

A STUDY TO ASSESS THE CHALLENGES OF HEALTHCARE PROFESSIONALS IN SPONTANEOUS IDENTIFICATION OF FALSIFIED DRUGS: UPGRADING PHARMACOVIGILANCE IN NIGERIA

Research dissertation presented in partial fulfillment of the requirement for the
degree of MSC in Pharmaceutical Business and Technology (QQI)

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Candidate Declaration

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I hereby certify that the dissertation with the below title

“A study to assess the challenges of healthcare professionals in spontaneous identification of falsified drugs: upgrading Pharmacovigilance in Nigeria” submitted for MSc in Pharmaceutical Business and Technology is the sole result of my work and where other authors work was used reference was duly acknowledged respectively.

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Acknowledgments

To my God, in heaven, I appreciate you for the gift of life and unlimited mercy and protection for seen me through this journey of becoming a master's degree holder.

Firstly, I would love to dedicate this dissertation to my Late father Snr Customs officer Mr. Odowgu Abraham Nwankwo, who had to suffer and sacrifice all jus to train me in school and provide all I needed in life u until is death. I say May his soul rest in perfect peace.

My unmeasurable gratitude goes to mum who through her daily prayers and motherly love kept me going in the quest for my master's degree in Griffith college. She is a virtuous woman who always gives me advice even when the situation seems tough, she was always there to help out.

I would also say a big thank you to the Pharmacy Association of Veterinary medical association of Nigeria, Nigeria medical association, and other healthcare professionals that help in responding to my questionnaire

And finally, this study would not be a success without my very own lecturers at Griffith College Dublin, Ireland for the knowledge they instill in me and especially Paul Blunnie my supervisor who always responds to me any time I need help, who offered me all the guidance through all the chapters of my dissertation I say a big thank you

Abstract

Drug Frauds are on the increase, falsified drugs are giving sleepless nights to both patients, healthcare professionals as well governments of different countries, and thus the regulation prohibiting the sales and production of falsified drugs cannot succeed with any form technological intervention. The study aims to evaluate several criteria that as contributed to the challenges of identifying falsified drugs among healthcare professionals- medical doctors, pharmacists, and other healthcare professionals in Nigeria. Through a questionnaire-based survey and phone interview for both the quantitative and qualitative analyses, respectively a review would be done. For this to be achieved the knowledge, awareness, and possible challenges faced by the professionals concerning falsified drug identification were considered to recommend an effective recommendation on different ways to improve such practice of pharmacovigilance in Nigeria.

In this thesis all the groups of healthcare professionals a comparison was made to ascertain different opinions on frequency observed on falsified drugs, ways of detecting falsified drugs, the technology used in identifying falsified drugs, as well as regulatory agency responsible for reporting of falsified drugs in Nigeria. A total of 131 responded to the survey of whom 62 (45.80%) were medical doctors and 43 (32.82%) were pharmacists as well as 43 (32.82%) were other healthcare professionals.

It was fascinating to see that 62% of the respondents agreed to the fact that they know how to identify falsified drugs (40 medical doctors, others 18, pharmacist 23) while 42%(13 medical doctors, others 17, pharmacist 12) of the respondents did not know. Only 6% of the healthcare professionals (7 medical doctors, 1 pharmacist) are not sure if they can detect fake drugs in Nigeria. From the study conducted it was unfortunate to note that pharmacists had average knowledge, awareness in comparison to a medical doctor who had better awareness of the in identifying fake drugs. However, 95% of all the respondents all agreed that identifying falsified drugs and reporting it should be made compulsory as part of the way of upgrading pharmacovigilance in Nigeria.

Some of the challenges that all respondents majorly agreed to are inadequate existing laws, ignorance among healthcare professionals, presence of non-health professionals in the health sector business, high cost of quality drugs, and finally the high level of corruption. All respondents also agreed that continuous learning can create more awareness of the challenges of falsified drugs, including heavy fines and sanctions on defaulters and also creating a

special department that would be tasked with the responsibility of monitoring falsified drugs in the market.

Key Words: Falsified drugs Identification: Knowledge, awareness and challenges, pharmacovigilance, identification system, Mobile Authentication System (MAS), TruScan, Radio Frequency Identification (RFI), Blackeye, healthcare professionals, Nigeria Agency for Food and Drug Administration and Control (NAFDAC), National Pharmacovigilance center.

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ABBREVIATION

NAFDAC: Nigeria Agency for Food and Drug Administration and Control

NPC: National Pharmacovigilance center

MAS: Mobile Authentication System

RFI: Radio Frequency Identification

W.H.O: World Health Organization

PV: Pharmacovigilance

HPRA: Health Products Regulatory Authority

PCN: Pharmacist council of Nigeria

NNPP: NIGERIA NATIONAL PHARMACEUTICAL POLICY

ADR: ADVERSE DRUG REACTION

NAGPP: NIGERIA ASSOCIATION OF GENERAL PRACTICE PHARMACIST

PSN: THE PHARMACIST SOCIETY OF NIGERIA.

NNHP: NIGERIAN NATIONAL HEALTH POLICY

SON: STANDARD ORGANIZATION OF NIGERIA

CHAPTER 1: INTRODUCTION

1.1 OVERVIEW

“The art of medicine consists of amusing the patient while drugs cure the disease” - Voltaire

The production and trading of falsified drugs in treating an adverse form of life-threatening conditions have been documented as one of the major issues contributing to the high rate of mortality and so much loss of confidence by the public and private sector concerning the Nigerian health sector. Hence falsified drugs are the product that is not original and authentic due to its production of using inaccurate quantities or ingredients to reduce its potency as well as neutralize the effect of the drugs. Documented report as shown that fake and substandard drugs as contributed greatly to different range of adverse forms of effect ranging from severe internal and external injury of the body system and organs, disability, paralysis, and serious complications which can lead to death. (Blackstone et al., 2014)

The issue of a falsified drug is a worldwide pandemic, this is because the effects can be felt from where the drug was produced to the countries where it is been supplied. Hence due to the most sophisticated means by which these offenders are going about their trade, it has been difficult for the various country to put measures that would end these crises. (Rae Ellen 2017)

Therefore, Nigeria is never an exception to this problem of falsified drugs which is ongoing at the moment. In so doing some people still have confidence in self-medication to treat themselves when they are ill, and in most cases, this drug is bought from vendors without any form of license to operate. In the last two decades, the problem of the falsified drug has been a very concerning issue which contributed to the death of over 150 children who died in 1989 due to a major error in the formulation. This was, in fact, a move that led to the establishment of NAFDAC which was tasked with the responsibility of tackling the issues of fake drugs. The main purpose was to ensure good, safe, and effective drugs were registered with the highest form of quality of drugs that is less expensive and cost-effective. (NAFDAC 2019)

In April 2001, the director-general of NAFDAC, Professor Dora Akunyili in fighting the issues of sale of falsified drugs worked hard to implement policy that would protect the drug market, but yet the presence of such continues and this makes me ponder the reason why. The ultimate questions are why does Nigeria still operate an open drug market system? Why do Nigerians in drug business breach the stipulated drug laws and regulation and still get away with it which

always lead to mass murder and more money to the banks of the offenders? To what time frame can healthcare professionals fight the battle of a falsified drug? All of which would be answered as we go along this study.

The continuous effect of major firms and organizations that deal with fake drugs and bridge the laid down laws and regulations, as assisted in reducing the falsified drug sales, however when things seem as if it's getting better different forms of illegal drug business will surface. I then wonder again, could it be that the agency itself is not doing so much to stop this evil activity, or could the major issues be from those who are selling these drugs themselves.

However, there is a need to maintain the highest form of drug quality and standards which is in line with very strict rules and guidelines that are enforced during the clinical trial phase and post-authorization. As we are all aware before a drug is certified it goes through various clinical trials from Phase 1 to Phase 4 before it enters the market to be sold to the public.

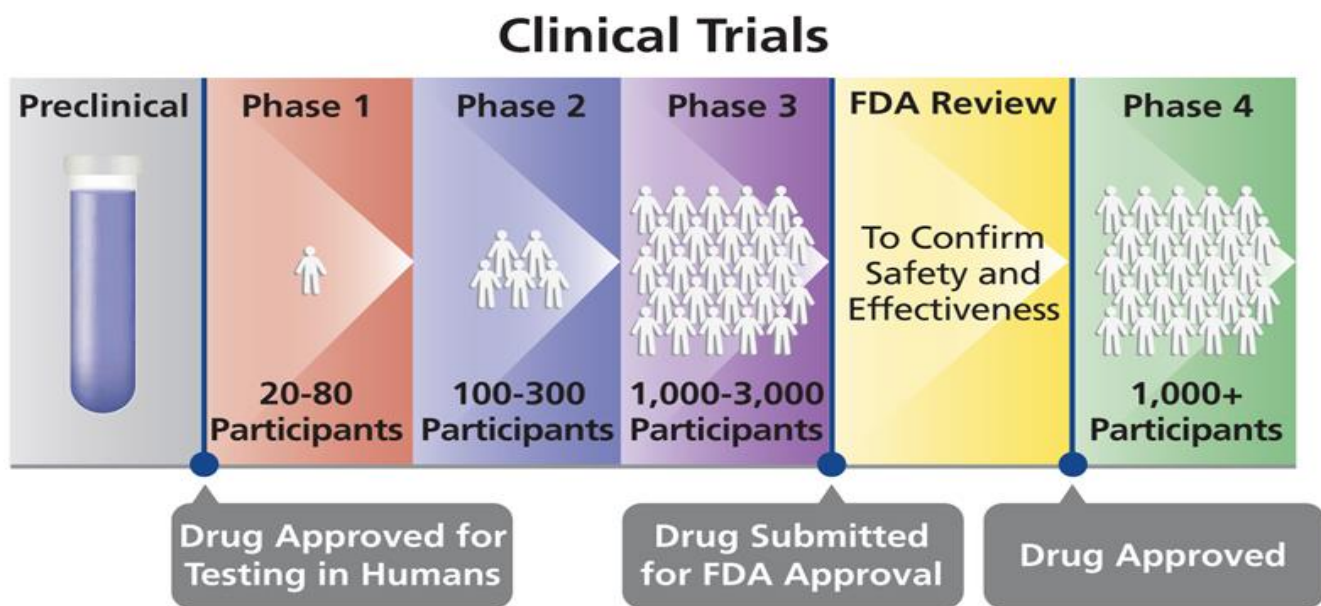


Figure 1: Stages involves in Clinical trial (Aidsinfo 2020)

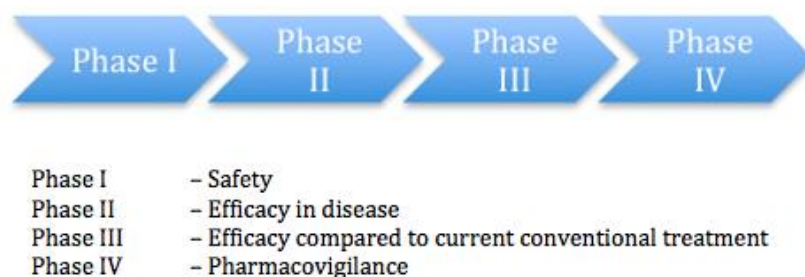


Figure 2: Pharmacovigilance in Phase 4

Over the years in response to good pharmacovigilance practice the agency as devised various means of assisting the health workers in combating the challenges of identifying falsified drugs. According to NAFDAC News (2013, p.11) “initially, the most common process that was developed by NAFDAC was the process of using the NAFDAC Registration Number on the product package for spontaneous identification of falsified drugs in Nigeria”. This led to the replication of fastmoving drugs to becoming the perfect business for most people even the original owners find it very hard to differentiate between fake and original. The health care professionals have been faced with challenges that as affected them in effectively identifying fake drugs due to the cloning process of these registration numbers that are been attached to the packages of the drugs as a result, they lose the battle every day due to the smartness of the offenders. (NAFDAC 2019)

Thus, is against these setbacks and the movement towards achieving the then-presidential target of no tolerance that the agency came up with various forms of technology. The objectives of these cutting-edge technologies were to assist healthcare professionals in spontaneous identifying of a falsified drug in the country and discourage the activities of those involved in drug falsification. (NAFDAC 2019)

Some of the anti-falsification system that were introduced include.

- ✚ **Truscan:** it is a device that generally uses the principle of Rahman's Spectroscopy to test the identity of a product in just one minute. With the help of the Truscan, it was possible to scan imported products at the ports of entry before it reaches the market without necessarily affecting the quality of the drug. (Vanguardngr, 2011)
- ✚ **Black Eye:** NAFDAC adopted this form of technology from the Israeli government a country that is very good at security instruments. It considers the same working principle as Truscan which depends on active thermography. Its working principle is very essential because it is a non-

destructive process. It works by comparing the medicinal drug that is under investigation to check whether it is more of a genuine product or fake. What the machine does is that it breaks down the component of the drugs and then tell you its active pharmaceutical composition or its inactive pharmaceutical ingredients (Vanguardngr, 2011). It is a faster means because the Black Eye allows thousands of tablets to be tested at the same time and it will test each one giving the chemical composition.

✚ **Radio Frequency Identification (RFID):** This involves the use of radio waves to verify data that is embedded on a tag attached to the medicinal products. The tag can, therefore, be read from up to distance away and does not involve the product in the line of the reader to be tracked. To read the data encoded on a tag, an interrogator then emits a signal to the tag using an antenna which reflects the result on the RFID computer system. (EPC-RFID 2020)

✚ **Mobile Authentication Service (MAS):** Since 2010 NAFDAC then deployed a mobile authentication service as another strategy in detecting substandard and falsified medicinal products. it uses a scratch code and short messaging service to enlighten and empower those who consume the medicinal products. With the aid of short codes and short messaging service to verify the originality of the products that were purchased. The consumer will first scratch a panel on the product which should reveal a unique one-time pin. The PIN is then sent toll-free to a short code using any of the GSM operators such as GLO, MTN, or Airtel and in return, the consumer receives a response stating if the product is genuine or not. (Akunyili 2010)

The awareness of all healthcare workers towards spontaneous identification and reporting of falsified drugs were instinctively positive to the system, the implementation of practicing the idea of spontaneous reporting when the fake drugs have been identified remain a serious issue to be solved. Little or no knowledge of proper guidelines and regulations, indecision as to who takes the responsibility of reporting among health care professionals, lack of good government policy concern drug regulations, poor network, lack of funding in the health care department resulting to most doctors and pharmacist trying to cut corners all in one way or the other contributes to the inefficiency of identifying and reporting falsified drugs before its get to the citizens.

The author's purpose for this study is to carry out a valuation with a focal point of identifying and accessing the challenges most healthcare professionals are faced with in spontaneous identifying as well as reporting of falsified drugs. The research would ascertain Nigerian awareness and the use of the system, its

effectiveness, of the various technological system of identifying fake drugs such as (MAS, Truscan, Black Eye, RFID).

1.2 OVERVIEW OF NIGERIA HEALTH SYSTEM

The World health organization report on Nigeria's health care system recently released ranked Nigeria overall health care system performance index at 187th among the 191 member states. Recently Nigeria was ranked 11th among 22 other nations with a high rate of TB level while death by malaria accounted for about 300,000 deaths and 100 million confirmed cases and evidence that shows why the country as so much falsified malaria drug. The current health expenditure is about 3.6% with 0.38% of physicians per 1000 population. About 1.9 million people living with HIV/AIDS ranking Nigeria as the 4th largest country with people living with the disease as well as death from the diseases. On the 7th of October 2019, the Center for Disease and Prevention issued a travel Health Notice for yellow fever outbreak which spread throughout the country with the ministry of health reporting cases of the disease in all 36 states. (Central Intelligence Agency 2020)

1.2.1Historically

In Nigeria, falsified medicines were first observed in 1968 when there was a deregulation of one of the major distributors of medicines as a result of the global recession that hit the world economy at that time and the consequent devaluation of the Naira. Thus, most drugs became very expensive and unaffordable for the masses leading to the issuance of import licenses for the drug to business individuals. Politicians always influence the implementation of such licenses which led to issuance to unqualified health personnel, history shows that Nigeria has been over-dependent on the importation of drugs from outside the country which led to unqualified persons bringing any form of medicinal products only for profit-making. This situation together with the high demand for drugs and limited availability of healthcare professionals as led to the availability of different forms of falsified drugs entering into Nigeria. (Ebenezer, 2015)

The country as so much huge potential for rapid growth and development, the countries health system still lacks good structure, and health professionals still find it difficult in tackling the issue of falsified drugs. History as it that the health sector was underfunded, corrupt, lack of government commitment towards providing quality healthcare services, and poor implementation policy. (Chinwendu 2008)

1.2.2Economically




The poor economic situation in Nigeria has also encouraged the business of falsified drugs. The Federal Government allocated about N47bn (117m euro) for all its capital expenditure in 2019 in comparison to N46 billion (115million euro) which was proposed for the 2020 budgets showing about 2.13 percent reduction. Furthermore, in 2019 the Nigerian government allocated about N51.22 billion (126 million euro) to basic health care provision funds against the N44.50 billion (110million euro) in 2020 which shows a reduction of about 13.12 percent decrease. Nigeria still faces hard times and challenges in its health sector including an inadequate provision and supply of health care professionals and poor health care facilities. Many of the country's citizens are all living in serious poverty and many cannot access quality health care services because they cannot pay for such services. (Business, 2019).

In 2018 alone data from the National Agency for Food and Drug Administration and Control shows that the agency had to destroy fake medicinal products worth over N4.7 billion in four major cities such as Abuja, Shagamu, Ogun state, Kaduna and Gombe. This led to the agency in June of 2019 to seal about 20 illegal drug shops and confiscate about N2million worth of falsified drugs in a market in Lagos. The NAFDAC Coordinator who gave an interview with the newsmen in Maiduguri said the traders were in serious possession of banned and expired products. The coordinator said the raid was done after "intelligence gathering and undercover assessment" he reiterated that the raid was in accordance to measure in place to ensure major stakeholders comply with regulations for safety and good quality of drug for citizens. (Allafrica, 2019)

1.3 Current Falsified drugs Directive Nigeria Vs European Union

1.3.1 Nigeria Falsified Drug Directive

1-Prohibition of sale of counterfeit drugs and unwholesome processed foods irrespective of anything to the contrary contained in any enactment or law any person who

-  Produces, imports manufacture sells, distributes, or in possession of.
-  Sells or displays for the purpose of re-sale
-  Aids or abets anybody who is involved in any act of falsified drug

2-Prohibition of sale, etc., of drugs or poisons in certain premises or places

- ✚ Any persons who hawk or trades or display products for sale or conspire
- ✚ Any drugs or poison in any place not duly licensed or registered by appropriate authority is guilty of an offense under this Act and shall be punished accordingly.
- ✚ By appropriate authority it means any authorized body granting licenses or register premises for the sale and distribution of medicinal products

3-Penalties

- ✚ Any person who commits an offense under section 1 and 2 is liable for conviction and fine not exceeding N500,000 or put in the prison of not less than 2 years or both
- ✚ Where a corporate body commits an offense under sections 1 and 2 shall be deemed guilty of the offense and may be proceeded against and punished accordingly.

4-Trial of offenses

- ✚ The Federal High Court shall be in charge of such trials.

1.3.2 EU Falsified Drug Directives

According to the European Union, falsified medicines are drugs that tend to show off as real and approved products. The EU has one of the strongest frameworks for licensing, manufacturing, and distribution of medicines which centers around the directive falsified medicine for human use, this is because only licensed pharmacies and authorized retailers are allowed to the resale of the medicinal product including any form of internet drug for resale. Thus, the European Union concluded that falsified medicines may contain the ingredient of low quality or in the wrong portions as well as deliberately and fraudulently mislabeled concerning their identity or source. They also include fake packaging with wrong active ingredients or misleading ingredients.

In July 2011, the EU decided to add more strength and solid protection for individuals who are at risk of buying falsified drugs, they adopted a different approach to complement the directive. This directive came into full force on 21 July 2011 while a member of states had to start applying its measures in January 2013. It introduced a form of safety measure which was grouped in four main pillars. (EMA, 2018)

1.Safety features of medicines: From the 9th of February of 2019 the marketing authorized holders are mandated to have two forms of safety features on the package of most prescribed medicinal products as well as over the counter

medicines. A 2-dimension barcode and an anti-tampering device. In practice the manufactures are meant to upload the information in the unique identifier to a repository called the central EU repository, wholesalers will also need to scan medicines at various point of the supply chain to confirm authenticity while pharmacies and hospitals will also scan to verify the authenticity before dispensing them to patients. (EMA, 2018)





2.Distribution of products: this was introduced as part of the directives for wholesalers and a definition of activities called brokering as well as a new responsibility for brokers.

3. Active Substances and Excipients: Effective from July 2013 all active substances produce outside the eurozone and imported into the zone would be followed through by a written confirmation from regulators of that exporting country. They emphasized that these statements are issued in response per manufacturing site and per active substance to make sure that the quality and standards of good manufacturing practice are always upheld. (EMA, 2018)

4.Sales of Drug Online: The EU as made it mandatory that all online pharmaceutical shops must have its logo affixed on its site called an obligatory logo This logo will allow patients and consumers to differentiate between authorized online pharmacies and approved retailers.

By far it is obvious that the Nigerian falsified directives do not address so much regarding the huge implication of falsified drug business. The European directives are much comprehensive and stronger, and Nigeria can learn from such a directive as it addresses different means by which fake drugs would enter the market. In summary, the European directive mandate shows the below(EMA, 2018)

1-Safety Features that would allow all applicable persons to

-  Always verify the authenticity of the medicinal product before it has been administered.
-  Spot out medicinal product of individual packs
-  Randomized number
-  Show evidence of tampering

2-There is a total obligation on the repackaged product which should show equivalent features liability

3-The government can make use of the system for reimbursement or pharmacovigilance related issues

4-There is a center repositories system in place which acts as a midpoint system for information.

Below are some Legislations under the Nigerian medicine laws which were designed to assist regulate medicinal products. However, these laws have not been able to discourage the business of falsified drug in Nigeria(Chinwendu 2008)

- ✚ Poisons and pharmacy Act Cap 366 of 1990: this act was formed to regulate the sales of compound that was termed has been toxic including regulating the distribution of such compound. However, this act was created without a clear definition of what is the term to be poisoned and what is not poisons
- ✚ Food and Drug Act Cap 150 of 1990: this directive only discourage the sale of some foods, drugs, cosmetics as well as any form of medical devices for treatment of disease. It goes further to discourage the importation, exportation, distribution, and sale of specified drugs as well as food in a dirty environment.
- ✚ Pharmacist Council of Nigeria Decree 91 of 1992: this decree requires a certain level of experience and knowledge about the profession before an individual can be qualified to be registered as a professional member of the council. It basically regulates the practice of profession and act as an investigative panel and disciplinary panel to all qualified pharmacy personnel.

1.4 RESEARCH PURPOSE

The author main purpose is to identify the challenges the Nigerian healthcare professionals are facing in spontaneous identification and reporting of any form of falsified drugs. The author would also ascertain the level of awareness of health care professionals in the use of the system such as MAS, Truscan, Black Eye, RFID) in identifying falsified drugs and determine how effective they are.

In other to tackle these realities my study will help in analyzing the knowledge, attitude including experience by health professionals of the use of this system in identifying fake drugs. Thou the current system in place for identifying and reporting falsified drugs are in place yet there is little effect to the menace caused by the sales of this drugs to the public which always leads to adverse effect especially the poor citizens who can't afford better funds to buy quality drugs

My thesis will by no means find a permanent solution to the drug problem in Nigeria. However, it a means of finding the next alternative solutions to making

sure that problems of falsified are reduced, and insight form healthcare professionals in fighting the menace of fake drugs sold in the streets as well as an open market which always leads to adverse effect in the community.

1.5 Significance of The Study

Concerning falsified drug identification which is recommended by N.A.F.D.A.C to all hospitals in Nigeria, there is a distinctive difference in the current study in the practice of achieving good pharmacovigilance, when compared with the attitude and mentality of health care professionals in the healthcare industry. The majority of professionals were observed to be aware of the system in place to identify the fake drugs, without any doubt the need for healthcare personnel to be fully involved in combating these issues cannot be overemphasize this is because by their level of expertise there should be a high level of detection. The agency is determined to solve the persistent issues of a fake drug problem and is motivated mainly by the huge profit to be made the agency was then restructured with a new measure in reducing the problem bearing in mind that the safety of human lives remains a paramount responsibility for the agency in the country.

However, this cannot be accomplished if the healthcare professional is not accustomed to the system of identifying this fake drugs and while there is still a high rate of falsified drugs on the loose in the street of Nigeria due to the open market the main reasons and factors behind this issues were illustrated by a various perception of the healthcare professionals which needed to be addressed.

1.6 Research Objectives

- ✚ To assess the knowledge and awareness of the identification of fake drugs among healthcare professionals.
- ✚ To evaluate challenges among the healthcare professionals in the fight of avoiding fake drugs from getting to the patient as well as reporting any offenders
- ✚ To make viable counsel and suggestion on how to improve the effective tracking and monitoring of fake drugs by healthcare professionals in Nigeria

1.7 Structure of The Study

The main focus of this study would be designed through the use of both qualitative and quantitative approaches. By quantitative approach, would involve the use of questionnaires and by qualitative approach, it would involve the use of phone calls interview.

The questionnaires would be structured for medical doctors, pharmacists, and other health professionals. The first group of the questionnaire was distributed to the medical doctor who prescribes the drugs in the university teaching hospital and the second group was for pharmacists. While any other professionals received the questionnaire to have their opinion.

The sections of the questionnaire were divided into 5 as follows.

1. The demographics data and education background including experience of the health care professionals.
2. The data on knowledge of falsified drug and how to detect it
3. The data on the awareness of reporting system
4. The possible challenges healthcare personnel are encountering in identifying falsified drug.
5. The data on possible improvement on counterfeit drug identification in Nigeria

Regarding the qualitative approach, a phone interview was conducted with experienced professionals. Though the professionals decide to remain anonymous in their opinion, a perspective from a medical doctor, pharmacist, and other healthcare professional enabled me to collect results that create a balanced conclusion on the subject matter.

1.8 HYPOTHESIS

Null Hypothesis: All health professionals working in Nigeria have a minimum knowledge of guidelines and regulations for identifying fake drugs and are also aware of their duty to report falsified drug. They also have minimum knowledge of practicing good pharmacovigilance as required by regulatory agency in the country

Alternate Hypothesis: Factors and challenges limiting good pharmacovigilance practice in Nigeria as well as the spontaneous identification of fake drugs in Nigeria due to limited knowledge of how the system works and lack of commitment towards using the system before prescribing the drugs to the clients.

1.9 CONCLUSION

This chapter shows the foundation of the study by describing the main context in which the research was carried out, an overview of the health system of Nigeria as well as the system used for identifying fake drugs, availability of poor medicines and weak regulations are also discussed.

Therefore, it is very important and significant to understand the factors that are been faced by health care professionals in Nigeria in spontaneous identifying of falsified drugs to give quality and affordable drugs to the public

However, in order to examine the level to which the impact of the use of poor-quality medicines, lack of identification, and reporting of falsified drugs as affected Nigeria, a more systematic literature review was conducted, and analysis was made. Thus, a detailed and comprehensive literature review is formally presented in chapter 2

CHAPTER 2: LITERATURE REVIEW

2.1 Introduction

"Medicine is not a book but mind, not a business but life" (William Osler)

Located in the western part of Africa Nigeria is known to be the most populous country with about 215 million people, it is projected that the population will increase to about 392 million by the year 2050 becoming the world's fourth most populous country. It is divided into 6 geopolitical zones. Because of this, it is expected that the population rate will continue to increase in the foreseeable future because of the high rate of given birth. The nation's capital and sit of power Abuja have not been able to implement good family planning to reduce and space birth because of lack of political will, lack of adequate government financing and the availability of good health care policy. (Central Intelligence Agency 2020)



Fig 3: The 6 geopolitical zones of Nigeria(Central Intelligence Agency 2020)

According to the latest figure released by W.H.O, an average citizen is expected to live between 50 to 54.5 and this is in comparison with other countries. The significant factor contributing to this low level was mostly attributed to challenges surrounding the Nigeria Health system which as translated to the high rate of mortality level in the country. This is so because an estimation carried out shows that in every five children one out of this kid is likely to die due to the huge challenges the country health system is facing. (World Population Review 2020)

However, the Nigeria National Bureau of Statistics considers the major effect of the rampant AIDS epidemic in the country. While some countries like the United States are in control of the situation Nigeria is still struggling with its health system. Fortunately, the numbers have improved slightly over the last 15 to 20 years. There are currently 3.1 million residents in this country that are living with HIV/ AIDS. (World Population Review 2020)

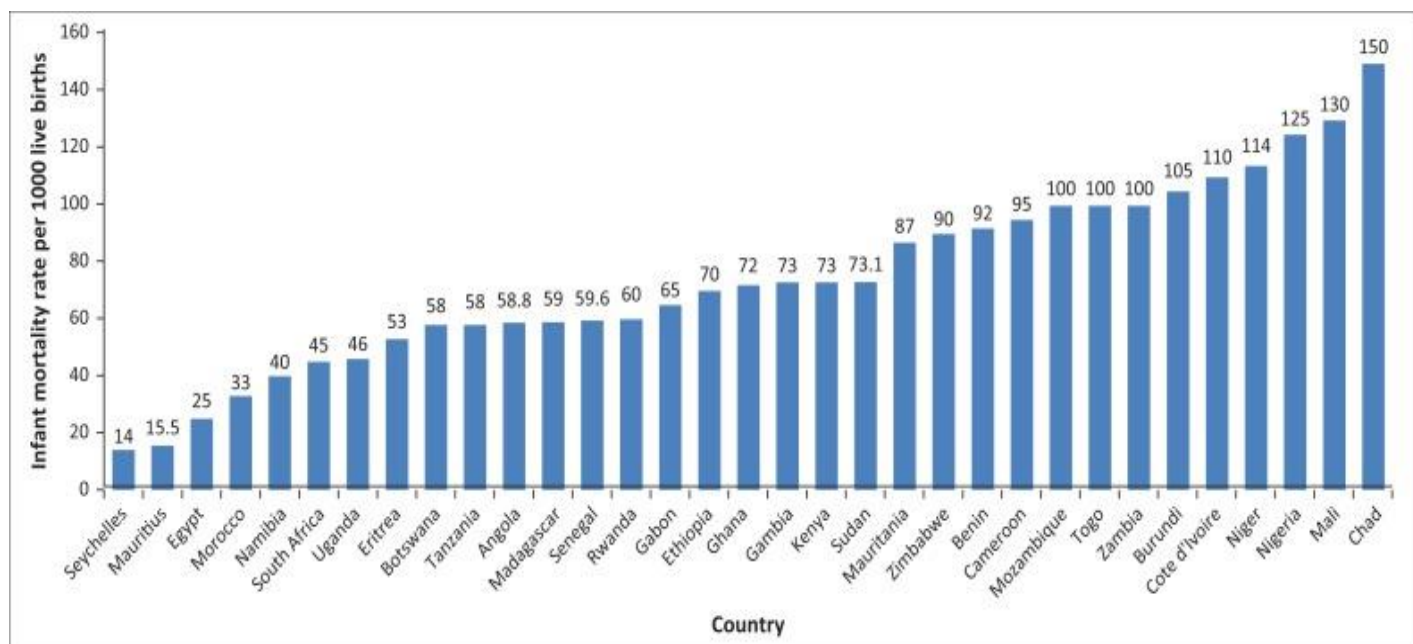


Fig 4: Nigeria Infant Mortality rate in comparison to other Africa Nations (Alemu, 2017)

2.2 Overview of the Nigerian Pharma Regulation System

The economy of Nigerian sparked a strong enthusiasm about various opportunities in the pharmaceutical market, about 5 years ago the country noticed an outburst of the revenue that the pharmaceutical economy is beginning to generate yet keeping hold of this promising aspect of the economy has proved harder than anyone could have expected. In recent times the plunge in the economic system of the country as cast big hopes to the prospect of this sector of the economy flourishing. As Africa Biggest economy it's been seen as the next frontier for the pharma sectors, however, its recent slide into one of the worst recessions has cast a big doubt of the regulation system surrounding the pharmaceutical sector. In forecast by the IMF put Nigeria GDP growth forecast to about 1.8% the lowest since 1987 even with such statistic there was still a strong belief that the pharma sector remains a strong prospect.it expected that Nigerian pharma market could reach 4billion dollar by 2026 if all goes well with its regulations (Tania et al 2017)

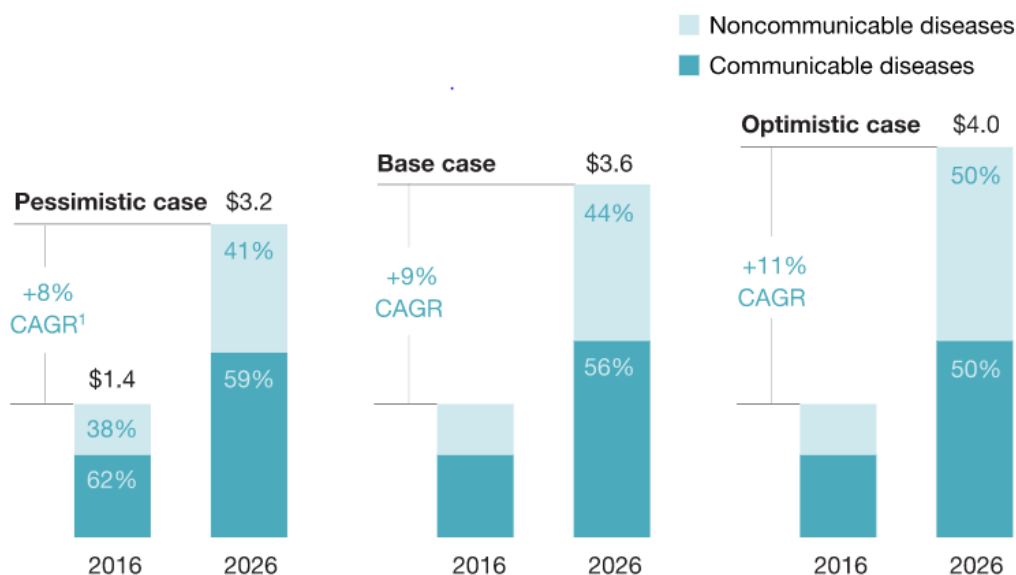


Fig 5: Value of the Nigerian Pharma market by Disease Type.

2.3 The Pharmacists Council of Nigeria Act (1992 No 91) (the Act).

The Act covers the major areas from drug registration, drug inspection, location and structure, drug distribution, and importation of pharmaceutical manufacturing equipment.

Registration of pharmaceutical premises 1-the regulations for pharmaceutical premises is for both new and renewal of old premises 2-a registered pharmacy must be the owner of a premise used for retail product 3-for a pharmacist business at least a registered pharmacist must be a board of directors and a senior pharmacist must be a direct personal control 4-if the main objective of the company is in manufacturing the board of directors must consist of registered pharmacy which would be in charge of the business.	Inspection location and structure of pharmaceutical premises 1-The inspection regulations provide for all pharmaceutical's premises 2-it shall not be located in an area where commercial activities are taken place. 3-if market or commercial activities is found growing near pharma premises such would be notified within 2 years to move to a new location 4-where more than one pharmacy shop is found in one premise such shall be well spaced out.	Registration for retail distribution and importation 1-A formal letter in form of application letter with the company letter headed must be sent to the consul 2-a duly completed PCNS form for registering the premises would be registered 3-a photocopy of annual license and registration fees payable to any bank in Nigeria 4-letter of resignation from previous employment if any 5-letter of accepting the resignation 6-letter of appointment at the new premises 7-the prescribed inspection registration fees payable to any bank 8-legal documents showing agreements between the owner of the company and pharmacist 9-company certificate of incorporation 10-copy of a memorandum of association 11-copy of directors' particulate 12-NYSC discharge certificate	Site registration 1-list of products to be produced 2-Company Organogram 3-The factory Layout 4-production layout 5-list of equipment in production and quality control department 6-source of water and Its treatment 7- report of all analysis of the water 8-report of all the suppliers of raw material and packaging materials 9-standard operating procedures 10-reports for all standard cleaning procedure 11-inspection fee
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		13-copy of the letter showing that the superintendent as only one job 14-letter of undertaking by the Managing director of the company stating that all affairs would be managed by the pharmacist 15-interstate movement form must be completed 16-Evidence of a pharmacist on the board of directors 17-The The current Annual license of the pharmacist is also required.	
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Table 1: Nigeria Pharmaceutical Regulation System (Ugochi 2020)

2.3.1 The Current Situation of Falsified Drug in Nigeria

The current situation of Falsified drugs has exposed the weak healthcare system which resulted in proliferating fake drugs has led to serious treatment issues and sometimes the death of many citizens of Nigeria. It even became a serious issue when original drugs are administered to patient and there is limited on no response form the drugs due to the previous intake of falsified drugs. (Akunyili, 2006)

The problem of the weak policy system and so much laxity in the system, as well as widespread corruption, are some of the primary reasons why it so easy to sell medicinal products that are falsified. Producers of these fake drugs sell this product cheaply to the popular chemists' shops which in turn would sell to the citizen. It should be noted that the main losers are the pharmacist and doctors who are prescribing and treating patients respectively, as the patient who is sick will not be cured resulting in the damage of the reputation of healthcare practitioners. In Nigeria, buying of quality medicines by the population is very important irrespective of their income level for the health care delivery system to succeed. This is because prices for medicines are still very high making it difficult for quality medicines to be accessed. Disorderly drug distribution and poor networking of supplied drugs as well as many unauthorized outlets as encouraged

the free movement of fake drugs leading to less accountability to the disposal of medicinal products which makes it difficult for regulations from the agency to work effectively. (Chinwendu 2008)

Due to a major decline in the quality of Nigeria's health structure and infant rate increasing day by day, keeping up with effective identification as well as reporting of these falsified drugs remains a serious burden and challenges that are yet to be solved. Insufficient healthcare professionals as reduced any form of good pharmacovigilance practices in Nigeria and as a result combating the effect of falsified drugs remains unresolved. Also, in Nigeria, the unfavorable working conditions and ignorance among healthcare professionals in the use of the system for identifying and reporting medicinal products that are falsified as reduced all efforts that are been channeled towards achieving laid down rules of good pharmacovigilance practice. Hence there is a need to upgrade the way by which the Nigerian system operates concerning good pharmacovigilance practice. Therefore, involving healthcare professionals is necessary since they are the frontline staff that either prescribe or dispense this drug.

It was observed that the huge increase in Nigeria falsified drugs incidence was also attributed to the haphazard regulations surrounding the license issued to those who are involved in the drug business was just issued by the politician in the '90s without any form of due diligence without taking into consideration the citizens health and the implications of their actions. As a result of this action, all of the beneficiaries of the import license discovered that so much money would be made from the drug business leading to the high emergency of drug importers. The market became very competitive and for competitors to stay above the other a fast way needs to be created to ensure that products are made available, some looked at importing fake drugs and medicinal products to have an edge over other competitors. In Nigeria today, drugs are still treated as general merchandise that is sold in the open market including moving cars, faceless medicines stores, boats, ships, and even in stores where provisions are being sold. This translates to the fact that the distribution network was handled by professionals who are only interested in profit-making at the expense of public health. (Nigeria bulletin 2019)

Another current issue occurred recently in March 2020 where 32 illegal pharmacies and famous chemist stores were shut down due to the illegal offenses surrounding the operations of the stores. The commissioner for health professor Akin Abayomi who made this known on Sunday after a review of the enforcement exercise carried out by the pharmaceutical inspectorate unit of the ministry for 2020 said that "the affected premises include 6 major areas in the local government area of the state". (Akin 2020)

A review shows that counterfeiting and substandard forms of anti-malaria drugs and antibiotics have shown in the table below are most common in Nigeria and does not generally mean that other forms of falsified drugs do not exist. There is a greater probability that other forms of drugs have not been tested or sampled for testing(Theodore 2007)

DRUG CLASS	EXAMPLES
ANTIMALARIALS	Artemisinin derivatives: dihydroartemisinin and artemether-lumefantrine Others: Chloroquine, Sulfadoxine-pyrimethamine, Quinine sulfate and Halofantrine
Antibiotics	Penicillin: Ampicillin, Ampicillin-clavulanate, Ampicillin cloxacillin, Amoxicillin, Cloxacillin) Macrolides: Erythromycin Sulphonamides (Cotrimoxazole, Sulphamethizole), Quinolones (Ciprofloxacin) Aminoglycosides: Gentamycin and Neomycin Other: Chloramphenicol, Tetracycline, Metronidazole

Table 2: Showing different forms of Falsified medicines(Theodore 2007)

2.3.2 W.H. O IMPACT ON FALSIFIED DRUG IN NIGERIA

In late 2006 WHO lunch a task force to help countries especially Nigeria fight the multimillion thriving dollar illegal trade in falsified drugs known as International Medical Products Anticounterfeiting Taskforces (IMPACT). Its major aim was to create a form of communication with Nigeria on how to put an end to the trade of fake drugs and studies. Dr. Howard said in his statement "We need to help people become more aware and also create a communication line that would help improve the situation of the falsified drug in Nigeria". The task force would ensure good public distribution of medicinal products, pharmacists, and hospital staff to inform the authorities about any form of suspicions about the originality of any form of the medicinal product. The agency noted that any reporters would be followed up through so that people who report about falsified drugs would be motivated to report again in the future. (World Health Organization 2020)

Enforcement officers in Nigeria would love to enforce fake drug identification on the spot but what the agency as noted is that due to the high level of corruption in the country it's very difficult for them to respect the agency. Reggi in is a statement said, "We could make packaging device that is resistant to forgery by using security features found in banknotes, but the problem is that our policy is sometimes not well respected enough".

Although it's very difficult to get a precise figure because falsified drugs are found almost everywhere in Africa and Nigeria is one of the main markets of such

business. In Nigeria, drugs are sold through the open market alongside food, fruits, and vegetables though people may be aware of the risk the fact is there is no other place to get cheap drugs. Reggi knows that the challenges are huge in Africa especially Nigeria, but he stressed that the agency is working with government agencies to create a database of products by which each medicinal product will have its unique number that would be tracked effectively. This they believe would greatly improve the situation as a product can be checked to ascertain if the medicine is genuine at the point of distribution into the pipeline. (World Health Organization 2020)

2.4: Overview of Pharmacovigilance in Nigeria

Nigeria joined the W.H.O international Drug Program in 2004 which started a new era of pharmacovigilance in Nigeria. As the west African country, the presence of different forms of disease burden and medication use becomes significant. As a result of this, there is more pressure increase on safe medicine practices by the government and healthcare professionals concerning the patient. The NPC is tasked with the duty of liaising with other international groups such as W.H.O, US Food and Drug Administration, and the European Medicines Agency in ensuring drug safety good quality drugs in Nigeria. (Olowofela et al., 2015)

The National Pharmacovigilance Centre (NPC) defines pharmacovigilance as “the science and activities which is focused at the detection, assessment, understanding as well as prevention of adverse effect and any form of drug-related problem caused by either substandard, falsifying, and expired drugs. In other parts of the world problems related to pharmacovigilance are issues like medication error, lack of efficacy reports, bad labeling of medicinal drugs, poisoning from drugs, and drug misuses. However, with all these issues listed Nigeria is not exempted as I provide an overview of pharmacovigilance in Nigeria about falsified drug reporting. (Olowofela et al., 2015) NAFDAC act CAP N1 LFN of 2004 as amended gave full legal backing into the activities which were carried out by the NPC to date. Also, a national policy on drug issued in 1990 and revised in 2005 shows the level of drug safety, the Nigerian national Pharmacovigilance policy, and the implementation framework serves as the policy document that serves as operational guidelines and rules governing the system.

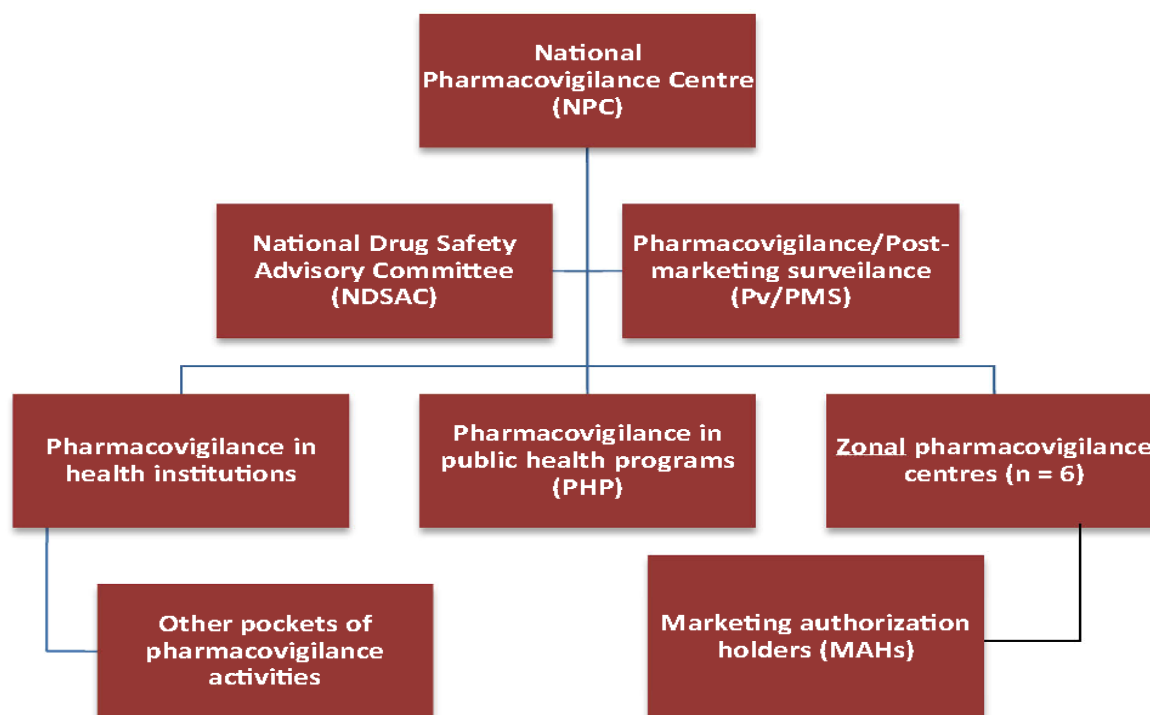


Fig 6: Nigeria Pharmacovigilance operations

A current study was carried out aimed at evaluating the attitude and practice of good pharmacovigilance practice regarding falsified drug the study involving medical doctors working at a well-known teaching hospital. A total of 100 doctors responded to the questionnaires, it was discovered that only 57.1% considered to check if drugs are falsified before prescribing, all of whom were aware of the procedure of reporting this offender. While the awareness of the existence of the National Pharmacovigilance Centre (NPC) was 51.4%. 30% have encountered adverse drug reactions due to fake drugs but only 2.9% have ever reported it. Most of the respondent 60% never considered falsified drug reporting system as an important tool in pharmacovigilance in the prevention of falsified drug-related issues (Adedeji et al., 2013)

2.5 Pharmacovigilance and Falsified drug identification

Pharmacovigilance (PV) in Nigeria is usually viewed and assumed that drug quality and its efficacy are always assured and as result, there is no need for safety monitoring regarding the quality of the drugs that is been provided to the patient. For many countries around the world where the business of counterfeit drugs has been reported, it became an obvious fact that it is no longer safe to make this assumption while monitoring and authenticity of medicinal products.

Pharmacovigilance must, therefore, be on the frontline and alert to any form of Falsified drugs because with counterfeits, a country may not just be

dealing with the medicine one assumes to be monitored. And hence there is a great call that pharmacovigilance scope should be upgraded beyond signal detection to other safety concerns and falsified medicines constitute one of those yet to be integrated safety issues. (Akunyili 2016)

A previous study was carried out to examine the level of pharmacovigilance program (PP) among different forms of health professionals in Nigeria. The study was designed to compare personal factors that were concerning the awareness of PP among the general public. The study made use of data that was collected through the country's HIV and AIDS survey which was collected through a group of the survey of women aged between 25-35 years and men aged between 25-45 years across all geographical areas of the country. It was noticed that the average age of the respondents was between 28.5 while the respondents were majorly made up of females of about 49.1% with 68.7% residing in the rural areas. Results show that out of the percentage of people that responded 26.6% was well aware of the PP and this was much higher with those people with higher education (55.5%) while those who have heard about campaign on adverse drug reaction were 80%. respondents who have to listen or had the opportunity to hear about this campaign in the urban city was more likely to have higher awareness level in Nigeria while those with a lower level of education background especially in the rural areas are significantly low.(Oluwafemi et al., 2017)

The writer designed this study to assess likely factors affecting the level of awareness of the Nigerian Pharmacovigilance program through data from HIV survey in 2012. He found out that the awareness level generally low and not much importance as been placed in this area of the health system to upgrade the sector. He further states that except for some little media advert in the urban city which was evident as to the reason why respondents in the urban areas as better awareness level, proper education system on the topic of adverse drug reaction in the education system of the country have not been fully incorporated. The writer believes that educating the profession about pharmacovigilance would have a good positive impact on the level of awareness across all individuals in the country.(Oluwafemi et al., 2017)

Results show that 49.1% of the total sample with 68.7% living in the rural areas are not aware while 19.6% was aware of the program in Nigeria. The ratio of men to female reporting awareness of the program was significantly higher when compared to the female respondents 38.8% to 33.1% respectively while the ratio of those who reported awareness of Pharmacovigilance program and those who have not heard about any campaign are 80.5% to 10.5% respectively in the urban areas with response rate of 98%

The author concluded that the awareness is generally low in rural areas due to insufficient NAFDAC campaign. This is because there was a greater percentage of the respondent in urban areas who had better access to listen to the campaign to be significantly aware of the program in comparison to the respondent who is found in the rural settings. Thus Arenes of PP could be enhanced through a more robust campaign that should cut across all levels of geographical areas of the country, they should implement a low level of advert such as jingles and handbills as this would intensify further awareness in the rural areas.(Oluwafemi et al., 2017)

Therefore the writer concluded that to detect falsified drugs Nigeria needs to upgrade its pharmacovigilance systems and not just focusing more on monitoring alone, to tackle this problem of falsified drugs national PV data needs to be feed into a global reporting system that can give a more actionable knowledge and intelligence to healthcare professionals and public health care policymakers. There is currently no form of a reporting system for the suspected case of falsified drugs which should be part of the database of the pharmacovigilance center.(Oluwafemi et al., 2017)

2.6 Awareness of Healthcare Professionals in Identifying Fake drugs

Concerning the country's healthcare professionals in identifying fake drugs, a survey was carried out to assess the awareness of the Mobile Authentication Service (MAS) over another system of identifying fake drugs in Nigeria by health care professionals in Nigeria such as Radiofrequency identification system, Black Eye, Truscan. A survey was used to evaluate health care professionals especially the pharmacist on their acceptance of the technology, it started with a questionnaire distributed to 326 community health care professional followed by an interview guide to explore any form of challenges faced in using the technology in Nigeria.

Results show that only about half of the healthcare professionals are aware of the system in place in identifying the fake drug and prefer the MAS system over every other technology system, about 40% of respondents are generally aware of this system while 60% are not aware. Furthermore 51% of a health care professional would recommend the use of these technologies to other practitioners while 54% of the respondent would encourage their clients to use it. The study shows that both awareness and perceived reliability are a major factor that plays an important role in the use of the systems. The finding further shows that the challenges were due to global system downtime, low power supply, the limited ability of consumers to use short message service all contributed to the limited

advantage that the system could have provided. Therefore, the study concluded that the level of awareness is moderate in comparison to the level of counterfeit drugs in the country. (Oyetunde et al., 2019)

Health care professionals (medical doctor, pharmacist) are professionals that usually have contact with people who are very ill at the most vulnerable time, therefore they bring awesome influence on the health and wellbeing of the patient. It should all start by health care professionals being fully aware of the issue combating counterfeit drugs starting by the use of the system at all times, this is because if healthcare professionals resolve to proactively play their part early enough in eliminating counterfeit drugs from their practice, a substantial achievement would be achieved. What it simply means that a self-regulatory measure that promotes rational use of the system they are accustomed to, uphold ethical practice, enhance professional practice and work for a common goal for the safety of the patient.

To win the war of falsified drugs, as the nation strives towards a healthy population the health care professionals should be fully aware and take responsibility for ensuring that no falsified drugs pass through them. This is because medical doctors and pharmacists are crucial professions in stopping these drugs from reaching the patients (Akunyili, 2007).

2.7 Challenges Among Healthcare Professionals in Identifying Fake Drugs.

Basically, in Nigeria, almost everything that comes into the country is either falsified or substandard starting from fake motor spare parts, to fake chemicals, and adulterated food items and falsified medicinal products. In reality, it appears that Nigeria is a dumping ground for any form of the falsified product. Over the years Nigeria's health system has been suffering from the period of so much forgery of products, counterfeit drugs, quack health professionals, street drug trading, quack chemist shops, and quack hospitals. An experimental suggestion has shown that there may be a more falsified drug in circulation than genuine and original drugs in circulation. What is more disturbing is the concept of falsified drug issues is that the effect of consuming such a form of medicinal products usually goes unnoticed most of the time except in most cases where it results in mass deaths. There is generally no factual data that shows the mortality and morbidity which is a result of consuming falsified drugs in Nigeria because of the level at which the pharmacovigilance practices are carried on in the country. One of the most tragic cases that shock the nations occurred in 1990 when 109 children were administered fake paracetamol and they all died. (Babalola et al., 2013)

This alerted the pharmacy society of Nigeria to pressurize the government to take a bold step towards regulating and controlling the menace of the falsified drug business in Nigeria. The government stepped in and created the counterfeit and fake drugs (miscellaneous provisions) decree No.21 of 1998. This decree was in place to discourage any form of sale and distribution of falsified drugs or poisons in open markets and without any form of a license of registration. It also added penalties and fines for any breach of the provisions of the decree, a special task force was then established to enforce these regulations and ensure compliance. (Babalola et al., 2013)

Given the issues affecting health care professionals, a study was carried on accessing the challenges of health care professionals in identifying falsified drugs. A survey was carried on by health care professionals working in a different regulatory agency, amongst the regulatory agency were (i) Federal task force on counterfeit and fake drugs (ii) The National Agency for Food and Drug Administration (III) The Pharmacists council Of Nigeria (IV) The Pharmaceutical Society of Nigeria, (V) Nigeria Association of General Practice Pharmacists, (VI) the Pharmaceutical Manufacturers Association of Nigeria. It was also observed that all these bodies have at the list in the past conducted seminars and reviews in the last two years on the issues of fake drugs, thus they have consensus agreement towards the topic. There was a 100% response rate from all seven organization who responded unanimously that the issues of falsified drugs in Nigeria was a major concern and it is killing the Nigerian health system.

The table below shows the challenges given by the different organizations for the continuous increase of falsified drugs in Nigeria.

Reasons	# of Respondents (N=7)
Laws are inadequate	6
Ineffective enforcement of existing laws	7
Non-Health Professionals in Drug Business	6
Loose control systems	2
The high cost of drugs	5
Greed	3
Ignorance	7
Corruption	4

Table 3: Reasons for Availability of falsified drugs in Nigeria

1- Ineffective Enforcement of Existing laws: All respondents (100%) agreed that the laws were not just properly enforced and its most common in developing countries. For instance, strict regulations have been placed in Bangladesh as a way of controlling numerous small and illegal pharmaceutical production of falsified drugs. Some of the respondents (60%) believed that fines in place were just too small to penalize offenders, for instance, N5000 fine or two years imprisonment. Healthcare professionals believed that fines should be increased to a more aggressive amount with more years in prison to scare and discourage their activities. (Babalola et al., 2013)

2-Nonprofessionals in Drug Business: Another 88% of the respondents in this study indicated that too many non-health care professionals in the drug business are a major challenge the professionals are facing leading to more falsified drugs in the market. In Nigeria pharmacist is authorized by law to produce, sell, distribute, import, export dispense medicinal products. Also, pharmacists which have registered shop in a premise can sell drugs in the community, however, some non-professionals can be authorized to sell patent medicines who are referred to as patent medicine vendors. They are generally involved in the sale of drugs like antibiotics, narcotics, and toxoids. Hence it was observed that such non-professionals do not know how to identify counterfeit and fake drugs. (Erhun et al., 2013)

3- lose control Systems: the majority of the respondent (85.7%) indicated that inadequate funding of the health system is a major cause of the system being out of control. One of the major functions of NAFDAC is to regulate and import medicinal products which are usually done by having inspectors at various land and seaports. As part of the decongestion process by the Nigerian ports authority, the agency together with Standard Organization of Nigeria (SON) was asked to move there operations in other to free up space from the seaports, this move was heavily criticized as this would encourage more influx of fake medicinal products into the country. one of the major criteria for sales of drugs in Nigeria is for it to be registered and most of the laboratory available are not well equipped for the volume of quality checks that need to be done, sometimes drugs are returned stating reasons of inadequate equipment and lack of logistics for proper inspection. (Erhun et al., 2013)

4- High Cost of Drugs: About 71% of the respondent also indicated that the cost of drugs was a major concern, this was because the cost of genuine drugs are very expensive attributing to the fact that local inputs of drug production are relatively small. (Erhun et al., 2013) A study was also carried out in 6 local government areas in Lagos state Nigeria to check that the cost of good quality drugs, its specification concerning international guidelines and level of API, and

impurity specification. Out of the 200 drug samples that were collected 30 of these drugs (29.3%) were falsely labeled, 76 (74.5%) were substandard, 78(76.5%) were poor quality and 24 (23.5%) were of good quality. It was discovered that of all 76 drugs that were declared substandard 28 were also labeled falsely, 17(56.7%) was found in an area of low-income earners, and 40 (52.6%) of the substandard medicinal drug products came from areas with high-income earners. Prices between these classes were compared, the average drug price for falsely labeled drugs was 383.33 NGN concerning 955.50 NGN concerning good quality drugs. This was evidence of why the prevalence of falsely labeled and substandard drug samples was high in Lagos. (Ndichu et al., 2019)

5- High Level of Corruption: about 57% of the respondent indicated that corruption was also a major challenge the health care professionals are facing in a bid to fight the menace of falsified drugs, it was evident that the magnitude of the corruption in this sector lead the Nigerian Assembly to establish the anti-corruption law enforcement agents 43% of the respondent attributed that greed in a bid to enrich one's pocket has also contributed to the prevalence of fake drugs all over in Nigeria it's hard to fight a corrupt system. "Get rich quick syndrome/value system that encourages all forms of corrupt practices enrichment. There are does who believes that the end justifies the means, in most case business owners agrees with some foreigners to import substandard product. (Erhun et al., 2013)

6- Ignorance: in total, about 100% of respondents all agreed that ignorance among health care professionals played a factor in the challenges of the drug available in the country. About 70% of the respondent attributed to a low level of literacy between citizens and health care professionals. The belief is that some health care might not even be aware of how to identify fake drugs even with the technology in place or they are aware of it and will not put them into practice. The falsified drug business has become sophisticated over the last decades and new and improved method are always in place to ensure they are not caught(Erhun et al., 2013)

The European countries are also not left out from the challenges of falsified medication with the establishment of European Falsified Medicines Directives, the challenges of falsified medicines in Europe are also on the increase at a dramatic rate. A 2010 survey was conducted by Pfizer in 14 major European countries to ascertain challenges still faced by health care professionals in identifying falsified drugs. It was observed that more than 10.5 billion euros was spent each year on falsified drugs and many of this drug was for weight loss, influenzas, and erectile dysfunction, and which are majorly counterfeit. One of the major challenges the European market is facing is the illegal online pharmacies and about 14,000 illegal

websites that sales falsified drugs were shut down. A survey was done on 530,000 medicinal products which were inspected by customs and regulatory authorities worldwide, out of these products 42,000 packages containing antibiotics, cancer medication, and antidepressants and dietary supplements were falsified. Worldwide sales of counterfeit drugs are over 75 billion dollars according to W.H.O about 1% of counterfeit drugs have penetrated the supply chain while 10% of all pharmaceuticals distributed around the world are falsified. (Peak-ryzex 2020)

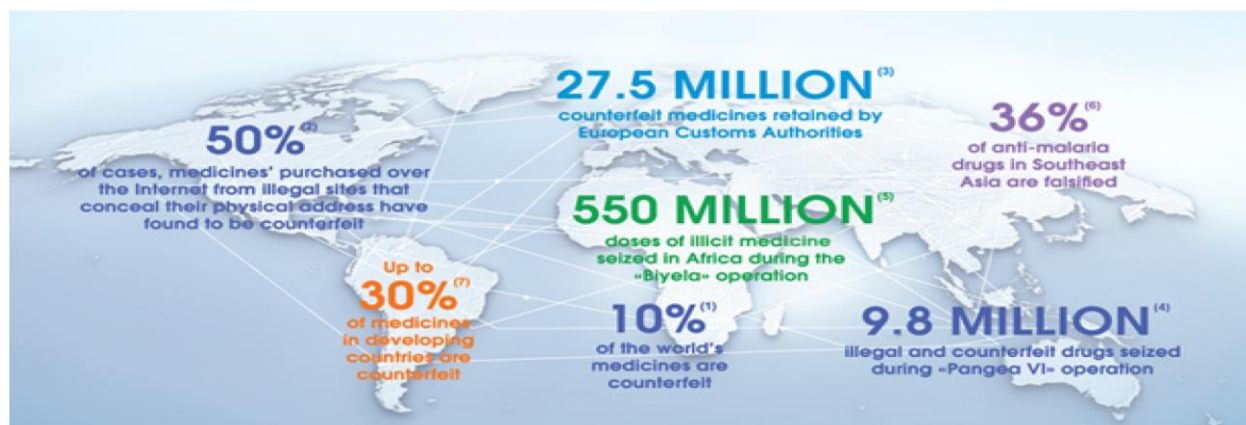


Fig 7: Word wide distribution of a falsified drug

2.8 Recommendation for Improvement of Falsified drug identification

On 25th January 2019, a study was carried out to evaluate the awareness of healthcare professionals towards the improvement of good pharmacovigilance practice in Nigeria. The author randomly selected six different teaching hospitals in the south-south zone of Nigeria, located in the coastal region of Nigeria and home to about 21 million citizens. This zone comprises six states Akwa-Ibom, Bayelsa, Cross-Rivers, Delta State he included an educational seminar by sending a text message every month through a short message service over a 12months periods followed by a questionnaire which was filled anonymously by health care professionals including the doctors, pharmacists, and nurses in regards to knowledge awareness of pharmacovigilance in Nigeria. A repeated cross-sectional study was then carried between January 2016 to April 2017, the design was selected because of the high probability of loss in follow up, resident doctor existing from the program and assign of other staff health care workers to other station.

A total of 40 questions was distributed in which 10 questions were in relations to health care professionals attitude, 18 focused only on reporting practices,

some other information's such as age, years of experience in the profession, sex, institution, knowledge of falsified drugs, reporting system, a regulatory agent of pharmacovigilance, perceptions and other practices in identifying fake drugs.

Results show an approximate number of post-registration Health care professionals working in the selected teaching hospitals who are eligible for inclusion in the study with over 2085 doctors (42.4%), 2662 nurses (54.2%), and 165 pharmacists (3.4%). A total number of 3099 HCPs in the intervention arm and 1813 in the control arm. However, only one-third of the HCPs in the intervention arm participated in the intervention invitation sent out. Also, a total of 811 HCPS (65% intervention and 35%) participated in the preintervention study (response rate of 70.8%) and 931 HCPS in the repeated cross-sectional study having a response rate of 77.6% (64% intervention and 36% control).

The writer shows there was a significant increase in knowledge across several items between the groups. The professionals from the intervention group were better educated and informed with improved knowledge on how to identify falsified drug, analysis shows that from the post and pre-intervention questionnaire there where little knowledge across several groups, the HCPs from the intervention group had a better understanding and knowledge of identifying fake drugs as well as attributes of fake drugs. Also, data shows that there was a significant increase in awareness among the southern zonal pharmacovigilance center concerning the control group. Furthermore, the survey shows that those respondents in the control arm prefer the pharmacist to identify and report falsified drugs even with the strong belief that all categories of healthcare professionals should be able to identify fake drugs. In conclusion, the writer showed improvement in the knowledge and practices including an efficient process of the reporting system will further assist professionals. (Opadeyi et al., 2019)

Another significant research was carried out in 2015 to access the attitude of healthcare professionals towards pharmacovigilance practice and falsified drug identification in Saudi Arabia. The study was aimed at investigating the knowledge and awareness of HCPs in governmental and private hospital settings. A survey among pharmacists, physicians, and nurses in 12 hospitals was conducted between November and December 2015. The survey consists of 18 questions assessing the knowledge awareness and attitude of HCPS towards the technology and science involved in identifying fake drugs as well as good pharmacovigilance practice. The data collected was then analyzed using Statistical Analysis Software (SAS 9.3). thus, the main outcome measures Knowledge, attitude, and practice of HCPS towards pharmacovigilance(Alshammari et al., 2015)

332 healthcare professionals completed the survey with a response rate of 72%, 110 (34%) physicians, 106 (33%) pharmacists, and 104 (32%) nurses more than half of the respondents have no idea of correct ways of identifying fake drugs. Two-Thirds of the participants 207 (65.5%) did not know the aim of post-marketing surveillance yet only 113 (36.9%) of the participants were of the pharmacovigilance drug safety center adding to this most of the respondent (78.4%) believed that reporting was professional obligations and hospitals should have a department for this. The writer then concludes that limited knowledge of pharmacovigilance would have affected reporting incidence. Thus, intervening through the education program and training need to be applied by the drug regulatory authority to enhance pharmacovigilance and drug safety. (Alshammari et al., 2015)

The problem of falsified drug identification is real and constitutes a major threat to the Nigerian population and the system needs so much improvement. A descriptive study was carried to assess the improvement of identification of counterfeit Drugs by the community in Lagos state, the research involves the use of 23 items of the questionnaire which was administered to consenting community pharmacists in 17 out of 20 Local Government Areas in Lagos State. A simple sample of health care professionals in the community who deals with medicinal drugs was recruited for this purpose this was gotten from the Association of Community Pharmacists in Lagos state. An effort was made to ensure adequate representation of Pharmacies in every local government area in Lagos state, data were collected for this study from 17 out of 20 Local government areas in Lagos state sample was chosen to show the allocation of community health care professionals registered in Lagos state. The writer had two sections to the questionnaire. Section A was designed to elicit demographic information of the respondents such as age, location, profession while section B was made up of 17 questions with a Yes or No answer and some questions was focused to determine the method employed by the respondents to detect fake drugs, factors that determines where they source their drugs, frequency of any form of the falsified drug. (Odili et al 2016)

A total of 100 copies of the questionnaire were distributed to the community 69 out of the 100 copies were responded to hence receiving a response rate of 69%. About two-thirds of the respondents 65.2% (45/69) were males and an age grade of 31-50 years made up about 73.3%. All respondents agreed that Nigeria's health system is flooded with falsified drugs and counterfeit drugs, 74% of the respondents describe the problem as a major, the remaining 26% as moderate. Some 86% of the respondents procured their drug products personally while 14.5 were not personally involved in drug procurement. 75% of

respondents sourced their drugs from middlemen and drug wholesalers while others source from the open market,

In the relation of detecting falsified drugs, 83% of the respondents agreed that they check for the originality of their drugs through the NAFDAC registration number. 80 percent believed that the job of identifying fake drugs is for the pharmacist. About 60% of respondents had experience in identifying falsified drugs through the use of NAFDAC technologies after receiving some form of training while no respondents reported ever receiving any help from regulatory officials in detecting fake and falsified drugs. 60% of respondents had reported the case of fake drugs to the regulatory authority. The writer then concluded that more awareness is needed to be made to expose healthcare professionals to the use of the system and this should be made compulsory, however evidence shows that HCPS that are trained have a better understanding, most health care professionals still lack the knowledge and personal attitude in using the technologies. There should be monthly training to further boost healthcare professionals in the use of the system. (Odili et al 2016)

This section discusses the various methods participants perceived that the agency should use in making sure the identification of falsified drugs using the technology systems is a success. This included suggestions from participants on actions that could be taken to help improve the system, respondents were then asked how they thought falsified drug can be identified spontaneously using the system available and one of the points raised through the interviews was to improve the general awareness of the system.

2.9 Improved Awareness Creation

Respondents suggested the need to raise awareness as the best ways of making sure this technology is in use and become more efficient. A major way that was thought of as a more efficient way of creating awareness about the technology is through creative awareness by advertising in different languages since Nigeria is multi-lingual culture. (Ebenezer, 2015)

“Well like I said they just need creative awareness. There is an urgent need to carry everybody along. This involves been creative on-air, place awareness in different languages teaching health care professionals how to use the system, do it in a different dialect, different languages so that people would understand the value of this system”

Community pharmacist 1 female

Some health care professionals believe that different means of awareness needs to be created to make it easy to identify fake drugs instantly and send reports. Aside the use of conventional means of adverts such as through the television, radio, and newspapers another interesting point raised was to find a way of reaching health care workers such as talking to them during health seminar workshops or gathering as stated below (Ebenezer, 2015)

"if awareness is really low then they should take the awareness to all forms of health workers seminars and workshops talking to people about the technology"

Pharmacist 5 male

Assistance by government and their agencies

Some people were of the view that the government and all available agencies play a vital role in the introduction and expansion of the systems. The respondent was of the opinion that government can by taking charge of the cost of using the systems which is currently been funded by health care professionals. This would go a long way in assisting the professionals since they don't bear the burden of purchasing the equipment. (Ebenezer, 2015)

"I tell you ones the government assist in helping the professionals to purchase this system they would be encouraged to use the system."

Community pharmacist 1 female

"in Nigeria to put up an advert on the news is so much. Half a million for a one-minute advert that's how much is been charged for a 2 minutes awareness. Who would love to spend a lot of money on a particular product? So, the government should intervene to help companies with a kind of discount to assist companies who produce original drugs at cheaper rates"

Policymaker 2 male

Choice of medicines that will be Technology enabled

For some reason, there was some disjointed agreement among respondents as to which medication should be made compulsory for the use of all forms of NAFDAC technology to test the quality drugs hence they suggested that it should be on drugs that are of high demand. However, except for the consumer, all stakeholders were of the single idea that using of this technology should be focused on medicines that are likely to be falsified using the technology on all forms of medicinal product (Ebenezer, 2015)

“well, I don't think that every medicinal product would like to copy or counterfeit. They are looking for those medicinal products that are of high demand whose products are moving very fast and very expensive. For me, that was what is important”

Community pharmacist 7 male

“For an economic reason, I don't think every medicinal drug should be waiting for the test, you why companies are doing everything possible to protect their products. If a product is not at risk of being fake, then there is no need”.

Policy marker 2 male

Authors	Year of Publication	Sample Size	Key Points from Article	Conclusion from Article
Adedeji et al	Evaluation of the attitude and practice of good pharmacovigilance practice in Nigeria teaching hospital I2013	100questionnaires response rate of 93.3%	57.1% considered to check if drugs are falsified 51.4% are aware of the existence of NPC 30% have encountered adverse drug reaction due to falsified drug 2.9% have reported 60% consider the reporting system ineffective	Increase awareness of the technology involved in reporting falsified drugs.
Oluwafemi et al 2017	Level of Pharmacovigilance Programme awareness in Nigeria 2017	68.7% response rate in rural areas 98% response rate in urban areas	49.1% are aware of campaigns by the government on pharmacovigilance program in rural areas 19.6% are not aware of the program in rural areas 80.5 are aware of the program in urban areas. 10.5% are not aware of the program	Pharmacovigilance system in Nigeria should be upgraded to involve tackling of falsified drugs and also create more awareness at all areas of the country with the use of jingles and handbill.
Oyetunde et al	Awareness of MAS over other systems such as RFID, Black Eye, Truscan	326 questionnaires were distributed	40% of respondent are generally aware of the system 60% are not aware of the system 51% recommended the use of the system	The level of awareness is relatively low in comparison to the level of the falsified drug. Health care professionals should be fully aware of this system and put it in use. They should be proactive at all times
Babalola et al	Accessing the challenges of health care professionals in identifying fake drugs	7 regulatory agencies took part in the survey	85.7% believes the law is available 100% believes laws are not enforced 60% believe fines and penalties are small	The writer concluded that inadequate laws, poor enforcement, ignorance among health care professionals, high cost of original drugs as well as a high level of

			<p>88% of respondents indicted non-health professionals</p> <p>85.7% respondent to lose control system</p> <p>71% of respondents to the high cost of drugs</p> <p>57% indicated corruption</p> <p>100% of respondent believes ignorance is a key challenge</p>	corruption are the main challenges facing the health care professionals
Opadeyi et al	Educational Intervention to improve the knowledge, attitude, and practices of health care professionals regarding pharmacovigilance	811 health care respondents in Pre-intervention study and 931 healthcare respondents in the post-intervention study	30.5% increase in the intervention group of healthcare professionals after receiving training on how to identify falsified drug,	Proper training and organizing seminars would lead to an improved knowledge
Odili et al	A descriptive study to assess the improvement of identification of counterfeit drugs 2016	100 copies of the questionnaire 69% response rate	<p>69% respondent agreed that Nigeria system is flooded with fake drugs</p> <p>74% describe the problem as major</p> <p>26% describe the problem as moderate</p> <p>83% check for originality of the drugs through NAFDAC Registration Number</p> <p>40% had no experience in identifying fake drugs</p> <p>81% have never reported</p>	<p>More awareness is still needed in other to improve the system.</p> <p>Improved knowledge on the use of the system is key to identifying fake drugs</p> <p>More training should be done to further boost healthcare professionals</p>

Table 3: Summary of publications from literature reviews

2.10 Conclusion:

After delicate research and study of different literature review on research papers, articles, journals from Nigeria and all around the world, it is obvious from the evidence gathered that the challenges surrounding falsified drug identification as continue to significantly become a serious issue despite sustained increase and efforts made towards pharmacovigilance practice in Nigeria by regulatory agency in Nigeria to combat these crises including educating healthcare professionals. Major findings from the literature review showed a low level of knowledge and poor attitude as the main factor responsible for healthcare professionals lack the spontaneous identifying fake medicinal drugs through the use of the system.

The majority of the respondents believed that the presence of falsified drugs is still a problem in Nigeria even with certain measures introduce to spontaneously identify the fake drugs. Some of the challenges that were identified were the high cost of original drugs, poverty, corruption, high level of corruption, inadequate laws and poor enforcement, ignorance among health care professionals, and the presence of non-health care professionals in the business.

The chapter presented the findings from the second phase of my research which also involved a semi-structured interview. Extensive samples of quotations from the different respondent were also used to build the confidence of the readers that the view presented accurately represent the reality of the persons and issues studied

CHAPTER 3: RESEARCH METHODOLOGY

3.1 Overview

SECTION NO	PRIMARY DATA	PART A	PART B
1	Approach	Quantitative analysis	Qualitative analysis
2	Philosophy	Positivism	Interpretivism
3	Source	Questionnaire: Microsoft forms app online distributed	Interview through Phone
4	Structure	6 sections made up of 33 questions	5- 15 mins phone interview
5	Subjects	Medical doctors Pharmacists Others	Medical doctors Pharmacist Other opticians, nurses, dentists

Table 4: Methodology and Data Collection

3.2 Research Approach

In order to determine the challenges and factors that as limited the healthcare professionals for identifying falsified drugs in Nigeria, the author made use of two methods, by using both questionnaire-based surveys and interviews through phone calls which was centered on medical doctors, pharmacist and other health professionals.

The author started by creating a survey (quantitative method) through the use of Microsoft forms and distributed online, this consisted of a core part of the research and they were requested to answer and fill the questions online. This enables the author to gather as much needed information and data used for analysis. Most of the questionnaire was outlined to show the general view towards identifying falsified drugs and check for the awareness of the professionals to the various famous of the system used in identifying fake drugs. Thus, this perception enabled the author to pinpoint how best to deal with these sets of health care professionals and give a possible recommendation.

Furthermore, a phone interview (qualitative method) was conducted to get the personal perspective, attitude of highly experienced health professionals towards falsified drug identification and also current pharmacovigilance practice in Nigeria, challenging factors that still encourage the business of falsified drug in Nigeria, awareness and possible recommendation that is sustainable for the system. The Data collected from both sets of health professionals would be compared to other literature findings to enable the author to give a concluding perception of the study carried out.

3.3 Research Philosophy

The research philosophy in line with the research work was well thought to be that of positivism and interpretivism. It was meant to explain all responses from the questionnaire which would assist the author in giving a well-balanced conclusion to the study conducted. The inference of this research was solely depending on different forms of observation that are quantifiable which helped in the analysis of the data gathered. Thus, the research would advance from been an hypothesis as the notion being studied was easily quantifiable and need a large amount of randomly selected professionals.

The health professionals were provided with a structured questionnaire in which data was collected, analyzed, and interpreted very objectively. The author only used the facts that were available to him at this point irrespective of different constraints that disrupted the data in the global crises of coronavirus. This was then enforced by the use of electronic survey options to avoid any form of unnecessary interaction with the respondents and encourage anonymous response so that professionals can fully express their answers in the survey without any biased mind.

By interpretivism approach information was obtained through a carefully selected phone interview method which then resulted in the main data that was designed by the personal view and values of healthcare professionals. These were done to be very subjective and paint a true picture of the reality of the situation in Nigeria. Also, it was related to a very high level of validity due to the information gotten from highly experienced professionals in the health system in Nigeria through the approach of interpretivism which was needed to obtain accurate results for the study.

3.4 Research Strategy

The strategy in place for the research was to access the awareness of the identification of falsified drugs, challenges, and viable improvement to fight the business of falsified drugs in Nigeria. As evidence of from the review conducted, it was discovered that there was no research showing at final solution faced by the issues of falsified drugs in Nigeria as it evident that one review or the other shows some slight variations because this is in comparison of the attitude, knowledge, and awareness of the use of available technology among groups in health professions in Nigeria.

Some of the participants in this survey such as medical doctors, pharmacists, and some other forms of healthcare professionals who received the survey were previously informed the core purpose of this research work which was concerning a master's degree with Griffith college. The question was then adjusted to a simpler version to aid easy answering. It was then administered over a different platform of health professionals in Nigeria such Pharmacy Student

association of Nigeria, Nigeria Association of veterinary medicines, Nigeria medical association, successfully practicing across all geographical regions of the country.

3.5 Design of the questionnaire for Healthcare Professionals

The questionnaire is a method up of 33 questions which are divided into 6 sections, the purpose of the study was design for the Nigerian healthcare setting specifically for healthcare professionals using an application called Microsoft Forms. This was then distributed randomly through the link electronically, and all survey was completed without the author's opinion. This situation encourages the idea of positivism so that respondents can fully express their opinion without any bias form.

The first part of the question started basically with an introduction to gain the consent of the respondents, allowing me to use their answer only for this purpose. The author assured them that the data that would be generated from this survey was in line with general data protection regulation (GDPR) and that their response was kept strictly confidential. The question must be answered before respondents can go ahead.

3.6 Primary Data Collection

The bellow is an outline of how the primary data would be collected.

Section 1: simply contains respondent agreement which as to be agreed before commencing the survey.

Section 2: it contains demographics information's about the respondents

Section 3: it consists of questions on the knowledge of healthcare professionals towards the falsified drug, how to detect falsified drugs, and the reporting system of falsified drugs. It also gives an insight into the different methods involved in identifying fake drugs as well as how effective the system is.

Section 4: it involves questions on awareness of how falsified drug is been reported in Nigeria. It virtually consists of who is responsible for reporting fake drugs and should the system have been made compulsory or voluntary across all forms of medicinal products. It also asked questions on any evidence of falsified drugs for the past 1 year and how many were observed including reported to the right agency.

Section 5: it contains questions that poised as challenges affecting healthcare professionals from identifying and reporting falsified drugs in Nigeria. It is encouraged to show the sole perception of healthcare professionals which limits them from achieving good identification rates

Section 6: This section consists of questions that are aimed at the recommended improvement that could be adopted to improve how to identify and report falsified drugs in Nigeria.

3.7 Sources

The questionnaire generated was distributed accordingly after the link was generated and send to different healthcare professionals' platform in Nigeria. The author gathered data from about 131 respondents which are made up of 60 medical doctors 36 pharmacists and 35 other health care professions. The author further utilized the Microsoft excel sheet on the result from the Microsoft forms to analyze the data which was collated. For further clarity, the author produced a pie and bar charts used to make comparisons where it matters.

Furthermore, interviews through phone calls were then performed with highly experience healthcare professionals for a better understanding of the knowledge, awareness, challenges the professionals are facing in other to identify fake drugs.

Selection of Medical Professional

The author got in contact with different professional associations of healthcare in Nigeria to assist with the study, though it was difficult to get in touch with these bodies with constant perseverance there was some positive feedback. After several explanations on the reason for the study, the author received a recommendation from a well experienced and qualified pharmacist and medical doctor who was willing to participate in the interviews through a phone call.

3.8 Access and Ethical Issues

A summary of the research study was first introduced and provided to the healthcare professionals who showed interest in the survey and interviews as they were all duly informed about this study concerning the requirement by the author in partial fulfillment of the master program. Caution was also taken when structuring the questions for the survey as careful observation was done in other not to infringe on any personal space of the respondents. It was also noted to be voluntary participation and the respondent response would be anonymous and at any time they wish they can opt-out from the survey without any recourse to nobody.

3.9 Inclusion and Exclusion Criteria

The professionals that were included in this research were medical doctors, pharmacists, and every other form of health care professional practicing in Nigeria. This set of people would have come in contact with drugs at any point in time in their professions. However, respondents who refused or decline to participate in this survey were automatically considered excluded from the study. Aside from this, no other form of criteria was considered in enrolling the respondents for this study and other future data analysis.

Furthermore, sample of letter of introduction was then attached to the questionnaire with the right answer for their informed consent before proceeding on the survey. Thus, it was solely on the discretion of the respondents to therefor take part or withdraw from the survey at their own will. Therefore, out of all the groups that got the links for the survey, those who decline to answer the questionnaire were encouraged to ignore the link, and those who answered and submitted the completed surveys were seen to have been voluntary.

3.10 Conclusion

For this survey, 33 questions were structured and distributed across different forms of healthcare professionals in Nigeria, both qualitative and quantitative approach was employed for this reason. A positivist philosophy was encouraged to hear to ensure an objective deduction from measurable facts was obtained. As part of the author's qualitative approach, a phone interview was carried out to get a better understanding and insight into the respondent's perception of the study.

The data collected from the survey was then analyzed and comparison was made regarding the literature findings of the previous chapter. The author hoped to ascertain the attitude, knowledge, awareness of healthcare professionals concerning falsified drugs in Nigeria as well as any recommendable improvement that can assist in spontaneous identification and reporting in Nigeria.

Thus, further analysis based on respondent responses that were generated from the survey is presented in the preceding chapter.

CHAPTER 4: FINDING AND ANALYSIS

4.1 Overview

This chapter provides answers which were generated from the questionnaire distributed online and examined accordingly. The result gotten from the data assisted the author to determine the awareness, knowledge, and challenges faced by healthcare professionals and provided the foundation for the author's conclusion of the research study needed to improve spontaneous identification and reporting.

Also following a phone interview conducted analysis was also drawn to establish any interaction with survey questionnaires, results, literature review, and the personal perspective of the author regarding the falsified drug in Nigeria.

4.2 Demographic Data (Questions 1-6)

4.2.1 Response Rate

The questionnaire was distributed to 150 respondents which comprised 50 doctors, 50 pharmacists, and 50 other health care professionals. A total of 131 respondents who responded were 60 medical doctors, 36 pharmacists, and 35 other healthcare professionals with a response rate of 87.3% response rate. Out of this response rate was made up of 49 respondents been women, 67 respondents been men and 15 of the respondents prefer not to avail their gender.

The improved response rate in respective of the coronavirus pandemic facing the world was down to constant reminders through phone calls and text messages that were sent daily and also attaching the surveys to different online healthcare professionals' platforms in Nigeria. It was also noticed that responses were also coming immediately after a call or constant plea were sent out

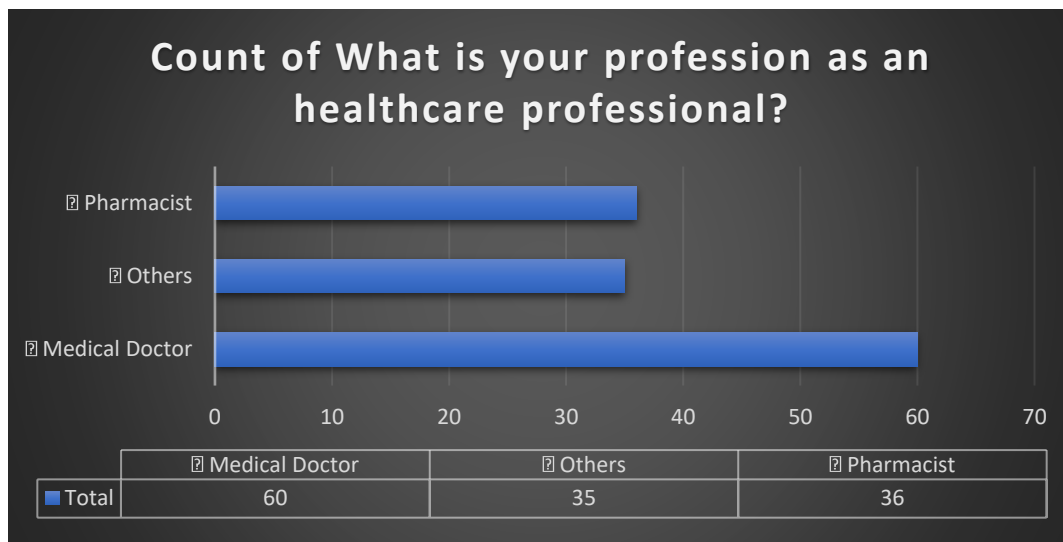


Fig 8a: Count of health professionals that responded

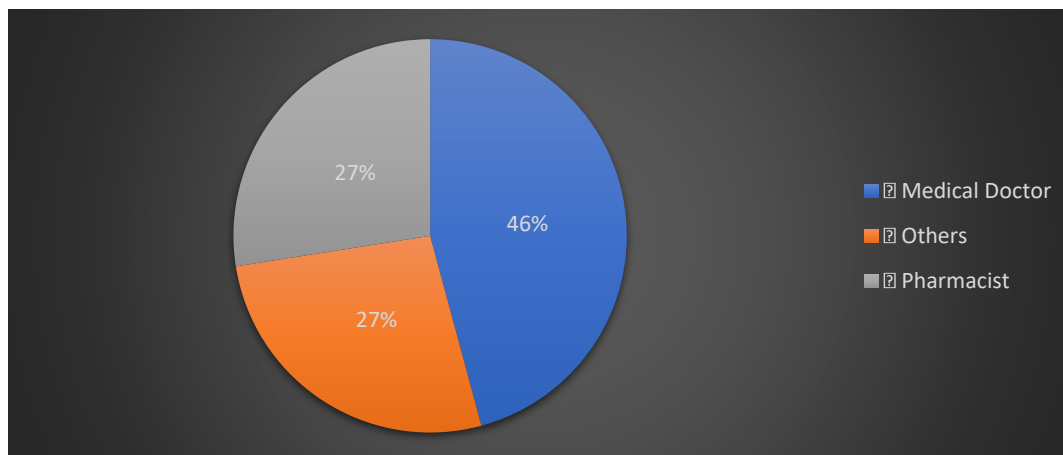


Fig 8b: Percentage of health professionals that responded

4.2.1 Level of Experience

Because of the 131 respondents who completed the questionnaire, 43 of the respondents were aged between 20 to 30 years of age, 61 of respondents aged 31 to 40 while 21 of respondents were aged between 41 to 50, and 6 respondents were aged between 51 and above. This shows predominantly young respondents responded to this questionnaire

In terms of years of active practice in the health professions, of all of the healthcare professionals who participated in this survey 52 respondents as 6 to 10 years of experience, 44 respondents as about 1 to 5 years' experience, 27 of the respondents as 10 years and above experience while only 8 respondents are practicing below one year. Hence the majority of the respondents are well experienced in their field of expertise.

Healthcare Professionals	Geographical Distribution				Years of Experience				Gender			Total Number of Respondents	Response Rate
	N	S	E	W	<1	1 - 5	6 - 10	>10	M	F	n		
Medical Doctors	22	19	10	9	7	18	22	13	30	21	9	60 out of 131	45.80%
Pharmacists	9	9	12	6	0	7	17	12	13	25	5	43 out of 131	32.82%
Others	6	15	12	2	1	19	13	2	24	18	1	43 out of 131	32.82%

Key: N= Northern; S=Southern, E=Eastern, W=Western; M=Male; Female; N=Neutral

Table 5: Demographics

4.3 Knowledge About Falsified Drug (Question 7-15)

The response generated from this section is remarkable and unfortunate as the survey shows a varied response and a significant number of healthcare professionals claim they know how to detect falsified drugs.

Question 7:

In analyzing the question about how to detect falsified drugs in Nigeria, 62% of the respondents agreed that they know how to detect fake drug (40 medical doctors, others 18, pharmacist 23) while 32%(13 medical doctors, others 17, pharmacist 12) of the respondents did not know. Only 6% of the healthcare professionals (7 medical doctors, 1 pharmacist) are not sure if they can detect fake drugs in Nigeria.

Results show a very interesting statistics among respondents who participated in the survey, just 25% of medical doctor has a good knowledge of identifying fake drugs in comparison of a pharmacist who has 14% of identifying fake drugs and 11% for other forms of health care professionals.

This confirms that there is still an average knowledge gap and even the medical doctor who prescribes this drug is still not above average in comparison to the pharmacist who has limited knowledge in identifying fake drugs as well as other healthcare professionals.

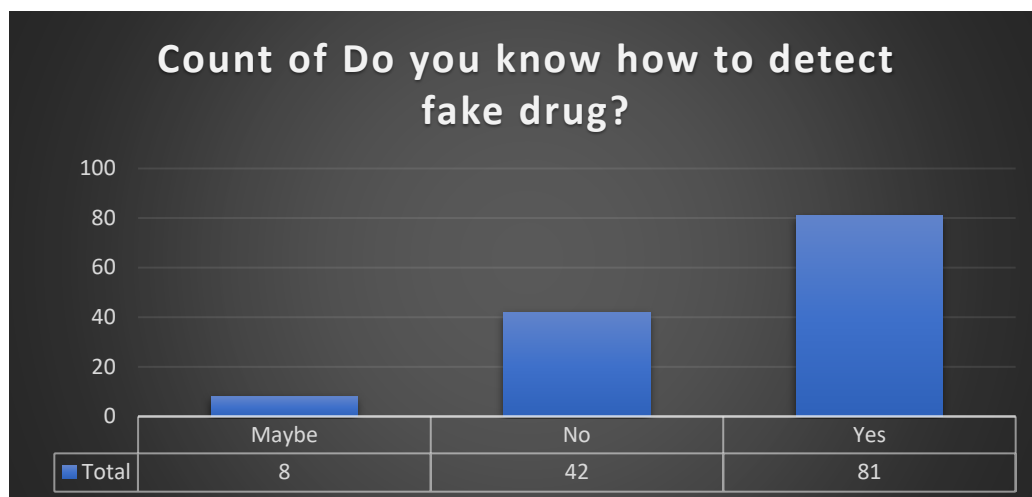


Fig 8a: Count of Knowledge healthcare professionals in identifying falsified drugs

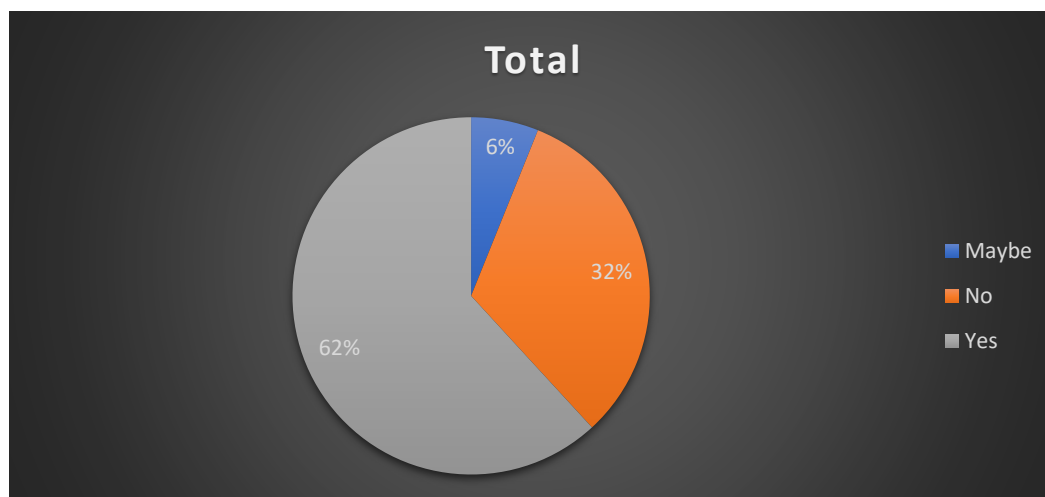


Fig 8b Percentage of Knowledge among healthcare professionals in identifying the falsified drug in Nigeria

Question 8

Question 8 is a follow-up question to question 7 to have an idea of the source of knowledge among healthcare professionals. It was designed to have an idea where they get information about falsified drugs in Nigeria. A total no of 14% respondents through the internet and social media (13 medical doctors, 5 pharmacists), majority of the respondents get their information through articles published a figure about 70% (30 medical doctor, 29 pharmacists, 33 others) while about 16% of the respondents (17 medical doctor, 2 pharmacists, 2 medical doctors) gets information through verbal communication

This shows that a medical doctor is well informed in a slight comparison with the pharmacist and other healthcare professionals. It was analyzed that majority

of the healthcare professionals' sources and rely on information from journals and articles published on information related to falsified drugs. However, despite the increase of social media awareness in the present time's healthcare professionals are not effectively using this means for spontaneous information to explore their knowledge

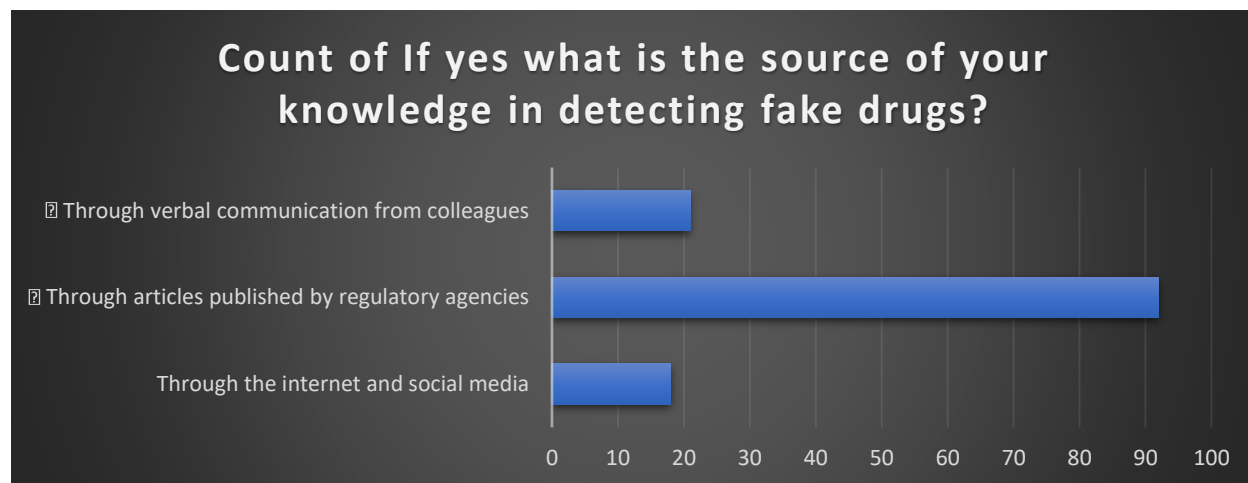


Fig 9a: Count of different source of healthcare Knowledge

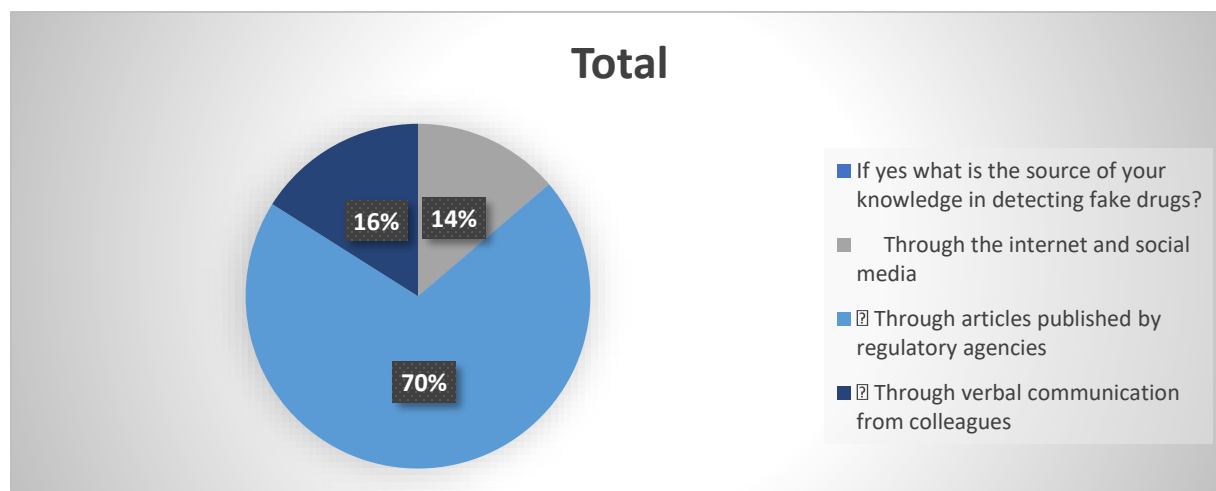


Fig 9b: Percentage of different source of healthcare knowledge

Question 9

To determine the healthcare professional's knowledge of which organization is responsible for handling pharmacovigilance in Nigeria, about 83% (42 medical doctor, 35 Others, 32 pharmacists) of the respondents identified the Nigerian Agency for Food and Drug Administration and Control (NAFDAC), 5% (medical doctor 6) of the respondent agreed that pharmacist council of Nigeria are in charge of pharmacovigilance while 12% (12 medical doctors, 4 Pharmacist)

selected World Health Organization to be in charge of pharmacovigilance in Nigeria.

Thus the survey showed a significant result, while few medical doctors and pharmacist selected W.H.O has been in charge of pharmacovigilance in Nigeria as well as pharmacist council of Nigeria, a majority of the healthcare professionals acknowledged the fact that N.A.F.D.A.C is the primary regulatory agency in charge of pharmacovigilance in Nigeria which is correct.

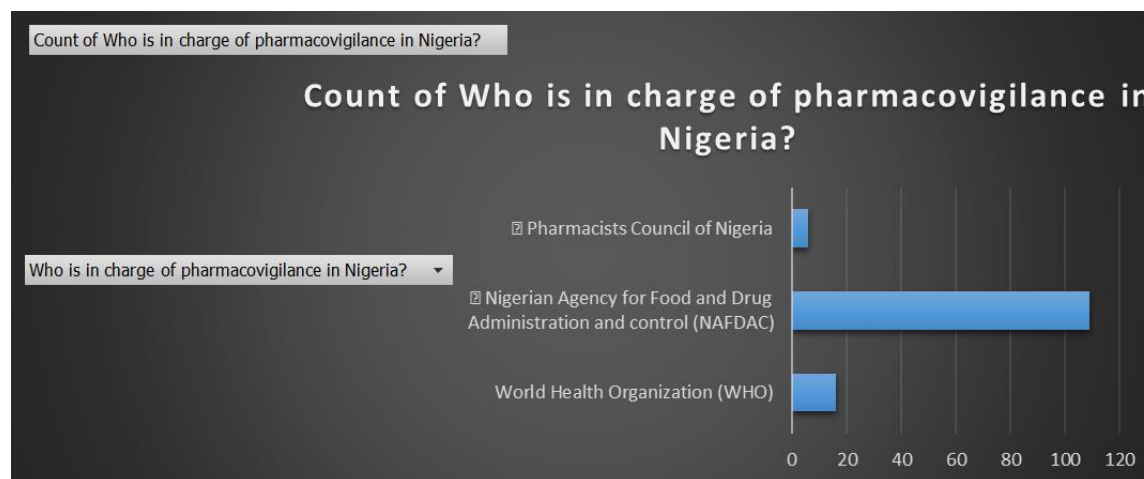


Fig 10a: Count of an agency responsible for pharmacovigilance in Nigeria

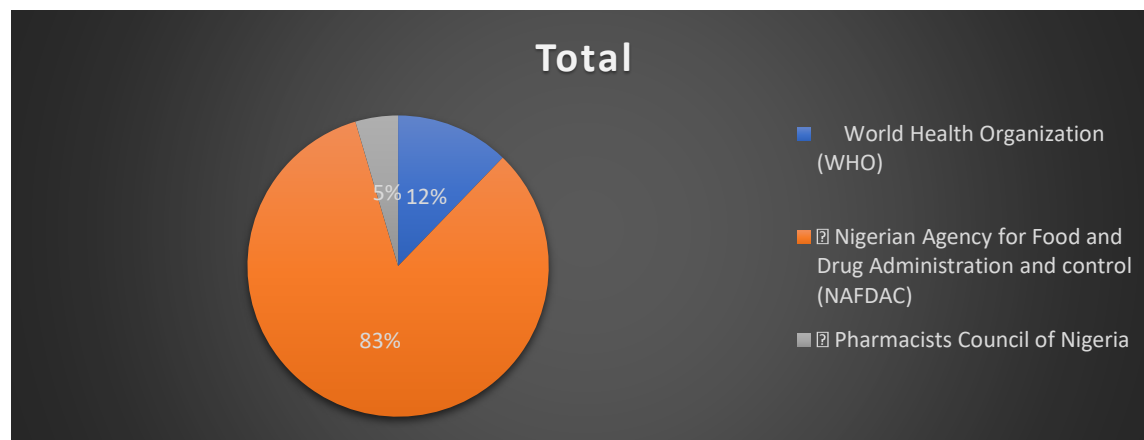


Fig 10b: Percentage of an agency responsible for Pharmacovigilance

Question 10

In regards of responsibility of the healthcare professionals who should be in charge of reporting fake drugs in Nigeria, 11% (11 Medical doctor, 10 Others, 2 pharmacists) of the respondents selected W.H.O as regulatory bodies in charge of reporting fake drugs in Nigeria, 75% (38 medical doctors, 33 others, 27 pharmacists) selected NAFDAC as the major agency of reporting fake drug,

12%(8 Medical doctors, 1 other, 7 pharmacists) selected pharmacist council of Nigeria while a significant 2% (3 medical doctors) only selected N.M.A as a reporting agency.

As depicted from the results it is obvious that majority of the healthcare professionals are very much aware of the agency in which they have to report any form of falsified drugs, however, it's still unusual that significant respondents of the pharmacist are still not aware of who to report fake drugs this is in contrast to other health care professionals who are majorly aware that all identified fake drugs needs to be reported to NAFDAC. Hence there is a poor familiarity of the pharmacist in reporting of identified fake drugs to the agency.

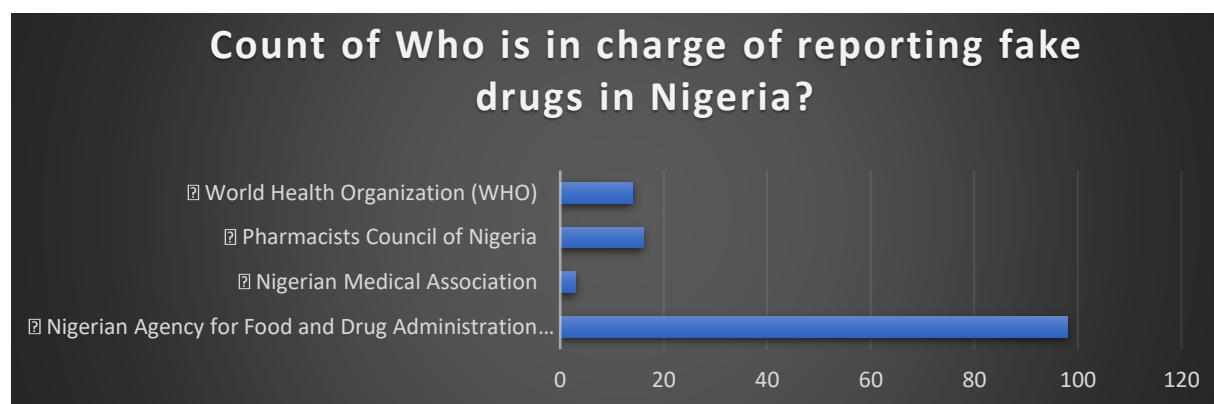


Fig1 1a: Count of the agency is in charge of reporting fake drugs in Nigeria

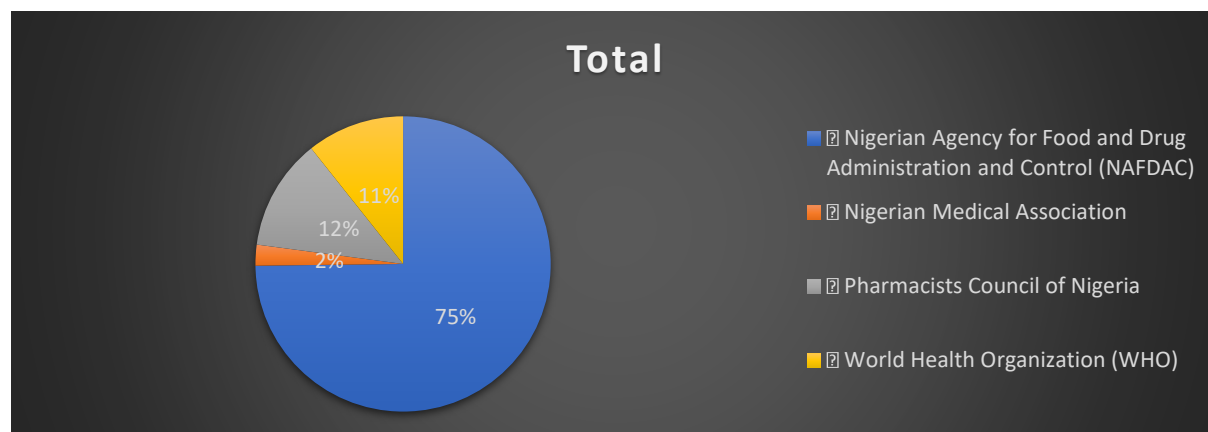


Fig1 1b: Percentage of the agency is in charge of reporting fake drugs in Nigeria

Question 11

This question is asking the healthcare professionals to identify which of the technology system of identifying falsified drugs are they familiar with. About 50% of the respondents (26 Medical doctors, 9 pharmacists, 31 others) selected Mobile Authentication system, 8% of the respondents (Medical doctors 2, pharmacist 8)

selected Radio frequency identification as a technology they are familiar with, 25% (18 medical doctors, 2 others 13 pharmacists) are familiar with Black Eye technology, 16%(14 medical doctors, 6pharmacist) of the respondents are familiar with truscan while just 1% of the respondents are familiar with all of the system.

Therefore, results show that half of the respondents are familiar with the most advance and latest system provided by NAFDAC in identifying fake drugs. However, the only contrasting issues are that the pharmacist is a little unfamiliar with this technology. Another interesting statistic is the familiarization of the black eye technology by health care professionals, however, whatever technology that was asked the main aspect to point out here is that health care professionals are significantly aware of one or more of the system with the highest percentage on MAS. The next questions were to know if they use this system and how effective it is which would be answered in the next questions.

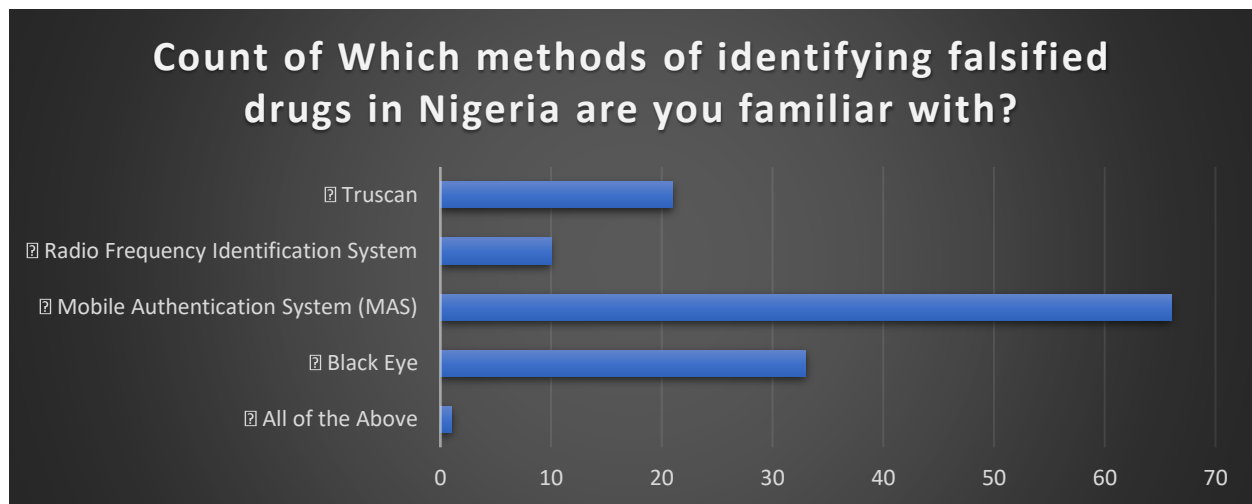


Fig 12a: Count showing technology healthcare professionals are familiar with

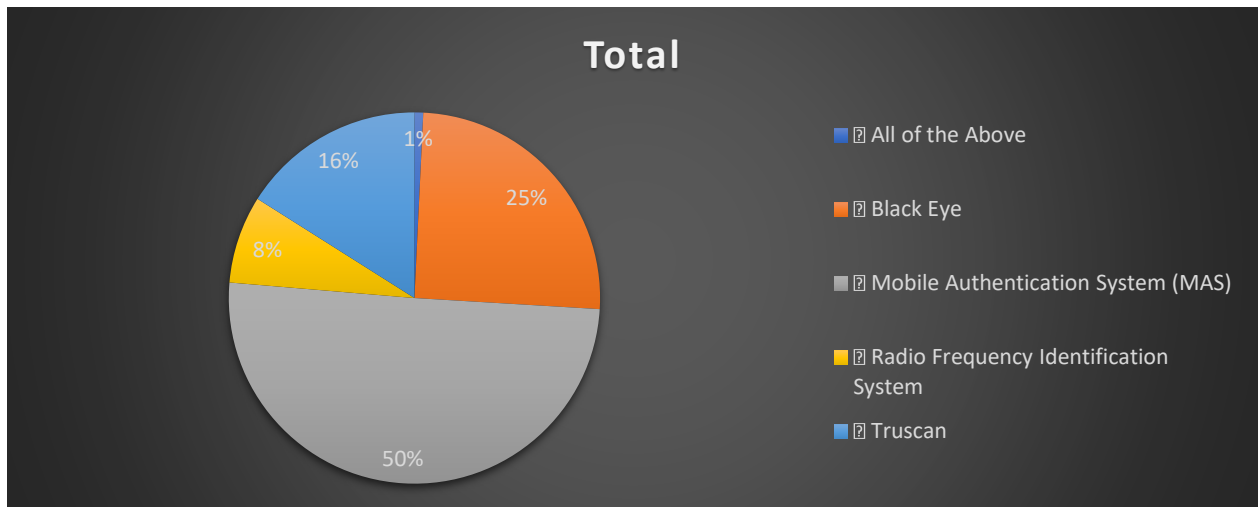


Fig 12b: Percentage showing technology healthcare professionals are familiar with.

Question 12

This question was set up to ask healthcare professionals if this system provided by NAFDAC is in use. 48% (24 medical doctors, 9 pharmacists 30 Others) are in use of any one of the systems to identify fake drugs while 52% (36 medical doctors, 27 pharmacist, 5 others) of the healthcare professionals who participated in this survey do not use any of the systems.

This is evident that despite a majority of the health care acknowledging the fact that they are familiar with one or two of the technology available, results show that below-average healthcare professionals make use of this system with the pharmacist who prescribes this drug shows a relatively low number which is a really sad statistic to show.

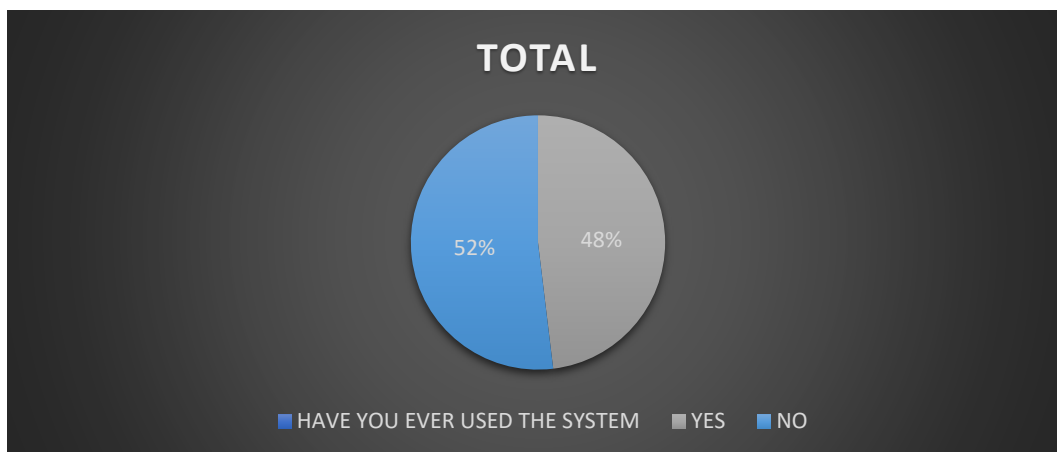


Fig 13a: percentage of frequency of the technology system been used



Fig 13b: count of the frequency of the technology system been used.

Question 13

In a follow-up question, this question was asked to know how effective the system used to identify falsified drugs. 47% (32 medical doctors, 23 pharmacists, 7 others) confirmed that the system is very effective, 44% (25 medical doctor, 7 pharmacists 27 others) are not sure if the system in place is effective while just 9% (4 Medical doctors, 6 pharmacists, 1 other) believed that the system is ineffective.

The result shows a significant below-average response. Just a few healthcare professionals believe that the system in place is effective, however, the population of healthcare is the medical doctor who acknowledges the fact that the system is effective in comparison to the pharmacist who doubts the system used in identifying falsified drugs.

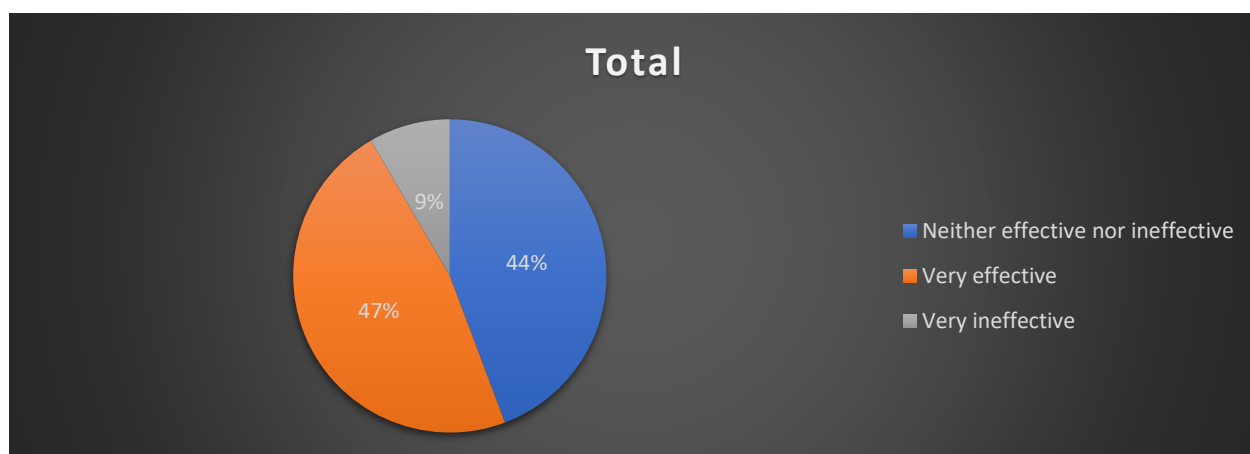


Fig 14a: Percentage of the effectiveness of the system

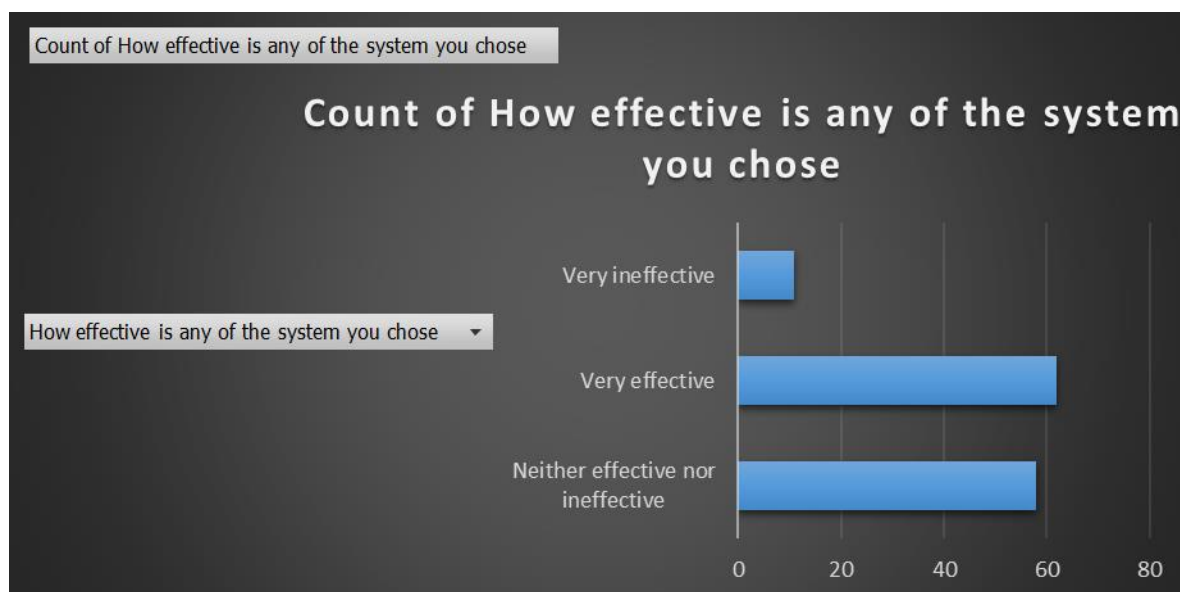


Fig14b: Count Showing the effectiveness of the system

Question 14

In order to know if healthcare professionals use this system to check for a falsified drug in Nigeria, respondents were then asked to confirm if they currently use this technology. 47% of the respondents (25 medical doctors, 9 pharmacists, 27 others) are currently using the system while 53% of the respondents (35 medical doctors, 27 Pharmacists, 8 Others) are currently not using any of this system.

From the result, this shows a moderate usage of the technology as healthcare professionals are not putting the system in practice in their day to day activities.

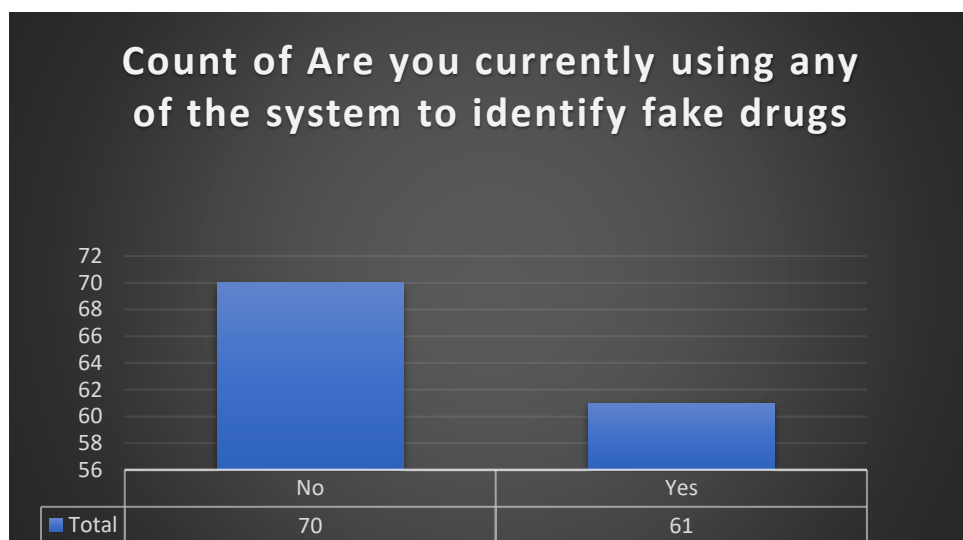


Fig 15a: Count showing the rate of current usage of the system

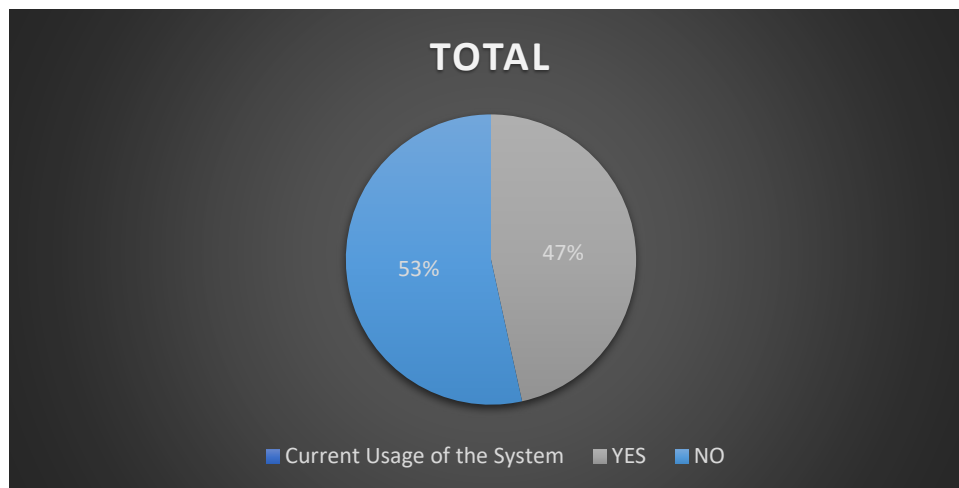


Fig15b: Percentage of the rate of current usage of the system

Question 15

This question was to get the view of the respondents of the most significant criteria used in identifying falsified drugs spontaneously. 61% of the respondents (29 medical doctors, 20 pharmacists, 31 Others) admitted to all criteria from an adverse reaction, uncommon drug reaction and life-threatening reactions, 21%(17 medical doctors, 8 pharmacists, 2Others) of the respondents admitted to checking for any life-threatening reactions to identify falsified drug, 14% of the respondents (10medical doctor, 2 others 6 pharmacists) only identify falsified drugs through uncommon drug reaction, while 5% of the respondents (4 medical doctors, 2 pharmacists) admitted to identifying fake drugs only through adverse reaction.

The majority of healthcare professionals rely on a different form of reaction to identify fake drugs rather than relying on the technology to spontaneously identify the drugs that are suspected to be falsified.

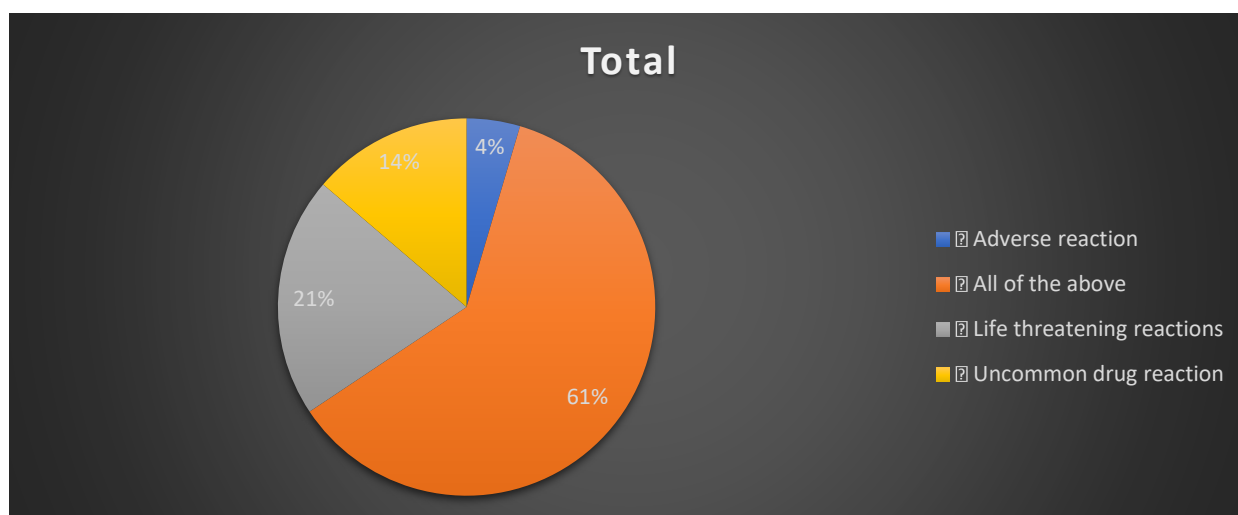


Fig 16a: Percentage of most significant criteria for identifying fake drugs

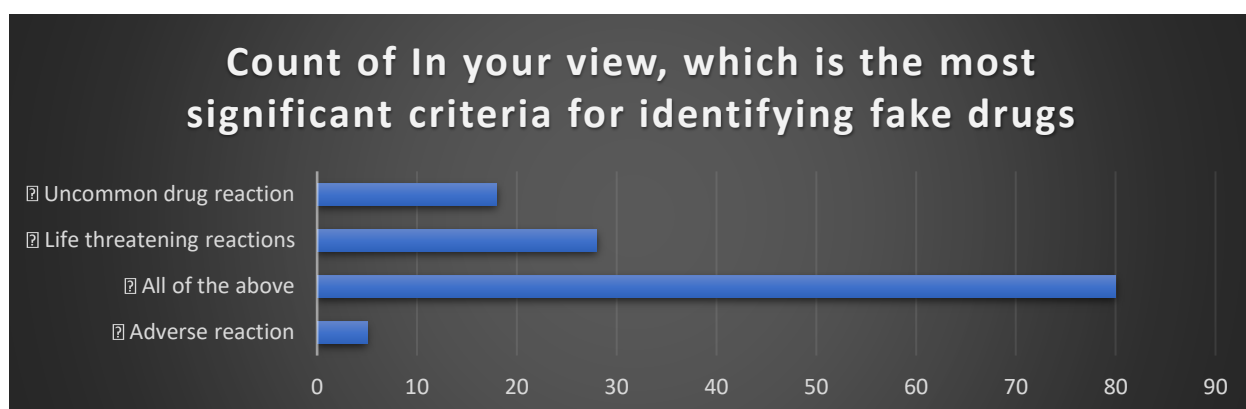


Fig 16b: Frequency of the most significant criteria for identifying fake drugs

4.4 Awareness of Falsified Drug Reporting System (Questions 16-22)

The responses of the section vary across the question to discover the awareness and as well as experience of healthcare professionals towards reporting of falsified drugs

Question 16

This question was asked to get the view of a healthcare professional who is responsible for reporting falsified drugs in Nigeria. 18% of the respondents (20 medical doctors, 2 pharmacist, 1 others) selected medical doctors, 9% of the respondents (6 medical doctors, 6 pharmacist) selected pharmacist, 54% (32 medical doctors, 28 pharmacist, 11 others) selected any of the above 18% of the respondents (1 medical doctor, 23 Others) selected others while just 1% (1 medical doctor) selected None of the above.

Therefore, in analyzing which healthcare professionals were perceived to be majorly responsible, the majority of the healthcare respondents agreed that both the pharmacist, a medical doctor, as well as other forms of health care professionals, should be responsible for reporting of falsified drugs in Nigeria.

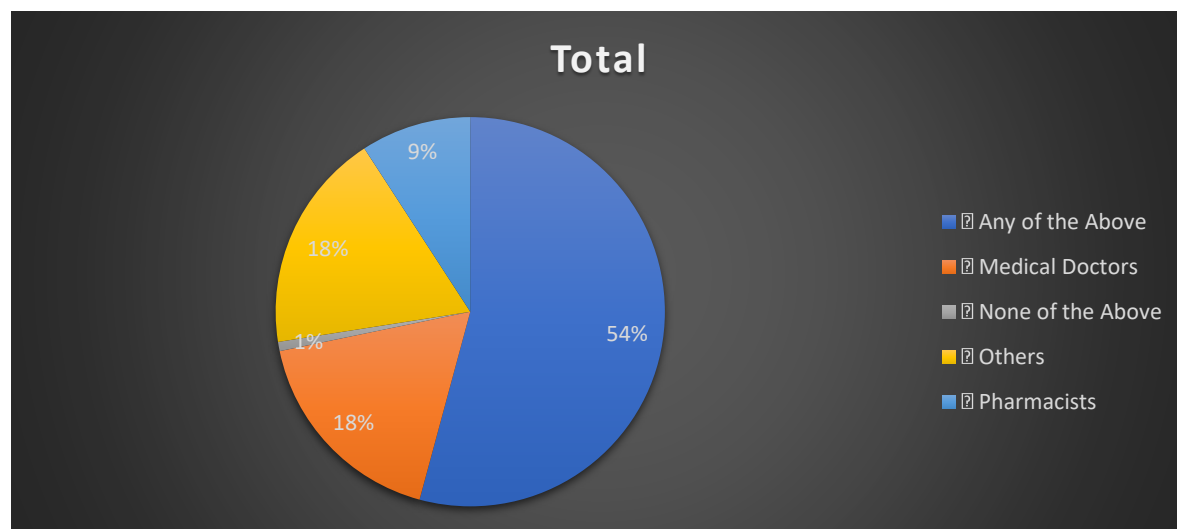


Fig 17a: percentage of healthcare professionals responsible for reporting

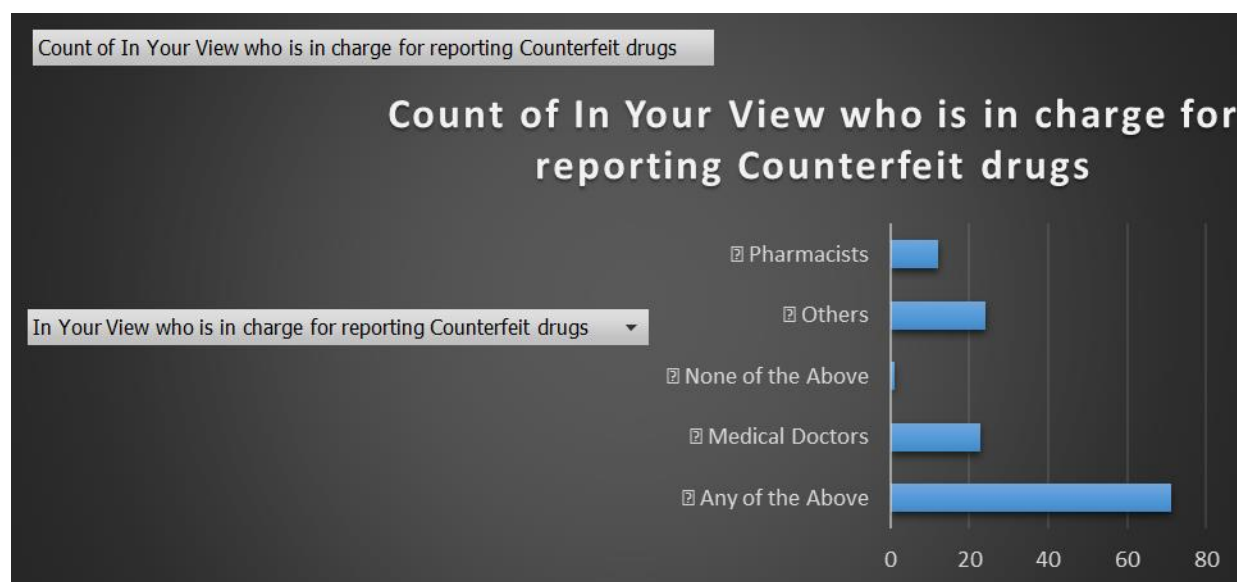


Fig17b: Count of health professionals responsible for reporting counterfeit drug

Question 17

This is a follow-up question to confirm if reporting of fake drug spontaneously should be made compulsory or voluntary. An overwhelming 95% of respondents (55 medical doctors, 35 pharmacists, 35 others) felt it should be compulsory in

Nigeria in comparison to 5% of respondents (5 medical doctors, 1 pharmacist) who suggested it remain voluntary.

Therefore, it is evident that all healthcare professionals would opt to make sure the reporting of a falsified drug be made compulsory like an obligation in Nigeria showing a favorable character to the importance of falsified drug reporting.

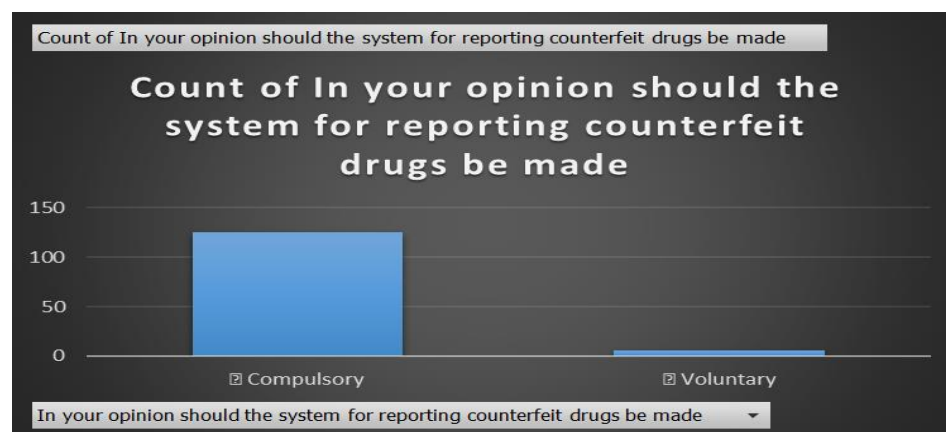


Fig 18a: Count of healthcare opinion of reporting falsified drugs

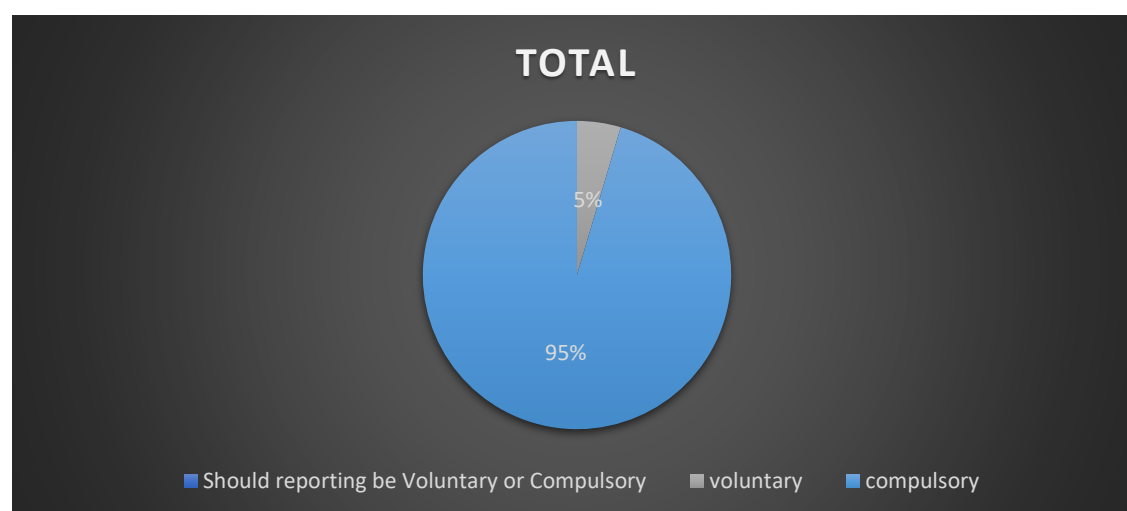


Fig18b: percentage showing if reporting should be made compulsory or voluntary

Question 18

This is also a follow-up question to determine the frequency in which observation of such falsified drug in Nigeria is observed by health care professionals, 54% of the respondents (32 medical doctors, 13 pharmacists, 26 others) admitted having observed falsified drug, 37% of respondents (23 medical doctors, 19 pharmacists, 7 others) had not observed any within this year. Only 8% of the respondents (5 medical doctors, 4 Pharmacist, 2 others) were unsure

All groups of health care professionals admitted having observed falsified drugs in the past 12 months, though it is only unusual for medical doctors and other healthcare professionals to observe more fake drugs than pharmacist within the past 12 months

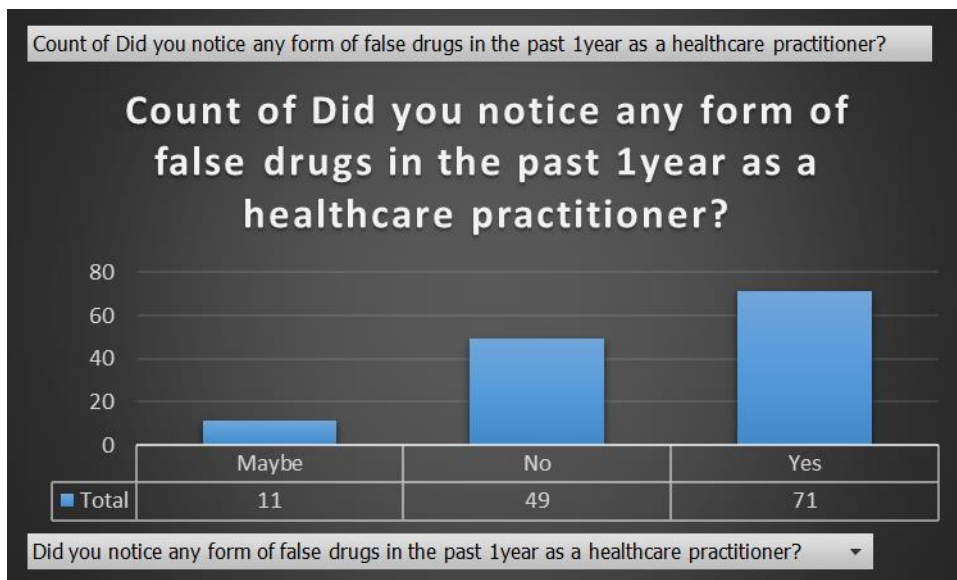


Fig 19a: Count of falsified drug notification in the past 1 year

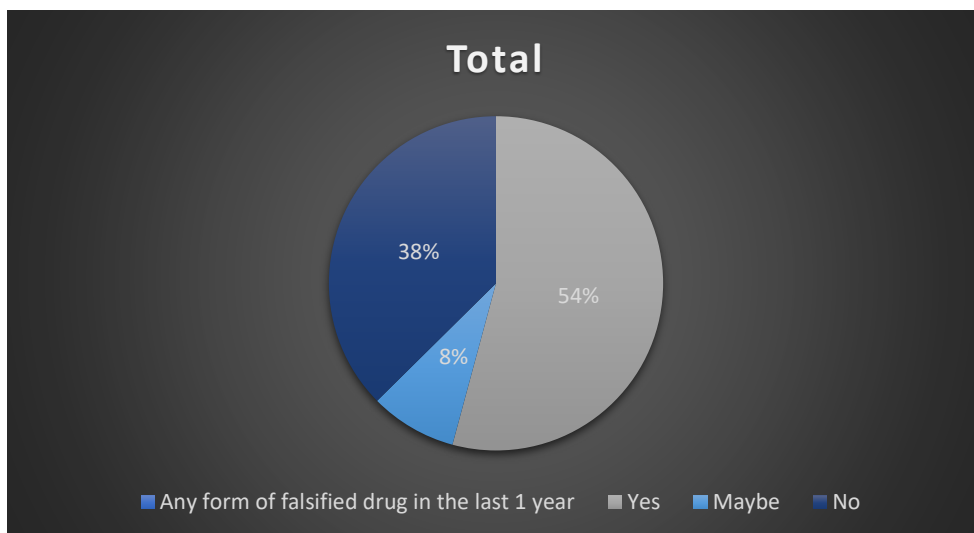


Fig 19b: percentage of a falsified drug for the past one year

Question 19

This question was asked in other to know how many falsified drugs have been discovered. 5% of the respondents (5 Medical doctor, 1 pharmacist, 1 others) selected over hundred drugs discovered, 21% of the respondents (2 Medical doctor, 2 Pharmacist, 23 others) selected between 75 to 100 drugs discovered,

20% of respondents (11 medical doctor, 7 Pharmacist, 8 Others) selected between 51 to 74 drugs, 30% of the respondents (24 Medical doctor, 12 Pharmacist, 3 others) selected 26 to 50 drugs, 24% of respondents (18 Medical doctors, 14 Pharmacist) selected less than 25 drugs discovered.

As a follow-up from the response of the preceding question, this shows a moderate frequency of falsified drugs among health care professionals practicing in Nigeria, with pharmacists showing low frequency in their practice than medical doctors and other healthcare professionals.

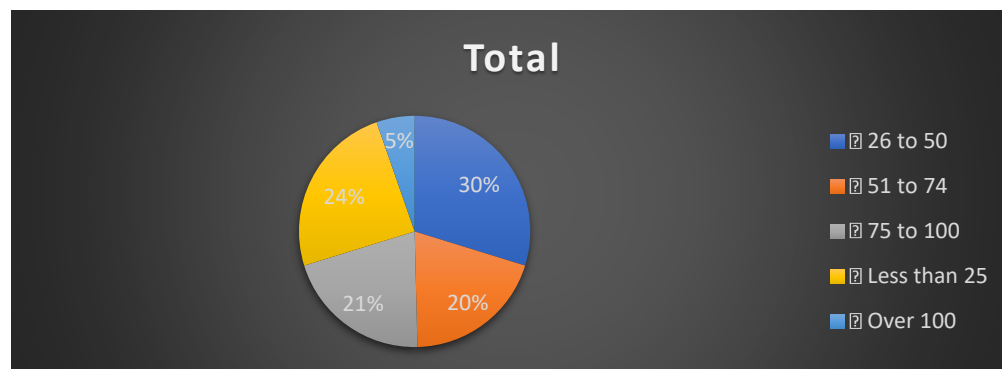


Fig 20a: Percentage of the frequency of falsified drug over the past 1 year

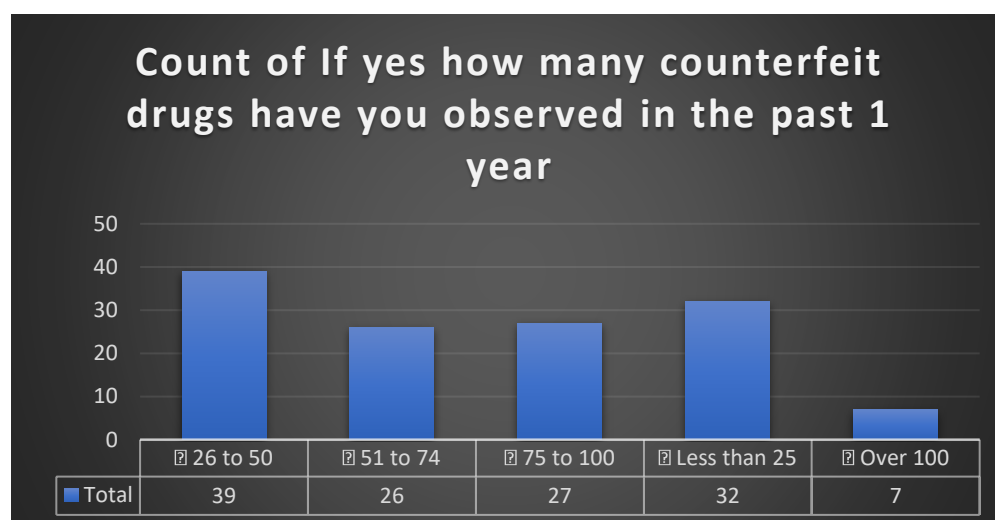


Fig 20b: frequency of Falsified drug over the past 1 year

Question 20

As follow up question, 15% of the respondents (12 medical doctors, 1 others, 7 pharmacists) report falsified drugs to the Nigerian Pharmacovigilance center, 26% of respondents (20 Medical doctors, 9 Pharmacist, 5 Others) selected professional bodies, 34% of the respondents (26 medical doctors, 18 Pharmacist) selected drug

manufacturers while 25% (2 medical doctors, 29 others 2 pharmacists) selected others

As depicted from the response generated healthcare professionals are reporting falsified drugs to the wrong people. More respondents seem to report to the drug manufacturers instead of the regulatory agency who should sanction such a company for producing falsified drugs. There was a huge discrepancy among all groups of healthcare professionals concerning reporting any falsified drugs identified, this is because only a little percentage of the respondents report falsified drugs to the National Pharmacovigilance center.

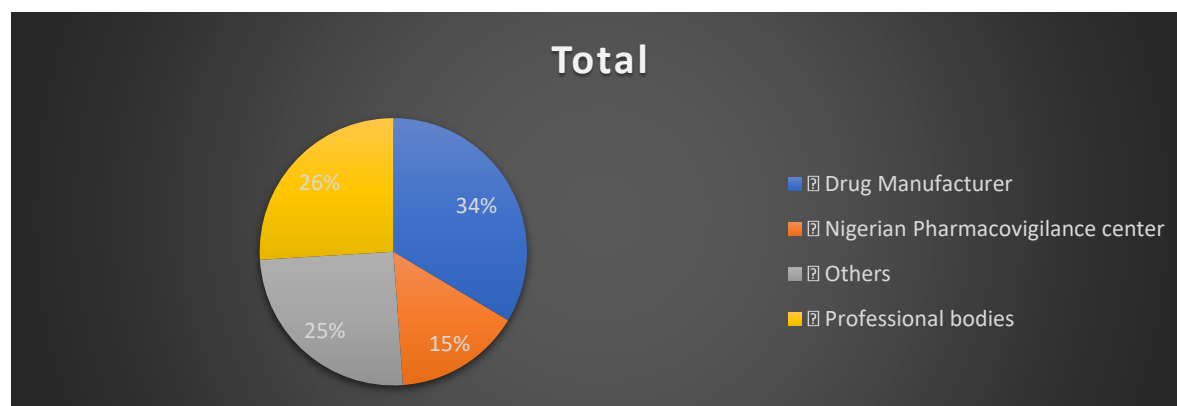


Fig 21a: percentage of an agency that receives falsified drug reports

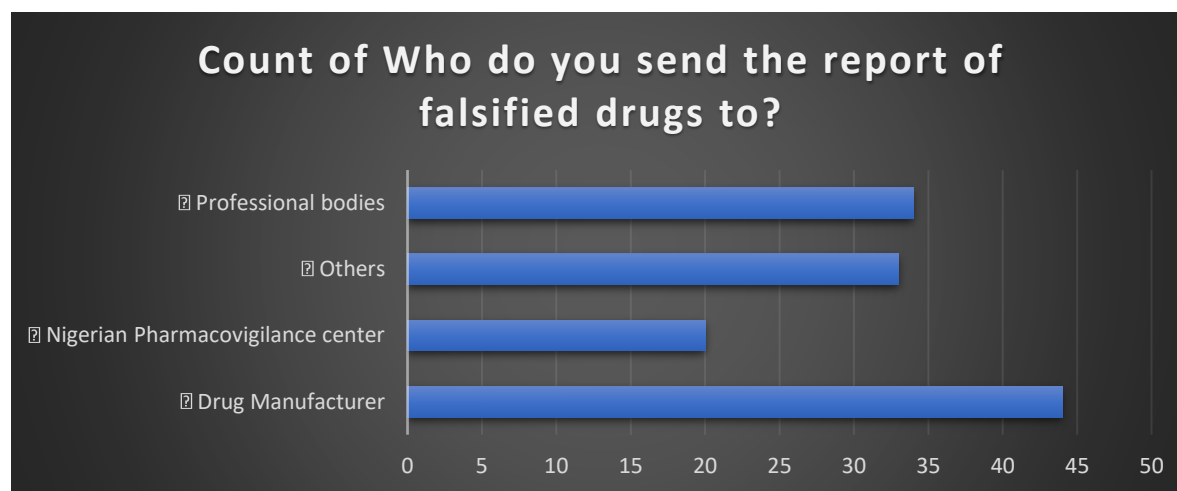


Fig 21b: Count of Agency that receives falsified drug report

Question 21

This question was to identify if there was any feedback from reporting any falsified drug. 42% of the respondent (21 medical doctor, 8 pharmacists, 26 others) receives feedback after reporting, 47% (32 Medical doctors, 22 pharmacists, 8 Others) admitted not receiving any form of Feedback after reporting while 11%

of the respondents (7 medical doctors, 6 Pharmacist, 1 Other) are not sure if they ever receive any form of Feedback after reporting.

The result shows a poor follow up and response culture from a regulatory agency that is tasked with handling falsified drug reporting. This really and unfortunate situation as a regulatory agency does not give feedback to the professionals putting the health system in jeopardy.

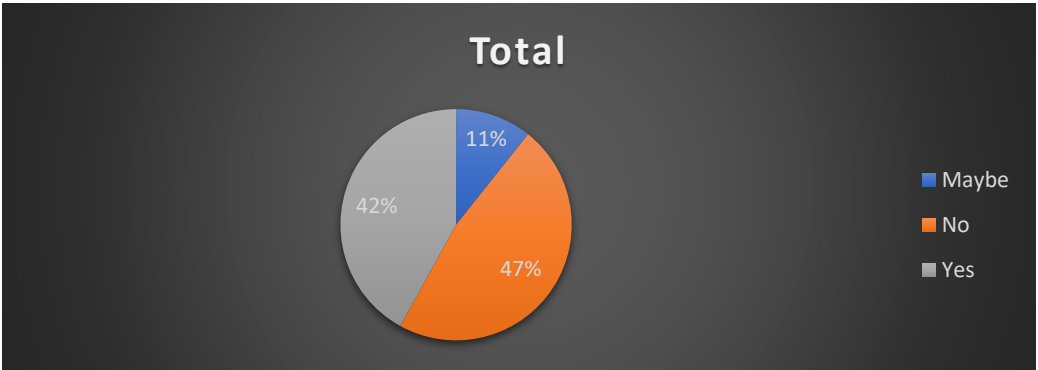


Fig 22a: percentage of any feedback received after reporting

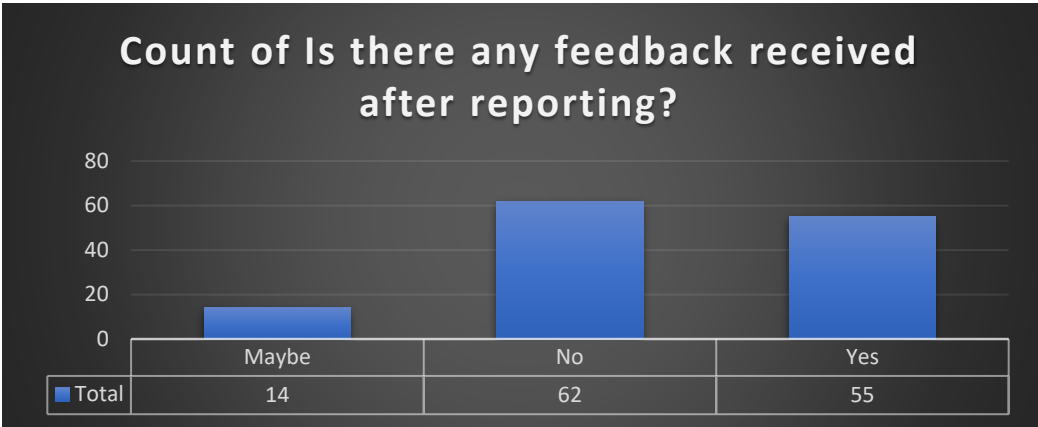


Fig 22b: Count of Falsified drug feedback report

Question 22

The question was asked to the respondents in improving their knowledge of the reporting system. A majority of the respondents 79% (45 Medical doctors, 24Pharmacist, 34 others) admitted to upgrading their knowledge while 21% of the respondents (15 medical doctors, 12 pharmacists, 1 Other) are not in support of upgrading their knowledge about falsified drug reporting.

Results confirmed that the majority of the healthcare professionals were open in upgrading their knowledge about falsified drug reporting system which is an interesting fact, despite the poor awareness or low reporting rate in Nigeria.

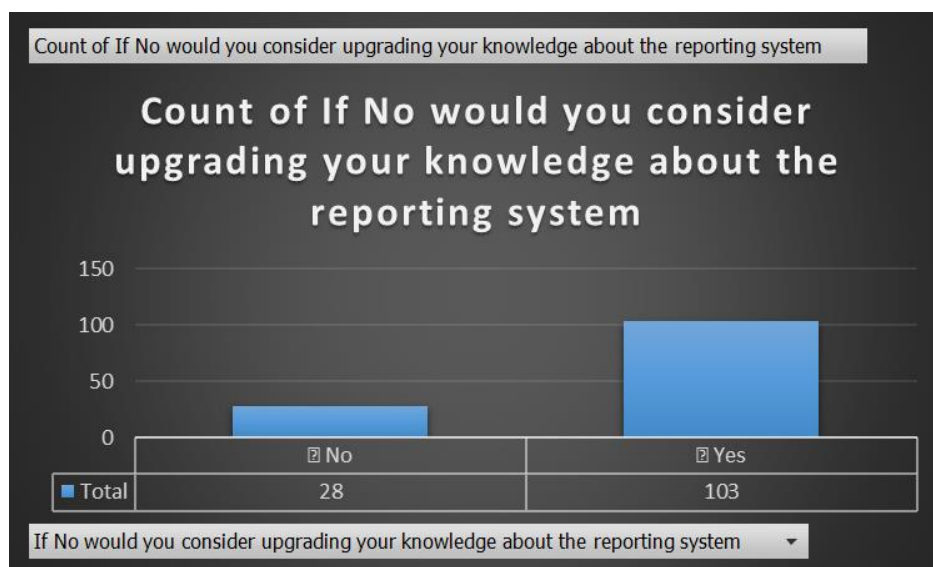


Fig 23a: Count of upgrading knowledge about the reporting system

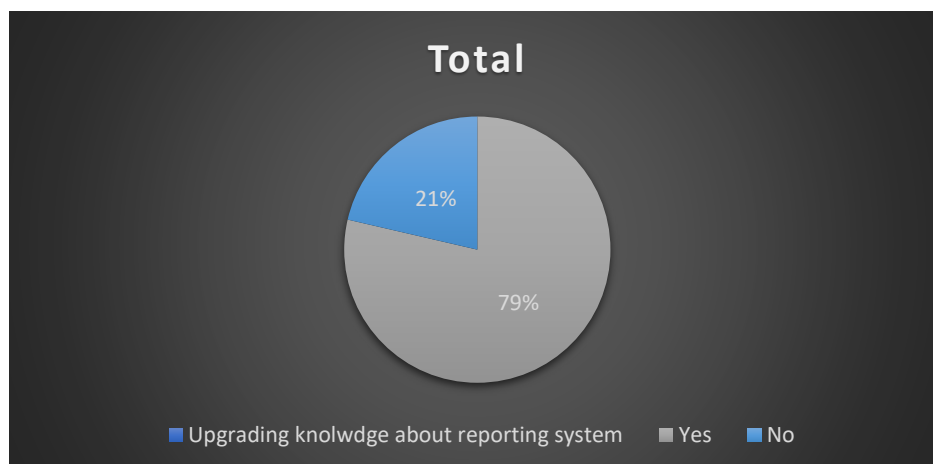


Fig 23b: percentage of Upgrading knowledge of reporting system

4.5 Challenges of Falsified Drug Reporting in Nigeria (Question 23-27)

In analyzing the major challenges among healthcare professionals in reporting offenders in Nigeria, respondents were provided a list of options to choose from. The author hopes to gain insight into the factor that serves as a current challenge in reporting those who are involved in the falsified drug business. Respondents were asked to either agree or disagree accordingly.

The largest percentage of 94% of respondents agreed that though the laws were available there is not much enforcement on the existing laws regulating medicinal products in Nigeria while 5% of the respondents disagree with this claim and only 1% are not sure.

62% of the Healthcare professionals believed that ignorance among health care professionals is another factor that poses a great challenge of falsified drug reporting while 8% disagree with this claim, 31% remain unsure if this is an issue.

60% of the respondents agreed that too much presence of Non-health care professionals in the drug business is a key factor, 30% remain unsure only 11% disagree with this claim.

63% of healthcare professionals think that the high cost of good and efficient drugs are factors affecting falsified drug reporting in Nigeria, while 9% disagree with this claim, only 27% of the respondent disagrees

Interestingly, 64% of the respondent agree to the fact that a high level of corruption in government policymakers is a major challenge the health system is facing, 24% remains neutral while 12% disagree outrightly.

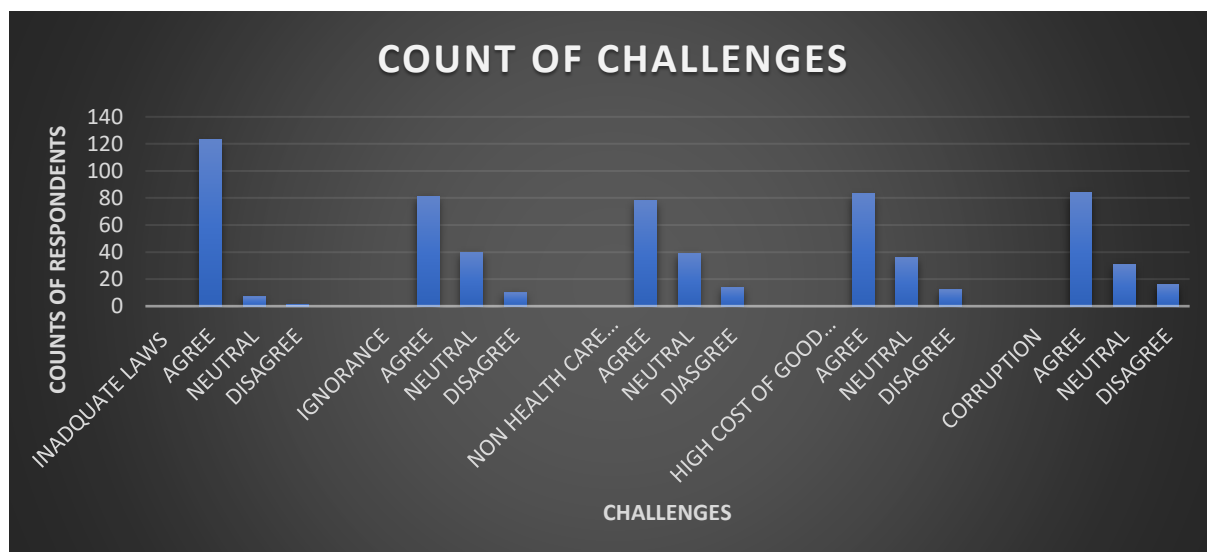


Fig 24: Count of Challenges of Falsified drug reporting in Nigeria

4.6 IMPROVEMENT OF FALSIFIED DRUG IDENTIFICATION (Question 28-33)

This entire section of the survey was drawn out in other to provide respondents considerations for the respondents to select from by either agreeing or disagreeing. The majority of the healthcare professionals agreed with all the recommendations proposed in the survey has been significant towards improving the falsified drug identification in Nigeria.

A huge percentage of the respondents about 86% agree that continuous learning will create more awareness which is the key to improving falsified drug identification in Nigeria 12% only disagrees and 2% remains neutral on this claim.

53% of the respondents agree that current regulations should be reviewed and make necessary adjustment if necessary 38% remains unsure while 8% disagree.

59% of the healthcare professionals believed that incorporating huge fines and sanctions for not identifying and reporting falsified drugs will help, 31% remain neutral while just 10% disagree.

As part of the improvement strategy, about 62% of the respondent believed that incorporating a form of remuneration on each drug identified would help improve the system, 25% neutral with this claim, 13% disagrees.

63% of the respondents agree that more awareness needs to be created to ensure both public and healthcare professionals are well aware of the system, 24% are not sure if this would work while 12% feel awareness is not the problem.

68% of the respondents agree that creating a special department task solely with the responsibility of falsified drug reporting in Nigeria would improve the health system, while 20% remains neutral to this claim only 12% disagrees outrightly.

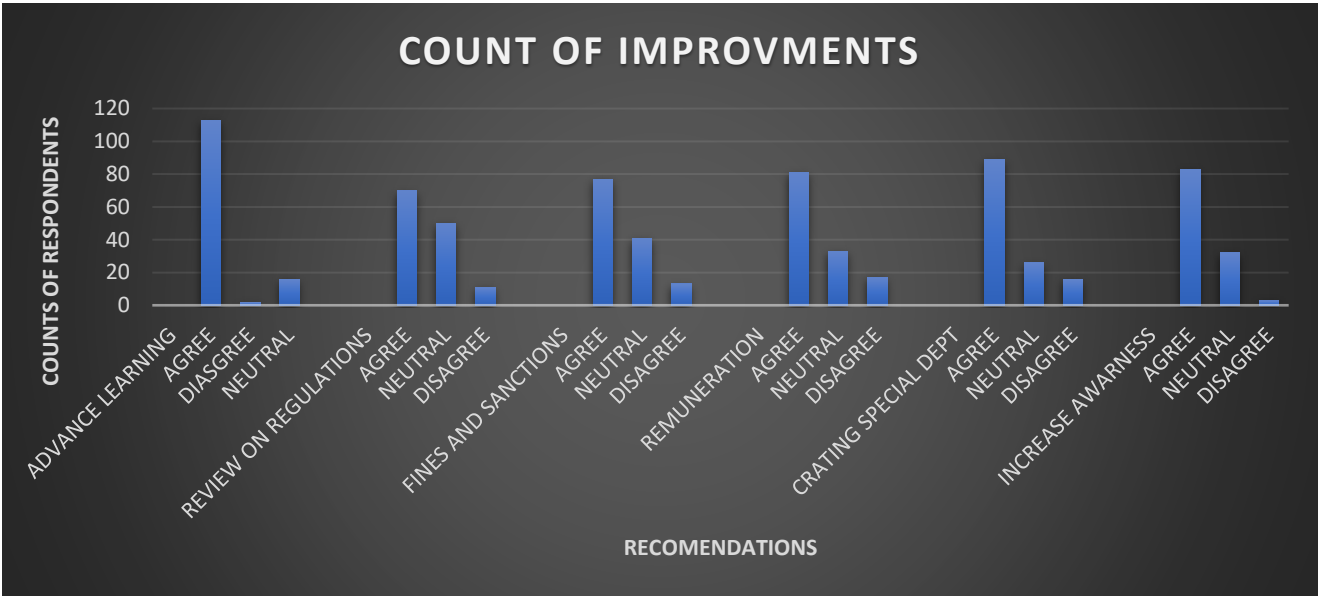


Fig 25: Count of improvement of Falsified drug Identification

4.7 QUALITATIVE ANALYSIS

4.7.1 Phone Interview with Medical Doctor (8 Years of Experience)

The author explored the opportunity to speak with three contacts only, this is due to the global pandemic as getting an interview with healthcare professionals was very difficult at the time of writing this thesis. However, the author was able to get in touch with two medical doctors, on the challenges of spontaneous identifying falsified drugs in Nigeria. They gave consent for the interview on the condition of an anonymous status; however, they were both over 40 years of age and had been in healthcare practice for a minimum of 8years.

They both admitted having observed 10 falsified drugs in the last one year but can't remember submitting any reports that same periods, but one of the doctors usually get in touch with the manufacturer alone 'that drugs are either expired or outdated'. The other health care professionals only came in contact with falsified drugs if a patient comes back to him with an adverse event and they would check the drug to see if it is original through experience. They also agreed that they had never received any form of feedback from reporting any form of falsified drug as a regulatory agency is always slow in taken any form of decisive decision on the issues of the falsified drug.

Both healthcare professionals were also asked to identify which system they are used to in terms of spontaneous identifying falsified drugs and reporting, they all believed that the Mobile Authentication Service system is the best option as it is very easy to operate and send information. Unfortunately, none of the healthcare professionals interviewed are familiar with the use of the systems to identify falsified drugs. They only believe in past knowledge about the drugs as well as experience on the drugs to check for any originality of the medicinal products that are suspected to be falsified.

The specialists agreed that the entire regulations surrounding the falsified drug reporting and identification should be reviewed as a matter of urgency, they admitted that the process currently in place does not encourage spontaneous identification and feedbacks. Though they recommended it should be made compulsory and incentives should be made available to encourage upcoming doctors, they further stated that more seminars and education should be centered on identifying falsified drugs and heavy fines should be sanction on those companies that are still in the business of falsified drug in Nigeria.

4.7.2 Phone Interview with a Pharmacist (8 Years' Experience)

The author was able to get in touch with a pharmacist who is well experienced in community pharmacy. He works in a teaching hospital and has an outlet in a community-based pharmacy shop. The author got in touch with him and scheduled an urgent meeting since he was also busy due to the COVID-19 situation in Nigeria. I needed to ascertain his professional view on challenges his profession is facing on identifying falsified drugs as well as reporting drugs that are falsified. He also gave consent verbally for the interview and use any information obtained on the condition of anonymity as he would not want anything to affect his job in Nigeria.

He understood the significance of good pharmacovigilance practice such as falsified drug identification in Nigeria health system. He admitted to regularly check if his drugs are falsified or original through experience and knowledge of the particular drugs. Thus, he has not reported any form of falsified drugs in the last 12 months of prescribing and selling any form of medicinal drugs. This goes to show why there is a very limited gap in the knowledge of pharmacy from the questionnaire in identifying fake drugs. However, he acknowledges the fact that regulatory authorities as the responsibility of handling falsified drugs, from his understanding pharmacist in hospitals were likely to report falsified drugs and get feedback than those having a community-based pharmacist shop as there was a more formal structure in a government based teaching hospital.

On the issue of falsified drug reporting to the regulatory agency, he admitted being familiar with the mobile authentication service systems but complains of several issues with the technology.

The excerpts below provide the missing link

"The response time is very slow. You send the text with the numbers but for days you will be fortunate if you ever get any response."

"Network does not help at times as service can be very poor"

"Most of the community-based pharmacist does not know the system and therefore we can not use what we do not know about"

.....extract from the interview

On the issue of creating awareness to the healthcare professional who is not privileged with the knowledge of identifying falsified drugs.

Below was his response

“From my point of view, the whole process of creating awareness by NAFDAC is shambolic. I only saw the advert ones on NTA(Nigeria Television Authority) but I must ask, how many people see the NTA every day, what is the fate of the rural dwellers where we have a higher population of our people..... an extract from an interview on this question

Furthermore, he complained that the biggest challenge they have in the professions is the regulatory authorities who are in charge of the health system of Nigeria. The health system all round is suffering and would continue to suffer if the right regulations are not put in place to discourage falsified drug business.

Below was his response

“ The regulations surrounding fake drugs business in Nigeria is just too weak, I mean how can someone who makes a lot of money form fake drug business be penalized with a fine of just 500,000 naira or 15 years in prison if he does not pay up?. Our system is corrupt most of the government top officials are involved in most of all this business I can tell they always have special cut for containers brought into the country, so my brother the challenges of the Nigerian health system is beyond just identifying falsified drug alone..... an excerpt from the interview on this question.

Another interesting fact he raised was a direct link between doctors and pharmacists just the way we have in Ireland. He complained that there is no platform where healthcare professionals interact with a pharmacist, thus there is no form of correspondence between medical doctor and pharmacy in terms of drug prescription and dispensing.

He also pointed out that most pharmacists would only report falsified drugs to the company to avoid losing business relationships as most drugs can be supplied to them on credits to resales and payback. Thus, in other not to lose the business relationship they only report falsified drugs to the manufacturer, and in most cases, they get feedback.

He finally recommended increased awareness and outreach of the need to identify a falsified drug to discourage the rate of the falsified drug in the market. However, his major concern is the government of Nigeria they are very corrupt, and greedy they want to make money from any means available and the Nigerian health sector can only improve if the mentality of our government official were changed.

4.8 Conclusion

From the survey conducted it is evident that most healthcare professionals especially medical doctors and other forms of healthcare professionals are familiar with one or more systems of identification in relative comparison to the pharmacist who dispenses this drug. The majority of the pharmacy are only familiar with identifying fake drugs through adverse reactions, uncommon drug reactions, and life-threatening conditions. However medical doctor and other health professionals admitted to the use of mobile authentication system as a tool for identifying fake drugs, only an average number believed its effective due to some challenges they are always facing, despite this concern they all agree to the do better if proper training are made available to enlighten them constantly of the use of the system.

NAFDAC through its National Pharmacovigilance center is in charge of reporting any form of falsified drugs and ensuring good pharmacovigilance practice such as ensuring the good and safe drug is available in the market, however they have failed in fulfilling their responsibility of raising awareness and making sure the right sanitization are made available to healthcare professionals. Most healthcare professionals source for information about falsified drugs through an article published and not through NAFDAC sanitization, as a result, most of them are not able to identify fake drugs if articles are not provided to enlighten their knowledge on the medicinal products. Very few healthcare professionals are aware of the guidelines and regulations of falsified drugs in Nigeria even those who are aware of the system send a report and rarely get an acknowledgment to know the next line of action which then results to the poor rate of reporting as healthcare professional are discourage to check if a drug is falsified or original.

This study reveals that only a few of the respondents have ever identified fake drugs as well as reporting to the regulatory authorities. This is disheartening considering the continuous increase of fake drugs in the market, the preferred action was to return the falsified drug to the manufacturer or supplier rather than reporting to the regulatory authority or destroying. Such action would prevent any possible arrest or prosecution and any possible redistribution of such goods

Healthcare professionals admitted that so many factors are contributing to the increase of falsified drug business in Nigeria ranging from healthcare professionals been ignorant, presence of non-health professionals in the business, corruption and high cost of drugs have all contributed in creating the challenges the health system is facing

Falling the interview through a phone call the health professionals agreed that all they rely upon to identify falsified drug was based upon their knowledge gained

in one way or the other or by experience on the originality of the drug which is very risky since those who are involved in such trade usually change dynamics and can still penetrate the market. The pharmacist claimed that the main reason while there is so many lapses is down to the corruption in the government as regulations are not enforced, a patient can access over the counter drugs form an open market without any prescription.

The majority of the healthcare professionals all agreed with the recommendation proposed in the survey while most of the healthcare professionals admitted creating a special department for easy reporting and feedback, incorporate a form of remuneration, as well as increase awareness, would encourage professionals to constantly monitor any form of medicinal drug.

In the next chapter, further conclusions are made concerning the research questions asked earlier. A contrast would be made from the previous literature review and final conclusion would be made.

CHAPTER 5: CONCLUSION

5.1 Answering the three main research questions

Question 1: Are healthcare professionals aware of the systems and methods available in identifying fake and counterfeit drugs, and its applicable guidelines in achieving a good pharmacovigilance practice.

From the data and responses gathered in the survey as well as responses from well experienced medical doctors and pharmacists during an interview conducted over the phone, it is obvious that awareness among healthcare professionals towards the issue of falsified drugs in Nigeria is above average. Firstly, the awareness is solely attributed to articles been published with training obtained in colleges, they also rely on verbal communication among colleagues to be aware of a falsified drug in Nigeria and the system that is available for identifying fake drugs.

Acceptance of different forms of the technology system by the respondents is moderate, however, the sole responsibility of creating awareness of falsified drug identification and good pharmacovigilance by the Nigerian Agency for Food and Drug Administration and Control through its National Pharmacovigilance centers still shows some relative gap. Though NAFDAC provided some structural advanced technology to identify falsified drugs spontaneously, despite this technology they have failed in converting these efforts to more improved awareness of the systems. A respondent who participated in the study encourages a better pharmacovigilance practice they recommended an upgrade in the way NAFDAC handles pharmacovigilance in Nigeria, they also encourage better feedback measures which should be targeted to healthcare professionals to bridge the gap created by the lack of use of the system

Question 2: What are the major factors that serve as a threat to the effective reporting of offenders involved in the fake drug business?

As a result of both questionnaires and phone interviews carried out, all groups of healthcare professionals attribute that the problem of Nigeria's health system is far beyond identifying falsified drugs in comparison with a country that has a better-organized health system. These include inadequate laws and poor enforcement of already existing rules and regulations, ignorance among healthcare professional, presence of Non-health care professionals in the health sector, high cost of good and efficient drugs as well as corruption in government policymakers.

Some other factors that contributed to the issues of falsified drugs are as a result of a lack of acknowledgment or feedback from a regulatory agency when a report is sent to them. Some of the healthcare professionals complained that they rather send a report to the manufacturer who they deal with in business than sending to the regulatory agency who would not reply at all. Hence the burden this factor poses on the Nigerian health system cannot be overemphasized as in practice it is more serious than we can ever think of and there is no evidence of hope that the challenges are ending anytime soon.

Question 3: What recommendation would help to improve fake drug identification and reporting among Nigerian healthcare concerning clinical practices.

Since there is an average knowledge of the system in identifying falsified drug among healthcare professionals, with the medical doctor showing signs that they are more knowledgeable than the pharmacist, the regulation and also guideline should be improved in other to have a seamless flow of information thereby improving the rate of reporting of fake drugs in Nigeria.

As shown through the survey and phone interviews all the healthcare workers agreed that the regulatory authorities should be very proactive by setting up different forms of pharmacovigilance sessions and continuing education programs to create more awareness in the less privileged areas and sub rural regions of the country. There should be a radical increment in publicity on the system used in identifying falsified drugs and how it works including the accessibility of the reporting method to healthcare professionals

Another interesting recommendation that was agreed upon by all forms of healthcare professionals is the review of current regulations of any form of falsified drugs in Nigeria, they all agreed that it should be a professional obligation among healthcare professionals.

Furthermore, the healthcare professional all believed that creating a special department tasked with the responsibility of tracking and monitoring issues on any form of a falsified drug would encourage professionals to trust the system and report more falsified drugs. They all agreed that incorporate huge fines and sanctions for not identifying and reporting falsified drugs, including remuneration for every falsified drug reported, would also assist in discouraging any forms of falsified drugs. However, the author believed that incentive or remuneration should be in the form of awards or recognition rather than financial reimbursements to encourage good pharmacovigilance practice and drug safety practices in the Nigerian health sector.

5.2 Comparing and Contrasting Results from Primary and Secondary Research.

The above-average of healthcare professionals who are knowledgeable enough for identifying falsified drugs through different sources aside from the technologies provided by NAFDAC which is an encouraging finding when compared with previous review. The zeal to upgrade their knowledge is also an encouraging aspect of these studies as they believed that learning is a continuous process. However, the lack of using the system provided by NAFDAC is relatively low as well as the current usage of the system, the result, when compared to similar studies, showed similar statistics. The observation has translated to a significant under-identification rate in comparison to the quantity of falsified medicinal drugs that are always available in Nigeria.

Other similar figures in comparison with an initial study showed that the majority of the healthcare respondents considered the systems ineffective ranging from the poor acknowledgment and poor network infrastructures. The falsified drug is a global issue and the challenges vary across regions. The general factors ranging from inadequate, poor enforcement by regulatory authorities to general ignorance among healthcare professionals, high cost of good and efficient drugs as well as corruption in government policymakers are to some extent the same as noticed from previous studies in Nigeria and other countries battling with the issues of falsified drugs. (Ugochukwu, 2017)

Other studies on issues of falsified drugs identification suggested that pharmacist is in a better position to identify this drug or either knowledgeable enough on falsified drugs. This study demonstrated that the medical doctor is more predisposed from all data gotten than other health care professionals. It's strange to see that medical doctor is better aware of this system provided by N.A.F.D.A.C despite their busy schedule this goes to say there is a knowledge gap somewhere for all pharmacist and other healthcare professionals.

Improving spontaneous identification and reporting of falsified drugs in Nigeria would greatly reduce the cost of the healthcare system in Nigeria which would further reduce the incidence of adverse events which is a result of falsified drugs consumed. While this study showed that all healthcare professionals agreed that more awareness needed to be created about falsified drug identification is also a similar aspect of previous studies. They need continuous learning programs in the form of a seminar to improve awareness, reviewing the current regulations, and see if any gaps are needed to close in comparison to other western countries like Ireland. Also as suggested by both groups of healthcare professionals falsified drug identification and reporting should be made compulsory and huge fines should be incorporated to anyone one who is found to be encouraging such business while previous studies indicate that remuneration is unethical, remunerations in form of excellence in work done could encourage such individual to continue identifying falsified drugs. (Chinwendu 2008)

5.3 Contributions and Limitation of the Research

The study was finished at a decent time only after data was generated from the questionnaires from about 131 respondents despite the global coronavirus ravishing the country including phone call. The data was analyzed and transferred to excel formats and charts for easy understanding as well as bar charts. While most of the resources on falsified drugs focused on a single group or one of the systems of identifying falsified drugs, the research compared both medical doctors and pharmacists including other forms of healthcare professionals and responses came from across all 4 geographical zones of Nigeria.

The principal limitation was relatively high for the author, firstly the global pandemic that shuts down the world discourage so many health care professionals from answering the survey as most of them were too busy fighting the pandemic. Also, factors such as the personal bias of the health professionals and high level of accuracy to attention to details could impact the interpretation of results obtained. The multiverse opinion of other non-respondents who also failed to respond to the question in the survey could have a huge impact on the outcomes of these studies.

While the intuition into NAFDAC's regulatory responsibility towards pharmacovigilance provided an understanding towards the awareness of falsified drug identification as evident from NAFDAC online website, the author still believes that the roles and activities of its National pharmacovigilance centers are yet to be defined in relations to this topic. Therefore, it thinks that the challenges impacting falsified drug identification could differ across each area in Nigeria due to there level of education, experience, awareness, and economic activities that are taking place in this region.

The author was privileged to know that the most agreeing responses from both groups concerning the contributory factor was inadequate laws and poor enforcement of already existing laws which was then followed by the high level of corruption in government policymakers which are charged with the responsibility of improving the health care system of the country. Despite the limited or averaged knowledge about falsified drug identification through this system, other factors were also met with more agreeing responses putting to the fact that there is a huge challenge in the health care system of Nigeria. Thus, further research can also be done on reducing this challenge.

5.4 Recommendation (The Way Forward)

In light of the findings, the recommendation below could be useful at various level

- ✚ There is an urgent need for the government to implement the provisions of the existing laws governing pharmaceutical products.
- ✚ All NAFDAC laboratory should be well equipped and funded to analyze medicines suspected to be falsified and such facility could also have training facilities to regularly educate staff
- ✚ Ensure that all forms of medicinal products are always scanned with the available systems.
- ✚ Collaborate with other countries like Ireland to buy new ideas on how to detect fake drugs spontaneously
- ✚ In most cases, the understanding, and practices of identifying falsified drug among health care professionals traditionally comes from laying down a foundation in undergraduate school, including knowledge gathered from training materials, articles, and verbal communication among colleagues and less from regulatory authority. There are so much knowledge resources available on the website in regards to falsified drugs and its growing trends but unfortunately, health care professionals are either not interested or have refused to use the system therefore in order to create more awareness, the awareness programs should be remodified by keeping the healthcare professionals informed on a regular base.
- ✚ Furthermore, there should be a review of the course content on all healthcare professional course outlines such as tutorials or seminars specifically for falsified drugs to be included in the final stage of their practice or studies. It should stress the importance of not being able to identify falsified drugs and the penalty involved if such medicinal drugs were prescribed or dispensed by any of the healthcare professionals.
- ✚ Also, most healthcare institutions should be able to establish an institution specifically designed to test the quality of drugs. This will help to create awareness and improve student knowledge of the use of the system for identifying falsified drugs.

For NAFDAC

- ✚ Creating a good medicinal distribution that is licensed for effective supervision. This can be made possible through government support and

creating a special unit called Good Distribution Practice (GDP) that monitors drug distribution such as the HPRA in Ireland

- ✚ Regular training especially to law enforcement officers, this will help NFDAC and military personnel in combating fake drugs
- ✚ The tariff placed for original drug imported should be reviewed because it creates a large cost in the markets as importers want to make back the money lost in registration.
- ✚ Tight security at all ports of entries in the country should be encouraged to curb the activities of the falsified drug coming into the country.
- ✚ A mini laboratory should be established at each state where NAFDAC is present, this will effectively reduce the stress of staff that has to travel long distance with goods for registration
- ✚ A planned routine inspection visits on imported products, this is because a five years wait is too long to believe that industry still maintains good manufacturing practice as seen during the first part of the inspection.
- ✚ There is also a need for the agency to develop a better plan in promoting awareness among healthcare professionals as well as the public since these drug makers have become sophisticated in their activities.
- ✚ To make staff incentive and salary commensurate to what is obtained with other big government agencies and recognition in the form of professional's awards should be encouraged.
- ✚ Creating a good working and comfortable environment for staff will encourage effectiveness all around

For Government:

- ✚ There is an urgent need for the federal government to have well-defined drug laws that must be effectively implemented by all government administration that comes to power and all arm of the legislation such as the judiciary that handles cases of violators without any form of der and trembles because it is so sad that agency makes so much efforts to arrest offenders but cases go to court and get denied and dismissed due to government interference.
- ✚ The judiciary should stop any form of delay in the prosecution of drug offenders and adjournment of cases that requires immediate action.
- ✚ The use of non-healthcare professionals in business should be reviewed. Since consumers would always buy from them the government should buy the idea of training them on basic ethics as it relates to pharmaceutical drugs

5.5 Recommendation for Future Research

Curbing the effect of a falsified drug in Nigeria is very difficult and the author believes that everybody should be involved in fighting this crime.

Therefore, in doing this further research needs to be carried on the public participation in spontaneously identifying falsified drugs. Since patients in the hospital, including those individuals who still buy drugs from the open market in Nigeria, are the critical groups who are been administered these drugs, they should be able to identify and report any drug suspected to be falsified. Also, research can be expanded to include nurses to improve spontaneous identification this can then be compared with the medical doctor's, pharmacist to ascertain their awareness about identifying fake drugs in Nigeria since they are also the first line in administering this drugs to the patient in hospitals as well as a nursing home.

Furthermore, future research can be carried out for falsified drug identification and reporting with a major focus on each particular states of the country. The author believes that results can be compared to the challenges each state is facing the challenges of curbing of falsified drugs in the states. Results can then be compared and those with fewer challenges can offer to advise that can be of help to other states for safe practices of drugs in the states.

A country like Ireland with a well-defined system in relations to health systems, a future study can be carried out with the regulatory authority of Ireland inform of interviews and possible seminars and meeting to compare the challenges both countries are facing and how they have been able to manage their situation better than Nigeria. The country can learn how to upgrade its pharmacovigilance practice from understudying Ireland, practicing good pharmacovigilance models is a critical issue that healthcare professionals can benefit from Ireland.

Lastly, a future study can be carried out on the use of the internet and social media as an avenue to increase the knowledge and awareness of falsified drug identification in Nigeria. This is because social media has become inextricably integrated into every individual life, most of us rely so much on Facebook, Twitter, Instagram, YouTube including Pinterest to keep up with different forms of information. From the data gathered it was evident that healthcare professionals did not receive enough information from different forms of social media.

5.6 Future Speculation of Nigerian Pharmaceutical Sector

By now is no news again that the Nigerian pharmaceutical industry is regarded as an African emerging economy with a huge prospect and expanding population which gives various investors in the sectors enormous opportunities. However, in the area of healthcare, numerous challenges as dwindle the sector which makes the sector largely untapped.

However, there is some major development that is been speculated to ensure the best international practices in the pharmaceuticals and production capabilities of the sector. One of the key areas that the pharmaceutical regulations are speculating is to improve the current methods of making drugs which were based on a labor-intensive strategy that has been in place since the 70s. the regulations are trying to enforce less human interference in the production of drugs which is prone to contamination. Another aspect is to move away from over-dependence on the importation of machinery, active ingredients, raw materials, and unregulated drug distribution which has been affecting the pharmaceutical industry in Nigeria.

Furthermore one of the major areas that would see developments soon is the local Pharmaceutical manufacturing as the federal government through the Central Bank of Nigeria is set to increase funding by authorizing all money bank to ensure that 60% of foreign exchange sales goes to local manufacturers as this is to ensure that the sector is becoming very attractive and competitive in other to meet international world standards. Though the author knows this is all speculations it is possible if these laws and regulations are implemented accordingly.

5.7 Final Conclusion

in concluding this study on the challenges, awareness, and knowledge of healthcare professionals in spontaneous identification of falsified drugs in Nigeria, all the participants in this study all agreed that the factors contributing to the challenges of spontaneous identification of falsified drugs in Nigeria range from inadequate laws, ignorance among healthcare professionals, high level of corruption among government officials who make this law. The laws governing the production, sale, distribution, importation, and exportation of drugs are not adequate to control the illegal sale of drugs in Nigeria. This comes as a result of the policymakers been corrupt as they take so much bribe to only make laws without enforcing it, a situation like this makes it difficult for healthcare officials to put all effort in making sure no fake drugs passes through them.

Why the healthcare professionals all agreed that the system of identified falsified rugs should be made compulsory, the author concludes that the Nigerian Healthcare professionals still need to understand the huge health problem of consuming fake drugs. This is a result of the data that shows that only 62% of the

respondents know how to detect the falsified drug in comparison with the number of drugs that floods the Nigerian market. A higher percentage of the respondents sourced their knowledge from articles published in respect of falsified drugs and of all the system mentioned for identifying fake drugs MAS may be a successful tool in identifying and reporting falsified drugs due to how users perceived it to be. This is because it is compatible with the use of a mobile phone for text messaging and quick response to authentication. However not all health professionals can use this system to identify fake drugs either they believed the system is ineffective or they believed in past knowledge and experience for identifying fake drugs. Therefore, the author concludes that the knowledge of healthcare professionals in identifying falsified drugs is above averaged.

A higher percentage of healthcare professionals believed that continuous learning and more education programs would help to increase the awareness of falsified drug identification in Nigeria. Thus, this shows the major willingness of healthcare professionals to further learn various ways to help improve pharmacovigilance and ensure drug safety in the country. The author also notes that various data from each question suggest that the pharmacist are lacking behind and no wonder they require more education to be able to identify fake drugs. There is a huge gap created in the relation of overall data provided on each question as a pharmacist was shown to have low responses in comparison to other healthcare professionals.

Also, the author believed that a form of incentive in form of professional recognition should be made available for everyone contributing to the fight against falsified drugs in the country as this would go a long way in encouraging other healthcare professionals. The government also needs to fund NAFDAC and provide necessary resources to organize seminars to assist the agency.

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FALSIFIED DRUG IDENTIFICATION IN NIGERIA: A SURVEY BY HEALTHCARE PROFESSIONALS

Dear Respondent,

My name is Chimezie Chris Nwankwo, a post-graduate student at Griffith College Dublin, Ireland. I am carrying out a dissertation research on counterfeit drug identification among healthcare professionals in Nigeria as part of my requirement for the degree of Masters (MSc) in Pharmaceutical Business and Technology.

The W.H.O defines counterfeit drugs as a product that was sold with the main aim to represent its original as well as the authenticity or effectiveness. It also focuses on pharmaceutical products with the right active ingredient but faking packaging, with the wrong ingredients without active ingredients or with little or no active ingredients.

Spontaneous counterfeit drug identification in Nigeria is very essential in upgrading the level of pharmacovigilance in Nigeria. This is an important fundamental activities that encourage a better understanding and assessment as well as spontaneous identification of counterfeit drugs related issues.

This survey is divided into 5 major areas which would be directed at collecting respondent demographics, knowledge, awareness, challenges and possible recommendations for improvement of identifying counterfeit drugs

Thus, the privacy of every participant involved would be highly protected and assured as no response will be linked to any participant and will remain strictly confidential. All data generated will be handled in line with General Data Protection Regulations (GDPR)

Thank you for your participation

* Required

1. Respondent Agreement *

☐

I agree to participate in this research, and I give my full consent to have my responses used only for this purpose

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DEMOGRAPHIC

2. What is your gender?

- ☐ Woman
- ☐ Man
- ☒ Non-binary
- ☐ Prefer not to say

3. What age group do you belong *

- ☐ 20 to 30
- ☐ 31 to 40
- ☐ 41 to 50
- ☐ 51 and Above

4. What is your profession as an healthcare professional? *

- ☐ Medical Doctor
- ☐ Pharmacist
- ☐ Others

5. In which geographical area in Nigeria do you practice? *

- ☐ Northern area
- ☐ Southern area
- ☐ Eastern area
- ☐ Western area

6. How many years have you been practicing in your professional field? *

- ☐ Not more than a year
 - ☐ 1 to 5 years
 - ☐ 6 to 10years
 - ☐ 10 years and above
-

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FALSIFIED DRUG IDENTIFICATION IN NIGERIA

KNOWLEDGE ABOUT FALSIFIED DRUGS

7. Do you know how to detect fake drug? *

☐ Yes
☐ No
☐ Maybe

8. If yes what is the source of your knowledge in detecting fake drugs? *

☐ Through the internet and social media
☐ Through articles published by regulatory agencies
☐ Through verbal communication from colleagues

9. Who is in charge of pharmacovigilance in Nigeria? *

☐ World Health Organization (WHO)
☐ Nigerian Agency for Food and Drug Administration and control (NAFDAC)
☐ Pharmacists Council of Nigeria

10. Who is in charge of reporting fake drugs in Nigeria? *

☐ World Health Organization (WHO)
☐ Nigerian Agency for Food and Drug Administration and Control (NAFDAC)
☐ Pharmacists Council of Nigeria
☐ Nigerian Medical Association

11. Which methods of identifying falsified drugs in Nigeria are you familiar with? *

☐ Mobile Authentication System (MAS)
☐ Radio Frequency Identification System
☐ Black Eye
☐ Truscan
☐ All of the Above

12. Have you ever used any of the system to detect falsified drug *

- ☐ Yes
- ☐ No
- ☐ Maybe

13. How effective is any of the system you chose *

- ☐ Very effective
- ☐ Neither effective nor ineffective
- ☐ Very ineffective

14. Are you currently using any of the system to identify fake drugs *

- ☐ Yes
- ☐ No
- ☐ Maybe

15. In your view, which is the most significant criteria for identifying fake drugs *

- ☐ Adverse reaction
- ☐ Uncommon drug reaction
- ☐ Life threatening reactions
- ☐ All of the above

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FALSIFIED DRUG IDENTIFICATION IN NIGERIA

Awareness of Falsified drugs Reporting System

16. In Your View who is in charge for reporting Counterfeit drugs *

- ☐ Medical Doctors
- ☐ Pharmacists
- ☐ Any of the Above
- ☐ None of the Above
- ☐ Others

17. In your opinion should the system for reporting counterfeit drugs be made *

- ☐ Compulsory
- ☐ Voluntary

18. Did you notice any form of false drugs in the past 1year as a healthcare practitioner? *

- ☐ Yes
- ☐ No
- ☐ Maybe

19. If yes how many counterfeit drugs have you observed in the past 1 year *

- ☐ Over 100
- ☐ 75 to 100
- ☐ 51 to 74
- ☐ 26 to 50
- ☐ Less than 25

20. Who do you send the report of falsified drugs to? *

- ☐ Nigerian Pharmacovigilance center
- ☐ Professional bodies
- ☐ Drug Manufacturer

21. Is there any feedback received after reporting? *

- ☐ Yes
- ☐ No
- ☐ Maybe

22. If No would you consider upgrading your knowledge about the reporting system *

- ☐ Yes
- ☐ No

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* Required

FALSIFIED DRUG IDENTIFICATION IN NIGERIA

Challenges of Falsified Drug Identification and Reporting

As a healthcare professional which do you consider as challenges of reporting offenders

23. Inadequate laws and poor enforcement of the already existing law *

Select your answer

24. Ignorance among Health Care Professional *

Select your answer

25. Presence of Non-Health care Professionals in the drug business *

Select your answer

26. High cost of good and efficient drugs *

Select your answer

27. High level of corruption in government policy makers? *

Select your answer

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FALSIFIED DRUG IDENTIFICATION IN NIGERIA

IMPROVEMENT OF FALSIFIED DRUG IDENTIFICATION

As a healthcare professional which do you consider as an effective means to improve falsified drug identification

28. Advance continuous learning and education programs to improve awareness *

Select your answer

29. A current review on regulations to make identification among health care professional better *

Select your answer

30. Incorporate fines and sanctions for not identifying and reporting any form of counterfeit drugs *

Select your answer

31. Incorporate a form of remuneration for every form of counterfeit drugs identified and reported so as to encourage good pharmacovigilance practice *

Select your answer

32. Increase awareness and publicity about all form of system in identifying and reporting all forms of counterfeit drugs *

Select your answer

33. Creating a special department task with the responsibility of receiving any form of complains about Counterfeit drugs. *

Select your answer

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