Griffith College

AN EVALUATION OF THE CONTRIBUTING FACTORS TO THE PREVALENCE OF FALSIFIED MEDICINES IN NIGERIA: FINDINGS AND RECOMMENDATIONS FOR PUBLIC HEALTH

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Research dissertation presented in partial fulfilment of the requirements for the degree of MSc in Pharmaceutical Business and Technology (QQI)

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DECLARATION

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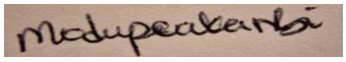
I certify that the dissertation entitled: "**AN EVALUATION OF THE CONTRIBUTING FACTORS TO THE PREVALENCE OF FALSIFIED MEDICINES IN NIGERIA: FINDINGS AND RECOMMENDATIONS FOR PUBLIC HEALTH***"* submitted for MSc to the Department of Pharmaceutical Business and Technology, Griffith College Dublin is the result of my own work and that where reference is made to the work of others, due acknowledgment is given.

Candidate's Signature: 

Date: 13- May-2023

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ABSTRACT

Falsified medicines are pharmaceutical products purposefully and unlawfully produced or mislabelled in terms of identity and source to appear genuine to unsuspecting victims. They pose a significant public health risk in Africa. In Nigeria, falsified medicines have negatively affected the reliability of the health sector. They cause incurable diseases, illness, and even death for consumers. Evidence regarding the contributing factors to the prevalence of falsified medicines in Nigeria is diverse and inconclusive. This study seeks to find out the contributing factors to the prevalence of falsified medicines in Nigeria. Interpretivism, induction and exploration were the research methodology that guided the study. Qualitative research method was adopted for data collection and analysis to elicit context and data rich information from the qualitative data. Eight public health professionals were recruited through purposive sampling from five regulatory/health institutions in Nigeria. Nineteen sub-themes further distilled into four overriding themes emerged to address the research questions, namely: systemic challenges; multidimensional risks; inadequate and weak measures; and systemic change. The study corroborates a significant body of the literature which identifies factors causing the prevalence of falsified medicines in Nigeria. It also validates existing research which identifies public health risks, industry health risks, economic health risks and government revenue risks as direct and tangential impacts of falsified medicines on public health. It finds that the current measures are weak and inadequate and recommends solutions which can engender systemic change in the pharmaceutical ecosystem in Nigeria. These include overhauling of the existing regulatory and enforcement mechanisms; entrenching good politics, socio-economic improvement of the conditions of Nigerians; and effective monitoring and surveillance of the pharmaceutical supply chain. These contributions add to existing knowledge and the literature and identifies the need for the Nigerian government to show more leadership, improve the welfare of majority of Nigerians who are poor, and deploy subsidies and interventions (such as health insurance scheme) to make more access available to poor Nigerians to get quality, safe and affordable drugs which can treat their health conditions and enhance their well-being.

Keywords: Prevalence of Falsified Medicines, Contributing Factors, Multidimensional Risks, National Agency for Food and Drug Administration and Control (NAFDAC), Systemic Challenges, Systemic Change, Public Health, Nigeria

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AMR - Antimicrobial Resistance

API - Active Pharmaceutical Ingredients

AQ - Antimalarial Q

FMOH - Federal Ministry of Health

FDA - Food and Drug Administration

FMIP- Falsified Medicines Identification Process

LMICs – Low and Medium Income Countries'

GMP- Good Manufacturing Practise

GPHF- Global Pharma Health Fund

MAS- Mobile Authentication Service

NAFDAC- National Agency for Food and Drug Administration and Control

NMA- Nigeria Medical Association

NDLEA-National Drug Law Enforcement Agency

PSN - Pharmaceutical Society of Nigeria

SSA- Sub-Saharan Africa: SSA

WHO - World Health Organization

CHAPTER ONE: INTRODUCTION

1.1 Overview

Counterfeit medicine is on the increase all over the world, it is a major issue in both developing and advanced countries. Substandard medicines raise costs for both patients and the healthcare system. An estimate from early 2000 discovered that 10% of prescribed drugs sold in the United States are falsified, while the statistic exceeds 50% in some parts of Africa and Asia (McManus and Naughton, 2020). Substandard medicines raise costs for both patients and the healthcare system. Some of these costs, such as wasting so much money on poor-quality therapies and trying to treat other complications, are incurred mainly by consumers and medical facilities. Counterfeit medicines can get onto the market through

fairly poor production of genuine drugs from lack of quality assurance through manufacturing and deliberate illegal activities. Policies have previously concentrated on curbing fraudulently falsified drugs, but some low-quality medicines that went through unverified regulatory procedures, are more common and harmful to public health. (Danraka, 2022).

1.2 Substandard Medicines - A Threat to the Public Health of the Future Generation

Falsified medicines are products that are purposefully and unlawfully produced or mislabelled in terms of identity and source to appear genuine(Erhun *et al.*, 2013). Counterfeit medications are thus passed off as genuine products to the unsuspecting victims due to the fact that their source and composition are forged and mislabelled, thereby endangering the public's health and resulting in negative drug outcomes. Substandard and fake medicines pose a significant public health risk in Africa. The World Health Organization (WHO) estimates that over 280,000 children die each year in sub-Saharan African countries as a result of using substandard medicines to treat pneumonia and malaria. (Okereke et al. 2021) . The challenges of the spread of falsified medicines in Nigeria have negatively affected the reliability of the health sector, resulting in incurable diseases, illness, and even death for consumers. (Danraka, 2022). Some of the incidents have resulted in death, even among children, due to the fact that most consumers are unaware of the quality of what they are purchasing or taking. (Ozawa *et al.*, 2018a). Falsified medications can have a variety of negative effects on patients and the general public, including having no therapeutic effects at all, promoting the spread of disease, and occasionally containing toxic ingredients that could result in treatment failure. Also, because they are fake, they could promote drug resistance, thereby putting the future of the public health of the next generation in danger.

1.3 World Therapeutic Classification of Falsified Medicines

Substandard medicine is a global problem that also impacts society economically and financially. Falsified medications come in a variety of therapeutic classes, and are sold with the sole intention of misleading the consumer about their validity, and efficacy, and can have a variety of negative effects, such as treatment failure, toxic effects, and development of antibiotic resistance (Orubu *et al.*, 2020). Following a manufacturing site inspection, the European Medicines Agency (EMA) recalled an active pharmaceutical ingredient (API) produced in India. (McManus and Naughton, 2020). Also, in the United States, all products found at the New England Pharmacy facility in Framingham, Massachusetts, were recalled

following an outbreak of fungal meningitis that was connected to injectable steroids (McManus and Naughton, 2020). According to (Rahman *et al.*, 2018), analgesics, anti-depressants, tranquilizers, and medications for sexual problems are the most frequently falsified medications that cause harm to human health, both in developing and developed nations. Painkillers, antipyretics, and teething gel or cough syrup which consist of diethylene glycol, had a significant negative impact on consumers from developing countries. Furthermore, the figure below categorises the number of cases of therapeutically substandard medications in both developed and developing countries.

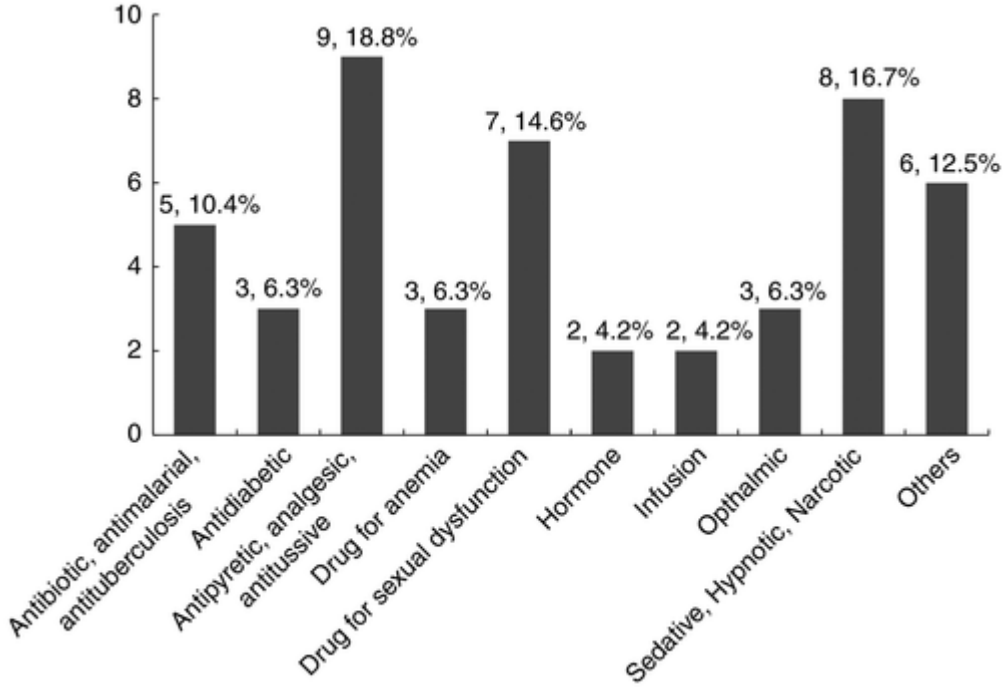


Fig 1: Therapeutic Category of Falsified Medicines (Rahman *et al.*, 2018)

1.4 Effects of Falsified Medicines in Sub- Saharan Africa

Substandard and fake medicines pose a significant public health risk in Africa. The World Health Organization (WHO) estimates that over 280,000 children die each year in Sub-Saharan African countries as a result of using substandard medicines to treat pneumonia and malaria. (Okereke et al. 2021) .The public healthcare system in Sub-Saharan Africa (SSA) continues to have significant flaws, making access to high-quality pharmaceuticals one of the region's greatest challenges.

Due to the lack of access to quality healthcare and medications in the majority of Sub-Saharan African (SSA) nations, consumers are depended upon drug sellers people selling fake

medications, mostly in rural areas (Ozawa *et al.*, 2018b). With a shortage of medical personnel, inadequate medical facilities, and severe financial constraints, there is still a risk that counterfeit drugs will continue to be a major cause of concern in Africa's healthcare systems. This is because of the estimate that more than 60% of people in SSA lack access to affordable, high-quality healthcare, including prescription drugs. The effects on the healthcare system have been devastating due to the rapid spread of fake medications in Africa, and the need to guarantee efficient verification has continued to draw attention on a global scale. Strong policy initiatives will be needed to stop the spread of counterfeit medicines in Africa which has the deaths of thousands of people yearly (Beargie *et al.*, 2019).

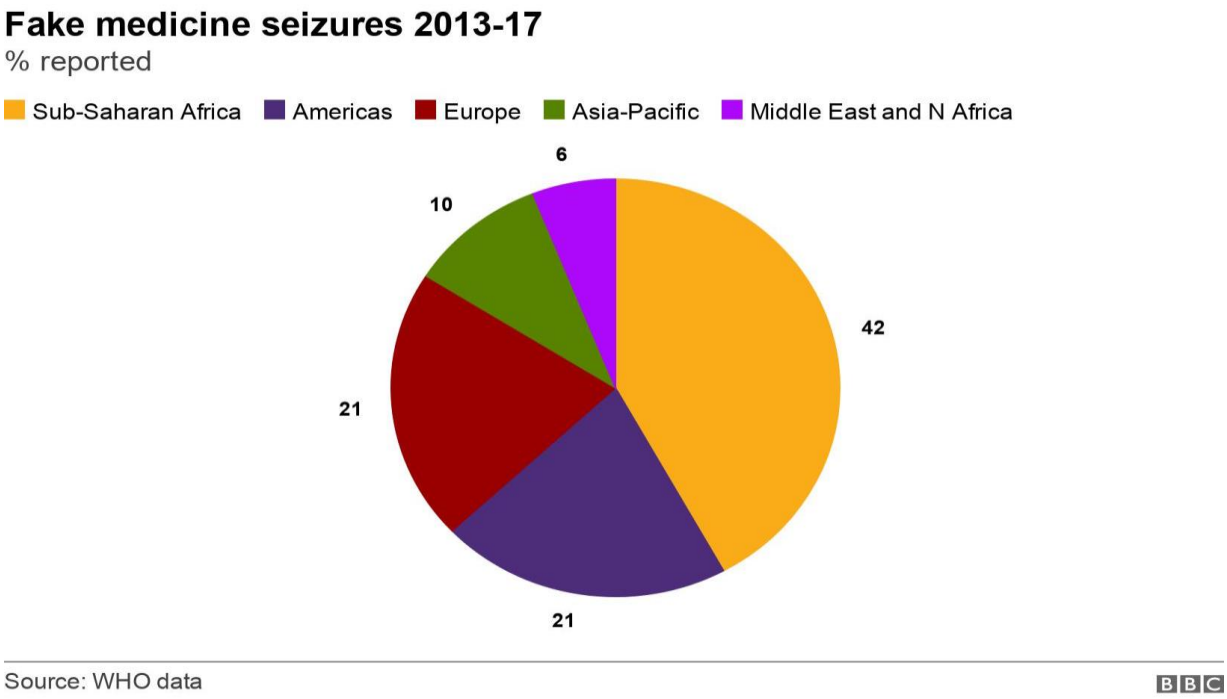


Fig 2:Percentage of falsified medicines in sub-Saharan Africa (Anon, 2020)

1.5 Nigeria's Current Situation with Regard to Falsified Medicine

The problem of falsified medicines in Nigeria is a significant public health challenge that has the potential to undermine the effectiveness of treatments and lead to serious health complications (Danraka, 2022). In Nigeria, Malaria is highly prevalent, thereby putting the entire population of over 200 million people at risk. Plasmodium falciparum is responsible for 99.7% of malaria deaths, with a high mortality rate (Beargie et al., 2019). Apart from the high prevalence of malaria, the standard of antimalarial treatments available in Nigeria has a

negative effect on the country's economy. Antimalarials are the most common substandard medications in Nigeria. A meta-analysis that was recently done found that 19.1% of all antimalarials tested were falsified.(Beargie et al., 2019) Fake medications are common in Nigeria due to inadequate drug control and little or no access to medicines in the health system.(Adigwe *et al.*, 2022) The situation is made worse further by the country's inadequate mortality and morbidity database (Adigwe *et al.*, 2022). Regardless of the fact that drug authorities performed important roles in limiting the spread of fake drugs from 40% to 17% between 2001 and 2005, the situation is still a major public health problem. The National Agency for Food and Drug Administration and Control (NAFDAC) was founded in 1993 to create a pharmaceutical environment that is free of falsified medicines by making sure there is an efficient registration of high-quality medicines (Orubu et al., 2020). NAFDAC is the main drug regulator and a Nigerian government agency that empowered to control and supervise the manufacture, export and import, sale, and use of medicines.

Prior to the creation of NAFDAC in 1993, counterfeit drugs had a significant and negative impact on individuals who innocently used them.(Pyzik and Abubakar, 2022). In 1947, for example, there were reports that fourteen children died after receiving chloroquine phosphate injections, and 109 children's death were reported in 1990 after receiving counterfeit paracetamol (Erhun *et al.*, 2013). During an epidemic in Niger in 1995, Nigeria supplied 88,000 Pasteur Merieux and SmithKline Beecham meningitis vaccines resulting in approximately 2,500 lives lost after vaccination. It was also reported in 2004 that three hospitals in Nigeria confirmed incidents of severe reactions caused by the ingestion of unsafe infusions manufactured by four Nigerian companies. The infusions were found to be strongly infected with microorganisms, and out of 149 brands of tested water for injection, 147 brands were contaminated (Erhun *et al.*, 2013). In addition, in November 2008, there were reports of death of 34 children from Nigeria between the ages of 4 months and 3 years; over 50 of these children were admitted to hospital with acute kidney damage after being given the medication "My Pikin," a teething mixture which contains paracetamol. The epidemic was caused by the use of diethylene glycol (DEG) as a paracetamol solvent. DEG was found as a result of an intentional replacement of propylene glycol which is a less toxic compound than DEG. Moreover, (Danraka, 2022) opined that despite the efforts of regulatory bodies such as (NAFDAC) to control the problem of falsified medicines in Nigeria, the problem persists. A more comprehensive approach is needed, including stronger collaboration

between regulatory bodies, the pharmaceutical industry and the public, as well as better education and awareness on the issue among the general public.

Fig 3: An Open drug Market in Nigeria (David, 2018)

1.6 Purpose of Research

The Nigerian public healthcare system faces a serious threat from counterfeit medicines due to a lack of access to safe, high-quality medicines. Counterfeit pharmaceuticals are still widely produced and distributed in Nigeria's rural and urban communities, where access to good, affordable public healthcare services remains a significant obstacle (Aki 201). Therefore, it is crucial to increase Nigerians' access to reliable, high-quality healthcare. In order to address the country's rising and pervasive incidence of fake medicines, a new strategy must be adopted. Therefore, in solving the problem of falsified medicines in Nigeria, a multifaceted approach is needed that addresses all of these contributing factors. Specifically, more research is needed on the factors contributing to substandard drugs.

The necessity of a research project that can produce results with both theoretical and practical values will enhance the identification of the major factors that contribute to the prevalence of counterfeit medicines. The main purpose of this research is to evaluate the current measures that have been taken to combat the spread of counterfeit medicines and propose new solutions to improve the regulation and enforcement of laws. The overarching goal of this study is to address the aforementioned and offer approaches or mechanisms that can significantly improve the confidence of patients or consumers in Nigeria's public healthcare system.

1.7 The Study's Significance

This study will be useful for both theoretical and practical applications as well as provide a basis for future research. Thus, this study will be important in the following ways: It will create awareness of the potential danger of counterfeit medications in Nigeria's public healthcare system and highlight the reasons why unified efforts are required to strengthen the regulatory environment.

It has the potential to produce results that public health officials can use to investigate new ways to improve on the usual strategies being adopted to stop the manufacture, processing, and distribution, of counterfeit medications in Nigeria. It will offer genuine insights into how Nigeria's rural population, which carries a large portion of the burdens associated with falsified medicines, can be successfully prevent the prevalence of counterfeit medications.

It will raise awareness of some important issues, particularly at the grassroots level, such as the negative effects of ingesting counterfeit medications, including, drug poisoning, and fatalities; social repercussions, including supply chain corruption and potential terrorist funding; and economic effects, and high treatment costs incurred by patients and consumers.

1.8 Aim and Objectives of Research

This study's aim is to investigate and analyse the factors contributing to the prevalence of falsified medicines in Nigeria's pervasive culture of falsified medications by interviewing public health experts on measures needed to combat falsified medicines.

The main objectives of the research are as follows:

i. To identify the factors contributing to the prevalence of falsified medicines in Nigeria.

ii. To investigate the impact of falsified medicines on public health in Nigeria.
iii. To evaluate the effectiveness of current measures used to combat the spread of falsified medicines in Nigeria.
iv. To examine the likely solutions that can improve existing regulations and enforcement.

1.9 Research Questions

The research questions that the present study will be seeking answers for are as follows:

i. What are the factors contributing to the prevalence of falsified medicines in Nigeria?
ii. What is the impact of falsified medicines on public health in Nigeria?
iii. What is the effectiveness of current measures used to combat the spread of falsified medicines in Nigeria?
iv. What are the likely solutions that can improve existing regulations and enforcement?

CHAPTER TWO: LITERATURE REVIEW

2.1 Overview

Poorer countries are affected by the production of falsified drugs, a public health challenge that is broad but underreported. It has led to a loss of public confidence in medicines and health structures and unnecessarily increased mortality and morbidity in many of these countries (WHO, 2017). Empirical findings in the literature suggest that more falsified than genuine drugs are being circulated in many low-income countries such as Nigeria (Akande-Sholabi and Adebisi, 2020; Aminu et al., 2017). Falsified medicines are a huge threat to the success of the Sustainable Development Goal 3 which seeks to achieve good health and well-being for all citizens of the world. As Shipalana et al. (2020) observe, the existence and proliferation of falsified medicines in many countries of the world means that reduction in infant mortality and improved maternal health may be difficult to achieve and diseases such as malaria, a severe public health problem in many parts of Africa, may persist. Speaking of Malaria, which is the cause of 11% of mortality cases and accounts for 30% of infant mortality in Nigeria alone, according to a WHO Global Surveillance and Monitoring System report, antimalarials and antibiotics which could have helped to ease the malaria disease burden in Nigeria are some of the most falsified drugs in the Nigerian pharmaceuticals market (Adigwe, 2020; Ekpenyong et al., 2018). This does not mean that high-income countries are immune from substandard and falsified medicines. In contrast, novel medicines such as steroids, hormones and supplements make up a large bucket of substandard and falsified medicines in high-income countries, while low-to-middle countries (LMICs) are targets of falsified and substandard antimicrobials which are vital for the treatment of life-threatening diseases such as tuberculosis, malaria and HIV-AIDS (Esposito, 2018). No single technique has been found to be capable of eliminating the public health threat posed by counterfeit pharmaceuticals due to the complexity of the problem. This literature review aims to understand the contributing factors to the prevalence of falsified medicines in Nigeria. Focus

will be on the definition of the concept “falsified medicines”, and the review of topics associated with the research topic.

2.2 The Concept of Falsified Medicines

Like most scientific terms or concepts, there is a diversity of opinions regarding what falsified medicines are depending on what institution or association is defining it, what each institution chooses to focus on and what country, region or jurisdiction is defining it. However, this does not suggest that the meaning of falsified medicines cannot be conceived as being substandard or unsafe drugs but this in itself will be simplistic if treated this way. To address the conundrum facing the right conceptualisation of falsified medicines, the World Health Organisation lumps falsified medicines within the category of ‘substandard/spurious/falsely-labelled/falsified/counterfeit’ (SSFFC) medicines (WHO, 2018). This new term SSFFC summarises what the international health body considers to be unsafe medicines. In other words, unsafe medicines are generally substandard, falsified and unregistered. To develop and advocate interventions to combat substandard and falsified medicines, the introduction of global standardised definitions can be considered a crucial step.

According to WHO, substandard medicines are authorised medical products produced by a known manufacturer with no intent to fool or defraud the patient but do not meet quality standards or specifications (WHO, 2020). When the technical capacity to enforce good manufacturing practices (GMP) and good distribution practices (GDP) is limited, substandard medicines enter the legitimate supply chain and get to consumers. On the other hand, falsified medicines are medical products whose identity and source are deliberately and fraudulently mislabelled (Nayyar et al., 2015). Unlike substandard medicines, falsified medicines are produced by an unknown manufacturer in unsanitary and unregulated conditions. Such medicines can contain dangerous contaminants and incorrect quantities of the active pharmaceutical ingredient (API) and inert ingredients.

Due to API degradation, substandard antimicrobials have a reduced antimicrobial potency, poor formulation (e.g. an antibiotic tetracycline is often found to be substandard owing to enhanced chemical degradation resulting from poor storage conditions in tropical climates) or

altered antimicrobial bio-availability (owing to excipient degradation) (Pisani et al., 2021). On the other hand, poisonous or toxic ingredients which are most commonly inert, containing ingredients such as chalk, flour or talc, have been found in falsified microbials (Wada et al., 2022). Ingredients in falsified microbials have been found to mask the clinical symptoms of infectious diseases. An example is a study which reports the detection of a falsified antimalarial (artemisinin), which only contained paracetamol (Oyetunde et al., 2019). The study states that patients administered with falsified artemisin may experience reduced fever, which is a short term symptom relief from paracetamol, but such delayed treatment may lead to the progression of the disease and death in some cases. This is why many affected jurisdictions with the presence of falsified microbials are experiencing the development of antimicrobial resistance (AMR) which is an outcome of administered falsified antimicrobial which only kills susceptible strains, reduces reproductive competition and allows more resistant strains to multiply (FIP, 2021). This shows that falsified medicines, just as substandard medicines, are unsafe for public health and have adverse consequences for the economy and society where they are prevalent. In this study, falsified medicines will be considered as unsafe medicines. This is the definition adopted by several other studies (IOM, 2013; Amankwah-Amoah, 2022; Tefera et al., 2022).

2.3 Falsified Medicines in Nigeria

Nigeria has been a country facing the prevalence of substandard and falsified medicines for many years. Although the National Agency for Food and Drug Administration and Control (NAFDAC) very recently reports that the percentage of substandard and falsified medicines to genuine drugs in circulation is declining to about 15% of the total supply of pharmaceuticals (Onyebuchi, 2022), this was not the case many years ago. For example, a regime of substandard drugs, unlicensed drug vendors, illegal pharmacy stores and hospitals reigned in Nigeria between 1985 and 2000 (Ubajaka, et al., 2016). This menace was not only prevalent in Nigeria, it was alarmingly a crisis situation in the whole of the West-African sub-region. There were speculations during those times that falsified and substandard drugs may

be more in circulation than genuine drugs (NAFDAC, 2011). Except in cases where it results in mass deaths, a worrisome aspect of the substandard and falsified drug hazard is that the effects of consuming such drugs go unnoticed. Mostly hidden in public health statistics, the effects of counterfeit drugs on patients are difficult to quantify since there does not appear to exist reliable data on the mortality and morbidity rates resulting from the consumption of these unsafe drugs in Nigeria (Ogbonna et al., 2015). It appears that the pharmaceutical industry and governmental agencies do not disclose most data on the epidemiology of unsafe drugs in Nigeria (Benjamin and Chidi, 2014). However, this is not peculiar to the pharmaceutical industry as reliable data on the workings and goings-on in many industries may not be in existence.

However, Nigeria has struggled to reduce the production and trafficking of counterfeit drugs without adequate infrastructure or political will to properly enforce legislation and standards over the past three decades (Ekeh and Adekoya, 2021). The public and the Pharmaceutical Society of Nigeria (PSN) mounted pressure on the Nigerian government to take incisive steps towards controlling the prevalence of counterfeit and substandard drugs in the country following the high trends of mortalities and morbidities that it caused among the population (Yakubu, 2020). The Counterfeit and Fake Drug (Miscellaneous Provisions) decree No. 21 of 1998 which prohibited the sale and distribution of counterfeit, adulterated, banned, and fake drugs or poisons in open markets and without a license of registration was promulgated by government. Furthermore, to help create a fake and substandard drug-free environment with the intent of ensuring effective registration of good quality drugs, NAFDAC was established in 1993 (Chinwendu, 2008). The agency underwent intense restructuring and reforms with the aim of revitalising NAFDAC's mandate to "safeguard the health of the nation" in 2001 under the charismatic and transformational leadership of Dr. Dora Akunyili as the new director-general of NAFDAC. As a result, the circulation of counterfeit drugs was reported to have been reduced by over 80% to what it was in 2001, while drug failure rates fell to roughly 16% in 2006 (Chukwuma, 2015). Counterfeit pharmaceuticals still remain prevalent despite NAFDAC's reported successes. Three Nigerian hospitals reported cases of adverse reactions from the use of contaminated infusions produced by four Nigerian companies in 2004 (Akunyili, 2010). It was established that 147 of the 149 brands of screened water for injection were found to be unsterile and the infusions were heavily contaminated with microorganisms. In November of 2008, after taking the drug "My Pikin" (meaning "my child" in local parlance), a teething mixture containing paracetamol, 34 Nigerian children, aged 4 months to

3 years died and more than 50 were hospitalised with severe kidney damage (Ogbonna et al., 2015). The outbreak was caused by the use of diethylene glycol (DEG) as a solvent for paracetamol which might be an inadvertent or deliberate substitution of propylene glycol, a less toxic compound than DEG (Nwankwo, 2020).

Several reforms have been witnessed in the pharmaceutical industry in Nigeria with the ongoing fight against the prevalence of substandard and falsified medicines in the country. This must have been why the NAFDAC claims in a recent report that the percentage of substandard medicines in Nigeria is about 15% of the total supply of pharmaceuticals in the country. This number is still high when compared to about 1% of substandard drugs in circulation in most developed countries (WHO, 2022). This is why the present study will be evaluating the contributing factors to the prevalence of falsified medicines in Nigeria from the perspectives of public health professionals serving as interviewees.

2.4 Factors contributing to the prevalence of falsified medicines in Nigeria

This section critically discusses the factors that have been published in the extant literature as contributors to the prevalence of falsified medicines in Nigeria. Some authors have identified the following factors as contributors to the prevalence of falsified medicines in Nigeria. These include ineffective enforcement of existing laws, high demand and erratic supply of drugs, involvement of non-professionals in pharmaceutical drug business, ineffective cooperation among different stakeholders, loose control systems, high cost of genuine drugs, high demand and erratic supply of drugs, illegal drug importation, weak regulatory systems, corruption, ignorance and greed (Akinyadenu, 2013; Hamilton et al., 2016; Alhedethe et al., 2017; Aminu and Gwarzo, 2017). These factors will be critically examined subsequently. But it is important to mention that there are different reasons for the emergence and prevalence of substandard and falsified medicines from region to region and country to country. This is due to the differences in the political, social, economic and cultural configurations of each jurisdiction (Bashir et al., 2020). Therefore, the reasons for the emergence and prevalence of substandard and falsified medicines in Nigeria may be different from those of other countries.

In the literature, there is a mention of the limited access to safe, affordable and quality medical products as a contributing factor to the prevalence of falsified medicines in Nigeria

(Aminu and Gwarzo, 2017; Akande-Sholabi and Adebisi, 2020). Nigeria presently has over 200 million human population. Therefore, it appears that one of the reasons for the prevalence of falsified or poorly made medical products in Nigeria is to fill the present void that exists in the country's pharmaceutical market. When people need or want medicines that they cannot obtain or afford, these falsified drugs fill such needs by selling lower than the proprietary versions which are expensive for many Nigerians. In a country that lacks sufficient insurance coverage by the national health system, and where people have to pay for their medications out of their own pockets, the price of a medical product becomes an important consideration for many patients and their families. People therefore may try a cheaper drug alternative, buy from an unlicensed supplier, or street market or over the Internet when or if a good quality medicine from a known supplier is too expensive. Thus, the first factor refers to the socio-economic conditions of the people. In Nigeria, which is reckoned as the poverty capital of the world, an embarrassing description of an oil-rich country but with millions of poor people, it appears that substandard and falsified drugs persist.

Another factor gleaned from the literature is the poor enforcement of regulations and pieces of legislation put in place to forestall the manufacture, distribution and consumption of falsified drugs in Nigeria (Ekpenyong et al., 2018; Adigwe, 2020). There is a persistent observation in many studies on this subject that there is lack of or poor enforcement of existing regulations against falsified drugs in Nigeria at all the levels of the supply chain. Some authors argue that it could be because there is a huge financial reward for medicine falsification, with profit comparable to narcotics trade, which lure some dangerous actors in Nigeria into the business at the expense of public health and safety (Eronmhonsele, 2015). However, unlike narcotic trade which carries heavy penalty in most jurisdictions of the world including Nigeria, the penalty for this kind of pharmaceutical crime is light. Likewise, the lack of international law and inconsistent definitions of this crime among different nations unfortunately make it difficult to extradite and prosecute falsifiers because medicine falsification has become an organised crime which is highly globalised (Ebenezer, 2015). A rigorous and unpredictable inspection regime and a competitive generics market will benefit consumers because an influx of generic medicines will likely reduce the circulation in falsified and substandard drugs when there is a system to assure consumers of the quality of such medicines (Ozawa et al., 2018a).

A vulnerable supply pharmaceutical drug chain is another factor. As Spink et al. (2018) observed, falsified and substandard medicines have infiltrated medicine supply chains in countries of all economic levels because their presence is not limited to countries with poor regulatory controls or weak pharmaceutical governance. Likewise, falsified medicines have also penetrated into the legitimate supply chain and flowed directly into hospitals, doctors and authorised pharmacists, or even go straight to the end users – patients – through internet sales and are not limited to circulation in unauthorised pharmacies and street markets (Akinyandenu, 2013). However, in Nigeria, it is observed that with NAFDAC's effective regulatory oversight over the years, the street markets and unauthorised chemist shops or pharmacies where these drugs can be found are reducing by the day (Iwokwagh, 2013). This has not stamped out falsified medicines in the country, nonetheless.

Lack of awareness of the problem due to under-reporting of the incidence is another contributing factor to the prevalence of falsified medicines in Nigeria (Oyetunde and Ilozumba, 2013; Aisagbonhi and Ilomuanya, 2016). It is difficult to develop an appropriate prevention strategy and monitor progress without a clear picture of the extent of the problem, which products are compromised, and where the products surface. A lack of awareness about substandard and falsified drugs among health workers and the general population is due to an insufficient understanding of the scope of the problem. While Ezurum (2015) argues that increasing public awareness will not in and of itself decrease falsified and substandard medicines because consumers cannot distinguish between safe and unsafe medicine in the marketplace, several authors in the literature believe that public awareness is a useful way of securing the required political will for correcting the problem and educating people on the warning signs of compromised and unsafe medicines (Adedini et al., 2016; Oladehinde, 2015). This view of public awareness is also shared by the WHO which recommends that public awareness concerning the growing trade in counterfeit drugs and the public health risks associated with them can help in taming the public health risk to its barest minimum (Adebisi et al., 2022). However, some authors have mentioned the need to have reliable and robust data around falsified and substandard medicines in Nigeria to aid public awareness and strengthen the fight against the prevalence of falsified medicines in the country (Ubajaka et al., 2016).

Other factors that have been identified as contributing to the prevalence of falsified drugs in Nigeria include poor detection methods; lack of global harmonisation (FMH, 2021),

corruption and conflict of interest, insecure and unfriendly environment, poor health seeking behaviour; collection of high taxes and tariffs from pharmaceutical products which make them expensive and unaffordable to majority of Nigerians, and heightened global control of narcotics (Yesuneh et al., 2022). Others are sophistication in clandestine drug manufacture, false declaration by importers, and inadequate cooperation from governmental agencies (Ogunsanya, 2020). Through qualitative data to be collected from public health professionals that will be recruited for the present study, upon execution, this study has the potential to validate, add to or refute these factors as the contributors to the prevalence of falsified medicines in Nigeria.

2.5 Impact of Falsified Medicines on Public Health in Nigeria

The impact of falsified medicines in Nigeria is multidimensional. There is a socioeconomic twist to the impact (Mgboko, 2021). By this, the direct costs of additional treatment and indirect social costs of lost confidence in the health system and the government are the economic and social consequences (Adigwe et al., 2022). The money patients spend on medical products that cause harm, or that do not work has also been identified as a socioeconomic factor which is a direct cost of substandard and falsified medical products to patients and their families (Okereke et al., 2021). Extra spending on health services and new medical products may also arise as a result of the toxicity, treatment failure, or infection resulting from failed prophylaxis. Therefore, in this sense, falsified medicines affect individuals who may fall victim to the low quality components of the medical products they buy which may not adequately meet their medical needs. It also affects legitimate producers who will have to spend more in the form of advertisements and campaigns to ensure that falsified medicines do not infiltrate their supply chains so that they do not lose sales to the counterfeiters. Governments are also affected as falsified medicines can have negative effects on jobs and foreign investment and also on the crime levels and the environment. Governments can also lose revenues that should have accrued to it as taxes, levies, rates and VAT whilst genuine brands can be damaged by the actions and activities of illegitimate drug manufacturers and distributors. More costs can be ramped up in incorporating anti-counterfeiting technologies into genuine products to make them difficult for counterfeiting while making them easy for consumers to identify and differentiate from fake substitutes.

While these points are valid and are important impacts of falsified medicines in Nigeria, this section will be considering the impact of falsified drugs on public health in the country.

First, the impact of falsified medicines on the public health in Nigeria would be increased mortality and morbidity. There is a consensus in the literature that falsified and substandard medicines pose a great threat to public health as well as individual health (Nwankwo, 2020; Adigwe et al., 2022). The consumption of these medicines may, at best, fail to improve patients' health condition, and at worst, may cause avoidable mortality and morbidity and also drug resistance. This is because the fraudulent drugs contain wrong dosage of ingredients, may have ingredients of low quality or wrong ingredients (Yesuneh et al., 2022). Any individual taking any product containing a dangerous contaminant (including dangerously high levels of the expected API) is likely to suffer harm, experience a longer bout of the disease if their condition goes untreated because the "medicine" they take contains no API, or the API is at sub therapeutic concentrations, and may even die.

Second is disease prevalence. When prophylactic products are substandard or falsified, or when infections are not cured or controlled, disease prevalence is likely to rise because such fake or unsafe drugs cannot prevent infectious diseases (Nnachi et al., 2022). This also applies to chronic conditions.

Third is antimicrobial resistance. While new and expensive lifestyle medicines, such as hormones, steroids, pills for erectile dysfunction and antihistamines are counterfeited and falsified in developed countries, the most commonly counterfeited medicines are those used to treat life-threatening conditions such as cancer, malaria, tuberculosis, HIV/AIDS, including various antibiotics (Garuba et al., 2009). While falsified antimicrobials can be diluted, the substandard ones often contain low and erratic drug doses. However, exposing pathogens to sub therapeutic doses of medicines selectively allows the growth of resistant organisms in either case. For example, rise of drug-resistant tuberculosis is a result of poor-quality drugs; same for drug-resistant staphylococcus infections and antimalarial resistance drugs (Jatau et al., 2019). Fourth, when disease resistant drugs are in circulation, this is likely to lead to treatment failures which have deleterious consequences on individual health and public health (Glass, 2014).

Another pernicious consequence of falsified drug on public health is the loss of confidence in the public health systems (Atholl and David, 2014). This is a dangerous trend when it happens because the people might now be forced to resort to self-help, use of herbal concoctions whose ingredients they do not understand and in some cases may refuse vaccination for their children or fail to take treatment as prescribed and even stay away from particular public health facilities (Blackstone et al., 2014). This loss of confidence may be further transferred to patients' loss of confidence in health professionals such as medical personnel, pharmacists and others.

These points above show how dangerous falsified and substandard medicines are to public health in Nigeria.

2.6 Current measures used to combat the spread of falsified medicines

There are many ongoing measures put in place to combat the spread of falsified medicines in Nigeria. One, over the years, the Nigerian government and its agencies have been committed to consumer awareness of the problem of substandard and falsified medicines in the country. NAFDAC, the Ministry of Health, the Standards Organisation of Nigeria, and health associations such as the Pharmacists Council of Nigeria and the Pharmacists Society of Nigeria and the Nigerian Medical Association (Animashaun et al., 2019). Through these awareness campaigns and outreach programmes, this has elevated the issue for practitioners, patients, and policymakers about the risks of unsafe drugs and possible responses. However, some authors still argue that government and the respective regulatory bodies are not doing this enough (Klantschnig and Huang, 2018). This may be due to the large size of Nigeria but this excuse also has been addressed. Many stakeholders in the industry believe that social media, the traditional media, ethnic associations, occupational groups including artisanal associations and the school system are adequate vehicles to reach millions of Nigerians (Okereke et al., 2021).

Two, there is the call for strengthening the provisions of the existing legislation and regulations.

Unlike LMICs, most High-Income Countries (HICs) have strict laws guiding the manufacturing, supply, distribution and dispensing of medicines, making it less likely that

falsified medicines penetrate the supply chain or that substandard medicines are produced (Velasquez, 2022). Such effective legislative and regulatory pharmaceutical environments ensure that access to affordable medicines, and innovation in new and better products are promoted while exposure of patients' risks to unsafe medical products is managed to the barest minimum. This is what is being advocated over the years in Nigeria. Some of its laws are outdated requiring updating them with stricter penalties and stringent prosecution methods while more robust medicine regulations, surveillance and law enforcement are expected to be effectively implemented. Aside NAFDAC, and a few other agencies, many studies find the enforcement of existing regulations and legislation as a strong measure that is weakly implemented to combat the spread of falsified medicines in Nigeria (Okereke et al., 2021). Some authors have also suggested the need to strengthen the regulatory rules, processes and agencies and to fund them in order to make them more effective in combatting falsified medical products in Nigeria (Ogunsanya, 2020; Mgboko, 2021).

Three, some authors believe that gradually the Nigerian government and its agencies are promoting good manufacturing and good distribution practices in the pharmaceuticals industry (Fatokun, 2016). While GMP refers to the minimum standards that medicines manufacturers must meet in their production processes, GDP emphasises that medicines are to be obtained from the licensed or authorised supply chain and are to be consistently stored, transported and handled under suitable conditions (Beargie et al., 2019). Some leading pharmaceutical manufacturers have been found to be toeing this line, investing in good manufacturing and good distribution practices (NAFDAC, 2020). Perhaps, reinforcing such good corporate behaviour through some incentivisation could help to inspire other manufacturers and distributors to embrace these modern practices.

Four, solutions to address street markets and online pharmacies. NAFDAC under Dr. Dora Akunyili was fearless in revamping the agency morally and institutionally and led the agency to clean up most of the street markets where substandard and falsified medicines could be found (NAFDAC, 2011). However, since it is a tenured position, after she left the office, NAFDAC has continued to toe that path, yet evidence from the literature shows that falsified drugs are still prevalent in many open street markets in Nigeria. The worrisome feeling this generates is that since Dr. Akunyili's feat of reducing substandard drugs to 16% during her time in office, NAFDAC recently claimed that the agency has reduced the rate of unsafe drugs in the system to 15% (Onyebuchi, 2022). A one-percent point reduction does not seem

to show much progress. Other current measures to combat the prevalence of substandard and falsified medicines in Nigeria include vigorous monitoring of manufacturers/importers of pharmaceuticals, promotion of local manufacturing of pharmaceuticals, pre-shipment provisional registration of imported medicines, deployment of monitoring and testing technologies (e.g. Mobile Authentication Service (MAS), Truscan (Raman Spectroscopy), GPHF Minilab, upgrade of Laboratories to Test Quality of Medicines, etc.) and continuous post-marketing monitoring of quality of medicines (Ogunsanya, 2020).

2.7 Modern Solutions for Combatting the Spread of Falsified Medicines in Nigeria

There are growing concerns, some of which state that the Nigerian government cannot be doing the same things and expecting different results when it comes to combatting the spread of falsified medicines in Nigeria (Olugbenga, 2013). Some authors think that there is need to overhaul the entire regulatory frameworks and legislative regimes (Oku, 2016), while some canvass the need for more political will, less corruption and improvement of the socio-economic levels of Nigerians so that they can afford proprietary drugs or their quality generic substitutes (Oseni, 2019).

According to Ajemigbitse et al. (2016), the emphasis on combatting falsified medicines was placed on the need to reinvent NAFDAC and other regulatory agencies. This is to be done by implementing staff re-orientation and motivation, modernising NAFDAC's regulatory processes and accelerating the earlier actions of NAFDAC, some of which involved stopping the importation of substandard and falsified drugs airbound or shipbound to Nigeria at the source destination. Regarding staff re-orientation, the authors argue that incorrigibly corrupt staff of INEC need to be retrenched or sent into retirement while those that remain need to be retrained and empowered with attractive incentives to make them commit to their duties. The authors also argue that NAFDAC and other regulatory agencies need to be restructured along the lines of upgrading their laboratories and warehouses, while constructing land border offices at Nigerian ports and developing standard operating procedures (SOPs) and automating their regulatory processes. These views have been corroborated by other studies such as Yakubu (2020) and Ekeh and Adekoya (2021). However, Ogunsanya (2020) points out that NAFDAC already has a post at most Nigerian ports which mounts surveillance at the ports of entry to deter importers from bringing in their substandard drug consignments into the country but that results have been lukewarm so far. This point was however negated by Akande-Sholabi and Adebisi (2020) who argued that NAFDAC requires support from the

political leadership of the country if the war against substandard drugs is to work. This is because some of those at the different levers of political power also have interests in the pharmaceutical sector and appear to support a relaxed regulatory environment which maintains the prevalence of substandard drugs in the country.

Some other studies have pointed out the need to further decrease the tariffs and taxes imposed on genuine drugs to make them available (Mgboko, 2021), while others affirm the need for streamlining registration guidelines and enforcing them strictly, monitoring good manufacturing practices of local manufacturers and establishing a West African Drug Regulatory Authorities Network to clean up the entire West African region of falsified drugs and their manufacturers and distributors (Nwankwo, 2020; Adigwe et al., 2022).

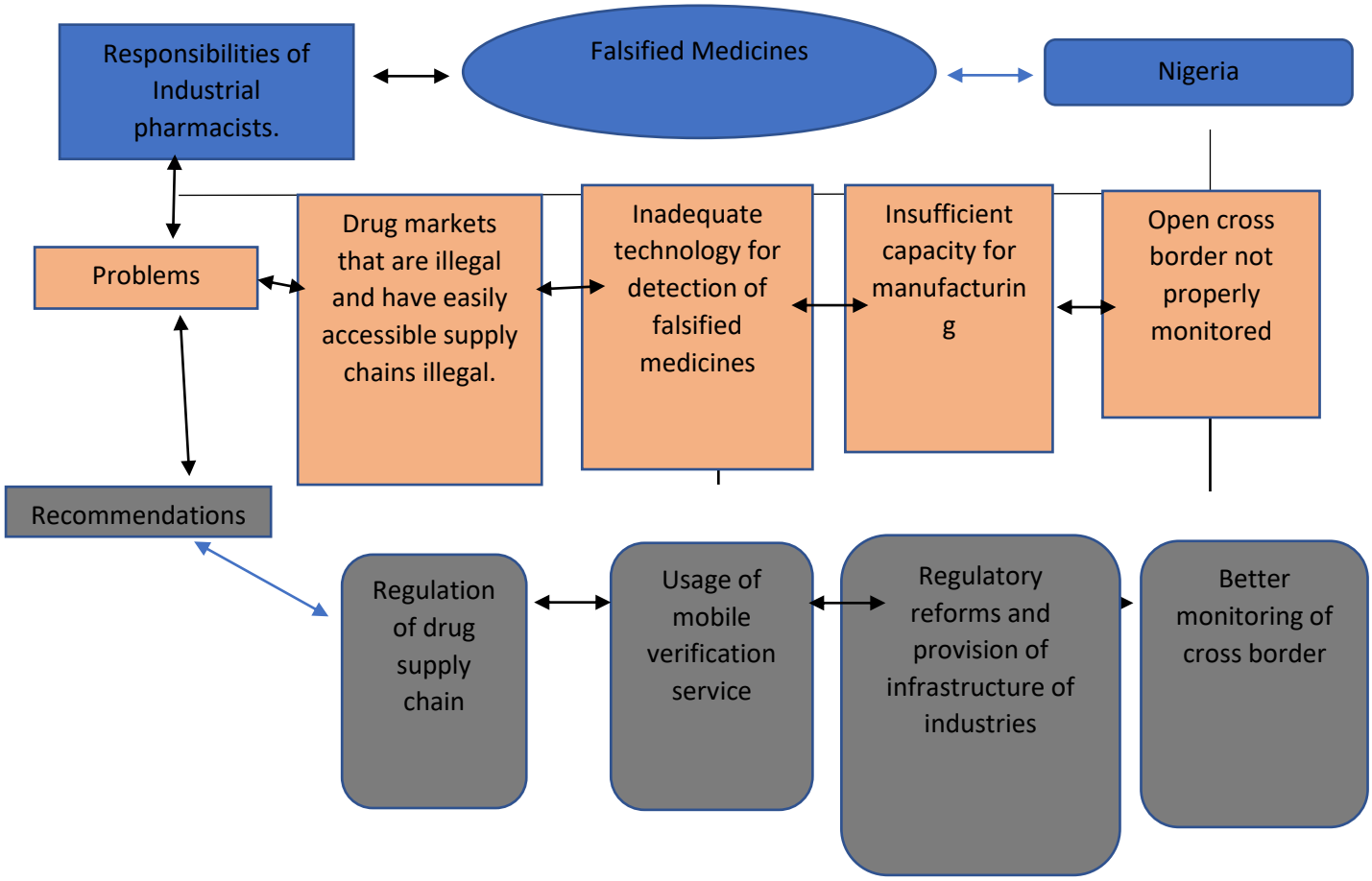


Fig 4. Overview of strategies needed to curb the spread of falsified medicines.(Adigwe *et al.*, 2022)

Through the qualitative data that will be collected from public health professionals that will be participating in the online semi-structured interviews to be put in place when executing the

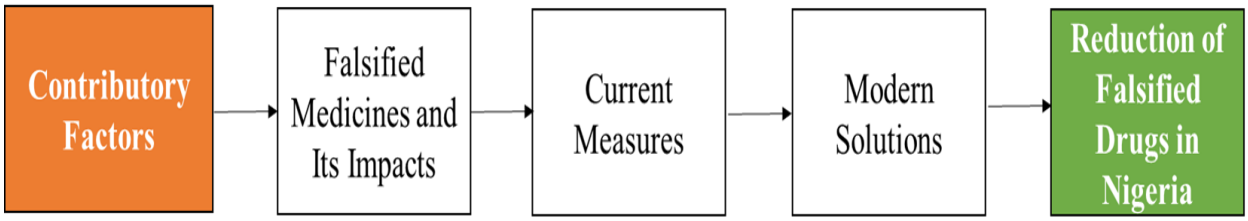
field aspect of this research, findings may have the potential to uncover modern solutions that can help in the fight against the prevalence of falsified drugs in Nigeria.

2.8 Conceptual Framework

Below is Figure 1 which captures the study's conceptual framework with an explanation underneath the diagram.

Figure 4

: Conceptual Framework



Collecting qualitative data from public health professionals, this research has the potential to reveal modern solutions that will lead to a reduction of falsified drugs in Nigeria.

2.9 Summary of the Chapter

This chapter has reviewed the literature on the subject "An evaluation of the contributing factors to the prevalence of fake medicines in Nigeria." It has established that counterfeit medicines are not good for any society including the Nigerian state. It has attempted to define what fake medicines are and differentiated them from substandard drugs. It has reviewed the factors contributing to the spread of counterfeit medicines in Nigeria, examined the impact of fake medicines on public health in Nigeria and appraised current measures and modern solutions that can help in reducing the prevalence of falsified medicines in Nigeria. Collecting qualitative data from public health professionals will allow this researcher attempt answering the research questions developed for the current study.

CHAPTER THREE: RESEARCH METHODOLOGY

3.1 Overview

This chapter discusses the research methodology adopted for this dissertation research. This covers, the research philosophy, approach, design, strategy, data collection method and analysis, and research ethics. Table 1 summarises the research methodology espoused for this study.

Table 1: Research Methodology and Primary Data Collection

Section No	**Stages**	**Research**
1	Philosophy	Interpretivism
2	Approach	Inductive Analysis

3	Design	Exploratory
4	Strategy	Qualitative Research
5	Data Collection Method	Interview
6	Instrument	Online Semi-Structured Interview via zoom
7	Interview Length	30 - 45 minutes
8	Research Interviewees	Public Health Institutions: NAFDAC,Pharmaceutical Council of Nigeria,Lagos State Ministry of Health and Federal Ministry of Health.

Source: Researcher, 2021

3.2 Philosophical Paradigm

Although there are three philosophical paradigms, according to Saunders et al. (2019), namely, interpretivism, positivism and pragmatism, most research studies can be divided into two dominant research philosophies, i.e. interpretivism and positivism (Cohen et al., 2007). Whenever qualitative and quantitative research assumptions, methods and procedures are used in research studies, they are guided by these research paradigms respectively. While interpretivism aligns with the qualitative research strategy, positivism is the research

philosophy mostly associated with quantitative research strategy (Saunders et al., 2016). Similarly, interpretivism employs constructivist or subjectivist standpoints which do not promote an understanding of social reality using the rigid scientific protocols of the positivist philosophical paradigm. To provide an in-depth understanding of social realities, interpretivism is anchored on an epistemological and ontological standpoint that the laws of natural sciences are inadequate for such an exercise. Therefore, because it aims at understanding social phenomena or issue of research interest by analysing the meanings people attach to them, interpretivism is phenomenological in scope and nature (Della Porta and Keating, 2008). In other words, interpretive researchers are concerned about meaning making using textual and visual analysis.

The interpretivist paradigm is also known to allow the probing of the research questions in order for the researcher to discover the contexts and data-rich information which can address

the “why” issues related to a subject (Ogunsanya, 2020). While this may not conform to the statistical significance of variables demanded by the law-like proposition of positivism, it allows researchers to go beyond the strict objectivity which may restrict an understanding of research problems beyond just numbers. This is the reason for the choice of this philosophy for the current research because it will allow the researcher to conduct an evaluation of the contributing factors to the prevalence of falsified medicines in Nigeria and make recommendations suitable for the promotion of public health in the country.

3.3 Research Approach

The inductive research approach is adopted for the study as it is best suited for a research study guided by interpretivism (Saunders *et al.*, 2019I). Inductive research approach is a method of reasoning whereby a body of observations is used to derive or arrive at a general principle. It allows inductive researchers to make broad generalisations using specific research phenomena or observations. While the truth of the conclusion of an inductive argument is probable, based upon the evidence available or given, it is different from deductive reasoning where a deductive argument is certain when the premises provided are correct (Hodkinson, 2008). Although the justification for the application of inductive reasoning to research has been found questionable (Holland *et al.*, 1989), its use nonetheless has generated considerable success. This is because while in deductive research, the truth of the premise determines the truth of the conclusion, in inductive research, there is an uncertainty when the conclusion derives from the inductive premise. Therefore, inductive reasoning or argument can only be justified inductively (Copi *et al.*, 2006). However, some authors have argued that since inductive research approach can provide researchers with a great deal of control and can be applied to a broad range of topics, it is seen to be highly adaptable when investigating any subject (Yin, 2018; Neuman, 2003). Aside its flexibility, other benefits of the inductive research approach include that it supports the generation of new theory and attends closely to the research context (Guest *et al.*, 2012).

3.4 Research Design and Strategy

The research design chosen for the study is exploration. Exploratory research design is more common in qualitative research investigations which do not incorporate much scientific method and statistical analysis. When a research problem is not clearly understood or defined,

exploratory research design becomes suitable for resolving it (Easterby-Smith *et al.*, 2008). It explores research questions that are new or that require to be studied in-depth, or when the data collection process is challenging in some way. It is, therefore, a methodological approach that is concerned with building or generating theory and is concerned with discovery (Davies, 2011). Applying it to the present study, in spite of the acclaimed efforts of NAFDAC, for instance, in identifying and stemming the prevalence of falsified medicines in Nigeria, it appears that the fight is not yielding the expected results (NAFDAC, 2020; Adeloye *et al.*, 2017; Eronmhonsele, 2015). Therefore, the exploratory design will allow the researcher to better understand the contributing factors that appear to sustain the prevalence of falsified medicines in Nigeria from the observations of public health experts who may help to proffer recommendations that may be found useful to regulatory bodies, pharmaceutical companies, government and other stakeholders in the pharmaceutical industry in Nigeria.

The qualitative research method is being used in this study to collect and analyse non-numerical data, namely, text, audio or video, so as to understand opinions, concepts and experiences. It can also be used to generate new ideas for research or gather in-depth insights into a problem (Hamilton *et al.*, 2016). Although it is commonly used as a research method in social sciences and humanities, increasingly, the application of the qualitative research strategy is applied in scientific and clinical areas such as public health, pharmaceutical and health sciences. There is a growing use of qualitative research method in public health and pharmaceutical sciences as the following studies show. Using the qualitative research strategy, there is a potential in this study to gain deeper understanding of the context, phenomena and experiences. And to understand human experience, qualitative research would allow this researcher to ask questions that cannot be easily put into numbers.

3.5 Data Collection of Primary Data

The interview method and a semi-structured interview guide as the instrument Data collection will aid the data collection process in this study. Public health experts with a deep theoretical and practical knowledge of Nigeria's public healthcare setting and the issue of falsified medicines will constitute the population of the research participants to be recruited for this research. To conduct a manageable study, a subset of this population will be recruited. The sampling method to be adopted for the study is the non-probability sampling method. Unlike the probability sampling method which is based on chance or randomisation, the non-

probability sampling method involves the selection of participants for a research using non-randomised or subjective techniques (Saunders et al., 2019). It is preferred to randomised or probability sampling method because it is easy, fast and inexpensive.

To this end, this research will be utilising purposive sampling technique, which is a type of non-randomised or non-probability sampling method. Purposive sampling ensures that those recruited for a research investigation meet the criteria developed or characteristics defined for that purpose (Della Porta and Keating, 2008). Therefore, the following criteria have been developed to guide the selection of participants for the semi-structured interview sessions planned for this study. They are as follows:

- Pharmacists, physicians and healthcare professionals working in health, regulatory and industry settings.
- Having not less than 3 years of experience which means these individuals should be at mid-level or supervisory positions in their respective organisations.
- Having experience in public health issues especially falsified medicines in Nigeria.
- Having experience in research, policymaking or public health interventions to rid Nigeria of the menace of falsified medicines.

The interview guide to be used for the semi-structured interview is attached in the appendix. Each interview sessions is expected to have a length of not more than 45 minutes. Questions asked are formulated to answer/address the research questions.

3.6 Sources

Both secondary and primary data are included for this study:

3.6.1 Secondary Source:

Secondary data refer to the data collected by researchers or people other than this researcher. For this study, journals, textbooks, and articles from established quality research databases were consulted. During the desk review, publications from ScienceDirect, Elsevier, NCBI, PubMed, BMC, Lancet, Sage, Google Scholar and others were consulted. These sources provided secondary evidence which established the need for this research, and identified the research problems associated with falsified medicines in Nigeria. Keywords used in the search process include “contributing factors” “AND” “falsified medicines” “AND” “Nigeria”.

To gain a robust understanding of the subject of inquiry, the data extracted were used to review the literature and lay a basis for the current investigation.

3.6.1 Primary Source

The qualitative primary data would be collected through one-one-one semi-structured interview sessions to be held on a video chat platform (e.g. Google Meet, Zoom or Microsoft Team). The overriding aim of the study which is to analyse contributing factors to the prevalence of falsified medicines in Nigeria informed the choice of qualitative data. This is to give depth, context and data-rich possibilities to the research findings and potentially advance the conversation with valuable insights and recommendations.

3.6.3 Data Analysis

The qualitative data will be analysed using the Gioia qualitative data analysis. To meet the demands by top journal publications, qualitative researchers employ the Gioia qualitative data analysis because it can meet the standards of rigour associated with trustworthy research (Wang and Gao, 2020). Using this qualitative data analysis, which is similar to content analysis, it involves developing first-order, second-order and third-order codes from participants' responses. The distillation of the general responses of interviewees by identifying common themes within them which are then assembled together make up the first-order codes. These first-order codes are distilled further into general ideas representing the participants' views/opinions. This is the second-order codes. The third-order codes then distils the second-order codes into single ideas or concepts which capture the kernel of participants' observations or views. It is the third-order codes that the researcher would discuss comparing these findings with the position in the extant literature.

3.7 Ethical Issues

Consent and confidentiality are two critical ethical issues to consider in any research. (Kothari, 2004). This research is ethically guided and will adhere to the highest level of ethics for detailed research. As a result, confidentiality will be maintained during data collection and analysis, and prior to conducting research. Also, where applicable, the consent of government

agencies and drug manufacturer firms will be sought. The researcher is already in talks with one of the key players in one of the public health institutions in Nigeria whose influence can provide an informal access to some of the target interview participants. This research is subject to the Griffith College Ethics Committee (GCEC). Before embarking on this study, the GCEC approved the study and its research topic; the consent and participant forms and the interview guide. This is the first ethical hurdle crossed by the researcher. Thereafter, the researcher has reached out to her contact within one of the leading public health institutions in Nigeria who has given assurance to the author that access would be granted to colleagues working within the public health organisation and others as may be required. However, in line with the GCEC demands, before participating in the research, each participant that initially agrees will be expected to complete the consent and participant's form bearing the summary of the research intent and objectives. Only those who freely give their consent to participate in the study will be allowed to participate in the interview sessions. The participants will be assured of the confidentiality and privacy of their information and responses and will be assured of their freedom to decide to discontinue with the research at any point as they may deem fit. They will be assured that the use of their information will be restricted only to this research and other excerpts that may be used in other research investigations with their permission. Their rights to privacy, anonymity and confidentiality would be guaranteed. There will not be a direct mention of their names or personal information in the research since only descriptors will be used to identify them such as Interviewee1, Interviewee2, Interviewee3, Interviewee4, and so on.

Participants will also be told that their interview sessions would be recorded but will be securely archived by the university pending the completion of this dissertation and conclusion of this programme by the researcher. Only quoted texts of their responses would be used in this and other research studies. As part of the research ethics adopted for this study, any research publication used will be cited and referenced adequately. Interview participants will also be treated to respect of their persons without any form of discrimination.

3.8 Conclusion

To illustrate the logical process employed in conducting this research study, this chapter has presented the research methodology. There was a discussion of the research philosophy, approach, design and strategy, and the reasons for choosing each one of them were provided for the current study. Typically, the qualitative research method chosen for the current

research is because it can answer the research questions, and at the same time provide depth, context and data-rich possibilities. This has the potential to expand the research area and the existing literature, providing both theoretical and practical contributions.

CHAPTER FOUR: RESULTS

4.1 Introduction

This qualitative research evaluates contributing factors to the prevalence of falsified medicines in Nigeria with the aim of making recommendations for public health. There is no consensus on research findings on this subject in the literature. The differences in opinions and results require that a study of this nature be put in place to collect primary data from professionals in the public health sector in Nigeria. Their responses, opinions and knowledge in answering the interview questions are expected to help shed light on the research questions. They are expected to provide specific insights on the factors contributing to the prevalence of falsified medicines in Nigeria, the impact falsified medicines have on public health, the effectiveness of current measures to combat their spread, and the likely solutions that can improve existing regulations and enforcement.

Eight interviewees were selected from five different public health institutions in Nigeria. Three participants were selected from NAFDAC, two from the Lagos State Ministry of Health, and one each from the Federal Ministry of Health, the Pharmaceutical Council of Nigeria and the Pharmaceutical Society of Nigeria. They were selected purposively because they met the inclusion criteria. Their recruitment was done to ensure that only experienced

public health professionals who had experience regarding the prevalence of falsified medicines in Nigeria were selected. They participated in the interview sessions after having completed their consent forms and sent them to the researcher.

4.2 Summary of Participants' Socio-demographic Information

Table 2 Participants' Socio-demographic Information

Section No	Description	Gender	Experience	Occupation	Public Health Institutions
1	Participant 1	Female	8+ years	Medical Director	Lagos State Ministry of Health
2	Participant 2	Male	3+ years	Pharmacist	Pharmaceutical Council of Nigeria (PCN)
3	Participant 3	Female	5+ years	Pharmacist	NAFDAC
4	Participant 4	Male	6+ years	Pharmacist	Pharmaceutical Society of Nigeria (PSN)
5	Participant 5	Male	3+ years	Pharmacist	NAFDAC
6	Participant 6	Male	4+ years	Medical Doctor	Lagos State Ministry of Health
7	Participant 7	Female	5+ years	Pharmacist	NAFDAC
8	Participant 8	Female	7+ years	Assistant Chief Nursing Officer	Federal Ministry of Health

Source: Researcher (2023)

4.3 Summary of Participants' Responses to Interview Questions

Summarised in Table 3 are the responses of participants who took part in the interview sessions.

Table 3 First Order Codes Summarising Participants' Responses

Interview Participants	Four Research Questions (RQs)	Responses
8 Participants	RQ 1: What are the factors contributing to the prevalence of falsified medicines in Nigeria?	• High cost of good quality drugs, inadequate drug distribution monitoring system and inadequate laws or poor enforcement of the existing drug quality control regulations. • Ineffective cooperation among different stakeholders, ineffective enforcement of existing laws, loose control systems, and high cost of genuine drugs. • Weak regulatory systems, ignorance and greed, high demand and erratic supply of drugs,

		involvement of non-professionals in pharmaceutical drug business, illegal drug importation, corruption. • You cannot ignore the role that politics, socio-cultural and economic experiences play in the prevalence of substandard and falsified medicines in a country. For instance, poverty of the people make them patronise quack medicine sellers, while corruption of some government officials explains why some manufacturers get away with their illicit drug production and distribution processes. • One of the reasons is the difficulty in accessing affordable, safe and quality pharmaceuticals by a large segment of the Nigerian population. This allows crooks and some criminally minded people to try to fill the void with counterfeit and fake drugs. • The price of quality medicines which is high, most times, explains the reason for the prevalence of cheaper alternative and fake medicines in Nigeria. • Since consumers pay out of their pockets, they are forced to buy whatever they can afford in order to maintain their health. • The reasons are obvious: weak enforcement of legislation and regulations make it easy for the manufacture, distribution and consumption of falsified drugs in Nigeria. • Lack of heavy penalty for pharmaceutical crime. • Lack of a competitive generics market and rigorous and unpredictable inspection regime and will benefit consumers because an influx of generic medicines will likely reduce the circulation in falsified and substandard drugs when there is a system to assure consumers of the quality of such medicines. • I would say that the entire pharmaceutical supply chain in Nigeria is vulnerable and until it is fixed, there will continue to be a prevalence of falsified medicines in Nigeria. • Internet sales of pharmaceutical products are compromising the legitimate supply chain. More regulation is needed in that area. • NAFDAC has tried in its fight against falsified medicines but the existence of street markets, unauthorised pharmacies and chemist shops contribute to the prevalence of falsified medicines in Nigeria. • Lack of public awareness is blunting the fight against the prevalence of falsified medicines and

		increasing public health risks in Nigeria. • Poor detection methods still persist in many parts of Nigeria. This is why NAFDAC is striving to fund its offices in all the six geopolitical zones so that they can help in improving detection of falsified drugs in the pharmaceutical supply chain in Nigeria.
	RQ 2: What is the impact of falsified medicines on public health in Nigeria?	• When there's failed prophylaxis or treatment failures, this would naturally lead to additional costs of treatment and health services which for low-income consumers may be too expensive for them and could lead to their avoidable deaths if they cannot afford quality healthcare services. • It could affect the confidence of consumers in the healthcare system. • It could lead to more harm for consumers of such drugs due to disease prevalence. • Producers of genuine drugs are affected as sales may drop when the falsified alternatives find their way into the genuine drug supply chain. Governments are also affected as falsified. • Falsified medicines are not good for any society and economy. They can lead to high incidences of sick and unwell people in the general population and this is not good for the economy. • It denies government of its revenues from VAT and tax. This is why NAFDAC as an institution is working hard to reduce the rate of falsified medicines in circulation in Nigeria. • It increases the level of morbidity and mortality in the general population, posing a great threat to public health. • Another point to note is antimicrobial resistance.
	RQ 3: What is the effectiveness of current measures used to combat the spread of falsified medicines in Nigeria?	• Although inadequate, there has been ongoing consumer awareness of the dangers of falsified medicine in the drug supply chain in Nigeria. Nigeria is a large country and reaching every nook and cranny in the country to create awareness is expensive. • Government is working hard to strengthen the enforcement of existing legislation but these efforts have not yielded the expected returns. • Some of the laws have been amended but there is need to increase the penalty for violations. • Insistence on good manufacturing practices by NAFDAC and the Standard Organisation of Nigeria (SON) is helping. • Regulators such as NAFDAC are curbing street markets and shutting down the operations of

		unregistered or unlicensed pharmacies, chemist shops and drug sellers in the open markets. • I would say that monitoring of manufacturers/productions of pharmaceutical products has been vigorous over the last few years. • There is also the deployment of monitoring and testing technologies (e.g. Mobile Authentication Service (MAS) etc.). • Establishment of NAFDAC's laboratory in each region for testing of products.
	RQ 4: What are the likely solutions that can improve existing regulations and enforcement?	• Overhaul existing regulatory frameworks and legislation. • Good politics free of corruption, citizen protection and improvement of their socio-economic well-being. These can allow citizens have the resources to afford quality pharmaceutical products. • I believe that NAFDAC should be restructured after the order of the Dora Akunyili era. Their staff should be retrained, retooled with the latest technologies to detect falsified medicines in the supply chain and they should be motivated to sustain the fight against falsified medicines in Nigeria. • Socio-economic improvement of the conditions of Nigerians. • Reduction in the taxes and tariffs imposed on genuine medicines. • Effective monitoring of the pharmaceutical supply chain while conducting random testing of products from time to time. • Punishment of wrong doers who violate the law and regulations guiding the pharmaceutical business in Nigeria.

Source: Researcher (2023)

When the first order codes or summaries of the responses of the participants is done, it generated the following patterns/themes as displayed in Table 4.

4.5 Second Order Codes Summarising Participants' Interview Responses

From the first-order codes, second-order codes showing main themes and patterns are displayed in Table 4.

Table 4 Second-Order Codes Showing Themes and Patterns

Interview Participants	Four Research Questions (RQs)	Responses

8 Participants	RQ 1: What are the factors contributing to the prevalence of falsified medicines in Nigeria?	• High cost of good and quality drugs. • Lack of an effective health insurance. • Weak regulatory and enforcement systems. • Bad politics and lack of political will. • Difficulty accessing affordable, safe and quality pharmaceuticals. • Poor detection methods still persist in many parts of Nigeria.
	RQ 2: What is the impact of falsified medicines on public health in Nigeria?	• Public health risks. • Industry health risks. • Economic health risks. • Government revenue risks.
	RQ 3: What is the effectiveness of current measures used to combat the spread of falsified medicines in Nigeria?	• Consumer awareness is inadequate. • Weak regulatory and enforcement mechanisms. • Weak punitive measures for violations. • Inadequate modern solutions e.g. GMP and technological aids.
	RQ 4: What are the likely solutions that can improve existing regulations and enforcement?	• Overhaul of the existing regulatory and enforcement mechanisms. • Good politics. • Socio-economic improvement of the conditions of Nigerians. • Effective monitoring of the pharmaceutical supply chain.

Source: Researcher (2023)

4.6 Third-Order Codes

Dominant, single-idea themes are further generated from the second-order codes (themes and patterns and depicted in Table 5.

Table 5: Third-Order Codes Showing Dominant, Single-Idea Themes/Patterns

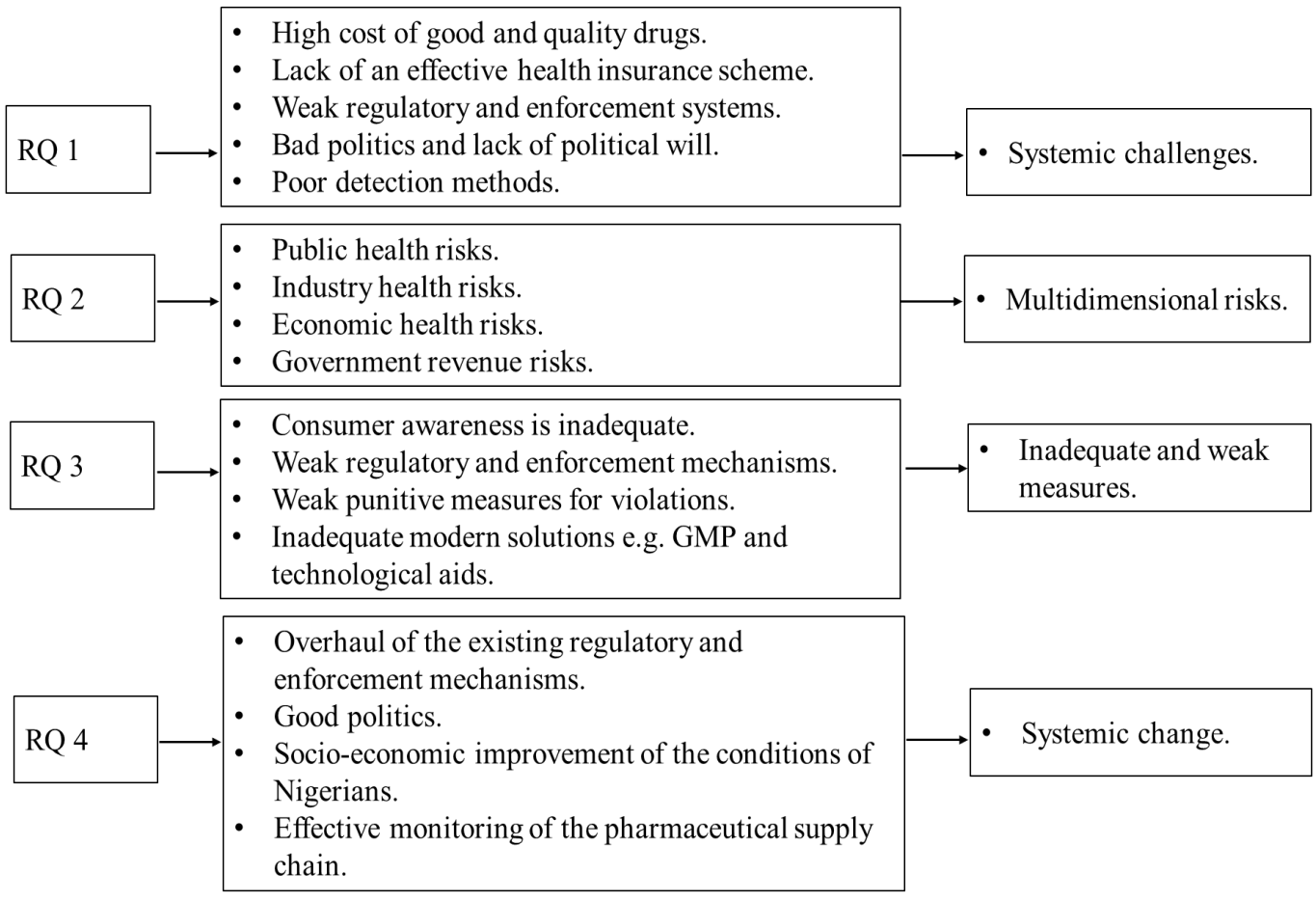
Interview Participants	Four Research Questions (RQs)	Responses
8 Participants	RQ 1: What are the factors contributing to the prevalence of falsified medicines in Nigeria?	• Systemic challenges.
	RQ 2: What is the impact of falsified medicines on public health in Nigeria?	• Multidimensional risks.
	RQ 3: What is the effectiveness of current measures used to combat the spread of falsified medicines in Nigeria?	• Inadequate and weak measures.

	RQ 4: What are the likely solutions that can improve existing regulations and enforcement?	• Systemic change.

Source: Researcher (2023)

4.7 Results/Findings

Figure 2 Coding Map Showing Themes and Patterns from Participant Data



Source: Researcher (2023)

4.8 Interpretation of the Results

The results of the primary research are presented below.

4.8.1 Results for Research Question One

Research Question One: What are the factors contributing to the prevalence of falsified medicines in Nigeria?

Emerged themes and patterns for question one are summarised as: high cost of good and quality drugs; lack of an effective health insurance; weak regulatory and enforcement systems; bad politics and lack of political will; difficulty accessing affordable, safe and quality pharmaceuticals; poor detection methods still persist in many parts of Nigeria. These themes point to one single idea which is systemic challenges.

4.8.1.1 High cost of good and quality drugs

All the participants (8/8) mentioned the high cost of good and quality medicine as a factor contributing to the prevalence of falsified medicines in Nigeria. For example, Participant 5 said "The price of quality medicines which is high, most times, explains the reason for the prevalence of cheaper alternative and fake medicines in Nigeria." This was also the opinion of Participant 2 who said, "High cost of good quality drugs makes it difficult for many Nigerians to afford such medications. And because they are eager to get one form of treatment or another, they easily fall prey to snake oil merchants found in open markets and sometimes in unauthorised chemist shops and pharmacies. Most times, their conditions worsen and before they can be attended to by genuine health professionals in the healthcare system, it is sometimes too late." Hamilton et al. (2016) and Alhedethe et al. (2017) have confirmed this finding in their studies where they mentioned that one of the challenges for the prevalence of falsified drugs in Nigeria was due to the high cost of quality drugs.

4.8.1.2 Lack of an effective health insurance.

Majority of the participants (6/8) also highlighted the absence of a working health insurance programme in Nigeria, which has exposed majority of Nigerians to falsified medicines. Participant 1 has this to say in this regard, "In the UK, all appointments and treatments are

free to patients (though paid for through taxes) including prescription drugs, under the National Health Service (NHS). But this is not available in Nigeria. Even the effectiveness of the National Health Insurance Scheme (NHIS) has been unstable, unpredictable and in fact has failed to deliver quality of care to many Nigerians who needed such a health insurance to cover their hospital bills and drug purchases. Largely, access to quality pharmaceuticals in Nigeria is determined by how large your pocket is." Participant 3 also emphasised the role of out of pocket expenses in getting quality drugs for patient treatment in Nigeria in these words: "Since consumers pay out of their pockets, they are forced to buy whatever they can afford in order to maintain their health. In a country where majority are poor and lack health insurance, there is no need to wonder why there is a prevalence of falsified medicines in the country." Buckley and Gostin (2013) validate this finding pointing out the role of the absence of health insurance as one of the factors responsible for the prevalence of falsified medicines in developing countries such as Nigeria.

4.8.1.3 Weak regulatory and enforcement systems.

There was a general consensus (8/8) that weak regulatory and enforcement systems in Nigeria was responsible for the prevalence of falsified drugs in the country. Although Participant 4 identified many factors responsible for the prevalence of falsified medicines in Nigeria such as corruption, involvement of non-professionals in pharmaceutical drug business, and illegal drug importation, the interviewee was emphatic concerning the role that weak regulatory and enforcement mechanisms played. According to Participant 4 "The reasons are obvious: weak enforcement of legislation and regulations make it easy for the manufacture, distribution and consumption of falsified drugs in Nigeria. Until the regulatory instruments are enforced without fear or favour and regulatory agencies do their job as they should, this issue won't easily go away for a long time." This was also the opinion of the seven other participants. This view has been substantiated in the literature by studies such as Ogunsanya (2020) and Mgboko (2021).

4.8.1.4 Bad politics and lack of political will.

A majority of the participants (6/8) identified the role that bad or poor politics plays in the prevalence of falsified medicines in the pharmaceutical supply chain in Nigeria. According to

Participant 7, “You cannot ignore the role that politics, socio-cultural and economic experiences play in the prevalence of substandard and falsified medicines in a country. For instance, poverty of the people makess them patronise quack medicine sellers, while corruption of some government officials explains why some manufacturers get away with their illicit drug production and distribution processes in spite of the clear violations of extant laws. I believe that if the political leadership shows strong political will to fight the menace of falsified medicine in the country, there’ll be hope to reduce the scourge.” This was the general sentiments that other five participants had regarding the role of political corruption and poor leadership as a factor in the prevalence of falsified medicines in Nigeria. This position has been corroborated by Tormusa and Idom (2016).

4.8.1.5 Poor detection methods still persist in many parts of Nigeria.

While all the participants admitted that the detection of fake medicines has improved in Nigeria, they lamented the poor detection methods in many areas especially communities and rural areas where the presence of NAFDAC is lacking. This is how Participant 7 perceived the problem: “Poor detection methods still persist in many parts of Nigeria. This is why NAFDAC is striving to fund its offices in all the six geopolitical zones so that they can help in improving detection of falsified drugs in the pharmaceutical supply chain in those areas but lack of funding and other institutional challenges can be a problem.” This is one of the challenges that the pharmaceutical industry in many developing countries face and this has been acknowledged in the literature as one of the reasons for the prevalence of falsified medicines in Nigeria (Oyetunde et al., 2019).

Participants’ responses all show that Nigeria is facing systemic challenges which have resulted in the prevalence of falsified medicines in the country.

4.8.2 Results for Research Question Two: What is the impact of falsified medicines on public health in Nigeria?

Emerged themes and patterns for question two are summarised as: public health risks; industry health risks; economic health risks; and government revenue risks. These themes point to a single idea which is multidimensional risks.

4.8.2.1 Public health risks.

Concerning the impact of falsified medicines on public health in Nigeria, participants (8/8) identified several risks that this menace portends for the health of many Nigerians. Participant 8 was of the opinion that "It increases the level of morbidity and mortality in the general population, posing a great threat to public health." In other words, the public health concern is that "It could lead to more harm for consumers of such drugs due to drug resistance, poisoning and disease prevalence" (Participant 2) and "It could affect the confidence of consumers in the healthcare system" (Participant 1). Therefore, the public health risks of the prevalence of falsified drugs in Nigeria are that it could lead to a failure to prevent or cure future disease which could increase morbidity, mortality and disease prevalence in the community or society. It would also hurt the integrity of the public healthcare system and what is a public healthcare system without the trust and confidence of the people? These views have been corroborated in the literature (WHO, 2020; Wada et al., 2022).

4.8.2.2 Industry health risks.

Majority of the participants (6/8) affirmed that falsified drugs could engender industry health risks. By this, they mean that the health of the industry by way of sales, sustainability and stability of operations can be negatively threatened and affected by the prevalence of falsified drugs. Participant 1 shared this perspective: "Producers of genuine drugs are affected as sales may drop when the falsified alternatives find their way into the genuine drug supply chain." "It causes drug resistance which could also reduce the effective life of a drug thus requiring more investment in new drug developments to address a disease" (Participant 2). "You know, falsified medicines can actually make drug production in a particular area of disease burden to be more expensive in the long run. This is because resistant pathogens would require treatment with more complex drugs when drug resistance arises as a result of a falsified medicine. This is why every responsible health institution, government and manufacturers fight the production and distribution of falsified medicines" (Participant 7). This result has been validated in the extant literature (Okereke et al., 2021; Pisani et al., 2021).

4.8.2.3 Economic health risks.

The issue of economic health risks arose in the interview sessions. A majority of the participants held the opinion that the prevalence of falsified drugs in Nigeria poses economic health risks. Participant 4 had this to say "When there's a failed prophylaxis or treatment failures, this would naturally lead to additional costs of treatment and health services which for low-income consumers may be too expensive for them and could lead to their avoidable deaths if they cannot afford quality healthcare services." Participant 3 also mentioned that "Falsified medicines are not good for any society and economy. They can lead to high incidences of sick and unwell people in the general population and this is not good for the economy." "Patients would become too sick to work and request more sick leaves to attend to their health or make additional visits to their physicians" (Participant 6). This result has been validated by Nnachi et al. (2022) in their study.

4.8.2.4 Government revenue risks.

Some of the participants, especially those in the regulatory arm of the pharmaceutical industry, pointed out that government revenue would be affected if falsified medicines are not taken out of the legitimate drug supply chain in the country. In the words of Participant 5, "It denies government of its revenues from VAT and tax. This is why NAFDAC as an institution is working hard to reduce the rate of falsified medicines in circulation in Nigeria." "The cost of anti-counterfeiting initiatives, aside the reduction in sales and tax and revenue, increase over time and the government bears the burden. And you know, the health sector is not the only sector supported by government. With limited funding, public health initiatives that could have bettered the health of the population can be put on hold" (Participant 7). This finding agrees with the results by Ozama et al. (2018) regarding the implications of substandard and falsified medicines to the government in low- and middle-income countries.
Thus, participants' responses show that there are multidimensional risks to the prevalence of falsified drugs in Nigeria.

4.8.3 Results for Research Question Three.

Research Question 3: What is the effectiveness of current measures used to combat the spread of falsified medicines in Nigeria?

Emerged themes and patterns for question three are summarised as: consumer awareness is inadequate; weak regulatory and enforcement mechanisms; weak punitive measures for violations; and inadequate modern solutions e.g. GMP and technological aids. These patterns point to a single idea which is inadequate and weak measures.

4.8.3.1 Consumer awareness is inadequate.

Concerning the effectiveness of the current measures to combat the spread of falsified medicines in Nigeria, majority of the participants (7/8) that consumer awareness is in place but that it is inadequate. Participant 8 had this to say, "Although inadequate, there has been ongoing consumer awareness of the dangers of falsified medicine in the drug supply chain in Nigeria. In our hospital here, we do a lot of sensitisation programmes where we hold enlightenment campaigns to educate our patients regarding the need to avoid falsified medicines and how to detect them. Nigeria is a large country and reaching every nook and cranny in the country to create awareness is quite expensive." However, Participant 6 believes that there is lack of public awareness. In his words, "Lack of public awareness is blunting the fight against the prevalence of falsified medicines and increasing public health risks in Nigeria." This contrasts the position of all the participants from NAFDAC who mentioned that there was awareness but that it was low because of funding. This confirms the finding by Okpe et al. (2016) that more consumer awareness in the fight against the prevalence of falsified medicines is needed in Nigeria.

4.8.3.2 Weak regulatory and enforcement mechanisms.

All the participants except three agreed that existing regulatory and enforcement mechanisms put in place to check the spread of falsified medicines in Nigeria are weak. They exist but are weak. Participant 2 says, "I would say that monitoring of manufacturers/production of pharmaceutical products has been vigorous over the last few years but the regulatory and enforcement mechanisms have been weak to catch some of the criminals. Even when they are caught, the penalty is like a slap on the wrist." This view was rejected by participants who

work for NAFDAC, the chief regulator of drugs and food in Nigeria. Participant 3 says, “At NAFDAC, we have continued to wage the war against substandard and falsified medicines in Nigeria. Take for instance, we insist that good manufacturing practices be carried out. We are curbing street markets and shutting down the operations of unregistered or unlicensed pharmacies, chemist shops and drug sellers in the open markets. We have deployed several technologies including the popular Mobile Authentication Service (MAS) which aims to educate consumers and to help them avoid buying fake medicines anywhere in Nigeria.” However, they admitted that certain penalties for criminals who engage in the production and distribution of fake medicines in Nigeria are not punitive or prohibitive enough. But it appears that a large section of the literature agrees with the notion that existing regulatory and enforcement mechanisms are weak and require more stringent application (Adigwe, 2020; Ekpenyong et al., 2018).

4.8.3.3 Weak punitive measures for violations.

There was a general consensus by the participants that the punitive measures for violations of pharmaceutical laws and regulations in Nigeria are weak. This was also the opinion of the participants recruited from the regulatory body, NAFDAC. “There is obvious lack of heavy penalty for pharmaceutical crimes going by existing Nigerian laws” (Participant 7). “This is why NAFDAC is urging the government to increase the penalty for falsified drugs in Nigeria as the agency ramps up efforts to meet its strategic goal of having just 5% prevalence of falsified medicines in the country by 2025. We also confiscate fake and expired medical products from manufacturers or their distributors and burn them aside seeking convictions for those we catch in the courts. All these are efforts put in place to reduce the prevalence of falsified medicines in Nigeria.” The issue of weak punitive measures for pharmaceutical offences in Nigeria has been written extensively on by different authors (Ozawa et al., 2018b; Ebenezer, 2015).

4.8.3.4 Inadequate modern solutions

Majority of the participants (6/8) believe that modern solutions to fighting the prevalence of falsified drugs in Nigeria is inadequate. However, a minority (2/8) said they would rather government and its agencies should focus more on the stringent implementation of the

existing solutions. “Government is working hard through NAFDAC and other regulators to strengthen the enforcement of existing legislation but these efforts have not yielded the expected returns. We already have the Mobile Authentication System, Radio Frequency Identification (RFID) system used to tag and track genuine medical products; TruScan that can detect counterfeit drug products; Black Eye, which examines the components of different drugs simultaneously. But we need to do more if we are going to win this war against falsified drugs” (Participant 3). Two other participants disagreed. They insisted that there was need for a committed application of the existing solutions. There is also disagreement in the literature about the adequacy of modern solutions. While Klantschnig and Huang (2018) and Ogbonna et al. (2015 argue that the present solutions are inadequate, Ajemigbitse et al. (2016) believe there is need for more commitment to the implementation of existing solutions.

Generally, there is a perception that existing measures used to combat the spread of falsified medicines in Nigeria are inadequate and weak.

4.8.4 Results for Research Question Four

Research Question 4: What are the likely solutions that can improve existing regulations and enforcement?

Emerged themes and patterns for question four are summarised as: overhaul of the existing regulatory and enforcement mechanisms; good politics; socio-economic improvement of the conditions of Nigerians; and effective monitoring of the pharmaceutical supply chain. These patterns point to a single idea which is systemic change.

4.8.4.1 Overhaul of the existing regulatory and enforcement mechanisms

Regarding the solutions that can improve existing regulations and enforcement in the fight against the prevalence of falsified medicines in Nigeria, all the participants mentioned the need to overhaul the existing regulatory and enforcement mechanism. Even the NAFDAC officials complained of the inadequate punitive measures in Nigerian laws and regulations which should be tightened. One of them said, “There is need to increase the punitive measures for violators of our pharmaceutical laws if we want to be considered a serious country. Punishment of wrong doers who violate the law and regulations guiding the

pharmaceutical business in Nigeria should be stiff" (Participant 3). However, Participant 6 says, "I believe that NAFDAC should be restructured after the order of the Dora Akunyili era. Their staff should be retrained, retooled with the latest technologies to detect falsified medicines in the supply chain and they should be motivated to sustain the fight against falsified medicines in Nigeria." This validates the findings in a substantial body of the literature which identify the need to overhaul existing regulatory and enforcement mechanisms in order to strengthen the fight against falsified medicines in Nigeria (Oku, 2016; Olugbenga, 2013).

4.8.4.2 Good politics

Similarly, all the participants believed that the role of the political leadership or government in the country was important to rein in the prevalence of falsified medicines in Nigeria. Participant 8 said it clearly, "Good politics free of corruption, citizen protection and improvement of their socio-economic well-being…These can allow citizens have the resources to afford quality pharmaceutical products. When government shows commitment to the eradication of falsified medicines in the legitimate supply chains in Nigeria, I think we would see more improvements." This finding has been confirmed by Oseni (2019) in their study.

4.8.4.3 Socio-economic improvement of the conditions of Nigerians

Improving the socio-economic conditions of poor Nigerians was also identified as a credible way to discourage them from buying falsified drugs because they are cheaper alternatives to the quality and genuine ones. According to Participant 1, "Most of my patients struggle to pay their bills. If they struggle to pay their medical bills, do you think they would be able to afford buying the drugs we recommend to them, some of which they cannot afford? Government needs to either improve the NHIS by ensuring that all Nigerians benefit from it and stop paying lip service to the improvement of the socio-economic conditions of Nigerians. Look at the UK, the NHS practically subsidises public health services for their citizens. We need to do better as an oil-producing country." This result validates the position in the literature that poverty is a major driver of the consumption of falsified medicines in developing countries (Akande-Sholabi and Adebisi, 2020).

4.8.4.4 Effective monitoring of the pharmaceutical supply chain

Majority of the participants (7/8) also mentioned the need for effective monitoring. Participant 4 says that "The regulators and other interested bodies need to ensure that there's effective monitoring of the pharmaceutical supply chain. They should also conduct random testing of products from time to time and pay unscheduled visits to drug manufacturing sites. This should help strengthen the fight against falsified medicines in Nigeria." This view has also been substantially corroborated in the literature (Ogunsanya, 2020).

A critical discussion of these results will be done in the next and final chapter of this research report.

CHAPTER FIVE: DISCUSSION OF THE FINDINGS AND CONCLUSION

5.1 Introduction

This study has examined the contributing factors to the prevalence of falsified medicines in Nigeria using the qualitative research strategy and the interview method for data collection. This last chapter discusses the results/findings of the research, identifies the contributions to the literature and concludes the study with recommendations.

5.2 Summary of the Results/Findings

Eight interview participants were recruited for participation in this dissertation research. They are all public health professionals working in different health or regulatory institutions in Nigeria. Three were from NAFDAC, two were from the Lagos State Ministry of Health, and one each was from the Federal Ministry of Health, the Pharmaceutical Council of Nigeria (PSN) and Pharmaceutical Society of Nigeria (PCN). They agreed to participate in the study of their own volition and also completed the informed consent forms. There were five pharmacists, two medical doctors and an assistant chief nursing officer. Four were male and four were female. They were at the supervisory and leadership levels in their organisations, which is important for this study as it was expected at their levels at work, they would have more informed and knowledgeable opinions of the industry and its challenges. To grant them the promised anonymity which is part of the guarantees for their participation in the research, they were given descriptors such as Participant 1, Participant 2, Participant 3…Participant 8. The participants were all aware of the prevalence of falsified medicines in Nigeria and were willing to share their experiences during the interview sessions.

5.3 Discussion of the Findings

Research Question 1: What are the factors contributing to the prevalence of falsified medicines in Nigeria?

The overriding theme that summarised participants' responses when they were asked what the factors contributing to the prevalence of falsified medicines in Nigeria was systemic challenges. In other words, these challenges may be unique to the Nigerian pharmaceutical system or environment. These systemic challenges are characterised by the high cost of good and quality drugs; lack of an effective health insurance scheme; weak regulatory and enforcement systems; bad politics and lack of political will; difficulty accessing affordable, safe and quality pharmaceuticals, and poor detection methods. The issue of the cost of genuine and quality drugs was recognised by all the participants as one of the reasons for the prevalence of falsified medicines in Nigeria. This result corroborates findings made in studies by Hamilton et al. (2016) and Alhedethe et al. (2017) that the prevalence of falsified drugs in Nigeria was due to the high cost of quality drugs. However, quality, safe and efficacious drugs are not really cheap in most countries of the world because drug development is an expensive process (. This is the reason many organised societies provide some sort of health insurance to enable poor and middle-class citizens afford such medications. Sadly, lack of an effective health insurance in Nigeria forces people to engage in out-of-pocket expenses for most of their medical treatments. This is also what obtains in most developing countries as Buckley and Gostin (2013) pointed out where there is the absence of or weak health insurance programmes which if available could have provided more members of the such populations with access to good and quality pharmaceuticals like what is obtainable in the UK through the NHS. The situation is further compounded by weak regulatory and enforcement systems. Although some authors believe that the Nigerian pharmaceutical industry requires new sets of laws and regulations that can address the modern challenges facing the sector (Aminu and Gwarzo, 2017; Akinyadenu, 2013), some other authors believe that existing laws and regulations are sufficient so long as they can be enforced (Ogunsanya, 2020; Mgboko, 2021). Therefore, it appears that the lack of enforcement encourages bad actors and criminals to continue their production or distribution of falsified medicines in Nigeria. Bad politics and lack of political will was also spotlighted for its role in the prevalence of falsified medicines in Nigeria. This is because political corruption which is rampant in Nigeria , and poor leadership (Ogunsaya et.al, 2020) weaken efforts to fight those involved in fake drugs in the country. Since only wealthy individuals and companies can be involved in drug production and distribution, it is a given that those involved in this illicit and

illegal activities which harm public health could be themselves members of the elite or could be funded by interests which have access to state protection and some sort of immunity from prosecution. The role of corruption and poor leadership as a contributing factor to the prevalence of falsified medicines in Nigeria was equally mentioned by Tormusa and Idom (2016) in their research on the subject. Difficulty in accessing affordable, safe and quality pharmaceuticals and poor detection methods were also identified by the research participants as culprits for the prevalence of falsified medicines in Nigeria. These factors have been validated in the literature by previous work such as Oyetunde et al. (2019) . Findings address research question one.

Research Question 2: What is the impact of falsified medicines on public health in Nigeria?

The overriding theme that summarised participants' views when they were asked what the impact of falsified medicines was on public health is multidimensional risks. These risks include public health risks, industry health risks, economic health risks, and government revenue risks. In other words, participants' responses showed that falsified medicines impacted Nigeria beyond the public health considerations. In impacting public health, falsified medicines have been found to increase the level of the disease burden and deaths in a given population as well as causing disease prevalence, poisoning or drug resistance. These could destroy the confidence of consumers in the public health system which could further push consumers away from the legitimate drug channels. This could complicate the issue especially when falsified medicine producers and distributors try to fill the void created by the mistrust that consumers have for the legitimate pharmaceutical supply chains. This is why developed countries have dedicated agencies, institutions and regulations to rein in falsified medicines in their supply chain. This is to ensure that consumer deaths, poisoning, diseased conditions and other negative public health outcomes are not worsened or caused by falsified drugs in their supply chain. WHO (2020) and Wada et al. (2022) have corroborated this in their studies. This does not mean that NAFDAC and other regulatory bodies are not doing their jobs but that their efforts are limited by systemic challenges identified as the dominant theme in the first research question.

Participants also revealed that falsified medicines could affect public health in the area of industry health risks. By this, they meant that genuine pharmaceutical product manufacturers could suffer loss in sales, could be forced to invest more in new drug developments when drug resistance arises because of falsified medicines in the system, and that they might have

to spend more on the cost of drug production to arrest diseases which have become drug resistant. This shows that such additional costs and expenses that drug manufacturers incur, as a result of falsified medicines in circulation, could be passed onto consumers, further increasing the cost of quality and safe medicines, and isolating a greater number of poor and middle-income people who may not be able to afford them. This result agrees with the findings by Okereke et al. (2021) and Pisani et al. (2021). Participants also identified economic health risks and government revenue risks as some other implicative risks that may arise as a result of the prevalence of falsified medicines in legitimate supply chains in Nigeria. Studies in the extant literature have confirmed economic health risks (Nnachi et al., 2022) and government revenue risks (Ozama et al., 2018b) as other risks associated with the impact of falsified drugs on the public health system in Nigeria. Economic risks refer to the additional payments that consumers may be forced to pay in buying genuine medications when they discover that their treatment is failing or has failed because the medications they used were falsified. They also refer to the consequences of having a population of sick and unwell people which would be injurious to national productivity. Government revenues could also take a hit if and when falsified medicines are allowed to remain in the legitimate drug supply channels in the country. Taxes, rates, VAT payments, registration and licencing fees and other fees that should have accrued to government would be lost. Thus, the impact of falsified drugs on the public health system is multidimensionally broad affecting the public health system directly and tangentially. Findings address research question two.

Research Question 3: What is the effectiveness of current measures used to combat the spread of falsified medicines in Nigeria?

Inadequate and weak measures was the overriding theme that summarised participants' views when they were asked what the effectiveness of current measures used to combat the spread of falsified medicines was in Nigeria. Describing this theme were sub-themes such as consumer awareness is inadequate; weak regulatory and enforcement mechanisms; weak punitive measures for violations; and inadequate modern solutions e.g. GMP and technological aids. Participants were of the opinion that the current measures used to tackle the spread of falsified medicines in Nigeria suffered from the inadequacy of consumer awareness. Consumer awareness has been regarded as one way to fight the prevalence of falsified drugs in any society (Okpe et al., 2016). In other words, the more consumer awareness there is in a public health system vis-à-vis falsified medicines, the less likely would bad actors and criminals be able to pull the wool over the eyes of consumers.

However, the challenge with this measure is that it is dependent on the literacy of the population in a country. Literature shows that the more literate a country is, the more effective the consumer awareness through any health promotion campaign to secure their health . Unfortunately, in Nigeria, with a low level of literacy among its population , especially with more illiteracy in northern Nigeria, this measure may not be effective unless health promotion activities are done in the local languages or using the Arabic language, since most residents in northern Nigeria are Muslims and can understand and communicate in Arabic. Another important measure participants identified were regulatory and enforcement mechanisms which they found to be weak. This reminds one of the ongoing debate between those who believe that Nigeria requires new legislation and regulations in the pharmaceutical sector to tackle the prevalence of falsified diseases (Aminu and Gwarzo, 2017; Akinyadenu, 2013) while opposers believe that existing regulations suffice so far they are implemented (Adigwe, 2020; Ekpenyong et al., 2018). However, it appears that although regulations exist, their weakness in terms of implementation may account as part of the reasons for the prevalence of falsified medicines in Nigeria. Other existing measures put in place to fight the prevalence of falsified medicines in Nigeria include punitive measures for violations which participants considered to be weak, as well as some modern solutions which they considered to be inadequate for a large country with a large population and territory. For example, it appears that punishment for producing, trading or using drug substances (e.g. cocaine, heroin and others) carry more penalty than engaging in the business or consumption of fake pharmaceutical products. This was also the observation made by Ozawa et al. (2018a) and Ebenezer (2015) that Nigerian laws do not prescribe heavy punishments for pharmaceutical crimes. Increasing the punitive measures, therefore, may contribute to a reduction of production and distribution of falsified medicines in Nigeria. Further, technology solutions put out by NAFDAC to improve detection of falsified medicines have been found to be inadequate not ineffective. This means more investment needs to be put in place by government to enable the escalation of existing technologies which could help in the detection of falsified medicines in Nigeria. Although authors such as Ajemigbitse et al. (2016) believe there is need for more commitment to the implementation of the technology solutions, Klantschnig and Huang (2018) and Ogbonna et al. (2015 argue that they are inadequate. Efforts in improving investment and deepening implementation in this direction could help to reduce the prevalence of falsified medicines in Nigeria. Results answer research question three.

Research Question 4: What are the likely solutions that can improve existing regulations and enforcement?

Systemic change was the overriding theme that summarised participants' responses when they were asked what the likely solutions were that could improve existing regulations and enforcement. Describing this theme are sub-themes such as the overhaul of the existing regulatory and enforcement mechanisms; good politics; socio-economic improvement of the conditions of Nigerians; and effective monitoring of the pharmaceutical supply chain. Participants harped on the need to overhaul the existing regulatory and enforcement mechanisms in Nigeria if the prevalence of falsified medicines is to be tackled frontally. Such overhaul should lead to the development of stiff punitive measures for pharmaceutical drug criminals, restructuring of NAFDAC to make more effective like it was under the late Prof. Dora Akunyili and retraining of their staff and the staff of other regulators. This finding confirms the position in a substantial stream of the literature which argues for the need to overhaul the existing regulatory agencies and strengthen existing regulations and laws to defeat the prevalence of falsified medicines in Nigeria (Oku, 2016; Olugbenga, 2013). The right leadership that would be concerned and intentional about bringing a lasting raft of positive changes regarding the reduction of falsified medicines in Nigeria was also identified as part of the solutions going into the future. Participants see this as good politics. This politics should frown upon corruption in the pharmaceutical sector and be committed to citizens' protection and well-being. This is also the conclusion of the study by Oseni (2019) where the author highlighted the critical role of politics in the fight against falsified medicines in Nigeria. To address the issue of poverty, illiteracy, ignorance and lack of health insurance, there is need for government to improve the socio-economic lives and statuses of Nigerians. Where most of the citizens cannot afford basic drugs because of their poor conditions, and against the backdrop of a non-functional health insurance programme, this puts many citizens in precarious and vulnerable conditions which fake drug producers and distributors could decide to exploit. This is also the view held by Akande-Sholabi and Adebisi (2020) who found in their research that poverty made many Nigerians to consume fake drugs which are cheaper and accessible to them.

Then, lastly, effective monitoring of the pharmaceutical supply chain has become imperative. One of the dangers of the present technological explosion in the pharmaceutical industry is that such technologies can also be used by criminals to hide their operations and fake drugs in circulation. This is why regulators led by NAFDAC need to improve their monitoring of the

pharmaceutical supply chain and they are to make this monitoring more effective in order to fish out criminals behind falsified medicines in Nigeria and also detect their fake drugs in the legitimate drug supply chains in the country. This position has been corroborated by Ogunsanya (2020). Results answer research question four.

5.4 **Contributions to the Literature**

The present study contributes important findings to the literature.

First, it validates existing results which have identified different problems and challenges facing Nigeria, which aided the prevalence of falsified medicines in the country. It describes them as systemic challenges. These challenges had something to do with the unique weaknesses and problems facing Nigeria such as high cost of good and quality drugs, absence of an effective health insurance scheme, weak regulatory and enforcement systems; bad politics, consumers' difficulty accessing affordable, safe and quality pharmaceuticals, and poor detection methods. Some of these factors are characterisations typical of pharmaceutical systems in most developing countries.

Second, it also corroborates the position in the extant literature that there was direct and tangential impact of falsified medicines on the public health system in Nigeria. The multidimensionality of the impact of falsified medicines is seen in the creation of public health risks, industry health risks, economic health risks and government revenue risks.

The study also confirms the general view held in the literature that existing measures put in place to tackle the prevalence of falsified medicines in Nigeria were weak and inadequate. Which means government and its agencies have more work to do in improving the existing measures on place.

Lastly, the study also validates the position in the literature that modern solutions that should be evolved to address the prevalence of falsified medicines in Nigeria should aim at systemic change. This change may include overhauling existing regulatory and enforcement mechanisms. It may also involve good and responsible leadership, improvement of the socio-economic realities of poor Nigerians and putting in place effective monitoring systems and processes of the pharmaceutical supply chain in the country.

5.5 **Future Research**

Future researchers may consider different research methodologies to vary the research data to be collected, or to increase the sample size of research participants so as to access more data for analysis. This could involve the deployment of the quantitative research method or a mixed methods strategy. The time horizon could also be longitudinal. This could allow the researcher to collect data at various times within the research period so that research outcomes can be compared for their robustness, similarity or differences. Comparative studies could also help in shedding more light on this subject to improve the understanding of the subject area in the literature.

5.6 **Recommendations**

There is need for the government to process the avalanche of data in the literature at its disposal to tackle the challenges limiting its fight against the prevalence of falsified medicines in Nigeria. Granted that drugs everywhere are usually expensive and are more expensive if they are prescriptive drugs, serious and responsible governments create intervention programmes. They increase/improve the socio-economic statuses of their average citizens who are poor, allow them earn decent wages or provide subsidy or health insurance schemes, all of which ensure that more citizens gain access to quality and safe medicine for the treatment of their conditions and well-being. Government needs to pay more attention to Nigerians including those in the rural areas who appear to be isolated from its health promotion programmes. Exemplary and effective leadership devoid of partisanship would help a great deal to block the loopholes in the system, punish perpetrators of pharmaceutical crimes and provide resources to improve detection and to give more Nigerians including those living in the rural areas more access affordable, safe and quality pharmaceuticals.

There is need to improve the anti-counterfeiting measures and programmes put in place by government. Since these have been found to be inadequate at worst or weak at best, improving these measures by strengthening existing solutions and expanding their felt impact in the general population can help in reducing the prevalence of falsified medicines in the country.

Government with its agencies should also improve its monitoring and surveillance of the pharmaceutical supply chain. Effective monitoring of the pharmaceutical supply chain including effective border control and surveillance could improve the odds in reducing the

prevalence of falsified medicines in Nigeria. Since most of the land borders in the country are porous, government should strengthen its security agencies (e.g. the customs, the immigration and the police) to man its many ungoverned spaces, some of which serve as routes to bring in falsified drugs into the country. This could also discourage terrorist financing channelled into fake drug production and distribution as witnessed in many fragile countries of the world.

There is need to show leadership. Any political leader that loves their people will not hesitate to mobilise funds that would help to escalate solutions needed to improve their access to quality, safe and affordable drugs and reduce or eliminate their dependence on fake drugs for their health conditions. Government should invest in the expansion of existing technology solutions which help in the monitoring and detection of fake drugs within the Nigerian territory. They should also invest in increasing the manpower of regulatory agencies, opening up laboratories in the states in the country and motivating the regulatory workforce to do their jobs as they should and to be able to take bribes or engage in corruption. More training is also required for regulatory agencies to boost the knowledge, skills and competences of their workforce.

5.7 **Conclusion**

This dissertation research employed the qualitative research method to study the contributing factors to the prevalence of falsified medicines in Nigeria with the aim to offering insightful recommendations from the findings made. Eight public health professionals were recruited through purposive sampling from five regulatory/health institutions in Nigeria. Findings show that factors contributing to the prevalence of falsified medicines in Nigeria were part of the systemic challenges facing the country. Government needs to show more leadership, improve the socio-economic realities of citizens and deploy subsidies and interventions (such as health insurance scheme) which could allow many more poor Nigerians to depend less on falsified medicines which are killing and poisoning them. Additionally, findings show that there is a multidimensional risk to the impact of falsified medicines on public health in Nigeria, some of which are direct and tangential. Existing measures are weak and inadequate which require government's focused investment and leadership to improve the present situation. Modern solutions to be applied to rescuing Nigerians from exposure to fake drugs may include an overhaul of the regulatory agencies, effective and benign leadership and effective monitoring

and surveillance of the drug supply channels in Nigeria. It is not enough for government to focus on alleviating the poor conditions of urban dwellers and restricting its interventions to them, the rural dwellers most of whom are poorer and more ignorant than the city dwellers also need to be a major focus of government's health promotion and intervention programmes.

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APPENDIX

Interview Guide

INTERVIEW QUESTIONS

Researcher: Hello. This interview is being recorded and the information is being used for my dissertation titled "An evaluation of the contributing factors to the prevalence of falsified medicines in Nigeria: Findings and recommendations for public health." Do you consent to me using your responses as data for my research?

i. Can you introduce yourself?
ii. What do you understand by falsified medicines?
iii. What are the factors contributing to the prevalence of falsified medicines in Nigeria?
iv. What are the current measures used to combat the spread of falsified medicines in Nigeria? And how effective are these measures?
v. How do falsified medicines impact Nigeria's public health?
vi. How do you think the strict enforcement of pharmaceutical regulations would impact counterfeit medication distribution in Nigeria?
vii. How could Nigeria deal with the enormous issues posed by unregistered drug sellers associated with the massive importation and distribution of counterfeit medications?
viii. Do you believe Nigeria's policies regarding the process for identifying counterfeit medicines are adequate?
ix. What are the likely solutions that can improve existing regulations and enforcement?