Assessing the Impact of Anti-Falsification Technology on Patient Choice of Prescription Medicines in Four Teaching Hospitals in Nigeria

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Candidate Declaration

I, Anonye Yagazie Okechukwu, hereby attest that the work titled:

"Assessing the impact of anti-falsification technology on patient choice of prescription medicines in four teaching hospitals in Nigeria"

contained in this master's thesis is entirely original. I confirm that when information has been taken from other sources, it has been duly referenced.

Signature ……**ANONYE**…… Date: ……10/05/2023……

Acknowledgement

I would like to thank my Father in heaven, my family and friends, supervisors, and lecturers at Griffith College Dublin. Its been a memorable experience and I am especially grateful.

Abstract

Background:

Falsified medicines over the years have had a major impact on both patients, manufacturing companies and national health budgets/insurance thus causing both economic and humanistic losses to stakeholders. It has caused an estimated loss of over 500 billion naira (625 million euros) to both local and foreign investors in the Nigerian pharmaceutical industry. This review analyzes data that was gathered between February 2023 to April 2023, through questionnaires designed to assess the attitude of patients who were filling prescriptions with the background knowledge of falsified medicine detection.

Aim:

This study's author theorized that authenticating labels and technology could affect the way patients see medicines and fill prescriptions.

Methods:

The study participants of 115 comprised of physicians 10%, pharmacist 47%, registered nurses 19%, medical laboratory scientists 15%, radiographer 2%, optometrists 3% and dentists 2% practicing across four teaching hospitals in Nigeria who participated through surveys. Data analysis was done using Microsoft Excel to produce charts, graphs and tables.

Results:

The analyzed data shows patients who have little or no awareness and those who gained awareness from their pharmacist or prescriber of medicine anti-falsification technology are likely to request for their prescriptions in its original packaging at a similar frequency. Whereas the data tilts and shows that those with little awareness are two-times less likely to suspect that a medicine is falsified when their treatment therapy fails and would often request for a change of brand or inform their prescriber as compared to the aware group who would immediately confirm suspicions that the medicine is "fake". However, both groups would request for a known brand or generic whenever the prescription medicine lacks features for verification rather than seek reassurance of quality from their prescriber or pharmacist. Some of the recommendations provided by respondents to stop the spread of falsified medicines is the purposeful reeducation of the public on the dangers of falsified medicines and ways to detect them using technology and report them as a way of cleaning up the supply chain. The study participants recorded an 85.2% willingness to report identified falsified medicines to the regulators and may opt for a stepwise approach through their healthcare providers or hospital authority or a more direct approach to the national authorities. This is also a notable indication of the public resisting falsified medicines spread in their various capacities. The participants also confirmed an 6.1% willingness to use mobile authentication service technology and other features to verify if their medicines are original, but a higher 20.2% of respondents would always prefer to use the NAFDAC registration number alone or in combination, while a 10.5% would depend on the presence of other verification features like insignias and seals.

Conclusion:

The study demonstrates that there is a good awareness of anti-falsification technology and that knowledge affects how patients interact with their prescription medicines and causes a bias for known brands/generics while blaming therapy failures on suspected falsified medicines.

Key Words: original packaging, Falsified medicines Identification and reporting, regulatory agencies, Knowledge, awareness and recommendations, pharmacovigilance, Mobile Authentication System (MAS), healthcare, NAFDAC registration number, Adverse Drug Reaction (ADR's).

Table of Contents

List of Abbreviations

ACPN - Association of Community Pharmacists of Nigeria

ADR's – Adverse Drug Reactions

AFRO - African Regional Office

API - Active Pharmaceutical Ingredients

CDSCO - Central Drugs Standard Control Organization

DSCSA - Drug Supply Chain Security Act

DQSAD - Drug Quality Security Act

EMA – European Medicine Authority

EU – European Union

FDA – Food & Drug Act

FMC – Federal Medical Center

IP - Intellectual Property

LASUTH - Lagos State University Teaching Hospital

MLS – Medical Laboratory scientist

NAFDAC – National Agency for Food, Drugs Administration and Control

NHIS - National Health Insurance Scheme

OECD - Organization for Economic Co-operation and Development

PBN – Pharmacy Board of Nigeria

eSASL - Simple Authentication and Security Layer

SE – South-East Region

SS – South-South Region

SW – South-West Region

NC – North Central Region

UHC – Universal Health Care

UBTH - University of Uyo Teaching Hospital

UNTH - University of Nsukka Teaching Hospital

USA – United States of America

UUTH - University of Uyo Teaching Hospital

WHO – World Health Organization

List of Tables

List of Figures

1.0. Chapter One - Introduction

1.1. Study Overview

This chapter is an introduction to this research. This study aims to provide a systematic review of the literature on the effects of anti-falsification labeling on the global commercialization of prescription drugs, and NAFDAC registration numbers as a verification factor in Nigeria's drug distribution system, and finally the effects of anti-falsification labeling on drug selection in four teaching hospitals in Nigeria. To do this, it was intended to examine patient opinion about issues relating to selecting high-quality medicines in Nigeria and how to improve the safety, quality and efficacy of medicines distributed in the country.

To better understand the impacts of anti-falsification labels in the dispensing of medicines at the four teaching hospitals which include University of Uyo Teaching Hospital in Uyo, University of Nigeria Nsukka, Federal Medical Center Kogi and University of Benin Teaching hospital. This study combined a quantitative and qualitative research approach with semi-structured survey questions for patients to provide feedback on issues highlighted.

This chapter proceeds by describing the context in which the research was done, including a general overview of the people of Nigeria's current state of health. The discussion of drug anti-falsification techniques currently in use in Nigeria in accordance with regulators then follows, providing background information for the study. Towards the end of the chapter, definitions of key terms and a brief history of drug falsification are given, and then a thorough explanation of the thesis' structure is provided.

1.2. Overview of Nigerian health system

The Nigerian health care system is ranked 163 out of 191 countries in the world using the universal health coverage system that was published by the Global Health Observatory in 2021. According to the WHO, the universal health coverage (UHC) is used to measure when a people have full access to quality healthcare services that they required at the right time, right place and not suffer financial distress because of it. Full healthcare services would involve disease prevention, treatment and recovery throughout the life span of the population. Essential medicine use is a critical part of the UHC system and the threat of falsified medicines infiltrating the drug market is an undeniable and unrelenting threat (World Health Organization, 2022). In the Nigerian economy, falsified antimalarial medicines are linked with over 12,000 deaths annually and a burden of over 500 billion naira in costs (Beargie *et al.*, 2019).

Nigeria has a major public health insurance scheme which is the National Health Insurance Scheme (NHIS) and private health insurance. Despite having a national healthcare system, Nigeria's public healthcare is massively underfunded, and this is because the government allocates only a small percentage of the yearly national budget to healthcare, with only about 3% of the nation's GDP attributed to hospitals funding, medicines provision, research, and training (The World Bank, 2022). This contrasts with the average 9.7% that other nations allocate to healthcare as advised by the WHO (OECD, 2021). Most Nigerians are not covered by the NHIS, which provides a cheap way to get medical attention and fill prescriptions. Only those employed by the government and organized private sector receive insurance cover-. Other government initiatives, such as the Drug Revolving Fund (DRF) scheme, which was established in 1988 in response to a WHO recommendation to ensure a consistent supply of affordable generic medications for primary healthcare facilities, do not appear to be producing the desired results. Following the initial success of the DRF scheme, maintaining the advantages of the essential drugs program became challenging due to a variety of problems, including stock-out syndrome. As a result, there

was a larger need to fill the gaps with cheaper, generics and combined with weak regulations, falsified medicines sale increased (Johnson *et al.*, 2015).

1.3. Definition of Terms

There are several terms that are encountered when discussing the subject of verifying medicine authenticity. These terms are falsified medicines, substandard medicines, counterfeit medicines and they are often used interchangeably but they do not have the same implied meaning in the regulatory landscape of the pharmaceutical business.

Falsified medicines are those that "intentionally/fraudulently misrepresent their identity, composition, or source," according to the WHO (World Health Organization, 2018). Falsified medications do not adhere to the high regulatory standards for quality, safety, and efficacy. They might hurt patients while also failing to effectively treat the illnesses for which they were administered. Falsified medications may contain poor-quality or even the incorrect ingredients, or they may not contain any active pharmaceutical ingredients (APIs) at all, or they may only contain APIs in the wrong amounts. Additionally, they might have their identities purposefully and fraudulently mislabeled and packaged. Those who market falsified medicines masquerade their products as genuine treatments for diseases. It may be harmful or ineffective, which frequently has detrimental effects on both individuals and society. Both inside and outside of academia, there is an urgent need for international cooperation to stop the spread of falsified medicines (Liu and Lundin, 2016). To understand this global problem, a literature review is conducted as a pilot study to identify knowledge gaps and insights for additional research.

Medicines that are manufactured while violating intellectual property rights or trademarks are considered counterfeit medicines (EMA, 2023). Here, medicines are made without seeking consent from the original manufacturer. The drug products contain the same active pharmaceutical ingredient in the same quantity as the original product but there is a high risk of non-compliance to regulatory requirement while violating IP rights. Counterfeit and falsified medicines are terms that are often used together when discussing the damages caused by poor regulatory supervision in a region. However, they are not the same and should not be used interchangeably because it is confusing and incorrect. To schematically differentiate between these terminologies on drug quality, falsified refers to an intentionally fraudulent manufacturing product, substandard refers to unintended errors that occur during the manufacturing process (often resulting in recalls), degraded medicines that become of low quality due to wrong storage conditions (Nayyar *et al.*, 2015).

In conclusion, a wholesome definition coined and accepted by the World Health Organization, British Pharmacopeia and United States Pharmacopeia, states that a drug product is identified as a falsified medicine if it has any of the following attributes observed with respect to the intention to mislead;

- Fraudulent packaging with the right amount of the right ingredient;
- Fraudulent packaging with the wrong ingredient;
- Falsified packaging without any active ingredients;
- Falsified packaging with the wrong amount of the right ingredient;
- Authentic packaging with the wrong ingredient (intentionally);
- Authentic packaging without any ingredients; or
- Authentic packaging with the wrong amount of the ingredient (deliberate).

1.4. Hypothesis

Anti-falsification technology introduction to prescription drug packages as well as the presence of a National Agency for Food Drug Administration and Control (NAFDAC) reg no influences wholesaler decision to market medications and patient acceptance of drugs.

1.5. Research Objectives

1. To assess the impact of the implementation of anti-falsification technology on the commercialization of prescription medicines on a global scale using literature review.

3. To evaluate the impact of anti-falsification labeling on medicine acceptance in the four teaching hospitals highlighted to be used in the survey.

4. To develop and provide suggestions for improving the implementation of drug authentication technology along the supply chain in Nigeria.

1.6. Research Questions

1. Do patients inquire about the authenticity of medicines or seek drug information at the point of sale?

2. When patients utilize the medicine authentication methods they are aware of, how does it affect their choices?

3. Are patients informed and willing contributors to pharmacovigilance in their facility?

1.7. Thesis Significance and Structure

According to the World Health Organization report in 2018, 11% of drugs sold in developing nations are fake, leading to 144,000 additional deaths each year from falsified antibiotics and anti-malarial medications alone (World Health Organization, 2017; World Health Organization, 2018). Hence, this research is intended to gather and analyse the impact of anti-falsification technology on the choice of prescription medications by patients in several tertiary health institutions in Nigeria. In Chapter one which is an introduction to the topic we discuss the existing need for quality medicines in healthcare facilities in Nigeria. Progressing further, we will discuss the relevance of this topic to the pharmaceutical industry both globally and locally because it will inform manufacturing companies and pharmaceuticals regulators about the importance of anti-falsification technology. Both in optimizing sales of their prescription medicines and restoring patient trust in the healthcare systems. The objectives and pertinent research questions are asked in this chapter one as well. Proceeding to chapter two we shall examine the available related literature on falsified medicines in Nigeria and discussing its economic and health impact to Nigerians. Chapter three looks at the methodology (primary and secondary research data) applied to obtain data and analyse it in line with the objectives mentioned in chapter one. The results received from the implementation of the methods detailed in chapter three will be displayed in chapter four to prepare the reader for its analysis, discussions and conclusion. To round up the thesis, all conclusions deduced, challenges encountered during the research, and recommendations for further research will be available in chapter five.

1.8. Conclusion

This chapter describes this research context, as well as an introduction of the Nigeria's healthcare system and the regulatory nomenclature used to define "fake medicines" globally. The significance of the thesis is also discussed in detail to show how this subject may influence future regulatory reforms in Nigeria. A

stepwise review of related published literature was carried out to determine the scope and effects of medicine anti-falsification technology in Nigeria, as well as the methods used to address the issue and give the research a direction. In Chapter 2, the specifics of the literature are formally presented.

Figure 1: Thesis structure

2.0. Chapter Two – Literature Review

2.1. Introduction to Literature

Nigeria has a population of about 215 million people, which is also the largest in Africa. Among West African countries, it has the second-highest doctor density, which is still quite low when compared to the actual need for a country with such a large population. Nigeria's health system now ranks 163 out of 191 nations, up from 187 out of 191 two decades ago, according to the World Health Organization (WHO). Government spending on health is significantly less than private contributions—by more than two trillion Nigerian naira. About 3% of Nigeria's GDP is devoted to the health sector, which is considerably less than the OECD average for healthcare spending (Statista, 2022).

2.2. Literature review

Reasonable effort was made to use articles and papers for the literature review that are written in English and no older than twelve years (2011 to 2023). Publications were not restricted to a geographic area because there has not been much research on the effects of anti-falsification technology on the use of prescription medicines in Nigeria's major public hospitals. Therefore because of a decreasing budget for healthcare in Nigeria, the government owned hospitals will try to find cost effective ways of providing medicines to the public and this will most certainly lead to purchasing generic drugs which inadvertently exposes the supply chain to falsified medicines.

For this literature review we shall only be discussing the impact of falsified medicines on patients' choice of prescribed medicines.

In Nigeria, there are various ways patients and medicines retailers have been trained to identify the authenticity of a medication. This includes looking out for key attributes which are physical appearance of the primary drug package, labelling and printing graphics, mobile authentication numbers, NAFDAC registration numbers. A close look at existing published literature on anti-falsification medicines technology reveals that majority of pharmacy retail stores were knowledgeable about the various ways of authenticating a drug product but often because of time constraints are not able to utilize all. Hence the authors propose for a more rigid approach from the regulatory agencies to prune the supply chain and provide security for authentic medicines which will inadvertently make it difficult for falsified and counterfeit medicines to reach the patient (Iloh *et al.*, 2021).

Having established the key parameters used to detect falsified medicines, we shall then examine the different schools of thought influencing the use of anti-falsification technology in Nigeria. Another literature reveals that only about one-third of the population of pharmacists who participated in the study are knowledgeable about the counterfeit and falsified medicines and the other portion of study participants are limited in their ability to mitigate the penetration of these drugs due to the gaps identified through the study. This is slightly different from the study in the previous paragraph by Iloh which demonstrated a general knowledge about how to identify falsified medicines.

The adoption of anti-falsification technology in Nigeria, using the mobile authentication service (MAS) which was launched in February 2010 by NAFDAC through a recent study found that 53% of community pharmacies in Nigeria have a broad acceptance of MAS. Industrial pharmacists have thus played a crucial role in Nigeria to ensure the use of only safe, efficacious and genuine medicines thereby making the use and acceptability of MAS generally feasible (Aminu *et al.*, 2017). To simply describe the mechanism the technology behind the MAS apply as an anti-falsifying measure, a patient receives a medication from a

pharmacy and using a communication tool such as a mobile phone, scratch codes and short messaging service (SMS) are used in the program to enable customers to confirm the legitimacy of medications at the point of purchase. The MAS is as simple as scratching the product's sticker to reveal a serial number code, sending the special pin to a short code, and receiving a response in a matter of seconds indicating whether the product is genuine or not (Oyetunde *et al.*, 2019).

These gaps are dependent on the actions of the regulatory agencies and they are poor legislation, inspection, collaboration with the public and security agencies, and poor cross border enforcement.

2.3. Objectives of the systematic literature review

The goals of this literature review were to discuss the;

i. The history of falsified medicines in Nigeria and the structures surrounding marketing medicines in Nigeria today.
ii. Global medicine anti-falsification regulations to curb counterfeiting and the role of regulators in Nigeria today in collaboration with pharmacovigilance efforts.
iii. The recommendations for future studies, limitations to the study as per literature review and the fight against poor quality medicines.

2.4. Methods

To discover what has been done in these areas, we shall use publications that describe the current anti-falsification technology and regulations in Nigeria as well as other parts of the world. And finally assess the strategies in place to combat these issues were sought out.

2.4.1 Search strategy

When the key words; falsified medicine in Nigeria were combined in the Nigerian Journal of Pharmaceutical Research through the African Journal Online website (AJOL) about 109 results were available for review. One of the articles identified assessed sixteen brands of ciprofloxacin antibiotic and the sampling technique was obtained from the Association of Community Pharmacists of Nigeria (ACPN). Physical and chemical assay tests were done on all sixteen samples in according to BP standards and it was discovered that 25% of the brands failed the chemical assay tests despite passing the physical attributes test. It was concluded that this poor showing is either because of counterfeit medicines deliberately being sold to patients of there is a lack of capacity to deliver quality medicines by these generics (Joda *et al.*, 2018). This can be extrapolated to explain the high preference of patients for brands when purchasing antibiotics and antimalarials. It also exposed the need for more post-marketing surveillance by regulators (Dunne and Dunne, 2015; Joda *et al.*, 2018).

Searching the same key words on the National Institutes of Health – PUBMED website, about 30 articles were retrieved. However, when counterfeit, substandard and poor-quality medicine and Nigeria were searched, there were 6108 results available to view. This goes to further establish that the terminologies are closely used even though they have different implications in the pharmaceutical industry. When the keywords pharmaceuticals and pharmaceutical products were searched in PUBMED instead of medicine, fewer publications were found. One of the articles by Okereke analyzed how industry-based pharmacists can contribute towards eradicating falsifies medicines from the Nigerian drug market. Some of the highlighted limitations was the issue of insufficient technology application in the process and most importantly the open drug markets which provided little shield to the supply chain from falsification (Okereke, Anukwu, *et al.*, 2021). Another was by Oyetunde which gave a deep dive into the mobile

authentication service concept in Nigeria as a tool to track and check drug falsification in Nigeria, as well as its acceptance level by pharmacists in the community level of practice. The limitations were discussed and how it could negatively impact sales when it failed to validate a product (Oyetunde *et al.*, 2019).

When a similar search was done in the ELSEVIER database by entering the same keywords used earlier, it yielded 60,921 results, comprising of articles, books and web articles. However, majority of them were of a broad context and not specific to the topic of interest. The Pharmaceutical journal (official journal of the Royal Pharmaceutical Society) was a more specific database and had two related articles on the subject matter. One of which discussed a global perspective on the growing problem of falsified and substandard medicines and the efforts been made globally to combat the effects. This is very essential to one of the objectives of this literature review which is to assess the global medicine anti-falsification regulations to curb falsification driven by regulators (Ghanem, 2019).

The search terms extent or scope of anti-falsification technology, consumer choice or falsified medicine, and Nigeria were combined to find more results. This did not, however, aid in the retrieval of any additional related articles. To find relevant articles, questions like 'patient attitude to anti-falsification technology", "pharmacovigilance studies in Nigerian hospitals" and 'proof of medicine authenticity in Nigeria" were also searched for on Google scholar and by doing so, many news articles and other pieces of "grey literature" were acquired, going beyond peer-reviewed studies and articles. Additional resource sites such as HAL online were identified through this approach.

A search of the term "falsified medicines" in the WHO regional library data database for the African Regional Office (AFRO) yielded 710 results; a repeat of the search by entering the same key words in the unified WHO international website yielded no relevant articles (World Health Organization, 2023).

There was no published research on the extent or impact of anti-falsification technology on medicine choice could be retrieved from NAFDAC official website when it was visited. Also, no public accessible database to view recorded cases of falsified medicines confiscated from the field inspections could be found on the NAFDAC site. However, other articles related to the issue of falsified medicine in the health sector in Nigeria and current initiatives and enforcement directives were obtained, about 275 results comprising of some articles, public notices and newsletters. Most of the articles were by Akunyili, the late former Director-General of the agency obtained from a Google search and one of which referred to studies by NAFDAC to determine the role of medical doctors in fighting falsified medicines through rational drug use, self-regulatory measures to maintain ethical medicine use. Also, a visit to the official NAFDAC website showed the improved regulatory reforms that promote anti-falsification regulations and associated enforcement directives (Akunyili, 2007).

In regards strategies employed by brands to stop the spread of falsified, counterfeit, and substandard medicines, the websites of major brands were visited. Sanofi uses technology to fight medicine falsification through authenticating products by labels and an innovative digital solution called Simple Authentication and Security Layer (eSASL), which is a non-visible labelling technology that uses e-finger technology to reduce production time (preventing stock-out syndrome) and cost by removing the physical labelling step (Sanofi, 2022). Other pharmaceutical brands that are visited include concerning their anti-falsification technology strategy in Nigeria were Takeda, Pfizer, Abbott, GlaxoSmithKline, Cadbury Pharmaceuticals Ltd., and Merck.

2.5. Objective 1

2.5.1. History of Falsified medicine in Nigeria

The falsification of medicines is not new in Nigeria and has traced back even till the late 60's. Before 1968, the only drug distributors in Nigeria were Crown agents which were representatives of a British company. After they were accused of monopolizing the market, they renounced their position and the Pharmacists Board of Nigeria (PBN) assumed control. The first post-colonial instance of medical fraud was soon after discovered and revealed. Due to the PBN's inability to manage the additional responsibility and its need to meet the country's drug distribution needs, it subsequently delegated authority to distribute medicines to state governments. Consequently, state governments gave licenses to medicine vendors, most of whom were traders, and the supply chain became decentralized. This decentralization opened a new pathway that enabled drug smugglers to exploit and import falsified medications (Prof Dora Akunyili, 2007; Peterson, 2014).

After the economic recession of the 1980s that affected the global economy thus ensuing the devaluation of the Naira, which is Nigeria's official currency, most of the population was unable to afford many drugs, which led to the issuance of drug import licenses to local distributors. Politicians had a significant impact on the implementation and issuance of these import licenses. This resulted in its issuance to unqualified individuals who often sought the cheapest generics as they did not fully grasp the implications of falsified medicines to the population. This circumstance, when combined with rising drug demand of a growing population, a shortage of pharmacists, and ongoing irrational drug use, led to an increase in the import of poor quality medicines by non-professionals because they were less expensive than real medications amidst little or no regulatory monitoring (Peterson, 2014). The Counterfeit and Fake Drugs Decree No.17 of 1989 was then enacted after it became clear that the country's current laws on the distribution of medications were unable to address the issue of poor drug quality. This led to the creation of the Federal Task Force, which is now a division of NAFDAC that enforces the laws. Decree No. 17 of 1989 was later replaced by Decree No. 25 of 1999, which included a stricter forfeiture penalty and a fine of N500,000 for offenders (NAFDAC, 2017c). This gross unregulation of medicine importation into Nigeria saw about 4000 different drug varieties available in the market by year 1990, whereas only 200 were required. Additionally, 50–60% of the drugs available were either falsified or of poor quality (Bo *et al.*, 2015).

2.5.2. Current situation of falsified medicine in Nigeria

It is difficult to determine the correct scale of the problem of falsified medicines in Nigeria, West Africa and the world at large. The manufacturing, distribution, and sale of pharmaceutical goods in Sub-Saharan Africa have enormous potential for improving the economics of the Nigerian pharmaceutical industry. The Nigerian pharmaceutical industry has historically been complicated due to the large number of stakeholders (manufacturers, national regulators, wholesalers and retailers, government ministries and other participants). Despite to their large human population (that could provide a reliable workforce) and wealth of resources, they have been unable to meet all of the nation's medicines needs and must therefore import essential medications from Europe, America, and Asia despite having about 130 registered pharmaceutical companies and 5,795 authorized pharmaceutical vendors and distributors (Asoko Insight, 2020).

The most circulated class of falsified medicines circulating in the Nigerian market are the antimalarial and antibacterial drugs often profiled to cost an estimated $890-$893 million annually in Nigeria (Beargie *et al.*, 2019). A common antibiotic by the name of Beecham Ampiclox has been falsified and even

counterfeits are being sold in the market for a significant discount to the real thing. Instead of setting prices that are competitive with other products on the market, brand-name multinational companies like Glaxo rely on their brand name, routine prescribing, and hospital marketing practices to sell their drugs. More products are available from Glaxo than any other brand-name multinational in Nigeria. Ampiclox is an old generation penicillin-based antibiotic (containing ampicillin & cloxacillin) and is largely ineffective against most bacterial infections due to growing bacterial resistance. Nevertheless, it is well known to the public and a "fast mover." Its low price and popularity thus makes it a prime candidate for falsification and market distribution (Peterson, 2014).

The persistence of poorly regulated open drug markets, where drugs are freely hawked and sold on street corners, bus stops, shops, and stalls, has been a major factor in the prevalence of falsified medicines in Nigeria's major cities. These markets are well-known in Nigeria as distribution points and transportation hubs for subpar and fake medications. Nigeria has several well-known open drug markets, including those in Kano (North West), Lagos (South West), and Onitsha (South West), as well as less well-known ones in Abia (South East) and Rivers (South-South) (Okereke, Adekunbi, *et al.*, 2021) . Due to constant needs for cheaper medicine supply sources by some hospitals caused by poor government funding, they patronize some of these open drug supplies and that is how falsified medicines may find its way into the pharmacies of tertiary health facilities. Government reforms supported the local manufacturing of pharmaceuticals to tackle the importation of substandard and falsified medicines into the country.

The odd demographics of the Nigerian population may be to blame for the inadequate health care delivery system in the country.

2.6. Objective 2

2.6.1. Implementing medicine anti-falsification technology globally

Globally, the trade of falsified medicines thrives on the lack of awareness of their presence in the market. However, with the increasing crackdowns on manufacturers, importers and distributors of falsified medicines and its counterparts, public awareness has been driven thus making it more difficult to sell. The major world economies in the United States of America, Japan and Europe under the guidance of the WHO has been able to combat falsified medicines to a standstill by utilizing available technology to aid the detection of falsified medicines. One limiting concerns in the fight that may have clouded problem solving in the past regarding falsified medicines is the persistent argument and muddle over terminology relating to subpar medicines (Newton *et al.*, 2011). This is a result of the problem being approached differently by public health authorities and intellectual property rights authorities. Some have argued that a specific definition for falsified medicines is not necessary in the fight against poor quality medicines however, that sentiment is not generally accepted (Caudron *et al.*, 2008).

Falsified medications are thought to cost the healthcare system an estimated $75 billion annually while generating an illegal revenue for criminals, as well as prolonged, serious illnesses, fatalities, and mistrust in healthcare institutions all over the globe (Blackstone *et al.*, 2014). Global stakeholders have united in the fight against subpar medicines over the past 12 years, and real progress has been made. The Falsified Medicines Directive, which was passed in the European Union in 2011, aims to improve patient safety by preventing the pharmaceutical supply chain from being infiltrated by counterfeit drugs and by enacting new regulations that more strictly regulate the supply chain. Furthermore, the issue is still growing on a global scale, making it harder for stakeholders—many of whom have limited resources—to work together. To secure global medicine supply chains, it is urgent that those with knowledge in policy, technology,

surveillance and monitoring, and supply chain work together (Buckley and Gostin, 2013; Blackstone *et al.*, 2014).

In the USA, the implementation of anti-falsification technology became paramount to safeguarding the drug supply chain even as the US FDA (Food and Drug Administration) has estimated that more than 10% of all drugs in use are likely to be falsified ( ). The FDA passed a directive called the Drug Supply Chain Security Act (DSCSA) which includes the US falsification directive, or DQSA (Drug Quality Security Act) and is anticipated to be fully implemented by 2023 after it was signed as a law in 2013, two years after the EU Falsified medicines directive was passed by the European commission. The DQSA summarily ensure that a proper inventory track of the medication is kept until it is dispensed in the pharmacy. Inotherwords, manufacturers and retailers of prescription-only medicines are required to provide the necessary information at the batch level and to record all transaction data. This directive made it possible to quickly identify and seize not only falsified but also stolen batches of drugs thanks to complete batch number traceability. The DSCSA ensures the safety of medicines in the USA.

In Russia, a Federal law called Law of 22.12 2014 N 429-FZ saw the birth of subsequent regulations that would oversee the sale of safe medicines. This expanded the authority of the responsible Federal Executive authorities and revised the regulations on the setup of state control and supervision of the quality of pharmaceutical products (Fayzrakhmanov, 2015). This makes it possible to quickly identify and stop the distribution of pharmaceuticals that don't adhere to the rules. There is a significant falsified medicines problem in Russia and it is becoming worse because of the ongoing war and sanctions from other western European countries which has limited the access to medicines (Parfitt, 2006). According to the Russian Minister of Health and Social Protection at the time, the value of the Russian market in 2006 was estimated to be between $253 and $337 million (224 and 269 million euros) and reasonably larger now almost two decades after (Fayzrakhmanov, 2015). The State Duma passed Law 61-FZ on the circulation of medicines in response to the situation, with the goal of enhancing drug safety (United Nations Environment Programme, 2010). Up until the end of 2017, a pilot project tracked the production and supply chain of pharmaceutical products available over-the-counter in the Moscow and St. Petersburg regions. The objective was to accurately identify fake drugs. All prescription-only medications must be serialized and aggregated starting in January 2020. Before 2014, falsified medicines made up a sizeable portion of the Russian pharmaceutical market. However, with the enforcement of stricter criminal laws and the imposition of 10-year prison terms for drug falsification and illegal distribution, the market for falsified medicines has seen a significant decline (Gowling WLG, 2015).

In low and middle-income countries across the globe, information technology tools such as 2D barcoding with drug safety alert systems, messaging services, databases to support visual inspections, reference libraries that support the identification of reported falsified and substandard medicines cases, and evaluation kits for field use are some of the innovations to tackle falsified medicines. These are cheap and accessible technology that are embedded into the supply chain system to track and trace medicines up until it arrives to the customer. In Nigeria, the mPedigree and Sproxil pioneered the mobile product authentication system in 2006 and 2009 respectively for detecting falsified medicines. In Kenya, the mobile app MyDawa also uses the scratch-to-reveal codes to verify the authenticity of medicines exported from Kenya to Nigeria. Another medicine authentication technology is the Tru-Tag which employs micro-tagging of tablets as a low-cost trafficking-proof technology (Rasheed *et al.*, 2018).

2.6.2. Anti-Falsification Regulations in Nigeria

According to a research done by Chekkit in 2020 shows that pharmaceuticals tops the list of commonly falsified and counterfeit products in Nigeria (Chekkit Technologies, 2020). To minimize the impact of this growing danger to public health the federal government of Nigeria (FGN) thus passed some legislations such as the Counterfeit and Fake Drugs and Unwholesome processed foods (Miscellaneous Provisions) Act (CAP C34, 2004) and was amended in 2015 empowers the National Agency for Food, Drugs Administration and Control (NAFDAC) Act of 2004 (NAFDAC, 2017d). The National Agency for Food and Drug Administration and Control (NAFDAC), Nigeria's regulatory body in charge of ensuring the quality, safety, and efficacy of medications and other health products, is primarily in charge of managing the regulation of medicines in Nigeria. To prevent the importation, distribution, and sale of counterfeit medicines in the nation, NAFDAC has put in place several regulations and guidelines. These regulations will punish those responsible for the production and distribution of counterfeit medicines with jail time and fines. The following are some of the medicines anti-falsification regulations in Nigeria:

i. Registration of Medicines: All drugs and other regulated products must be registered with NAFDAC before they can be imported, distributed, or sold in Nigeria. The registration process involves a rigorous evaluation of the quality, safety, and efficacy of the product. When the registration is complete the applicant receives a unique “NAFDAC no” for the approved product (NAFDAC, 2017f).

ii. Good Manufacturing Practices (GMP): The GMP regulations for the manufacture and distribution of pharmaceuticals must be followed by all pharmaceutical companies. GMP guidelines guarantee a high-quality manufacturing process that complies with global standards (NAFDAC, 2017a).

iii. Post-Marketing Surveillance: Post-marketing surveillance is carried out by NAFDAC to keep an eye on the efficacy and safety of medications sold in Nigeria. The surveillance also aids in locating fake or inferior medications that have entered the market (NAFDAC, 2017e).

iv. Mobile Authentication Service (MAS): The MAS is a technological strategy that enables customers to text-verify the legitimacy of drugs. A response confirming the authenticity of the drug will be sent to customers who text a code from the drug's packaging to a special number (NAFDAC, 2012).

v. NAFDAC Investigation and Enforcement Directorate: The directorate oversees investigating and prosecuting instances of drug fraud and other pharmaceutical offenses. To track down and prosecute offenders, the directorate collaborates closely with law enforcement organizations (NAFDAC, 2017c).

vi. Import and Export Regulations: To ensure that only genuine goods are imported or exported, NAFDAC regulates the importation and exportation of drugs and other regulated products (NAFDAC, 2017b).

Along with publishing its anti-counterfeiting strategies in Nigeria, the National Agency for Food and Drug Administration and Control (NAFDAC) also suggested harsher penalties for falsifying medications. Through WHO prequalification, international partnerships with bodies like the FDA of the United States of America and The Central Drugs Standard Control Organization (CDSCO) of India, laboratory upgrades, creating an enabling environment for regional pharmaceutical industries, training for NAFDAC staff, overseas GMP inspection, and cutting-edge technology TruScan are all part of the organization's strategy

to combat drug falsification in Nigeria. Even though millions of fake medicines have reportedly been seized in Nigeria by NAFDAC, the situation persists because the root cause has not been fully addressed. A study on strategies to combat substandard and counterfeit medicines in Nigeria and the role manufacturers will play discussed stronger border protection as a way of stopping rebranded medicine from being shipped into the country. The study also called for better adoption of MAS technology and a reform or better regulation of the supply chain and intensification of the prosecution of corrupt regulatory officials and illegal distributors (Ogbonnaya, 2021; Okereke, Anukwu, *et al.*, 2021).

2.6.3. Medicine authentication technology

The Mobile Authentication Service is an anti-falsification system set up by NAFDAC to detect falsified, counterfeit and substandard medicines in the Nigerian pharmaceutical market. It was fully launched in 2012 and required by every antibiotic or antimalarial brand or generic approved for use in Nigeria. It is a service provided by third-party private information-communication technology firms for health technology implementation and deployed with the intention of improving the detection of falsified medicines and improving public trust in medicines. The service is approved by NAFDAC and is offered to manufacturers and importers in Nigeria for use on antibiotics and antimalarials (NAFDAC, 2012).

Recent NAFDAC implementation guidelines state that before deploying any medicines, the marketing authorization holder of those medications must notify NAFDAC and the MAS provider must confirm the medicines' NAFDAC registration status. To make sure the desired product meets acceptable safety, efficacy, and quality standards. When MAS are deployed, service providers send safe and secure data about the deployed MAS to NAFDAC (NAFDAC, 2012).

On the secondary or primary packaging of MAS-enabled medications, there is a label that carries a scratch panel that conceals a one-of-a-kind, 12-digit pin or alphanumeric code for one-time use as a product personal identification number. Patients must scratch the card and send the free SMS codes to the short code listed on the MAS label (for example, 1393) using a mobile phone. They should then receive a response indicating whether the medication is real, fake, or stolen. The first line of the message will read "OK, Original" if the medication is authentic. This response is now the same for all MAS providers.

Additionally, the response typically includes some health advice and recommendations that are directed at the patient population that the medication is used to treat. The consumer must contact the contact center using the contact information listed on the secure label if they don't hear back after sending the text to confirm its authenticity. Below is a typical message for a medicine, which was authenticated using unique code 663408765756:

> “OK
>
> GENUINE Product, 1 Pack, Genuine Batch
>
> We care about your health
>
> M-Pedigree hub.goldkeys.net More: ghub.ai/XqsTw “

List of MAS Service Providers		
S/N	**MAS Service Provider**	**Short Code**
1	PharmaSecure	38351
2	Sproxil	38353
3	Savanté	38120
4	UBQ-t/Kezzler	20966
5	M-Pedigree	1393

Table 1: List of Mobile Authentication Service Providers ***(NAFDAC, 2012)****.*

Figure 2: Image Showing Oxclav-625 Tablets MAS Label Before Authentication

A study to assess the level of awareness, identification and utilization of anti-falsification medicine technology among medical professionals in South-Eastern Nigeria was done in 2021, which is 9 years after the mobile authentication service was deployed by NAFDAC and the results were significant to the objectives of this research. It is expected that almost a decade after the MAS was deployed the respondents feedback proved that there is a 100% awareness of the technology but there was a reliance on labelling, packaging and printing features to authenticate medicines rather than using the MAS verification system at the point of care (Iloh *et al.*, 2021). Another major study published in the Kampala International University Journal of Social Sciences on the awareness and adoption of MAS technology in

South-western Nigeria showed that there was a 65% awareness of the MAS technology but a low 20.3% utilization and adoption in the region (Adekoya and Ekeh, 2021).

Figure 3: Image Showing Oxclav-625 Tablets MAS Label After Authentication

2.6.4. Pharmacovigilance amongst healthcare professionals in Nigeria

The essence of discussing this is because the role played by the stakeholders involved in the drug distribution cycle is critical to maintaining a legit supply chain of medicines. Pharmacovigilance is defined by the WHO as "the science and activities involved in the identification, evaluation, comprehension, and mitigation of unfavorable drug effects or any other potential drug-related issues" (World Health Organization, 2015). There are key pharmacovigilance indicators that are used to evaluate the effectiveness of a nation's pharmacovigilance systems and these are structural indicators, process indicators and outcome/impact indicators. The structural indicators look out for the regulatory framework that guides and enables pharmacovigilance to be carried out, while the process indicators look at the mechanism of collation and analysis of pharmacovigilance reports, and finally the outcome indicators assess the level of changes brought about by the pharmacovigilance activities (World Health Organization, 2015).

Several factors, including the creation of the regulatory body NAFDAC in 1993, and the enactment of the Nigerian National Drug Policy in 2005, have contributed to the growth of pharmacovigilance in Nigeria. The Nigerian pharmacovigilance policy document introduced in 2012, created solid awareness on drug safety at a national level, and advised the creation of the zonal centers to cover the country's six geo-political zones. The actualization of this policy has led to significant progress in pharmacovigilance implementation (NAFDAC, 2017e). This stratification by zonal centers also served as a guide in the design of survey questions for this study. This explains why major teaching hospitals in four major regions of

Nigeria was chosen for this study. With growing concerns around medicine use, pharmacovigilance in Nigeria has seen a broad range of applications amongst healthcare professionals. In the Nigerian context, falsified and counterfeit medicines have received most attention while medication errors, incomplete effectiveness reports, acute and chronic poisoning, estimating drug-related mortality, as well as drug abuse and misuse, are additional issues that have not yet been fully addressed (Oshikoya *et al.*, 2009; Olowofela *et al.*, 2016). Since underreporting has been the main obstacle to the expansion of pharmacovigilance in Nigeria and globally, the determination of the burden of these various issues has been subpar (Isah *et al.*, 2012; Sandberg *et al.*, 2022).

A study was conducted to assess the level pf pharmacovigilance in six tertiary hospitals in the South-South region of Nigeria. All six hospitals were confirmed to have offices designated for pharmacovigilance activities but only three were fully or partially functional (Opadeyi *et al.*, 2018). Another related study was conducted in the Lagos State University Teaching Hospital (LASUTH) amongst healthcare professionals comprising of doctors, nurses and pharmacists with a total of 129 participants. The study revealed that pharmacists were more likely to report adverse drug reactions compared to the other professions, while 45% of the participants confirmed that they had reported an adverse reaction at least once during their period of practice (Ogundele *et al.*, 2012). The study's findings showed that among the population of healthcare professionals surveyed, reporting of adverse drug reactions has not yet become a common practice. This is largely because the hospital under study was not conscious of an effective pharmacovigilance reporting system. In Nigeria, reporting drug safety concerns by healthcare professionals is voluntary, and some of the challenges surrounding the underreporting ADR's and falsified medicines include litigation fear, a lack of knowledge of the issue, the belief that "known" adverse drug reactions (ADRs) are exempt from reporting requirements, a lack of time to verify using the MAS, and complicated reporting procedures (Ogundele *et al.*, 2012).

Another related study on pharmacovigilance in six tertiary health facilities in South-South Nigeria was conducted involving 811 participants. The research was conducted in two phases; the first phase involved assessing their history of reporting ADR's using the national reporting form and the data showed only 12% had ever used it. The second phase was conducted after educational intervention was done using the SMS communication system to teach the healthcare workers about pharmacovigilance and then another survey was conducted which showed a 31.6% increase in the number of ADR reports. A major lesson from this study is the emphasis on how regular system evaluations, training for healthcare professionals, and overall system strengthening can help the discipline of pharmacovigilance, which is expanding. This will in-turn help pharma companies to further assess the safety of medications in the Nigerian population and promote farther studies on safety (Olowofela, 2018).

2.7. Objective 3

2.7.1. Limitations and Recommendations of the review

This study evaluated used a systematic literature review conducted, assessed the impact of anti-falsification technology on patient choice of prescription medicines in four teaching hospitals in Nigeria and looked at the regulations and initiatives in place in Nigeria to curb medicines falsification using technology. However, this review has several limitations, one of which includes the lack of information on falsified medicines and substandard medicine. Although, the literature review showed that some studies have been carried out to explore the history and determine the cause of falsified medicines in Nigeria. A lot of studies has been done regarding the awareness, role and attitude of healthcare professionals to

falsified and counterfeit medicines also with respect to anti-falsification technology in Nigeria (Adigwe *et al.*, 2022). In line with this study, it would be worthwhile for future related studies to conduct quantitative research aimed at exploring the depth of challenges (such as governmental inefficiencies that encourage the spread of substandard and falsified medicines, poor access to medicine information which leads to irrational drug use) that surround medicine use.

Other areas identified from the literature that may need to be explored further include determining why regulatory authorities have not extended the use of anti-falsification technology to other classes of medicines such as anti-diabetics, anti-hypertensives, and cholesterol-lowering medicines and efforts to counter the current methods used by counterfeiters to beat the system. There is also very limited information on the reporting of encounters of falsified medicines belonging to these other drug classes, this is significant to this study as available MAS technology is only applied to antibiotics and antimalarials as they are believed to be the most falsified class of medicines. Therefore, this is a relevant area for this study as we evaluate the effect that anti-falsification technology has on the patient choice of prescription medicines in Nigeria in relation to anticipated future trends in chronic disease management.

Another limitation encountered in the review when visiting the official websites of the major regulator NAFDAC, showed there is no publicly accessible database to view reported falsified medicines cases and show details for alerting the public. This would have been very beneficial to this study and help establish strong areas of interest for surveys and interviews. In addition, there was no way to obtain data from these teaching hospitals on their average number of prescriptions written by the hospital staff and the number that are filled in the hospital pharmacy.

A final significant finding from the review is that, despite the numerous initiatives taken by pharmaceutical firms and regulators to stop the sale of counterfeit drugs in Nigeria, no study could be found to measure the success of any of these initiatives in disenfranchising counterfeiters. Also, the perceptions of stakeholders before regulations were made is often not sought regarding how best to handle suppressing falsified medicines sale and use. It is important for their opinions to be considered as previous similar instances confirm that it is a successful strategy to engage the public in the fight against falsified medicines as it yields better outcomes because of the experience-based opinions on they provide (Masefield *et al.*, 2021).

2.8. Conclusion

The findings from the second stage of my research, includes a structured review of academic papers and other related content, with the aim of giving readers more assurance that the viewpoint presented accurately reflects the reality of the issue researched., extensive extracts from the various related studies were also used.

We examined the regulations that have helped to stem the circulation of falsified medicines globally in major markets and in Nigeria. Thus, the resonating results show that most respondents in previous related studies thought that despite the introduction of several measures to make it easier to spot fake drugs, the circulation of fake drugs remained a problem in Nigeria. Despite widespread knowledge of the medicine anti-falsification technology available for use at the point-of-care, some of the difficulties mentioned also revolved around its poor utilization and adoption. Others had to do with a subpar pharmacovigilance culture present in healthcare environments. Although ineffective law enforcement is another important factor, the inaction of medical professionals was indisputable.

3.0 Chapter Three - Methodology

3.1. Introduction to the chapter

To use a multifaceted strategy for exploring all the factors necessary to achieve the aims of this research, a literature review on medicines' anti-falsification technology and the regulatory strides in Nigeria was conducted, details of which are already presented in chapters 2. A 2-part survey was then conducted using questionnaires containing a mix of multiple-choice questions and open questions. The first part had 4-sections that sampled questions for the quantitative analysis of results to determine the extent of exposure to prescription medicines in the various tertiary hospitals, validate participants inclusivity or exclusivity, and the role anti-falsification technology played in acceptability of medicines. While the second phase has only one section and contains 3 questions, it presented a qualitative data gathering research approach that uses open-ended questions to gather opinions and perceptions of stakeholders. The semi-structured questions for this qualitative research on relevant issues need to satisfy the objectives of this phase of the research. This chapter goes into depth on the theoretical framework that drives this research, it will show how the study was designed for simple data collecting and analysis, and why they are preferable to others. It also discusses the ethical difficulties raised throughout the course of this research.

3.2. Methodology

3.2.1. Research approach

For the objectives of this study which is to assess the impact of anti-falsification technology on patient choices of prescription medicines in the selected tertiary hospitals located in four of the six geopolitical zones in Nigeria, a survey amongst healthcare professionals in the institutions was conducted. The author made use of two methods, by using both questionnaire-based surveys (closed-ended) and semi-structured questions (open-ended). The questionnaires were designed for medical professionals and included Pharmacist, Medical Doctors, Dentists, Registered Nurses, Medical Laboratory Scientists, Radiographers, and Optometrists.

The author started by creating a survey (quantitative method) using google forms and distributed links to the survey via the respective professionals' groups (e.g. pharmacists group in UUTH, radiographers group in UNTH) in each institution for individuals to participate, this consisted of a core part of the research and all responses were received and stored on the cloud online. This enabled the author to gather as much needed information and data anonymously to be used for qualitative and quantitative analysis. Most of the questions was outlined to show the different ways patients interact with the various medicine anti-falsification technology available, how it affects their acceptance of prescription medicines and their attitude towards exposing the sale of falsified medicines. There was also opportunity to receive possible recommendations from health care professionals on how best to tackle the lingering problem of falsified medicines circulating in the country.

Additionally, semi-structured open-ended questions (qualitative data collection) were used to elicit the views and recommendations of healthcare professionals regarding falsified medications. Firstly, by probing their readiness to report allegedly fabricated medications (pharmacovigilance), which might have failed the literature review identified medication verification process (MAS). Also, to evaluate the awareness of the authorities in charge of receiving pharmacovigilance complaints and reports regarding adverse effects from prescribed medications. Finally, what degree of responsibility should manufacturers

bear when their medicines result in therapy failure. To enable the author to provide a concluding assessment of the study's findings, the data collected from the health professionals would be compared to pertinent literature.

3.2.2. Research Philosophy and Paradigm

The position of the researcher for this study examined data and opinions in line with the philosophy of positivism and interpretivism. This research began with a hypothesis about the relationship between the presence of anti-falsification technology on prescription medicines and acceptance by patients. Therefore, inferences can be made from both the quantitative data and qualitative data gathered. Hence, a wide range of participants are required to participate for the hypothesis to be considered a theory in future broader research.

The participants were provided with a questionnaire in which quantitative data was collected, analysed, and interpreted as a positivist. According to positivism, nothing can be known for sure if it is not measurable in this way. Scientific knowledge is derived from the accumulation of data gleaned from observation without regard to theory or value (Alharahsheh and Pius, 2020). To reaffirm the positivist philosophy, the researcher will only focus on factual, trustworthy data obtained through the online survey. Through inductive reasoning, data will be accumulated about how respondents make decisions about filling their prescriptions and the impact anti-falsification technology has on that. To, avoid any physical constraint to the study that may arise from distance to participants, an online survey was used to interact with respondents and get instant access to submissions. This strategy is believed to further remove possible bias in the data as submissions are received anonymously and not in person.

The interpretivism approach was used to analyse the qualitative data that was obtained from the second part of the study. The foundation of interpretivism is the idea that reality is arbitrary, complex, and socially constructed (Alharahsheh and Pius, 2020). Therefore, the researcher can only comprehend another person's reality through their own experience of it. This experience may be distinct from another person's and influenced by the latter's historical or social context. Interpretivist approaches rely on observation and questioning to unearth or create a rich and in-depth understanding of the phenomenon being studied (Alharahsheh and Pius, 2020). The questions were semi-structured (open-ended) and outlined as forms that allow respondents freely write out their opinions and recommendations regarding falsified medicines in Nigeria.

3.2.3. Research Strategy

The African Journal Online website (AJOL), PubMed, ELSEVIER, WHO regional library (AFRO), NAFDAC official website, and websites of pharmaceutical companies were the six databases that were searched for this systematic review and meta-analysis. The strategy in place for the research was to access the impact of anti-falsification technology on the acceptance of prescription medicines in Nigeria. However, to do that the researcher needs to assess the awareness of the participants, and because some of these verification features appear on the primary or secondary packaging as seen in Figure 2, we need to assess how important it is in encouraging the patient to accept the product after its been dispensed.

Then the assessment would progress to assessing the feedback ranges that can assist the identification of falsified drugs, challenges to the process, and recommendations for improvement. As evidence of from the literature review conducted, it was discovered that there was often not a lack of knowledge of anti-falsification methods, but a lack of utilization of the technology available to verify products.

The study was conducted among medical professionals and prior to participating they were informed about the nature of the study and its significance to improving medicine quality in Nigeria as well as it being part of the requirements for a master's degree in Pharmaceutical Business and Technology from Griffith college Dublin. The questions were distributed through associated groups of the various medical professionals in their official online groups.

3.3. Summary of methodology

SECTION	PRIMARY DATA	PART A	PART B
1	Approach	Quantitative data	Qualitative data
2	Philosophy	Positivism	Interpretivism
3	Strategy	Survey by Google forms	Survey by Google forms
4	Structure	4 sections made up of 13 questions.	1 section made up of 3 questions.
5	Subjects	Pharmacist Medical Doctor Dentist Registered Nurse Medical Laboratory Scientist Radiographer Optometrist	Pharmacist Medical Doctor Dentist Registered Nurse Medical Laboratory Scientist Radiographer Optometrist
6	Data analysis	Inductive and deductive analysis	Thematic analysis

Table 2: Methodology and Data collection

3.4. Primary research design

The research was done in two phases (Part A and Part B) to meet all the study's objectives. While the second was qualitative, the first was quantitative. To identify the shared objectives crucial to the study, the research design should conceptually address the "why" and "what" of a research project. The technical design, data collection methods, analysis plan, and sampling plan are all determined by the research design and is executed by dividing the research process.

There are three research designs; Quantitative, Qualitative, and Mixed-Research design. The quantitative could be experimental or non-experimental. This study utilized the non-experimental approach and conducted a survey research for the quantitative aspect of the research (Jongbo, O. C., 2014; Asenahabi, 2019). The researcher was able to simplify the objectives or hypothesis of this study so that it could be understood by participants using the relationships between variables in the objectives. The survey research was selected because it can reach many participants in a short amount of time and can provide a numerical description of perspectives, opinions, or trends of a population by studying a sample of that population. A survey research could be a descriptive, analytical, school or genetic research (Asenahabi, 2019). This study employed a descriptive survey method using the questionnaire survey method and shared 16 questions to the various participants. The survey was also cross-sectional meaning that the observations were obtained at more than one point in time involving a fresh sample of participant each time the questionnaire was filled in the four different teaching hospitals and did not alter any of the

variables. This study was also designed to be a cross-sectional descriptive research because it was not intended to identify the cause of the problem of falsified medicines in circulation but rather observed how participants chose prescription medicines based on its relevance and considered recommendations on how to protect the supply chain from adulteration. It is also not an exploratory research because it is not investigating a topic that is lacking information depth but rather the opposite as the matter of falsified medicines is a global pandemic and several reports have been published about it. This survey's sample bias control posed a significant challenge because it could seriously impair the generalizability of the results to the population. Additionally, the degree of the results' reliability is ultimately determined by the respondents' willingness to cooperate, and how much information they know about the topic (Wabwoba and Ikoha, 2011).

Qualitative research design produces data that is not quantifiable using open-ended questions. This approach enables the researcher to comprehend issues by investigating them in their own specific context and the meaning that individuals bring to them. Therefore, certain aspects of the questionnaires (1 section made up of 3 questions) was designed to address the qualitative aspects of the research objectives and the data collected revealed the participants viewpoint (Rovai *et al.*, 2013; Asenahabi, 2019). This gives room for non-predetermined responses to be received and provide a wider view to the topic. The researcher combined both the quantitative and qualitative research designs into this study on the theory that both have shortcomings, so gathering both balanced out the shortcomings of the other. Unlike if a single approach is adopted to a specific study, this mixed approach will lead to a better understanding being obtained from this study in line with the objectives (Creamer, 2018).

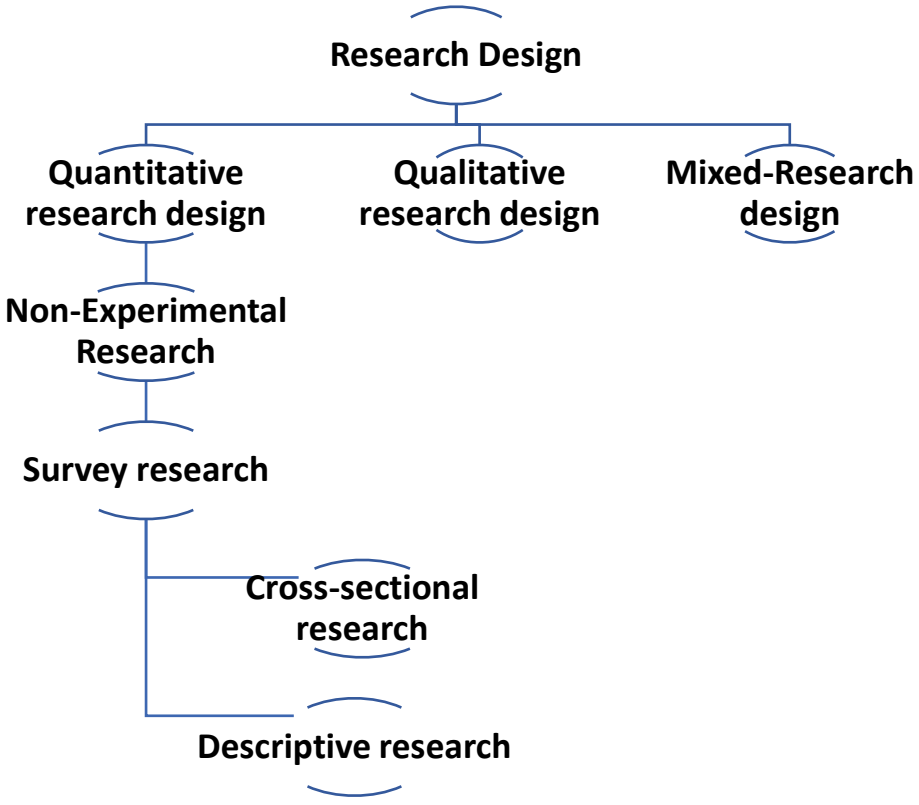

Figure 4: Overview of the research design

3.5. Ethical design

Ethical approval was obtained from the supervisor of this study at Griffith college Dublin ethics committees (copies of the ethical approval documents can be seen in appendix 1). The healthcare professionals who expressed interest in the survey were first given a summary of the research study after being properly informed that this study was required for the completion of the author's master's degree requirements. Additionally, care was taken in how the survey's questions were put together to avoid revealing the respondents' personal data while leveraging on observations made in their capacity as healthcare professionals. Additionally, respondents were informed that participation was voluntary and that their responses would be kept anonymous and could withdraw from the survey at any time without completion.

3.6. Data collection process

Keeping with the research design for data collection, an outline below describes how the survey questions were split into 2 sections in line with research objectives;

The study's introduction merely provides information that respondents must understand before taking the survey.

Section 1 retrieves data on the respondents' profession, and length of practice as healthcare professionals. Additionally, it evaluates how healthcare professionals interact with anti-falsification technology when filling prescriptions in their respective teaching hospitals informed with the knowledge of falsified medicines. It also provides insight into the various techniques used to spot fake medications, including the most popular ones, and evaluates whether therapy failures call attention to falsified drugs.

In Section 2, it is determined how much people in Nigeria are aware of the importance of reporting suspected falsified/counterfeit/substandard medicines. Additionally, it accesses how thoroughly participants practice pharmacovigilance on ADR's. Finally, advice for regulators on how to implement stronger medicine anti-falsification laws to deal with the problem of falsified medicines.

3.7. Study setting

The survey was conducted across teaching hospitals in Nigeria located in four of the six geo-political zones in Nigeria. This includes South-west Nigeria, South-south Nigeria, Middle-belt Nigeria (North-central) and South-east Nigeria. This includes the University of Benin teaching hospital, University of Uyo teaching hospital, University of Nigeria teaching hospital, Federal medical centre Kogi. These tertiary institutions were chosen because of they are the major tertiary hospital in their states and geo-political region, serving as a referral centre and providing a wide range of medical and out-patient services to a cumulative population of >13,674,325 people. Each of the tertiary hospitals also serve as a training site for their respective medical schools and have well-staffed departments which would come in very handy to this study (Sasu, 2022).

Having established the strategic position of these hospitals, it is important to note that they also function as fully diversified health institutions that serves their respective states and regions. Their patients comprise of low, middle and high-income earners as well as rural, peri-urban and urban dwellers, as is very typical of Nigeria. This study’s conceptual design develops from the understanding that these health professionals interact more often with a great percentage of the population that receive health services, health information, drug information and fill prescription medicines in the region. This further reinstates

the importance of assessing how these health professionals interact with anti-falsification technology on medicines sold in the hospital. The researcher believes that if the right information is transmitted to these enlightened people they could further educate the general population and make the regulators duty of enforcement easier.

3.8. Sample size and Sampling technique

The "patients" in this study weren't drawn from the general population; instead, they came from the hospital staff. This might not reflect the opinions of the other patients who are do not work in healthcare/medicine. However, the sample population have something in common with patients who visit the hospital which is their shared concern about their health and safe medicines. The google survey platform would be used to deliver the survey to the respondents to get immediate feedback. Therefore, as a result, it will be distributed amongst healthcare workers who are also patients receiving prescription medicines in their various hospitals. The research aims to develop a thorough understanding of the impact of anti-falsification technology on patient choice of prescription medicines in Nigeria using studies done on an enlightened subset of the medicine using population.

In addition, a purposive sample strategy was utilized in this study. It was critical to select the correct persons with appropriate educational qualification and work experience in this study to get relevant and impactful data, which could then be used to conduct an analysis and accomplish the objectives. Many eligible to participate in the study would be on the criteria of being medical professionals who fill prescription medicines in the hospital facility. However, those who participate will do so with ease and on their own volition. All four teaching hospitals were contacted and through their department representatives and the survey links were shared. However, the expected participation was lower than anticipated because most participants refused to participate due to conflict of interest and lack of interest.

3.9. Inclusion and Exclusion criteria

3.9.1. Inclusion criteria

I. Persons who are medical professionals licensed to work in Nigeria.
II. Persons who work in the health facility selected in this study in any of the listed professions.
III. Persons who consented to participate in the study.
IV. Persons who have purchased prescription medicines at least once in the past from the selected health facility.

3.9.2. Exclusion criteria

I. Persons who are not medical professionals licensed to work in Nigeria.
II. Persons who do not work in the health facility selected in this study in any of the concerned professions.
III. Persons who refused consented to participate in the study.
IV. Persons who have never purchased prescription medicines at least once in the past from the selected health facility.
V. Persons who have never used a medicine authentication feature.

3.10. Conclusion

This chapter gave a thorough explanation of how the methodology used in the study was developed. Additionally, it covered the preparation for data analysis, sample size, and the research methodology employed and how well suited for the study's objectives. It demonstrated the various ethical issues that

arose in both quantitative and qualitative research throughout the research process as well as any potential methodological restrictions that may have been placed on this study. The results of this research are presented in the next chapter and conclusions drawn from the study in Chapter 5.

4.0. Chapter Four - Findings

4.1. Overview

This chapter of my dissertation presents and discusses the results of this study. The result gotten from the questionnaire distributed to the groups of included participants generated data which will assist the author to determine the impact of anti-falsification technology on patient choice of prescription medicines in the respective health facility. The data presented below is the cumulative data from the four teaching hospitals involved in this study. This information provided will support the author to draw conclusions in line with research objectives.

4.2. Demographic data

4.2.1. Nature of participants (Question 1 and 2)

The survey questionnaire was disseminated to about 170 eligible participants consisting of 50 prescribers (25 medical doctors, 15 optometrists, 10 dentists), 60 pharmacists, 30 nurses, 20 medical laboratory scientists, and 10 radiographers. While 115 participated, consisting of 54 pharmacists, 22 registered nurses, 17 medical laboratory scientists, 11 medical doctors, 3 dentists, 2 radiographers, 3 optometrists, and 2 invalid responses giving a response rate of 67.6%. Amongst the participants, 66 are female and 49 are male. Reminders were sent to the respondents in their groups calling for participation during the time frame allocated for data collection, and most responses were received right after reminders were sent out. After the time frame elapsed, data collection ceased, and the survey no longer accepted responses.

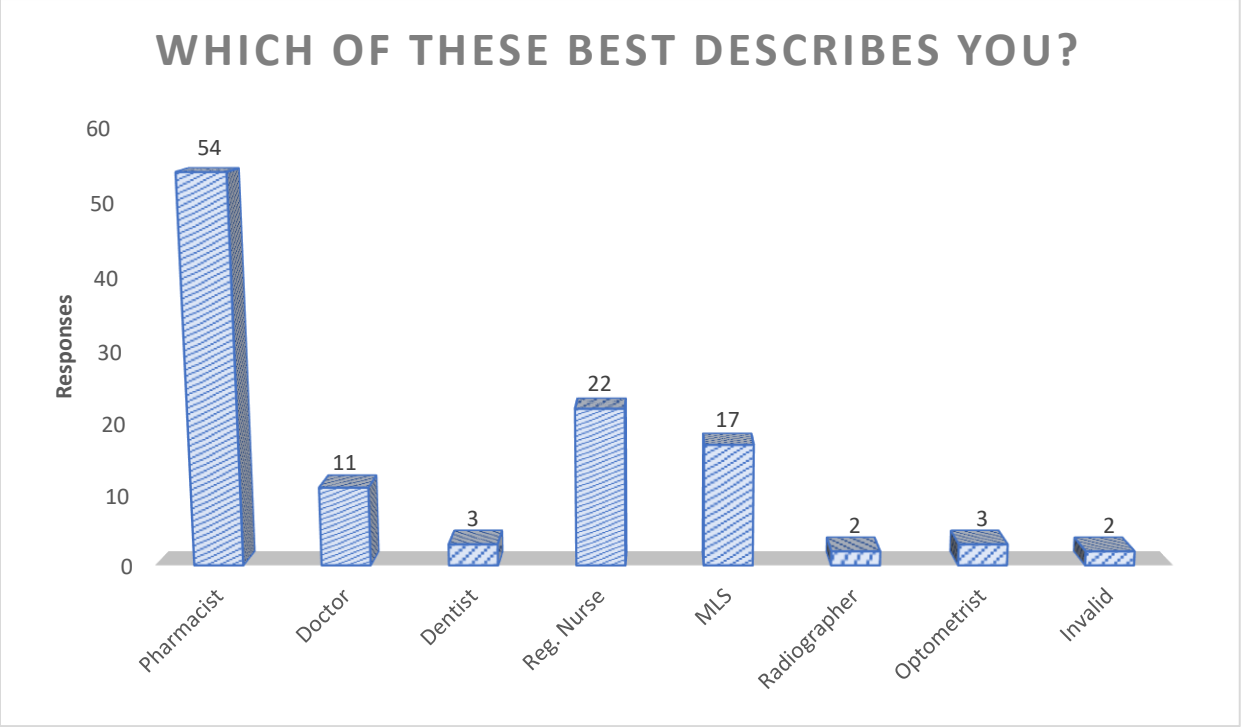

Figure 5: Graphical presention of participants professions in the site.

4.2.2. Years of experience - Question 3:

Regarding the length of time participants had been practicing, of all the healthcare professionals who took part in the survey, 63% had 4 to 10 years of experience, 21% had roughly 0 to 3 years of experience, 10% had been practicing with 11 to 15 years of experience, and only 6% had more than 16 years of practice under their belt.

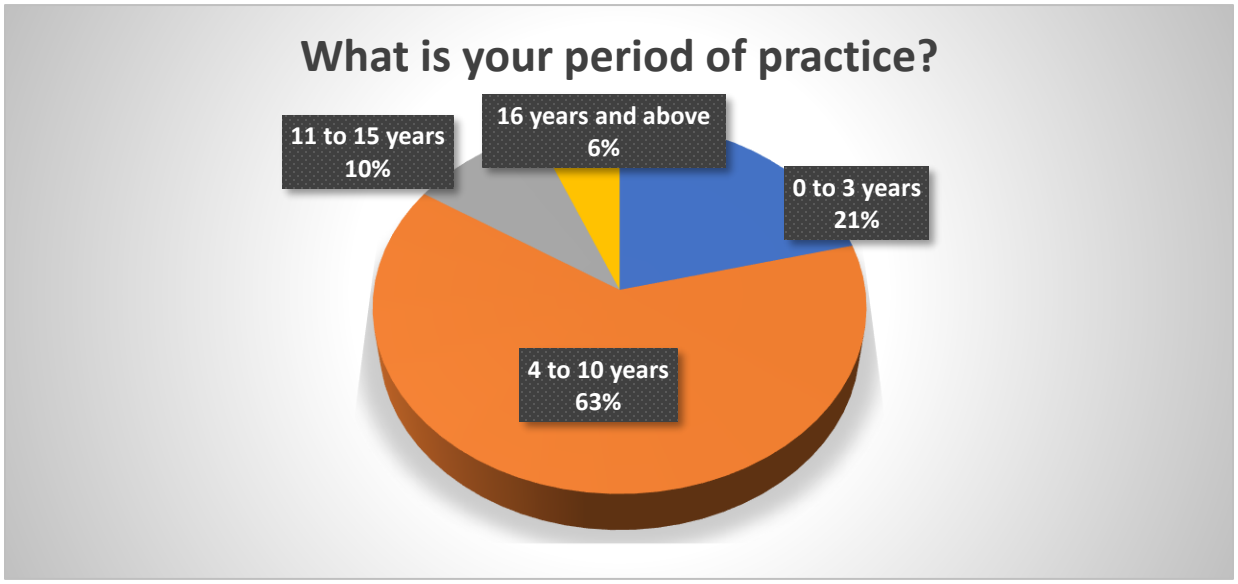

Figure 6: Graphical presentation of participants period of practice

4.2.3. Question 4: Sex

To assess how respondents interacted with prescription medicines and the associated anti-falsification technology, participants gender was taken note of. The cumulative data shows that amongst those who participated, 66 are female and account for 58% of responses, while 48 are men and take up 42% of responses.

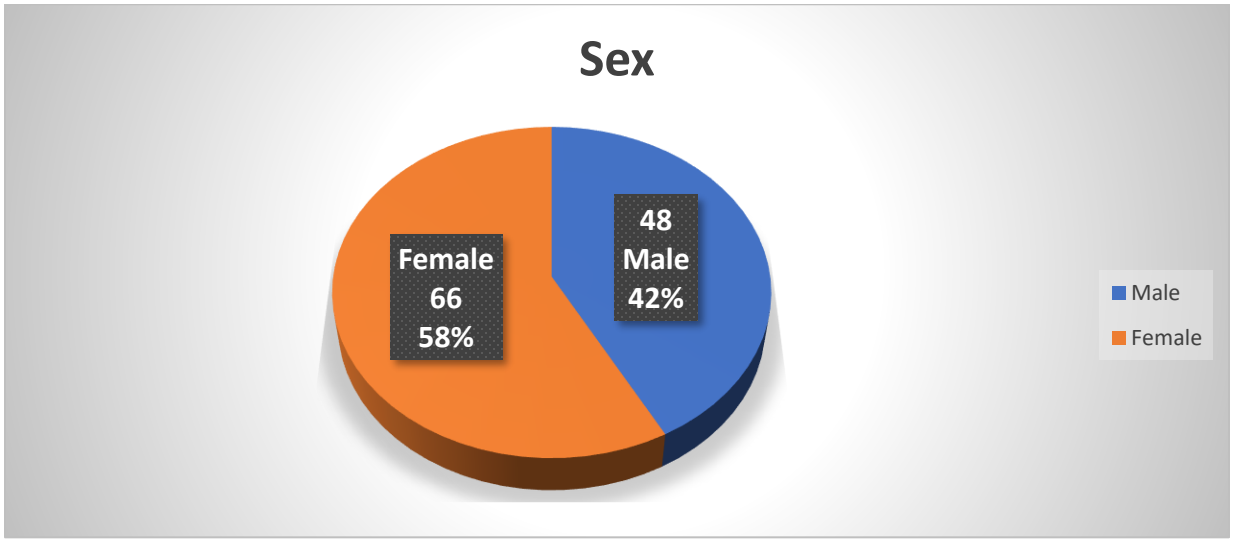

Figure 7: Pie chart showing the gender distribution of participants

4.2.4. Site Familiarity - Question 5:

Several patients confirmed that they have a history of filling prescriptions at their respective hospital pharmacy. According to the data gathered from the survey, 106 of the 115 respondents claimed that they have filled prescriptions before, giving a convincing 92.2% participation rate. While 6 of the remaining 8 said they have not used the hospital pharmacy before and 2 said they were not sure.

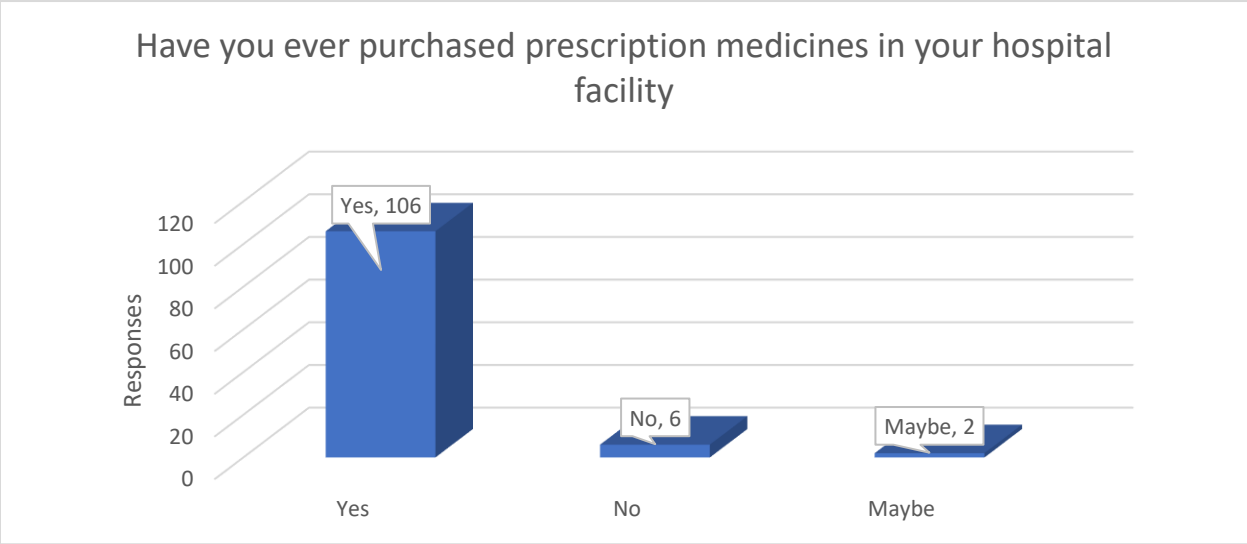

Figure 8: Graphical presentation of participants familiarity with the site of the study

4.2.5. Hospital Pharmacy History - Question 6:

According to the survey data, some customers have been filling prescriptions at the site of the survey across different time periods. 50 respondents have only been filling prescriptions for a period of 0 to 3 years, another 22 respondents have done so for 3 to four years, the third group of 39 respondents have done it for over 5 years, and the remaining 4 responses were invalid because their selections were not clear. Most of the participants had reasonable experience in the purchase of prescriptions at the survey site.

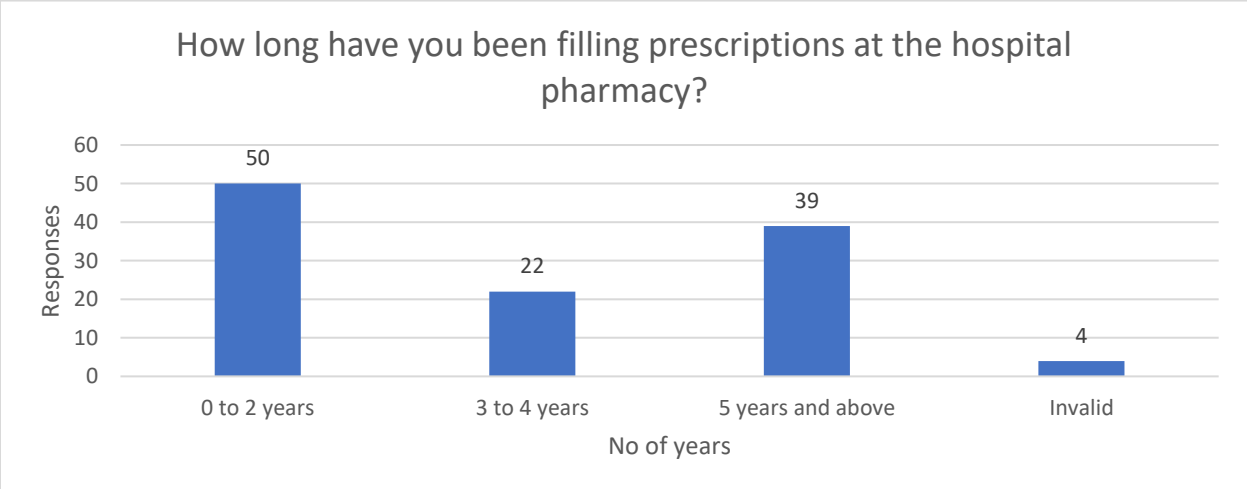

Figure 9: Graph showing patient prescription filling history at the site

4.2.6. Summary of Demographics

Participants	Zonal Distribution				Period of Practice (years)				Sex		Hospital Pharmacy use (years)			Total No of Respondents	Response Rate (%)
	SS	SE	SW	NC	0 – 3	4 – 10	11– 15	16+	M	F	0-2	3 - 4	5+		
Pharmacist	9	4	14	27	13	35	4	2	26	28	32	7	15	54 of 114	47.3
Medical Doctor	3	1	4	3	0	8	3	0	6	5	0	4	7	11 of 114	9.6
Dentist	0	1	1	1	0	2	1	0	3	0	0	2	1	3 of 114	2.6
Registered Nurse	7	8	4	3	4	14	0	4	6	16	5	6	9 (2*)	22 of 114	19.2
Medical Laboratory Scientist	5	6	2	4	5	9	3	0	5	12	10	2	4 (1*)	17 of 114	14.9
Radiographer	1	1	0	0	0	1	0	1	1	1	0	0	2	2 of 114	1.7
Optometrist	1	1	1	0	1	2	0	0	0	3	2	1	0	3 of 114	2.6
Invalid	0	1	0	1	1	1	0	0	1	1	1	0	1	2 of 114	1.7

Table 3: Table showing the relationship between respondent demographics and site data

4.3. Knowledge about anti-falsification technology (Question 7 – 13)

4.3.1. Knowledge of medicine anti-falsification technology - Question 7

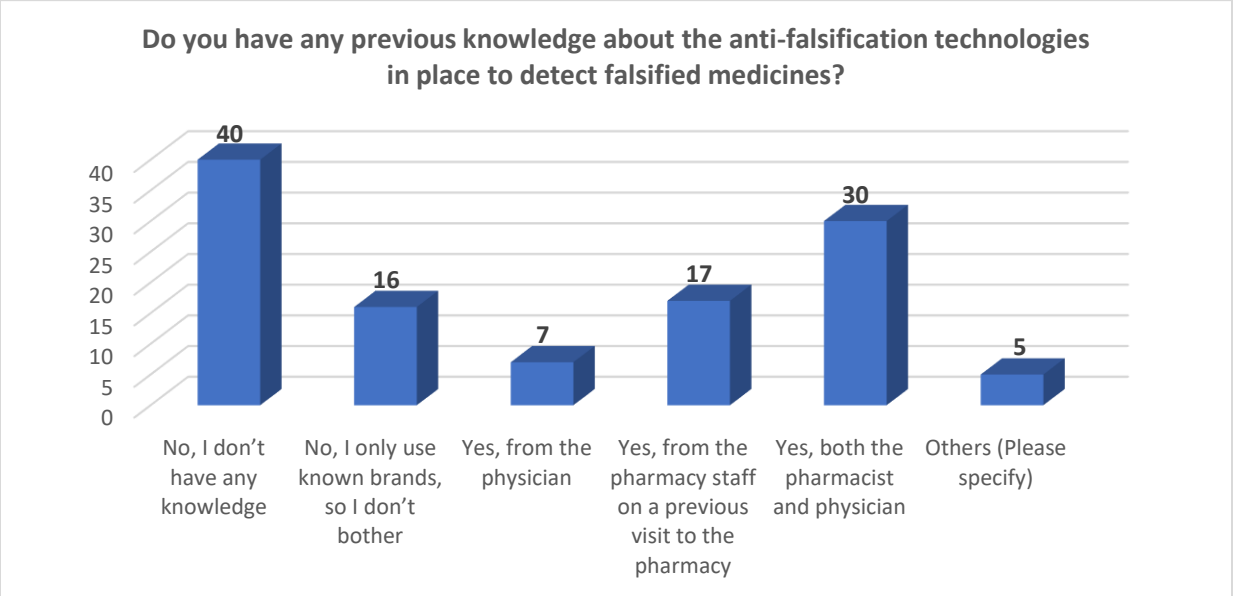

Figure 10: Graph showing respondents awareness of medicine anti-falsification technology.

According to survey data gathered across the four teaching hospitals involved in the study, 40 (34.7%) of the respondents claimed they were unaware of medicine anti-falsification technology, while 16 (13.9%) claimed they don't care because they only use recognized brands rather than generics, 7 (6%) acknowledged having knowledge of the technology and credited their doctors, and another similar group of 17 (14.7%) claimed they learned about it from the pharmacy staff. The second-largest group of 30 respondents (26%) stated that their pharmacist and prescriber were both sources of knowledge for them. 5 respondents, the smallest group, claimed (4.3%) that their knowledge was obtained from other sources.

4.3.2. Original Packaging - Question 8

When asked about preferences in their prescription packaging, like whether they insisted on receiving their medications in the original packaging, 95 participants—or 82 percent—confirmed they did. Another 15 participants—or 13 percent of participants—said they didn't care what packaging their prescription medications came in. A few responses claimed that they never receive prescriptions in original packaging (0.8%), that they prefer other methods of receiving prescriptions (1.7%), and that they prefer it removed (0.8%).

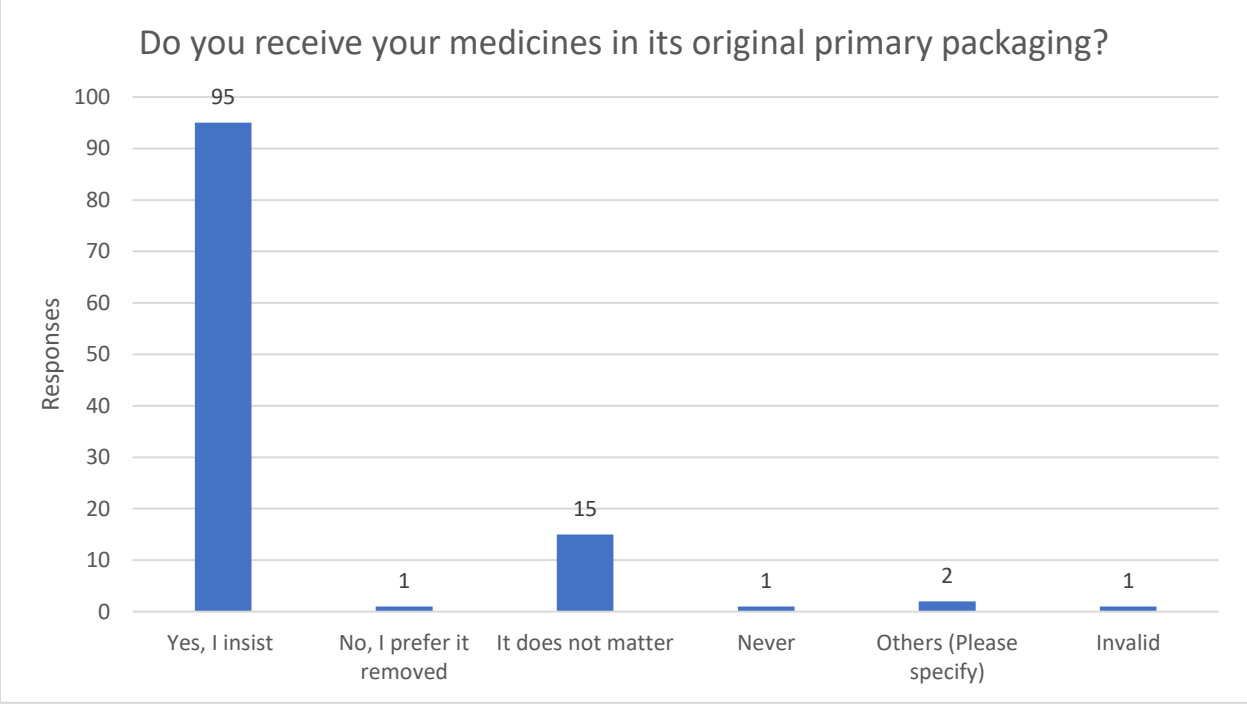

Figure 11: Graph showing patient preference for prescription medicine packaging

4.3.3. Use of medicine authentication measures - Question 9

Regarding the use of medicine verification measures by patients when filling prescriptions at their pharmacy, the respondents' feedback was well distributed with 60% - 69 responses (which is most of the participants) confirming the use of NAFDAC registration number followed by the use of MAS by 25% (29 responses), while the use of labelling graphics 7 responses (6%) and physical appearance of the drug pack was adopted by 8 (7%) participants.

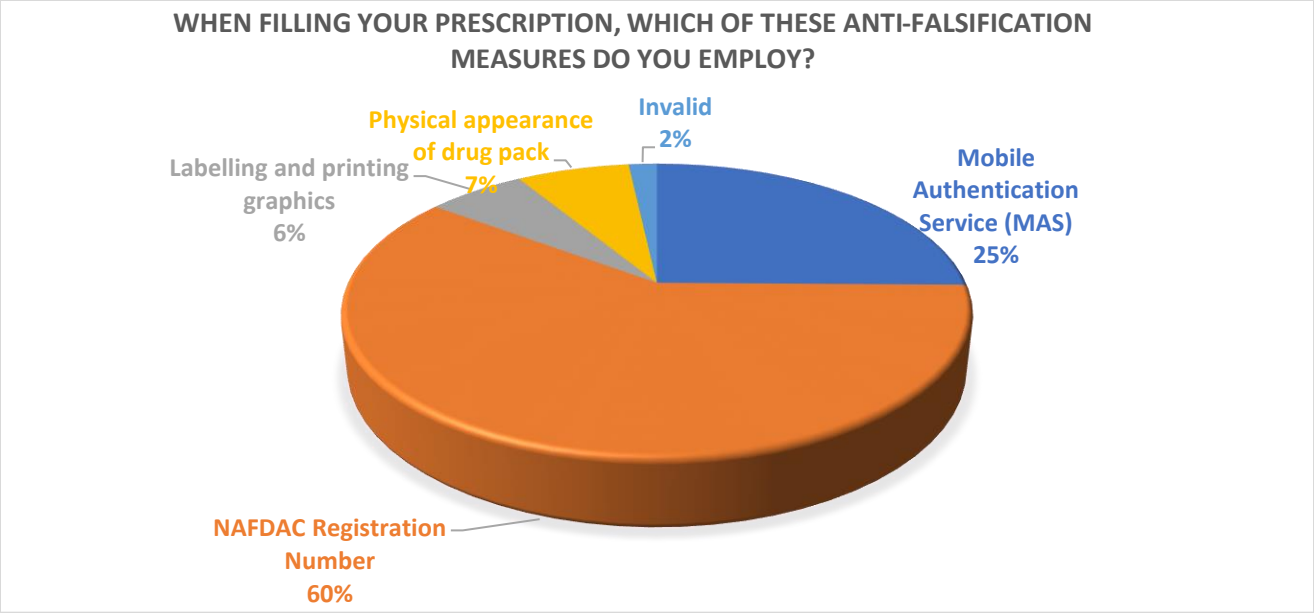

Figure 12: Pie chart showing common medicine anti-falsification measures employed

4.3.4. Lack of verification features - Question 10

According to survey results, if a prescription drug lacked verification features, 68% of participants said they would ask for a well-known brand, totaling 79 responses. However, a silent majority of 24 patients, or 20.8%, said they would seek assurances about quality. Of the 10 respondents, the group with the fewest responses (8.6%) says they would take any generic that was offered. Therefore, it is reasonable to assume that this is an important factor in a patient's decision to use a prescription drug.

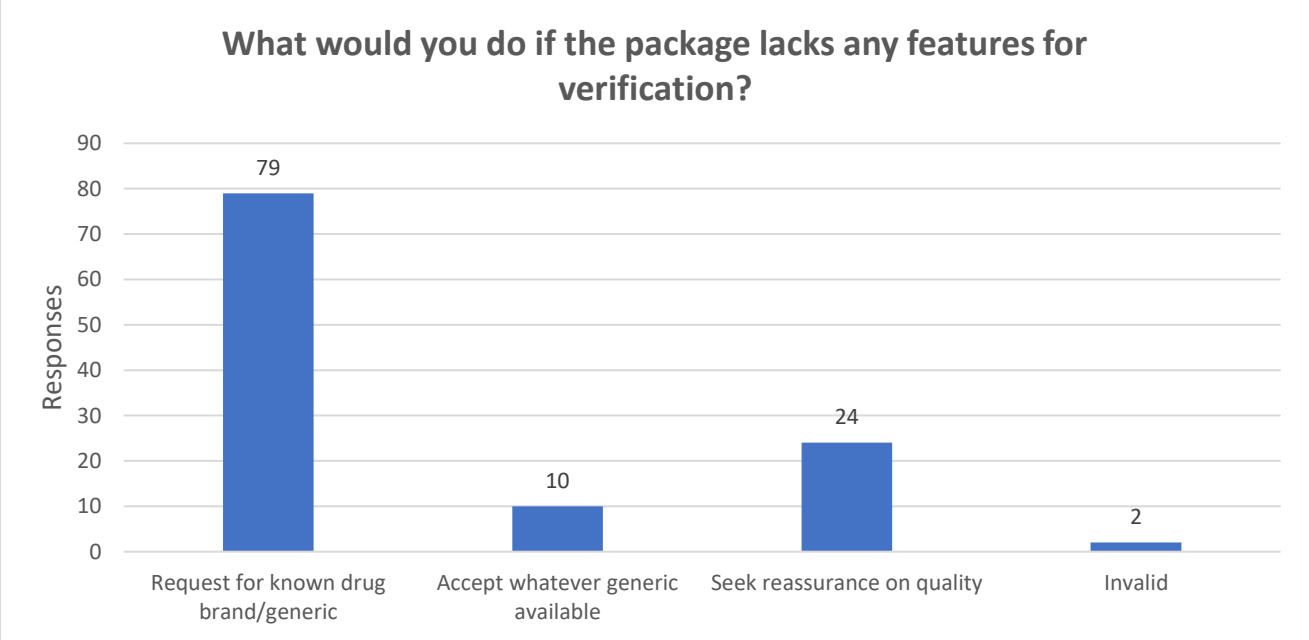

Figure 13: Graph showing common reactions to lack of medicine varication features

4.3.5. Medicine Information - Question 11

According to survey findings, the questions patients are likely to ask the pharmacist while filling their prescriptions borders majorly on the dosage of the medicine, the registration status of the product, expected side effects of the medicine, the authentication of the medicine using MAS, and finally the availability of cheaper alternatives. Patients who claimed to include all these queries when filling their prescriptions covered 45% (52 persons) of the responses, while a second majority of 22.6% (26 people) claimed their questions bordered only on the product having a NAFDAC registration number.

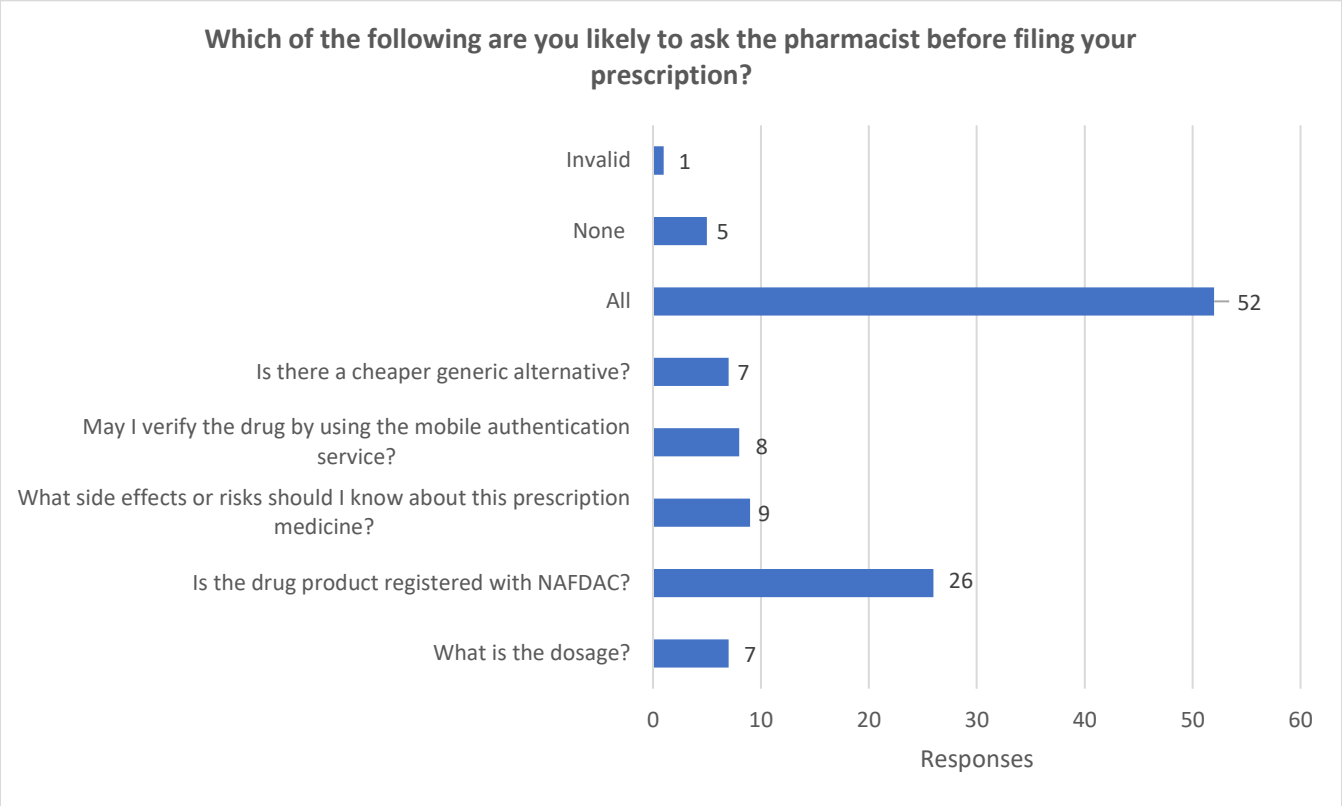

Figure 14: Graph showing common patient enquiry at the pharmacy

4.3.6. Summary of Awareness of Anti-falsification Technology

1.

	Do you receive your medicines in its original primary packaging?				
	Yes, I insist	No, I prefer it removed	It does not matter	Never	Others (Please specify)
Do you have any previous knowledge about the anti-falsification technologies in place to detect falsified medicines?					
No, I don't have any knowledge	31	1	6	1	1
No, I only use known brands, so I don't bother	14	0	2	0	0
Yes, from the physician	6	0	1	0	0
Yes, from the pharmacy staff on a previous visit to the pharmacy	15	0	1	0	1
Yes, both the pharmacist and physician	26	0	4	0	0
Others (Please specify)	3	0	1	0	0

Table 4: Table showing relationship between patient awareness of medicine anti-falsification technology and preference for medicine primary packaging

2.

	What would you do if the package lacks any features for verification?			
	Request for known drug brand/generic	Accept whatever generic available	Seek reassurance on quality	Invalid
Do you have any previous knowledge about the anti-falsification technologies in place to detect falsified medicines?				
No, I don't have any knowledge	28	5	7	0
No, I only use known brands, so I don't bother	12	2	2	0
Yes, from the physician	5	1	0	1
Yes, from the pharmacy staff on a previous visit to the pharmacy	10	1	6	0
Yes, both the pharmacist and physician	20	1	9	0
Others (Please specify)	4	0	0	0

Table 5: Table showing relationship between patient awareness of medicine anti-falsification technology and attitude towards medicines lacking verification features

3.

	When the prescribed medicine is not effective do you suspect it's a falsified medicine?				
	Yes, I do	I notify the health authorities (NAFDAC)	I try a different brand/generic	No, I inform my prescriber	Invalid
Do you have any previous knowledge about the anti-falsification technologies in place to detect falsified medicines?					
No, I don't have any knowledge	10	1	16	11	1
No, I only use known brands, so I don't bother	3	0	5	8	0
Yes, from the physician	1	1	2	3	0
Yes, from the pharmacy staff on a previous visit to the pharmacy	11	0	2	3	1
Yes, both the pharmacist and physician	10	1	7	12	0
Others (Please specify)	0	0	3	1	1

Table 6: Table showing relationship between patient awareness of medicine anti-falsification technology and suspicion of falsification

4.4. Awareness of Pharmacovigilance (Question 12, 13, 16)

4.4.1. Proof of Authenticity - Question 12

According to survey findings, patients look out for proof of authenticity on their prescription medicines when filling prescriptions. Amongst the various factors that are used to verify authenticity, the most frequent occurring factor was the NAFDAC registration number at 20.2%, followed by the presence of authenticating features at 10.5%, then the presence of authenticating numbers like the MAS at 6.1%. The selection of several factors by some participants is also noted as the combination of the three major factors was the third most selected option at 6.1% also. The use of trusted brands and trusted manufacturers is also a notable factor as its selection contributed to 4.4% of the selections.

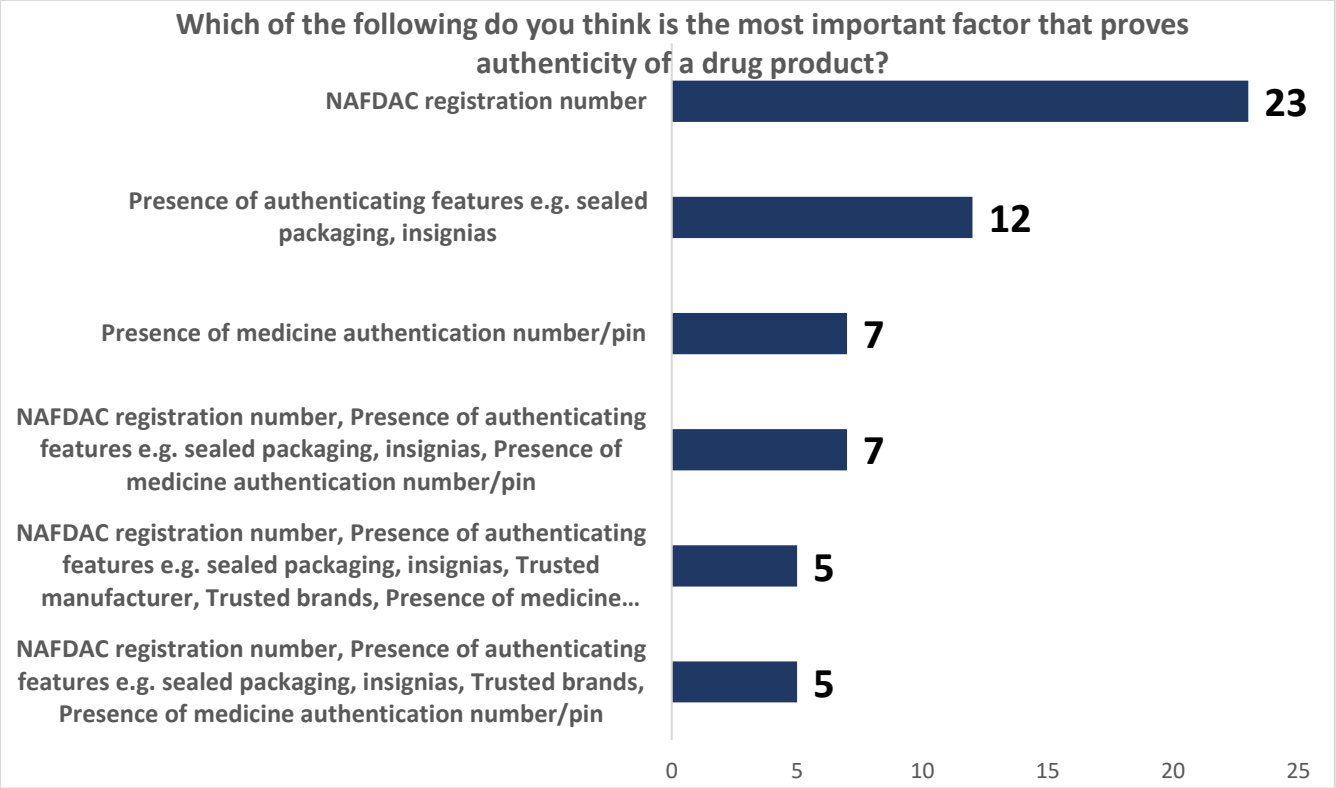

Figure 15a: Graph showing the selection of factors used to prove medicine authenticity.

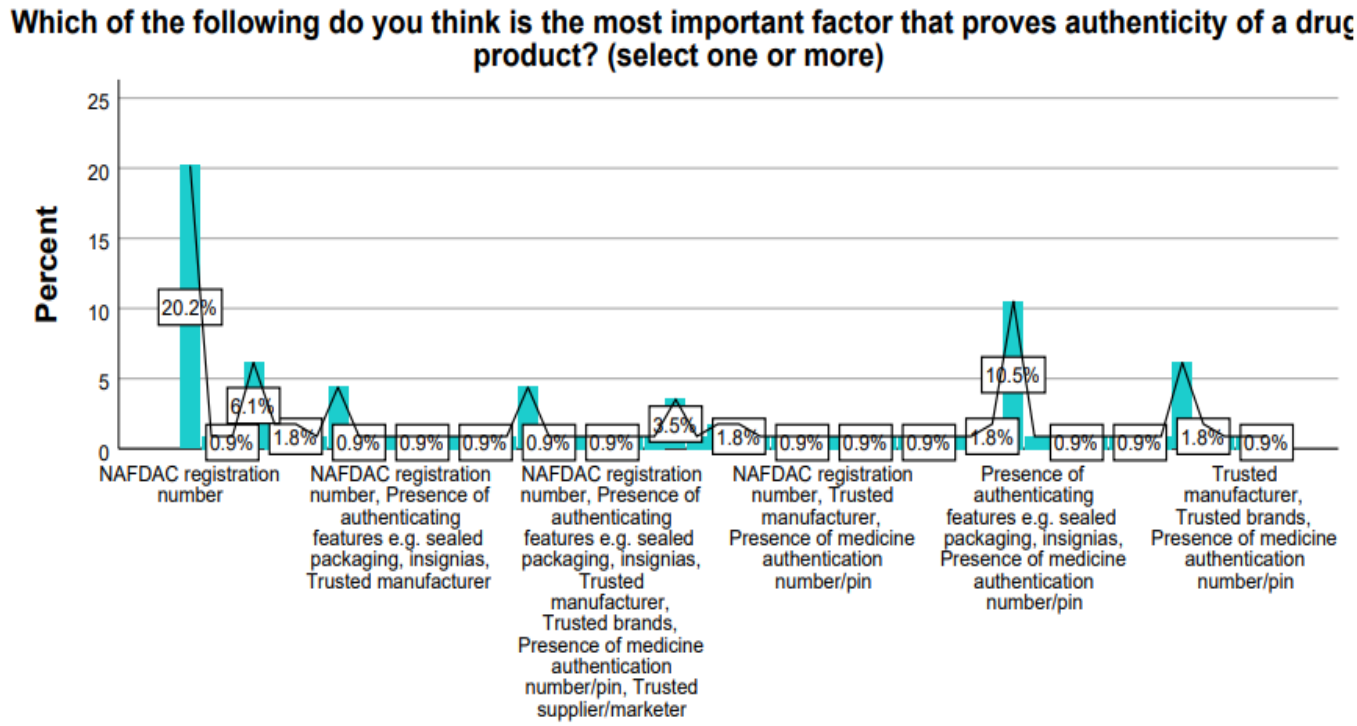

Figure 15b: Graph showing the percentage selection of factors used to prove medicine authenticity

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4.4.2. Suspected Falsified medicines - Question 13

In assessing how patients perceive prescription medicines they receive for their ailments which does not produce the desired or expected efficacy, data was collected from the respondents. This revealed that 33% say that they will inform their prescriber about the failed therapy, another close 30% say they will suspect that they received a falsified medicine, while a similar 30% say they will try a different brand/generic, and finally a small 3% say they will notify the health authorities about the product. See Fig. 15.

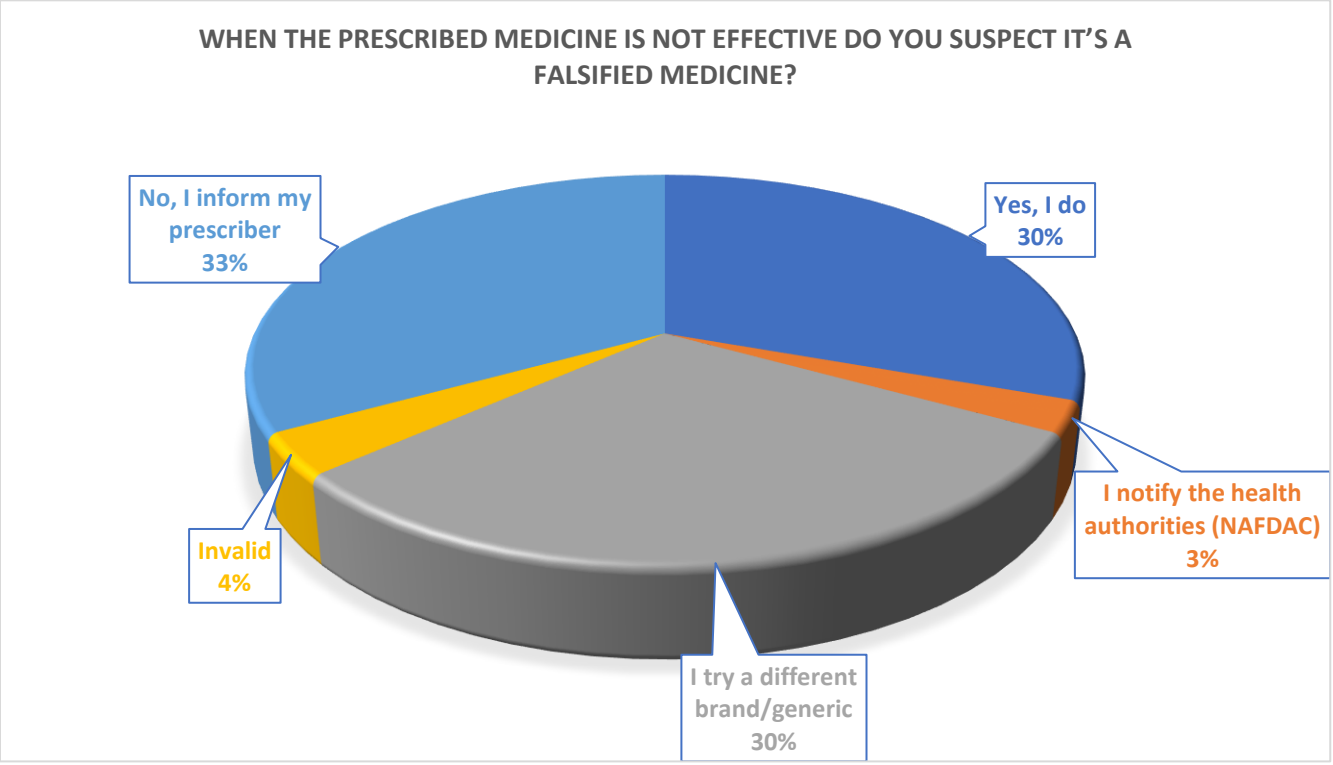

Figure 16: Pie chart showing patient attitude towards suspected falsified medicines

4.4.3. Trust in Quality - Question 15

With regards to the depth of trust patients have in the quality of medicines they receive in their various hospitals, 31% of respondents confirmed that they had a 75% level of trust. None of the respondents claimed to have 100% trust in medicine quality which is a poor record considering the dependence on these health facilities for healthcare and affordable medicines. Another 8% claimed they had a 50% trust in the medicines purchased while filling prescriptions. On the good side, the lowest trust level obtained was the 50% trust level and no one reported a 25% trust level.

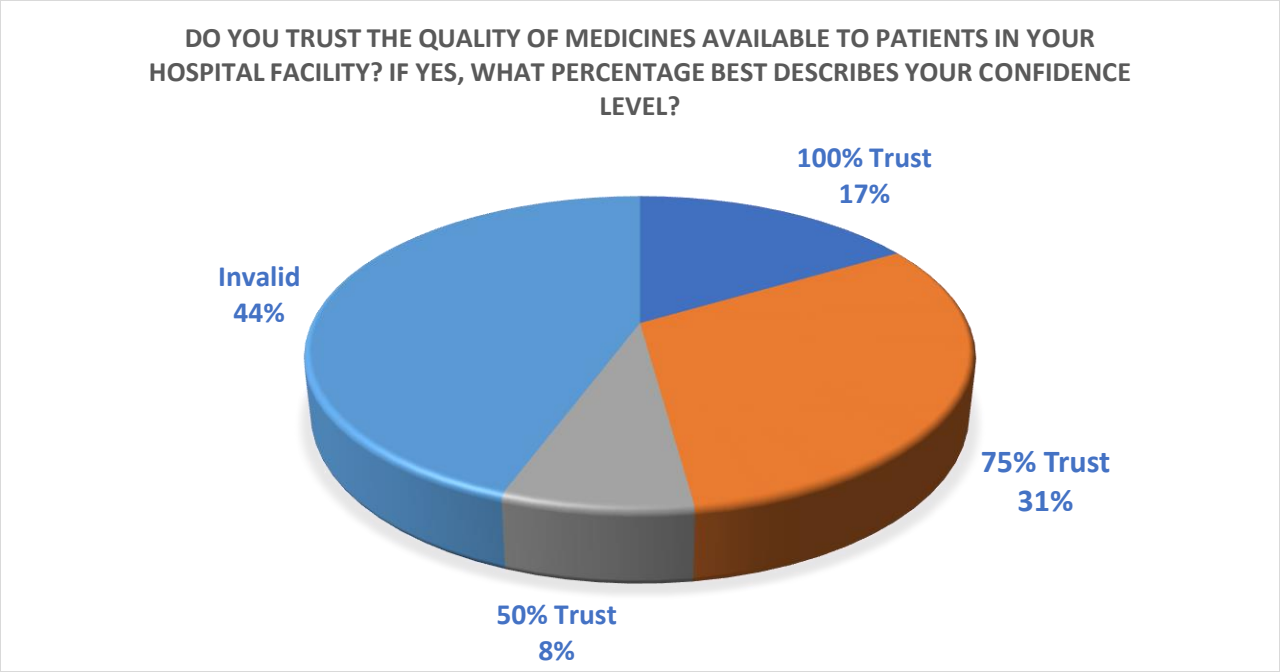

Figure 17: Pie Chart showing the level of trust patients have in the quality of prescription medicines

4.4.5. Pharmacovigilance - Question 17

On reporting the willingness to report cases of falsified medicines, the data suggests that 98 (85.2%) of the respondents confirmed that they would report suspected falsified medicines to the right authorities. Another 14 (12.1%) respondents say "maybe" they will report it, while a final 1.7% of respondents say they will not.

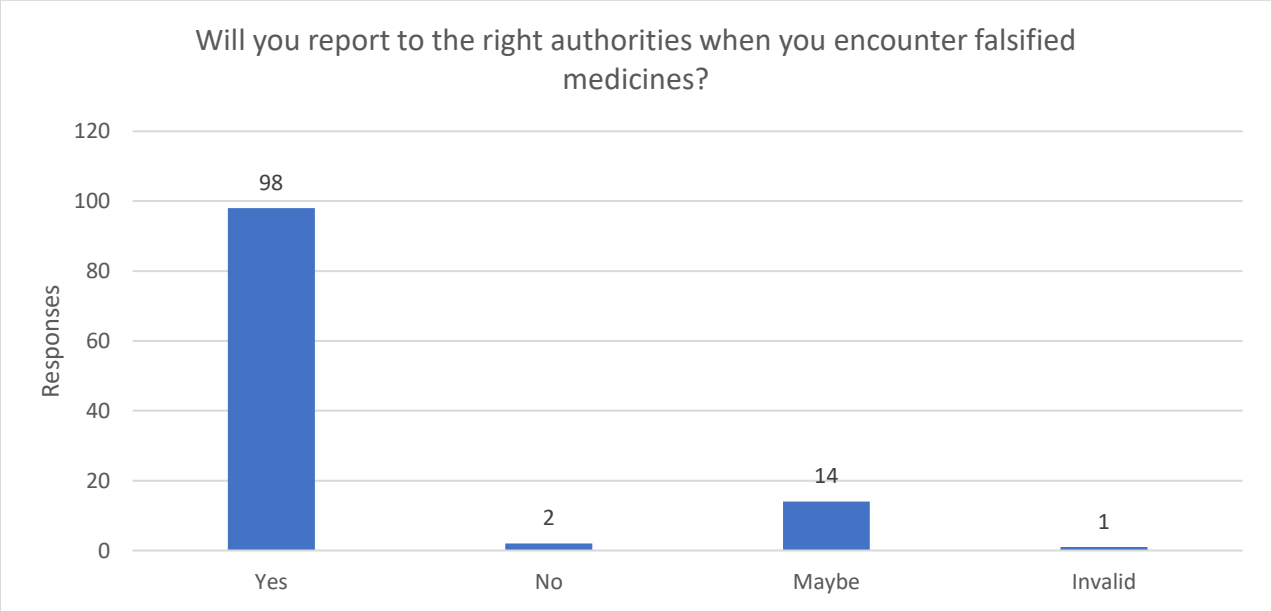

Figure 18: Graph showing the willingness of survey participants to report falsified medicines

4.5. Qualitative Data

4.5.1. Recommendations - Question 14

As previously stated in the methodology chapter three, two open-ended, semi-structured questions were included in the survey with the aim of exploring the opportunity to learn firsthand from participants. These policy suggestions/recommendations could contribute in limiting the spread of falsified medicines. However, only few of the responses received went all the way to give detailed answers to the challenge of falsified medicines.

Amongst the responses received the common theme was an emphasis on intensifying regulatory efforts that clamp down on falsified medicines. NAFDAC the pharmaceutical regulator was frequently mentioned in the responses, MAS, and other authentication technologies were called for. All responses related to the regulator NAFDAC was not all about prosecution of those promoting falsified medicines, some respondents encouraged re-education of promoters involved in the harmful act of the dangers their actions pose to the society's health and educating patients on how to identify and avoid falsified medicines. Another popular response was for medicines to always be dispensed in their original primary packaging and make it illegal to do so. this way it would be possible for every customer to validate the authenticity of medicines they were consuming.

Some responses clamored for better collaborations between law enforcement agencies and regulators to penalize anyone found guilty and improve communication channels for patients to be able to report cases of suspected falsified medicines they may encounter. Also, some recommendations bothered on ways of securing the supply chain through closure of open market sales of medicines and encouraging the practice of sourcing medicines for hospitals from appropriate sources. to do this one respondent advised for integration of technology that helps track stock movement from manufacturers to end users.

Finally, another common suggestion was the quality control practices employed by the regulators before issuing NAFDAC reg no to products. they advise for efficient post-marketing surveys to routinely monitor the circulating stock of approved medicines.

4.5.2. Contacting the authorities - Question 16

In contributing to pharmacovigilance regarding the reporting of falsified medicines received when filling prescriptions respondents were asked if they knew the right authority to report to when they encounter it. The responses were received and recorded which revealed that many participants claimed to report to NAFDAC regulators. To quote one of the responses received

"NAFDAC as a regulatory body is saddled with the responsibility of check mating the durability and effectiveness of a drug in its Potent or falsified state, and they receive reports from all Pharmaceutical bodies to monitor and limit these excesses."

However, a few of the respondents said they would escalate the report in a stepwise approach, firstly from the hospital authorities/management before reporting to the national regulators.

4.6. Conclusion

Based on the results gained from the quantitative analysis, findings and interpretation above, it is important to note that there are numerous factors that can impact the choice of prescription medicines in tertiary health facilities. The data also suggests that the participants who in this case are healthcare professionals are knowledgeable of the systems of identifying falsified medicines and are also willing to

report suspected cases. the study was able to establish that the participants are qualified to participate with sufficient work experience and can utilize their knowledge of medicine anti-falsification technology when filling prescriptions by looking out for any lack of verification features or insisting on receiving their medicines in original packaging.

NAFDAC is the national regulator of pharmaceutical products in Nigeria and majority of the respondents are aware of that and that serves as a guide to the respondents in the identification of falsified medicines. However, on the issue of recommendation to improve the distribution of only safe and effective medicines, many of the respondents believe that they have failed in fulfilling their responsibility. they suggest better awareness creation to increase the adoption of MAS, excellent quality assessment of products receiving approval, stronger enforcement of laws that punish offenders and finally encourage a culture of post-marketing surveillance that will sustain quality.

This study also reveals that when pharmacotherapy fails following the use of prescription medicines, a large section of respondents believes the medicine is falsified and some would prefer to notify their prescriber about it rather than report it to the regulators. this is believed to stem from the culture of poor pharmacovigilance practice. it has also been established that there is a firm relationship between the knowledge of medicine anti-falsification technology and the preference to receive prescriptions in their original packaging, choices that will be made if that original packaging lacks any authenticating features, and finally the suspicion that the medicine is falsified when therapy fails. This and more will be discussed in accordance with the research objectives and a contrast with the literature review in the concluding chapter 5.

5.0 Chapter Five – Conclusion

5.1. Introduction to chapter

The above study looked at how medicine anti-falsification technology has changed the landscape of the pharmaceutical sector with significant economical and clinical outcomes. Patients are no longer at the mercy of the words of affirmation of their dispensary and can now verify their prescription medicines authenticity with their mobile devices from anywhere in the world.

The study's definition was focused on the belief that medicine anti-falsification technology and increasingly available drug information has impacted the sale of prescription medicines in Nigeria by influencing how patients make their choice on brands or generics. Also, an insight into patients' outlook with regards their role in the struggle against the proliferation of falsified medicines.

5.1. Answering the main research questions

Question 1. Do patients inquire about the authenticity of medicines or seek drug information at the point of sale?

From the data and responses gathered in the survey from experienced medical professionals, the shared level of awareness and lack of knowledge of medicine anti-falsification technology amongst the participants as assessed in question 7 is almost equal. This is a good result because it highlighted the progressive work physicians and pharmacy staff are doing to educate patients and guide patients on how to identify falsified medicines at the point of sale. The shared responses were between the "No", "Yes" and their variables which identifies the specific sources the knowledge of medicine anti-falsification technology may have come from. This assessment is important because medicine adverse effects are a critical part of pharmacotherapy. Inotherwords, patients knowing how their medicines work helps them know what to expect while taking their medicines and how to avoid dangerous drug-drug interactions, drug-food interactions in multi-drug therapy.

By asking their pharmacist while filling their prescriptions as assessed in Question 11, we can see that questions ranging from safety to quality, and authentication by MAS are asked by the respondents and this further reinforces the understanding that patients are taking responsibility for their safe medicine use. Also, concerns about authenticity are most of the time settled by patients requesting for a known brand or generic that they trust and reluctant to try new products, this is another reason why authenticating features should be well popularized to the public so that if falsified medicine traffickers infiltrate the supply chain with products that look like the known brands, the patients will still proceed with caution and authenticate using MAS.

Therefore, it can be deduced that patients while filling prescriptions in their health facility always inquire about MAS, NAFDAC reg no, potential side effects and availability of generic cheaper alternatives or a combination of all four questions.

Question 2. When patients utilize the medicine authentication methods they are aware of, how does it affect their choices?

This research question is a crucial part of the research topic and was answered across three questions in the survey conducted. Participants were assessed to know their knowledge of medicine anti-falsification technology, how they would choose medicines if the drug product lacks feature for verification, and their attitude towards the medicines when it does not treat the ailment completely. The comparison between

these three questions are available in Table 4, 5 and 6 in Section 4.3.6. As mentioned earlier, there is a balance in the number of participants who know about medicine anti-falsification technology and those who do not. Table 4 shows that more participants who do not have any knowledge about it and those who insist on using known brands will are most likely to insist on receiving their medicines in its original packaging in the same way as participants who were informed of it from their physician, pharmacist or pharmacy staff. There is no significant difference between both groups in this regard.

In another comparison in Table 5, the data shows that when the prescription medicine lacks verification features, respondents who do not have any knowledge of medicine anti-falsification technology will most certainly request for a known brand or generic as opposed to the group of respondents who are knowledgeable as they would prefer to request for a known brand or generic and seek reassurance on quality from the physician or pharmacist/pharmacy staff.

The final comparison in Table 6 shows that when the prescribed medicine is not effective, patients who are not knowledgeable and do not bother about knowing are 59% less likely to suspect that it is a falsified medicine, while those who are knowledgeable of medicine anti-falsification technology are most likely to suspect it's a falsified medicine. This narrative is further solidified by the data saying that the lack of knowledge makes the respondents more willing to try a different brand or generic or inform their prescriber about therapy failure. When compared to the informed group we can see that those who learned from their pharmacist/pharmacy staff are 47.6% less likely to try a different brand/generic and equally likely to inform their prescriber in the same frequency as those who are not informed about medicine anti-falsification technology.

Therefore, it can be rightly said that the knowledge of medicine anti-falsification technology and the quality of interaction between patients and their prescribers or dispensary staff can influence patient choice of prescription medicines.

Question 3. Are patients informed and willing contributors to pharmacovigilance in their facility?

It has been identified that the respondents are aware of the criteria/features used to identify falsified medicines and it's been established that they are willing to utilize them. This research question was assessed across a few survey questions; Figure 17 shows that 56% of the respondents trust the quality of medicines sold in their facility at a trust level of 50% and above. This significant amount of trust could be related to the fact that 98% of the respondents will report to the authorities whenever they encounter falsified medicines when filling their prescriptions. When further investigated, the data also shows that the respondents will often report the suspected cases to their physicians, their pharmacists, then the hospital authorities before escalating it to the National regulators NAFDAC. This is an interesting detail that could improve the fight against falsified medicines in the public health sector as patients are encouraged to speak up about medicine related observations.

5.2. Comparing the Primary and Secondary Research

The cost of healthcare provision in Nigeria would be drastically reduced by improving identification and reporting of falsified drugs in Nigeria, which would also lower the frequency of ADR's and death caused by the consumption of falsified medicines. This study's finding that the increased awareness of falsified medicines is needed is consistent with findings from earlier studies. To increase awareness, the current laws need to be improved on and penalties for infringing them tightened, as well as identifying gaps that could limit implementation and filling them to catch up to other developed nations,

then integrating learning programs that reeducate healthcare professionals on latest tactics used by falsified medicine traffickers (Okereke, Anukwu, *et al.*, 2021). Most respondents in this study confirmed that they are knowledgeable and utilize a few or all the medicine anti-falsification technology and features available to the public when filling prescriptions. This is in the same direction as the literature review and an improvement on the finding in the earlier study. The cited article says that 45% of the participants were likely to engage in pharmacovigilance reports, while in comparison to this study's data that shows a 98% willingness to participate in pharmacovigilance and report suspected falsified medicines to the authorities (Ogundele *et al.*, 2012). Also, a similar pharmacovigilance study in the literature review highlighted the massive improvement in the pharmacovigilance reports by healthcare professionals when educational interventions were done in the study site. This is like the recommendations made by this study's respondents when asked in question 14 on recommendations to curb the spread of falsified medicines. They reverberated the importance of educating the public on how to avoid and identify falsified medicines using existing technology like MAS (Olowofela, 2018).

Another related study on the utilization of MAS in the literature review pointed out that the respondents in that survey opted to verify medicines by their label and package feature rather than use the MAS, and that is a similarity in this study. This study's data showed that the NAFDAC number was the most commonly used feature for authenticating medicines and was 3 times more likely to be used than the MAS as seen in figure 15a and 15b (Iloh *et al.*, 2021).

5.3. Recommendations and Limits of the study.

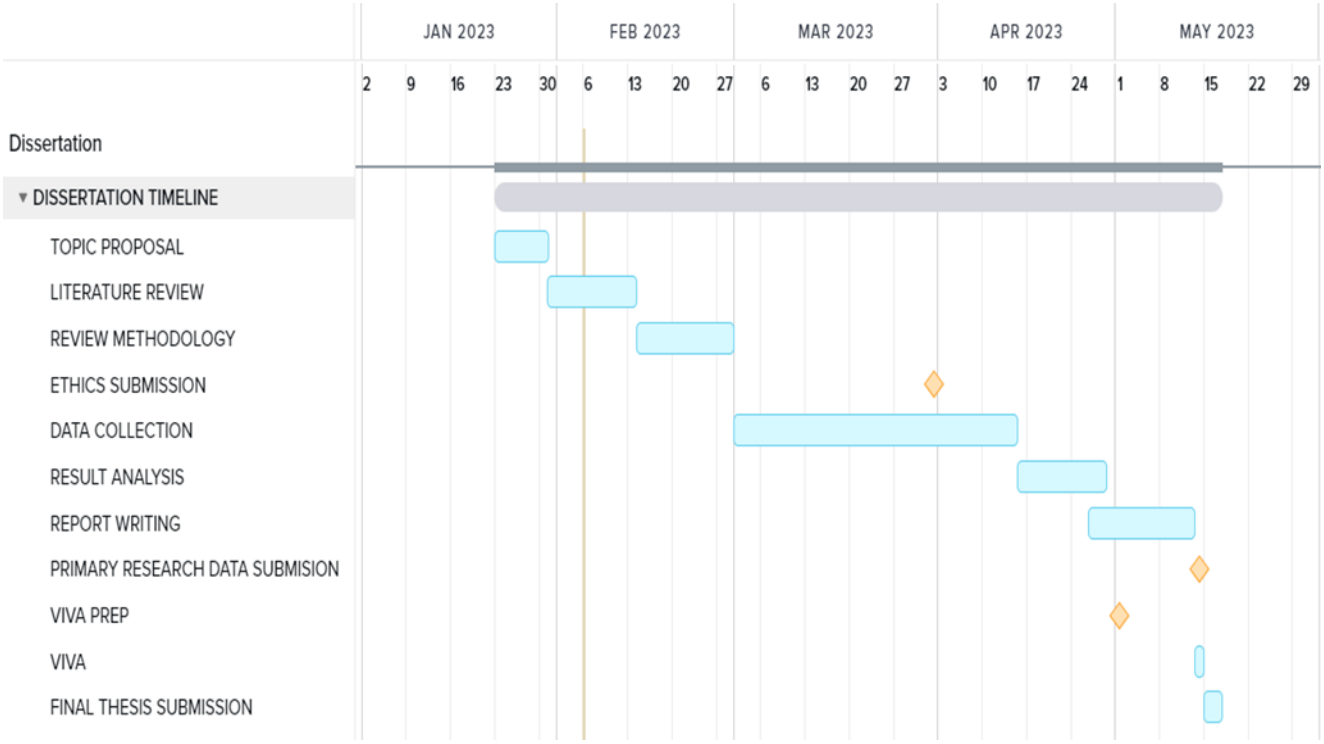

Figure 19: Gantt chart showing study timeline

The study was completed in 110 days and feedbacks were received from 115 respondents who participated in the study using the questionnaire across 4 geopolitical zones of Nigeria. The cumulative

data was retrieved from the google form for each of the four teaching hospitals and exported into an excel sheet where it was collated for further analysis. The quantitative data was presented in bar graphs, pie charts and column graphs and the qualitative data was discussed from an interpretivism philosophy. Comparisons were done using the key variables that best describe the key objectives of the study.

Limitations: A major limitation to this study was the unwillingness of the healthcare participants practicing in the site of this study to fill out the survey. This could partly be blamed on the national elections ongoing in the state and fiscal and economic challenges the respondents were dealing with during the timeline of this study. Another factor which is the fear of exposure their responses to the hospital authorities, however, these fears were resolved when reassurance of anonymity was given to the respondents and the importance of this survey to the design of more effective regulations against falsified and substandard medicines.

Recommendations for Regulators: Having established that medicine anti-falsification technology can impact the choices of patients when filling prescriptions, the attention of this research leads this study to build on the recommendations of the respondents that there is a need to improve the national regulatory presence in the field. The adoption of technology such as the MAS for on-the-point verification of medicines, medicine serialization and verification technology to track medicines through the supply chain, and a library database to record information on confirmed cases of falsified medicines accessible to the public. Also, public knowledge of the NAFDAC registration number as a way of identifying original medicines is a grand step, but the education of the public using national orientation agencies would further expand the range of that knowledge and also put patients in a better position to identify falsified medicines. By mandating manufacturers to put unique identifiers on their drug products as a way of exposing falsified products. Finally, a recommendation for the regulators to strive to restrict the use of prescription medicines only under the guidance of a valid prescription from a qualified prescriber will further improve the quality of pharmacovigilance reports on ADR's and failed pharmacotherapy.

Recommendations for Respondents: The respondents are encouraged to imbibe the culture of verifying each pack of prescription medicines using the MAS despite time constraints. This will always assist the service providers to track original stock movement and intercept falsified medicines in supply before they are consumed by patients. Also, receiving medicines in their primary packaging is a safe practice that should be encouraged at the point of care because there is a lesser risk of receiving the wrong medication and unexpected adverse drug reactions can be easily traced to the batch and investigated. Finally, reporting positive and negative experience with prescriptions to pharmacists and prescribers is good for improving the quality of healthcare available to Nigerians.

5.4. Future Research Recommendations in Nigeria

A future study to assess the success of a nationwide campaign designed to sensitize the public on how to identify and report falsified medicines. This study could utilize communication channels like newspapers, radio, social media, billboards and SMS. After the campaign ends a survey could then be conducted to receive feedback on best solutions to mitigate the falsified medicines problem.

Also, another research could be done to critically assess the existing way of marketing drugs outside medical and ethical supervision (prescriptions) through open market distribution of medicines by patent medicine vendors. The study would track patient pharmacovigilance reports generated after the patronage of these patent medicine vendors and could provide much needed data to help regulators drive

new laws to regulate the sector and thus make it an illegal way of handling medicine. This would be the gray area where substandard/falsified medicines meet the law.

Finally, a research to assess the adoption of medicine authentication technology on other classes of medicines, going beyond antimalarials and antibiotics to include medicines used for treating long term illnesses and measure the impact it would have on securing the supply chain while looking out for an increase or decrease in the incidence of identified/reported falsified medicines.

5.5. Final conclusions

In the conclusion of this study that assessed the impact of medicine anti-falsification technology on patient choice of prescription medicines in four teaching hospitals in Nigeria, all the participants in this study confirmed that there is a strong relationship between knowing how to identify falsified medicines, receiving prescription medicines in their original packaging and reporting therapy failure to the health authorities. The importance of educating consumers was repeated severally throughout this study in the literature review and the feedback collation for this study. The data also showed that patients were more likely to report cases of suspected falsified medicines to their prescriber than the regulatory authorities, therefore designing a system to retrieve this data from prescribers, pharmacists and the patients themselves outside the tradition ADR report form could be a game changer.

There is also a lot more required from the regulators to maximize the adoption of information technology innovations introduced for drug safety by regularly performing post-marketing surveillance and using mobile quality control labs for on the spot testing of samples. This strategy is essential because some trafficker may just print any random no on a product package and call it NAFDAC no because they know very well that patients will not be able to verify if it is truly registered.

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Appendices

Appendix 1

Ethics Application & Declaration Form

DISSERTATION TITLE: ASSESSING THE IMPACT OF ANTI-FALSIFICATION TECHNOLOGY ON CONSUMER CHOICE OF PRESCRIPTION MEDICINES IN FOUR TEACHING HOSPITALS IN NIGERIA

RESEARCHER'S NAME: ANONYE YAGAZIE OKECHUKWU

PROGRAMME OF STUDY: MSC PHARMACEUTICAL BUSINESS & TECHNOLOGY

SUPERVISOR'S NAME: CHIEDOZIE CHIAMAKA

DECLARATION:
The information in this application form is accurate to the best of my knowledge. I undertake to abide by the principles outlined by Innopharma/Griffith College ethics policy in my research dissertation. I confirm that I have completed a full ethics assessment for my research dissertation as per the college guidelines. I will not begin my primary research until such approval from my supervisor and/or ethics Committee has been obtained.
I pledge to carry out my research according to the Innopharma/Griffith College academic integrity standards. Any results presented in my dissertation will be from my own, original research, I will reference and/or acknowledge any material or sources used in its preparation and I will not plagiarise the work of anyone else.

For Student:
STUDENT SIGNATURE: ANONYE YAGAZIE

DATE: 20/02/2023

The research contained within this research dissertation proposal has been approved.

For Supervisor:
Ethics Committee Approval Required: Yes ☐ No ☑

SUPERVISOR SIGNATURE: CHIAMAKA N CHIEDOZIE

DATE: 08/03/2023

For Ethics Committee (if required):
Ethics Committee Approval Given: Yes ☐ No ☐

ETHICS COMMITTEE MEMBER SIGNATURE:

DATE:

Appendix 2

Survey Questions

Question 1

ASSESSING THE IMPACT OF ANTI-FALSIFICATION TECHNOLOGY ON PATIENT CHOICE OF PRESCRIPTION MEDICINES IN UNIVERSITY OF UYO TEACHING HOSPITALS, UYO, AKWA IBOM NIGERIA.

Question 2

ASSESSING THE IMPACT OF ANTI-FALSIFICATION TECHNOLOGY ON PATIENT CHOICE OF PRESCRIPTION MEDICINES IN UNIVERSITY OF NIGERIA TEACHING HOSPITAL, ENUGU NIGERIA.

Question 3

ASSESSING THE IMPACT OF ANTI-FALSIFICATION TECHNOLOGY ON PATIENT CHOICE OF PRESCRIPTION MEDICINES IN UNIVERSITY OF BENIN TEACHING HOSPITAL, BENIN CITY, EDO STATE NIGERIA.

Question 4

ASSESSING THE IMPACT OF ANTI-FALSIFICATION TECHNOLOGY ON PATIENT CHOICE OF PRESCRIPTION MEDICINES IN FEDERAL MEDICAL CENTRE LOKOJA, KOGI NIGERIA.

Consent Statement

I would like to invite you to take part in this research study. However, I would like to give a brief description of the study, why the research is being done and what is required of you. Please take time to read the following information carefully and ask questions for more clarification.

This research is designed to show the impact of anti-falsification technology on patient choice of prescription medications in four tertiary health facilities across Nigeria. The spread of falsified medicines in the global and Nigerian market despite present regulations is a huge concern to the process of delivering quality healthcare services in Nigeria. Prescription medications are drugs that require medical supervision around their use and should only be obtained with a prescription from a qualified prescriber. Responses obtained from this survey will be very confidential. For more information, kindly reach out to me at yagazonline@gmail.com .

At the end of this research, all dissertation research projects and their content will be made accessible in the college library and could potentially be made available in online e-journals or repository.

1. Are you a medical Professional?

    - Yes
    - No

2. Which of this best describe you?

    - Pharmacist
    - Doctor/Dentist
    - Nurse Practitioner
    - Medical Laboratory Scientist
    - Radiographer
    - Optometrist

3. What is your period of practice?

    - 0 to 3 years
    - 4 to 10 years
    - 11 to 15 years
    - 16 years and above

4. Sex

    - Male
    - Female
    - Prefer not to say

5. Do you have any experience in purchase of prescription medicines at the hospital pharmacy?

    - Yes
    - No

6. How long have you been filling prescriptions at the hospital pharmacy?

    - 0 to 2 years
    - 3 to 4 years
    - 5 years and above

7. Do you have any previous knowledge about the anti-falsification technologies in place to detect falsified medicines?

    - No, I don't have any knowledge
    - No, I only use known brands, so I don't bother
    - Yes, from the physician
    - Yes, from the pharmacy staff on a previous visit to the pharmacy
    - Yes, both the pharmacist and physician
    - Others (Please specify)

8. Do you receive your medicines in its original primary packaging?

    - Yes, I insist
    - No, I prefer it removed
    - It does not matter
    - Never
    - Others (Please specify)

9. When filling your prescription, which of these anti-falsification measures do you employ?

    - Mobile Authentication Service (MAS) [scratch to reveal pin]
    - NAFDAC Registration Number
    - Labelling and printing graphics

- Physical appearance of drug pack

10. What would you do if the package lacks any features for verification?

    - Request for known drug brand/generic
    - Accept whatever generic available
    - Seek reassurance on quality

11. Which of the following are you likely to ask the pharmacist before filing your prescription?

    - What is the dosage?
    - Is the drug product registered with NAFDAC?
    - What side effects or risks should I know about this prescription medicine?
    - May I verify the drug by using the mobile authentication service?
    - Is there a cheaper generic alternative?
    - All
    - None

12. Which of the following do you think is the most important factor that proves authenticity of a drug product? (select one or more)

    - NAFDAC registration number
    - Presence of authenticating features e.g. sealed packaging, insignias
    - Trusted manufacturer
    - Trusted brands
    - Presence of medicine authentication number/pin
    - Trusted supplier/marketer
    - Popularity and drug acceptance
    - Assurance from dispensing pharmacist
    - Assurance from prescriber

13. When the prescribed medicine is not effective do you suspect it's a falsified medicine?

    - Yes, I do
    - No, I inform my prescriber
    - I try a different brand/generic
    - I notify the health authorities (NAFDAC)

14. What policy suggestion could limit the spread of falsified medicines?

15. Do you trust the quality of medicines available to patients in your hospital facility? If yes, what percentage best describes your confidence level?

- 100%
- 75%
- 50%
- 25%

16. Do you know the right authority to report to when you encounter falsified medicines?

17. Will you report to the right authorities when you encounter falsified medicines?

- Yes
- No
- May be

Appendix 3

Question 14 – Cumulative responses

- Jail sentence for defaulters
- NAFDAC quality control scheme
- POM should only be dispensed by a pharmacist
- Inspection by NAFDAC
- Mobile Authentication services
- Having authentication number
- Other
- Better awareness
- Constant supervision by organized body
- The manufacturer that introduce these falsified drugs are out there, I believe if the organizations in charge of drug monitoring can go to them, educate them better on the effect of their actions to human lives and the penalty of their actions.
- Ensuring all specified drugs are NAFDAC Registered, with the Manufacturer label and Pin, and phone contacts for effective communications on drugs on who don't follow the required guidelines
- Nafdac registration number
- Introduction of more sophisticated systems to prevent falsification
- Nafdac number authenticator
- An indent monitoring
- No idea
- Better awareness
- Only nafdac registered medications should be allowed
- Set up a strict governing body
- Having a body consisting of professional pharmaceutical agents, (could be a 5-man body) to check the constituents of the active substances used In producing drugs, before it's been produced and taken into the market for consumption by patients and clients.
- Working with regulatory, industry Organizations, International agencies such as WHO, and law enforcement (e.g. Interpol) to identify and combat fakes.
- Authentication pin
- Having the drugs been approved by NAFDAC
- The NAFDAC body should ensure all the drugs sold in the pharmacy are properly registered and drugs should only be dispensed according to prescriptions
- All prescribed medications should be filled with the original packet. The patient should always verify the NAFDAC number and authentication pin before accepting prescribed medications.
- Prioritizing Educating consumer.
- If consumers of these drugs are well educated on how to Identify falsified drugs, where to report, the dangers of falsified drugs. It will help restrict the manufacturers of these drugs.
- Intensive monitoring
- Proper monitoring
- Presence of authenticating features

- Total removal of touts from drugs handling
- Always verify the brand
- should only be dispensed according to prescriptions
- The national agency for food and drugs, administration and control should do their job
- Proper Nafdac regulation
- Punitive measures for defaulters
- Convict offenders
- Drug sale restrictions to licenced pharmacist only
- NAFDAC should ensure proper investigation before letting a product into the market space
- Mandatory Quality control and assurance routine check for every Hospital purchased medicine.
- Quality control unit in every Health facility
- Proper medicines regulations
- Accurate implementation by law enforcement agencies
- Empowerment of the Pharmacists body
- Sanctions and penalties for those found failing to comply
- Better awareness
- Long term jail for anyone guilty of that
- Best Policy to limit falsified spread of Medicine is to ensure all drugs coming from the Manufacturer has a tracker with a verified pin as tag to help consumers differentiate the right from the falsified drugs
- Nafdac seal
- Ensure that only authentic drugs, with Nafdac numbers, MAC scratch pin are made available into the hospital
- Authentication tokens/numbers/QR codes that can be easily scanned by the end user to confirm proof of quality
- Closure of open drug markets, sourcing from appropriate sources
- Stop parallel import, ensure quality assurance tests are carried out on all imported medicines, ensure all manufacturing plants are W.H.O certified
- Procuring from the right source
- Public awareness of drug authenticity by NAFDAC
- NAFDAC intensified surveillance
- QC lab within the hospital facility
- Routine check by authorities
- Quality assurance test
- A special body should be established apart from Nafdac that will majorly specialize in verification of drugs in the hospitals, community Pharmacy and other drugs outlet.
- Use of MAS, Registration with NAFDAC
- Physicians and prescribers should prescribe the medicines they know is good and not just they have gotten tip from a marketer of a particular product.
- Mobile codes
- Ensuring that all drug products Carry mobile authentication number
- Purchasing directly from the company
- Direct Purchase from Pharmaceutical Companies could limit falsified Medicine

- There should be Nafdac no of each prescribed medication
- Nafdac
- Using barcode to get validation
- Our regulations bodies should ensure quality control measures are taken before drugs enter the market
- NAfdac regulating all medications coming into the market
- Buying drugs directly from pharmaceutical companies.
- Only licensed individuals should be responsible for drug importation and prescribing
- Better awareness
- Simple authentication systems
- One of the policies to implement is to Install track and trace systems across board which will help provide clean and well-regulated supply chains. These systems can help provide situation reports in real time which could help authorities analyze and provide solutions immediately.
- Nafdac no
- Restriction of drug production to registered and government approved pharmaceutical companies.
- Public enlightenment and implementation of instant laws
- Nafdac to inspect all drugs released into the market

Appendix 4

Question 16 – Cumulative responses

No

YES

NAFDAC

Nafdac

NAFDAC

Yes, NAFDAC

No I don't

Yes NAFDAC Authority

Yes I do.

Yes

NAFDAC

Nafdac

No

NO

NDLE

Yes, something is written on the body of the drug

NAFDAC and FDA

NDlEA

NAFDAC

NDLEA

YES

Yes

No

NAFDAC

Nafdac

Nafdac

The hospital authority

Yes. NAFDAC

Yes

The Nigeria National Agency For Food and Drug Administration and Control (NAFDAC)

Yes

NAFDAC

No

NAFDAC

Nafdac

yes

Not sure. Probably NAFDAC

The hospital management first

no

Pharmacovigilance

Probably NAFDAC

Nafdac or NDLEA

Yes, NAFDAC

Yes.

Yes NAFDAC as a regulatory body is saddled with the responsibility of check mating the durability and effectiveness of a drug in its Potent or falsified state, and they receive reports from all Pharmaceutical bodies to monitor and limit these excesses.

Nafdac

Nafdac, NDLEA