፍ እንደ (ፖሊሲ፣ ደንብ፣ መመሪያ)

ለ. ስርዓት / መዋቅር

ሐ. መርጃዎች

የሰው ሀይል አስተዳደር

በጀት

መ. የመረጃ ልውውጥ ዘዴ ከሌሎች ባለድርሻ አካላት ጋር

አስመጪዎች

አከፋፋዮች

በጤና ተቋማት ውስጥ የሚሰሩ የጤና ባለሙያዎች

3. በኢትዮጵያ የህክምና መሳሪያዎች የድህረ-ገበያ ደህንነት ክትትል ደካማ አፈፃፀም ከጀርባ ያሉትን ምክንያቶች እንዴት ይገልጹታል? አስረዱት። ህግ, ደንብ, መመሪያ; ከፍተኛ የአስተዳደር ቁርጠኝነት; ግንዛቤ; የሰለጠኑ ሰራተኞች፣ ቅንጅት እና ግንኙነት ለ/ n ባለድርሻ አካላት

4. የህክምና መሳሪያዎች የድህረ-ገበያ ደህንነት ክትትል ፕሮግራም ያለመኖር ተጽእኖ ምን ይመስልዎታል?

ሀ. ታካሚ

ለ. የጤና እንክብካቤ ባለሙያዎች

ሐ. የጤና አጠባበቅ ሥርዓት

መ. የቁጥጥር ባለስልጣን

ሠ. የገበያ ፈቃድ ያገኙዎች

ረ. የሀገር ኢኮኖሚ

5. በኢትዮጵያ የሕክምና መሣሪያዎችን ከገበያ በኋላ የመከታተል ልምድ እንዴት ማሻሻል ይቻላል?

6. በኢትዮጵያ ውስጥ ውጤታማ የሕክምና መሳሪያዎች ደህንነት ክትትል ፕሮግራም ለመፍጠር ከባለድርሻ አካላት ምን ይጠበቃል?

ሀ. የቁጥጥር ባለስልጣን

ለ. የተፈቀዱ ተወካዮች/MAHs

ሐ. የጤና እንክብካቤ ባለሙያዎች

መ. ሌሎች ፍላጎት ያላቸው አካላት ለምሳሌ. MOH

6. ለፕሮግራሙ ውጤታማ ትግበራ ለወደፊቱ ምን ይጠቁማሉ?

Annex 3

Informed Consent Form for participants

Dear Respondent,

My name is Meaza Giragn. I am a second year MSc in regulatory Affairs (medicine regulation truck) student at School of Pharmacy, College of Health Science, Addis Ababa University, and I am working my research on the vtitle "Post market safety surveillance of medical devices, regulatory challenges and its future perspective in Ethiopia in the partial fulfillment of the degree of Masters (MSc). The purpose of this thesis is to assess the current practice of the post market surveillance of medical devices from local legal representatives of medical device manufacturer (Market Authorization Holder, MAH) and National Regulatory Authority (NRA) perspectives. The result obtained from the study will be a preliminary for others who will be interested and want to do further study in this area of field and also it is used as an input and an initiation for policy and decision makers for modification of the policy as well as post market strategy. To achieve the study objective, your honest and genuine participation by responding to the question prepared is very important and highly appreciated. So you have been selected to be part of this study and therefore I would like to collect data from you.

The data collection will be carried out mainly by the principal investigator of the study. The data collected from each participant will be entered into a computer where it will be maintained in password control. Hard copies of completed instruments will be kept in a locked file and will be available only for research study staff. The interview will take approximately 25 to 40 minutes. The study principal investigator may contact you again only if it is necessary to complete needed information. The participation in this study is volunteer based and you have the right to leave at any time of data collection. You are free to refuse to answer any question that is asked.

Meaza Giragn

Phone Number: 0912209208, Email: meazagiragn@gmail.com

N.B Signing this Consent indicates you understand what will be expected of you and are willing to participate in this study. Read and Agreed { } Read and Refused { }

Sign Respondent:_____

Sign Interviewer: _____ Date: ____/_____/___

Annex 4

Ethical Clearance

በ ፋርማሲ ት/ቤት
የኢቲካል ሪቪው ኮሚቴ

አዲስ አበባ ዩኒቨርሲቲ
Addis Ababa University

School of Pharmacy
Ethical Review Committee

To: **Meaza Giragn**
School of Pharmacy

ቀን Date: July 15, 2021

ቁጥር Ref. No.: ERB/SOP/309/13/2021

Re: Ethical Clearance

It is to be recalled that you submitted a research proposal entitled **"Post-Market Safety Surveillance of Medical Devices, Regulatory Challenges and its Future Perspective in Ethiopia"**. The committee thoroughly reviewed the proposal based on its operational guidelines and found that it fulfills all ethical requirements stipulated in the guidelines. This is, therefore, to inform you that the proposal is ethically approved for implementation.

With best regards,

Shemsu Ume[illegible] (PhD)
Chairperson, ER[illegible]
School of Pharmacy
College of Health Sciences
Addis Ababa University

00251156 02 12 | 1176 | ቴሌክስ Telex: 21205 | ፋክስ Fax: 00251(11)1558566 | ቴሌግራም Cable: AAUNIV

Annex 5

Plagiarism Checked Document

Document Information

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Similarity	4%
Analysis address	anteneh.belete.zauni@analysis.urkund.com

Sources included in the report

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W	URL: https://www.who.int/health-topics/medical-devices Fetched: 11/13/2020 8:37:00 AM	1
W	URL: http://www.imdrf.org/docs/ghtf/final/sg1/technical-docs/ghtf-sg1-n071-2012-definition-of-terms... Fetched: 1/17/2023 6:55:00 PM	2
W	URL: https://www.asianhhm.com/technology-equipment/current-scenario-regulation-monitoring-medical-devices Fetched: 11/4/2019 3:19:33 PM	1