

Incorporating Pharmacogenomics into Point-of-Care in Nigeria: A Theory of Change Approach

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

Innopharma Faculty of Pharmaceutical Sciences
Griffith College Dublin

Dissertation supervisor: AnneMarie Larkin

Oritsejeminoyor Cinderella Tuesimi

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CANDIDATE DECLARATION

I hereby declare that this thesis titled “Incorporating Pharmacogenomics into Point-of-Care in Nigeria: A Theory of Change Approach” submitted as a requirement for the MSc in Pharmaceutical Business and Technology, is an original product of my own efforts. Furthermore, I ensure that whenever the work of others has been referenced, appropriate acknowledgment has been provided.

Candidate signature: Oritsejeminoyor Cinderella Tuesimi

Student number: 3089852

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Abstract

Pharmacogenomics (PGx) is the exploration of how genes impact an individual's reaction to drugs. This emerging field merges the study of drugs (pharmacology) with the study of genes and their functions (genomics). Its goal is to create personalized medications and doses that are safe and effective for each person based on their genetic composition. PGx aims to guarantee that patients receive the appropriate drug at the correct dosage. PGx holds promise for personalized medicine, but its integration into health systems, especially in a developing country like Nigeria, poses significant challenges.

This study aimed at exploring the developing an operational model for the implementation of PGx in Nigeria, using the theory of change (ToC) framework. The ToC approach was employed to identify critical preconditions, interventions, and outcomes required to achieve the long-term goal of PGx implementation. Data was collected through mixed-methods, through survey and interviews with multi-stakeholders. The findings were used to explore the development of a potential model for PGx implementation in Nigeria.

This is a challenging task because Nigeria, like many low- and middle-income countries, faces many health system challenges such as inadequate infrastructure, limited human resources, and insufficient funding. In the context of these challenges, the ToC framework was applied. The ToC is a management tool used to establish long-term goals and then work backwards to determine the required steps or conditions needed to achieve those goals.

The ToC was used to identify the critical factors based on stakeholders needs to identify facilitators for successful PGx implementation in Nigeria which included capacity building, policy development, high-tech equipment and skilled personnel, ethical issues around genetic testing, infrastructure upgrade, public awareness, education and training for health providers, stakeholder and government engagement.

The survey revealed that participants had a robust understanding of PGx, with 70% expressing their willingness to incorporate it into their clinical practice. It was found that 37% of respondents foresaw potential applications of PGx in oncology, 22% in infectious diseases, and another 22% in clinical genetics. Challenges hindering the implementation of PGx at the point-of-care were identified as inadequate infrastructure, limited research funding, lack of knowledge and awareness among healthcare professionals (HCPs) and the public, insufficient training for HCPs, inadequate data

availability, prohibitive cost of testing, and a lack of governmental policies and regulations. These barriers align with findings from secondary research.

Upon further dialogue, respondents suggested that the presence of an innovative government, enhanced awareness and education on PGx, specialized training for HCPs in PGx testing, the establishment of necessary infrastructure and the provision of technologies for PGx testing, along with appropriate funding, would serve as facilitators for the integration of PGx into healthcare delivery at the point-of-care in Nigeria.

This operational model investigated here offers a strategic roadmap for how PGx could be effectively integrated into the Nigerian healthcare system. It could potentially have a significant impact on clinical practice and patient outcomes. The model also offers valuable insights that could be used to guide similar efforts in other developing countries. However, the researchers note that further research is needed to evaluate the model's effectiveness and adaptability in real-world settings.

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Abbreviations

Adverse Drug Reactions – ADRs

African Pharmacogenomics Consortium – APC

Clinical Decision Support Systems – CDSS

Disability-Adjusted Life Year – DALY

Electronic Health Records – HER

General Data Protection Regulation – GDPR

Genome-Wide Association Studies – GWAS

Healthcare Professionals – HCPs

Human Heredity and Health in Africa – H3Africa

Informed Consent Form – ICF

Lateral Flow Immunoassay – LFIA

Local Government Health Authorities – LGHAs

National Agency for Food and Drug Administration and Control – NAFDAC

National Drug Law Enforcement Agency – NDLEA

National Health Insurance Scheme – NHIS

National Institute for Pharmaceutical Research and Development – NIPRD

National Pharmacovigilance Centre – NPC

National Primary Health Care Development Agency – NPHCDA)

Noncommunicable Diseases – NCDs

Over-the-Counter – OTC

patient information leaflet – PIL

Pharmacists Council of Nigeria – PCN

Pharmacogenomics – PGx

Point-of-Care – POC

primary healthcare – PHC

State Governments – SG

Theory of Change – ToC

World Health Organization – WHO

1 Introduction

Pharmacogenomics (PGx), the study of how genetic variations influence individual responses to medications, has the potential to revolutionize the field of personalized medicine (Hicks et al., 2016). By tailoring drug therapies to a person's unique genetic makeup, PGx can enhance treatment efficacy, reduce adverse drug reactions, and improve overall patient outcomes. However, the integration of PGx into clinical practice, particularly in resource-limited settings like Nigeria, remains a formidable challenge. This research aims to explore the development of a model that could use to implement PGx point-of-care (POC) using the Theory of Change (ToC) framework to guide the process.

1.1 Overview of the Nigerian Healthcare System

Nigeria's healthcare system is divided into three distinct tiers that reflect the political structure of the nation: local (primary), state (secondary), and federal (tertiary). These tiers constitutes the public healthcare system (Idowu and Okedere, 2020). For the majority of Nigerians, the primary healthcare (PHC) system serves as their first point of contact and is responsible for providing the populace access to basic healthcare services. Preventive and basic curative treatment, maternity and child health, immunization, family planning, and health education are the main areas of emphasis (Aregbeshola, 2021). The Local government health authorities (LGHAs) are in charge of providing PHC services, while the National Primary Health Care Development Agency (NPHCDA) is the main organization in charge of implementing and coordinating PHC activities (Ubochi *et al.*, 2019) (Aregbeshola, 2021). The State Governments (SG) are in charge of secondary healthcare services, which are primarily offered at General Hospitals. With a wider selection of diagnostic and therapeutic treatments, these hospitals provide more specialized care. They are made to serve patients whose needs are more complex than what is provided at the primary level. Secondary care institutions act as referral centres for PHC facilities (Aregbeshola, 2021).

The highest level of care, known as tertiary care, is given in specialized hospitals, federal medical facilities, and teaching hospitals. For complex medical diseases, these facilities provide cutting-edge diagnostic, therapeutic, and management services (Aregbeshola, 2021). The majority of tertiary healthcare facilities are associated with universities and are in charge of carrying out research and educating healthcare professionals (HCPs). The Federal Ministry of Health oversees their administration (Balogun, 2021). The coordination of the national health policy's implementation, as well as the provision of planning and technical assistance, are part of the responsibility of the federal government (Balogun, 2021).

In Nigeria, the private healthcare sector is expanding quickly and taking a significant role in the delivery of healthcare services. Private healthcare providers offer a range of services, from basic medical attention to specialized medical care. The services offered by private HCPs range from routine medical care to specialist medical treatment. (Aregbeshola, 2021).

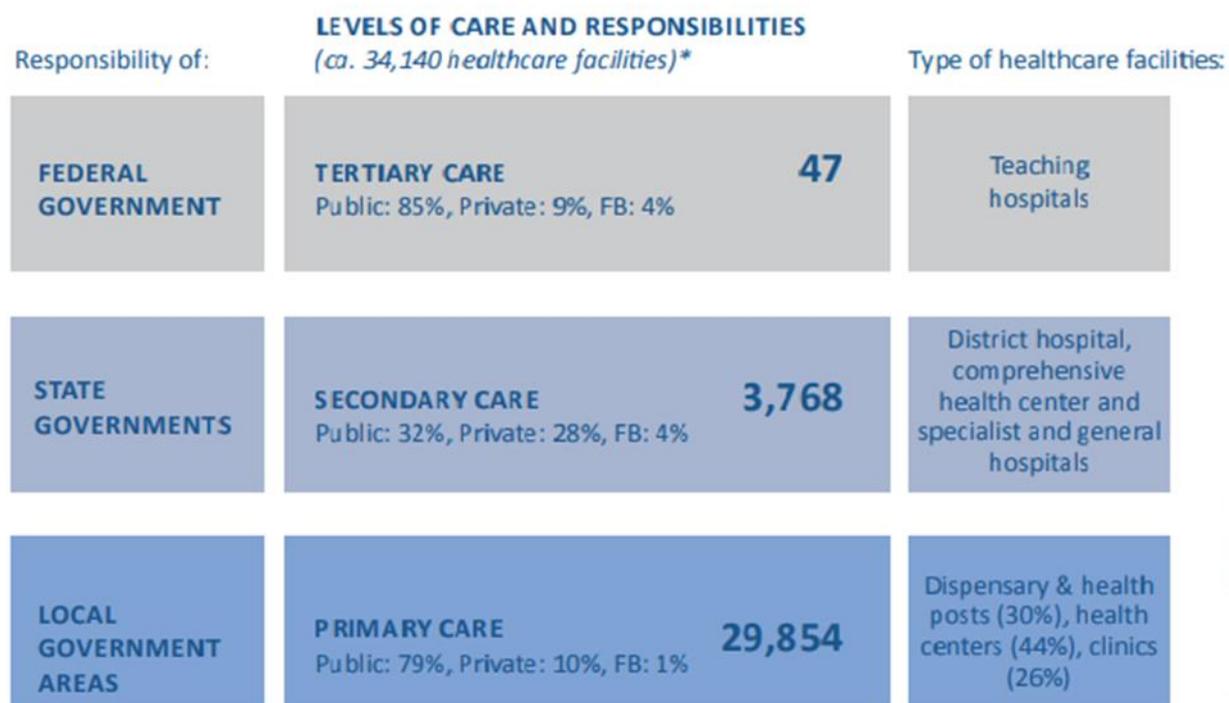


Figure 1.1 The levels of care and responsibilities across the different health system in Nigeria (PharmaAccess, 2016).

The National Health Insurance Scheme (NHIS) is another crucial component of the Nigerian health system. It aims to provide financial protection and improve access to healthcare for all Nigerians but it covers a small fraction of the population, leaving many Nigerians to pay out-of-pocket for healthcare. Nigeria has one of the lowest per-capita healthcare costs in the world, the country's low-quality healthcare is primarily caused by the inadequate health budget. Nigerians contribute significantly more to their health than people in any other country in Africa due to the federal government's poor funding of healthcare (Balogun, 2021).

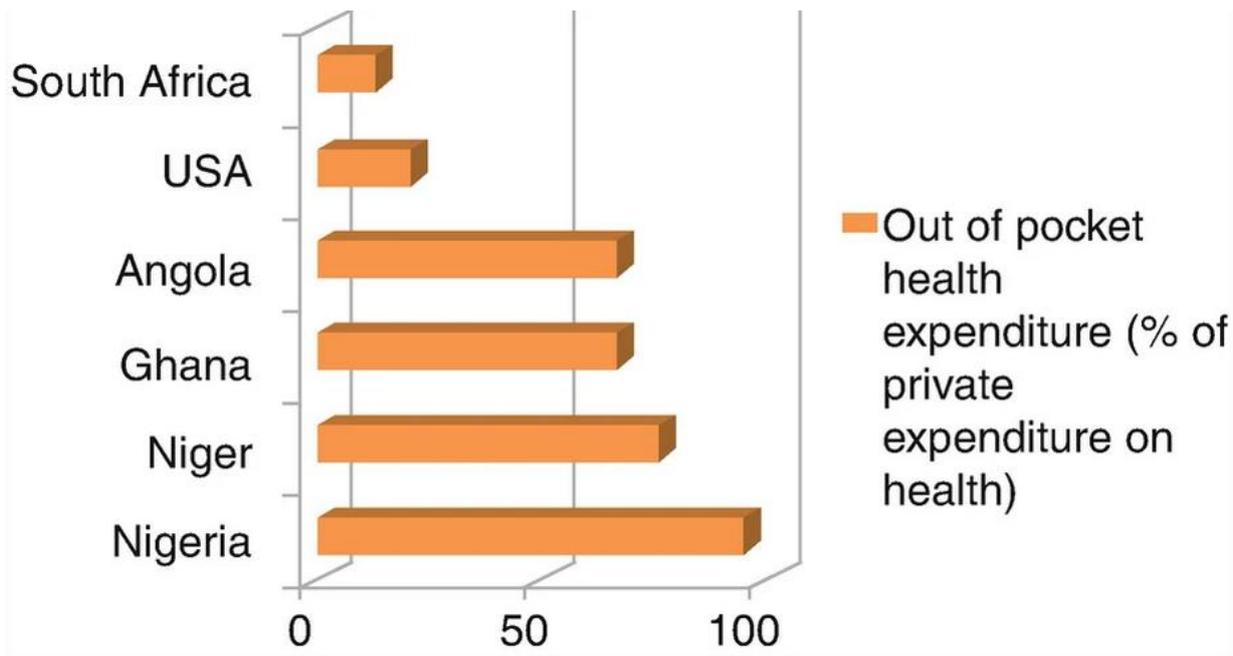


Figure 1.2 Out-of-pocket health expenditure (percentage of private spending on health) in selected countries around the world (Balogun, 2021).

With nearly 200 million citizens and an anticipated increase of 401.31 million by 2050, Nigeria is the most populated nation in Africa (World Population Review, 2023). Nigeria's healthcare system faces challenges in meeting the needs of its growing population. When assessed on a global scale, it ranked 142nd out of 195 countries (Usoro *et al.*, 2021). According to Adenipekun (2023), Nigeria consistently witnesses a significant brain drain phenomenon, with highly skilled healthcare professionals leaving the country for opportunities abroad, contributing to one of the highest rates of brain drain globally. The study by Ogueji *et al.*, (2023) HCP mistrust within the Nigerian healthcare system was thoroughly examined. The findings revealed that this mistrust stemmed from various factors that negatively impact the system. These factors encompassed a compromised educational system, low morale among healthcare workers due to inadequate compensation, lack of professionalism within the healthcare workforce, misinterpretation of laboratory investigation results resulting in misdiagnosis, inadequate availability of medical equipment, limited accessibility to essential services, workforce shortages, absence of patient-centered care, and insufficient healthcare financing. With several diseases outbreak yearly, it's clear that the current health system is weak and ill prepared to evaluate, monitor and control disease within its population (Usoro *et al.*, 2021).

Ranking of leading age-standardized rates of disability-adjusted life years (DALYs) relative to comparator countries in 1990																									
Country	Malaria	Diarrheal diseases	Lower respiratory infections	Protein-energy malnutrition	Measles	Neonatal sepsis	Meningitis	Preterm birth complications	Neonatal encephalopathy	Iron-deficiency anemia	Tuberculosis	Road injury	Fire	Low back pain	Stroke	Falls	Congenital anomalies	Tetanus	Maternal disorders	Epilepsy	Syphilis	Ischemic heart disease	COPD	Interpersonal violence	Asthma
Solomon Islands	6	2	1	5	3	5	6	1	1	1	12	5	12	8	15	13	1	7	3	5	15	11	13	12	14
Papua New Guinea	9	3	15	9	4	6	9	2	2	4	15	6	14	6	1	14	6	11	12	6	9	8	12	9	15
Djibouti	3	5	9	14	10	7	10	12	11	5	4	15	13	13	9	2	11	5	10	11	5	10	5	7	4
Laos	5	11	12	6	8	3	5	10	4	7	14	4	4	3	13	4	15	15	8	2	6	13	14	13	13
Kyrgyzstan	1	1	7	1	1	1	1	5	15	2	2	10	1	5	14	6	12	1	1	3	1	14	15	14	1
Sudan	7	8	3	13	5	8	7	7	9	9	6	8	11	15	4	1	7	4	9	7	13	4	2	1	3
Cameroon	13	10	4	10	12	10	11	8	7	8	5	14	9	11	5	12	5	6	11	15	14	7	6	3	5
Nigeria	15	13	11	15	15	15	14	13	14	13	10	13	15	14	3	15	4	12	7	10	10	2	1	15	6
Mauritania	4	12	5	7	14	12	8	9	10	15	8	11	6	10	6	5	3	10	15	9	12	5	4	5	11
Cambodia	8	4	8	4	9	4	3	11	6	12	13	3	2	2	12	3	14	14	5	1	8	12	9	4	12
Tajikistan	2	9	13	2	2	2	2	15	13	3	1	7	3	7	11	7	10	2	2	4	2	15	3	6	2
Senegal	12	14	10	3	13	9	12	3	3	11	11	1	5	1	2	9	2	8	13	14	4	1	8	2	9
São Tomé and Príncipe	10	6	2	11	6	11	4	6	8	10	3	2	7	9	8	8	13	3	4	8	3	3	11	8	7
Côte d'Ivoire	14	15	6	8	7	13	13	14	12	6	7	12	8	4	7	11	8	9	6	13	7	6	7	11	8
The Gambia	11	7	14	12	11	14	15	4	5	14	9	9	10	12	10	10	9	13	14	12	11	9	10	10	10
Ranking of leading age-standardized rates of disability-adjusted life years (DALYs) relative to comparator countries in 2010																									
Country	Malaria	HIV/AIDS	Lower respiratory infections	Neonatal sepsis	Diarrheal diseases	Road injury	Protein-energy malnutrition	Preterm birth complications	Meningitis	Neonatal encephalopathy	Iron-deficiency anemia	Low back pain	Fire	Tuberculosis	Maternal disorders	Congenital anomalies	Falls	Stroke	Epilepsy	Sickle cell	Major depressive disorder	Interpersonal violence	Ischemic heart disease	Syphilis	Cirrhosis
Solomon Islands	5	1	2	5	5	4	6	1	6	1	1	11	7	13	5	2	8	15	3	6	1	11	11	12	10
Papua New Guinea	7	7	15	6	6	5	8	2	8	2	3	12	11	15	8	7	11	4	5	3	8	9	9	9	14
Djibouti	6	13	6	7	9	14	13	7	9	9	11	13	14	10	12	9	3	8	11	7	14	12	5	3	5
Laos	3	2	8	3	8	7	5	11	5	5	5	3	3	14	6	15	6	12	1	1	12	13	12	7	7
Kyrgyzstan	1	5	5	1	1	8	1	10	1	15	2	6	2	3	2	12	7	14	4	5	5	14	15	1	15
Sudan	8	10	3	8	10	9	11	5	7	8	10	15	9	4	7	3	1	1	8	8	15	2	1	15	1
Cameroon	12	15	12	11	13	13	12	8	14	10	7	9	12	5	14	8	14	5	15	14	3	4	8	14	12
Nigeria	15	12	11	15	11	15	15	14	13	13	12	14	15	8	13	4	15	3	9	15	2	15	4	13	9
Mauritania	9	8	10	12	12	11	9	12	11	11	15	8	10	7	15	6	9	6	13	9	7	6	6	11	8
Cambodia	4	4	4	4	2	6	4	13	2	6	9	2	1	11	3	13	2	11	2	2	6	8	13	5	3
Tajikistan	2	3	7	2	4	3	2	9	3	12	4	5	4	2	1	14	4	13	6	4	9	5	14	6	11
Senegal	11	6	9	10	14	1	3	4	10	3	14	1	5	9	9	1	10	2	12	10	4	1	2	4	4
São Tomé and Príncipe	10	9	1	9	3	2	7	3	4	4	6	7	6	1	4	5	5	7	7	11	13	3	3	2	2
Côte d'Ivoire	14	14	14	14	15	12	14	15	14	8	4	13	12	11	10	13	10	14	13	10	10	10	10	8	13
The Gambia	13	11	13	13	7	10	10	6	12	7	13	10	8	6	10	11	12	9	10	12	11	7	7	10	6

Figure 1.3 Disability-adjusted life years (DALYs) disease burden in Nigeria compared to other countries (Institute for Health Metrics and Evaluation, 2023).

The numbers represent the ranking of each cause across countries based on age-standardized Disability-Adjusted Life Year (DALY) rates. Here, a rank of 1 signifies the best performance, while a rank of 15 indicates the worst performance.

Noncommunicable diseases (NCDs) cause about 25% of all deaths in Nigeria (see figure 1.4). This fatality is caused by a lack of disease surveillance and management, a lack of funds, a labor shortage, unequal access to healthcare, and poor healthcare system. There is no official estimate of the morbidity and death from medicine use in the nation (Adesina *et al.*, 2020) (Olowofela *et al.*, 2016).

In their study, Adesina *et al.*, (2020) stated that addressing the risk factors can prevent these deaths. They proposed that individuals, the government, interdisciplinary and multidisciplinary researchers,

politicians, etc. should all be involved in addressing the risk factors to the diseases. The underdeveloped health system in Nigeria often leads to low-quality services and various issues such as drug abuse, self-medication, drug resistance, and adverse drug reactions (ADRs) (Usoro *et al.*, 2021).

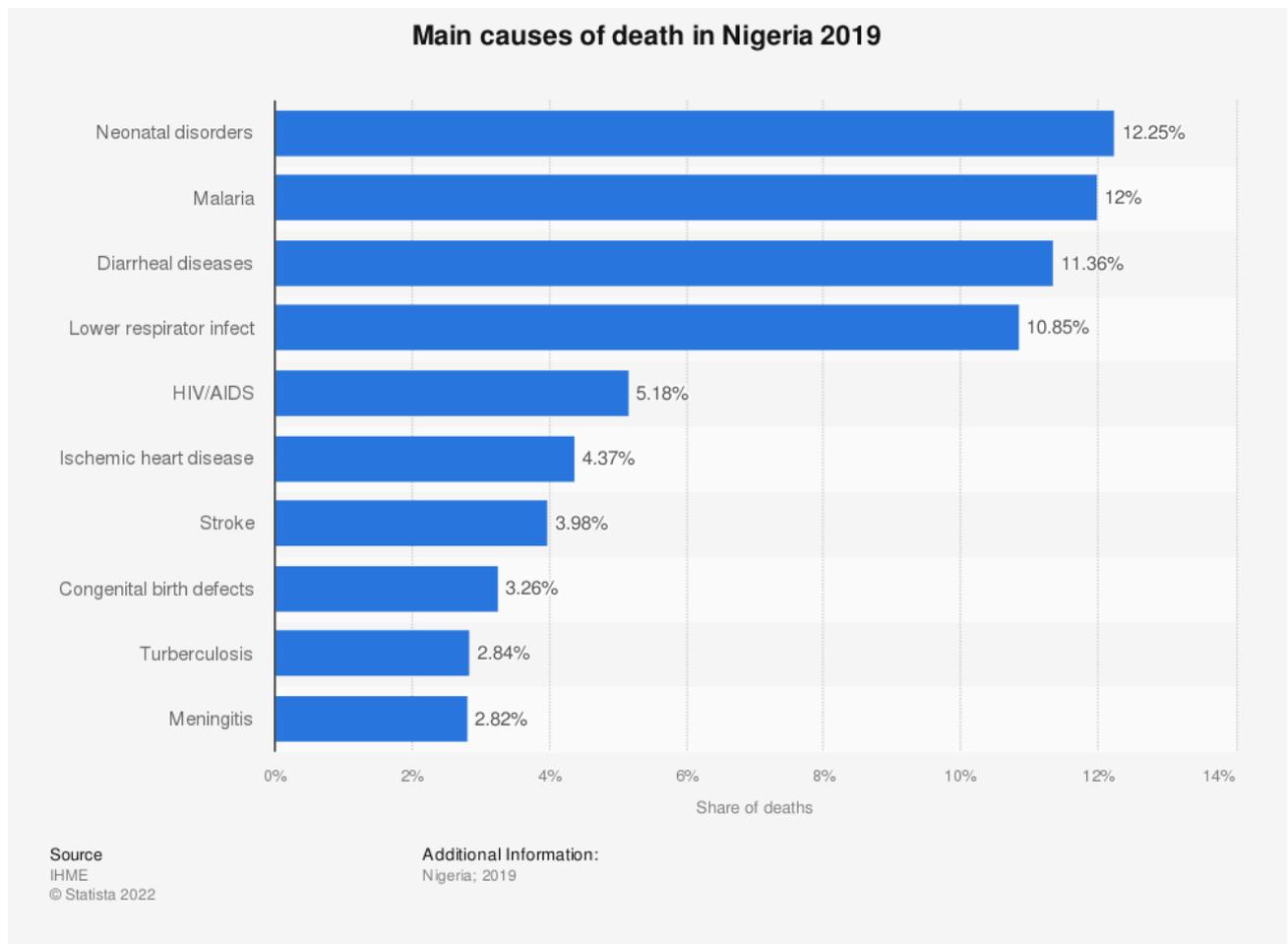


Figure 1.4 Diseases that cause most deaths in Nigeria.

Adverse drug reactions (ADRs) are a significant public health concern in Nigeria, contributing to increased morbidity, mortality, and healthcare costs (Micaglio *et al.*, 2021). ADRs are caused by drug-gene interactions associated with genetic variations that affect drug metabolism, transport, and target interactions (Akhideno *et al.*, 2019). The cytochrome P450 (CYP) family of enzymes plays a significant role in drug metabolism, CYP2C9, CYP2C19, and CYP2D6, are known to metabolize a large proportion of drugs. Variations in these genes can result in different enzymatic activity levels, ranging from poor to ultra-rapid metabolism, which can significantly affect drug efficacy and risk of adverse reactions (Malki and Pearson, 2020). Pharmacogenomics uses genetic variations to identify patients at higher risk of experiencing ADRs, allowing healthcare providers to adjust medication regimens or select alternative treatments (Malki and Pearson, 2020).

Pharmacogenomics (PGx), the study of how genetic variations influence individual responses to medications, has the potential to revolutionize the field of personalized medicine (Hicks et al., 2016). By tailoring drug therapies to a person's unique genetic makeup, PGx can enhance treatment efficacy, reduce adverse drug reactions, and improve overall patient outcomes (Krebs and Milani, 2019). PGx testing can help identify genetic markers that determine how an individual metabolizes specific drugs. This information enables HCPs to prescribe the most appropriate medication and dosage for each patient, maximizing therapeutic benefits while minimizing the risk of side effects (Rigter *et al.*, 2020). By tailoring drug therapies to an individual's genetic profile, PGx can improve treatment outcomes for a wide range of medical conditions, such as cancer (Miteva-Marcheva *et al.*, 2020), cardiovascular diseases (Al-Mahayri *et al.*, 2022), and psychiatric disorders (van Schaik *et al.*, 2020). In Nigeria, there are ongoing efforts to introduce PGx-guided treatment, and studies are currently underway to assess the prevalence of genetic polymorphism among individuals living with HIV who are undergoing highly active antiretroviral therapy (Bolaji et al., 2019).

The Theory of Change framework offers a systematic approach to analyse and address these challenges by mapping out the causal pathways and preconditions necessary for achieving the desired outcomes (De Silva *et al.*, 2014). The Theory of Change (ToC) framework serves as a valuable tool for designing, implementing, and evaluating complex interventions, including the integration of point-of-care (POC) services for pharmacogenomics (PGx). It offers an effective mechanism for developing evidence-based strategies for operational change, control, and improvement.

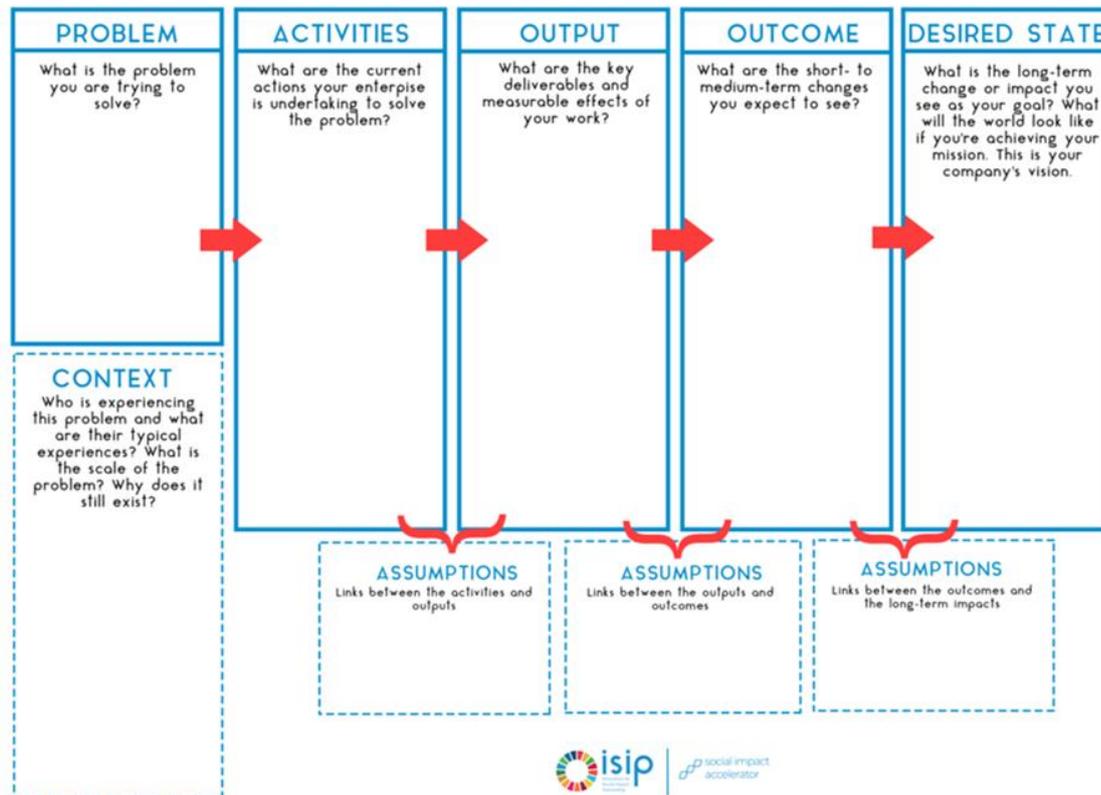


Figure 1.5: An illustration of the theory of change framework (ISIP, 2018).

The inspiration for this study is based on the study by Adedeji et al., (2022), who used the ToC to successfully implement electronic health records in primary care at Festac Primary Health Centre in Lagos, Nigeria.

To my understanding, the ToC framework has not previously been applied in the field of pharmacogenomics (PGx). Consequently, to provide a roadmap for this investigation, we will be guided by the studies of Caraballo et al., (2017), titled "Multidisciplinary model to implement pharmacogenomics at the point of care," and Petry et al., (2020) in their work "Implementation: A Guide to Implementing Pharmacogenomics Services."

1.2 Research Purpose

The purpose of this research study is to explore the development of a systemic, evidence-based approach to address the challenges and barriers associated with integrating PGx into clinical practice in a resource-limited setting. The study will evaluate the knowledge, attitude, and perception of multiple stakeholders towards PGx services. The study will also identify the barriers and facilitators to implementing of PGx testing in POC. This research will also investigate the feasibility, acceptability, and effectiveness of a PGx POC service in Nigeria by conducting an in-depth analysis

of the contextual factors, identifying barriers and facilitators, and outlining the required interventions for successful implementation. By exploring the complex interplay between the healthcare system, regulatory landscape, and other relevant factors, this research aims to develop a comprehensive model that may serve as a blueprint for integrating PGx POC services in Nigeria. Ultimately, this research may contribute to the advancement of personalized medicine in Nigeria, paving the way for improved patient care and better health outcomes.

1.3 Research Objective

The overall aim of this study is to explore the development of an operational model for the implementation of PGx in Nigeria.

The specific objectives are as follows:

- To Identify key stakeholders involved in the implementation of PGx in Nigeria and understanding their roles and responsibilities.
- To develop a potential model for the implementation of PGx in Nigeria using the Theory of Change framework.
- To assess the feasibility of implementing the proposed model and identifying potential barriers to implementation.
- To evaluate the impact of the proposed model on patient outcomes
- To provide recommendations for policymakers and healthcare providers on measures to effectively implement PGx in Nigeria.

By achieving these objectives, the outputs from this research study have the potential to be used to develop a comprehensive model for the implementation of PGx in Nigeria, which can be used to guide future research and policy decisions.

Research Question

1. What is the current knowledge and awareness level of HCPs regarding PGx?
2. What are the potential barriers and facilitators to implementing PGx at the point-of-care?
3. What is the most important outcome to measure successful implementation of PGx in point-of-care?
4. How can the theory of change approach be used to guide the successful incorporation of PGx into point-of-care?

1.4 Significance of study

The outputs from this study which is focused on the development of a model for the implementation of PGx POC in Nigeria using the ToC have the potential to gain important insights into the possibility of the integration of PGx into clinical practice in Nigeria. Successful application of PGx across healthcare has the potential to revolutionize personalized medicine by tailoring drug therapies to individual genetic profiles leading to enhancement of treatment efficacy, reduction in ADRs and ultimately significantly improve patient outcomes. This study seeks to develop a model that facilitates the implementation of PGx POC services in Nigeria, directly contributing to better healthcare for its population.

The study brings together professionals from various fields, including the scientific disciplines of genetics and pharmacology, healthcare, and public policy, promoting interdisciplinary collaboration and knowledge exchange. Such collaboration can lead to innovative solutions and a comprehensive understanding of the factors affecting the implementation of PGx POC services in Nigeria. The findings of this study may inform policymakers and healthcare practitioners on the necessary steps, investments, and regulatory measures needed to successfully implement PGx POC services in Nigeria. In the longer term and further development this research has the potential to influence healthcare policies and practices that promote the adoption of personalized medicine and enhance the overall quality of healthcare provision in Nigeria.

The ToC framework has the potential to represent a useful tool for developing a model for the implementation of PGx point of care in Nigeria. This framework helps to identify the key components of the implementation process and determine the most effective strategies for achieving the desired outcomes. The study will provide valuable insights into the challenges and opportunities associated with implementing PGx in Nigeria and will help to identify the most effective strategies for overcoming these challenges.

Overall, by developing a model for the implementation of PGx point of care in Nigeria using the theory of change framework, the quality of healthcare can be improved and ensure that patients receive the most effective treatments possible. Additionally, the study can provide valuable insights into the challenges and opportunities associated with implementing PGx in Nigeria, which can inform future research and policy decisions in this area.

1.5 Structure of the study – Research Design

Primary data will be acquired through mixed-methods research, combining both qualitative and quantitative research methods. The quantitative research methods such as online surveys will be used to gather data from different occupational background in order to gain a vast perspective of PGx and identify significant similarities among variants. The survey will be designed using Microsoft Excel and distributed to participants via LinkedIn.

The survey targets a variety of stakeholders in Nigeria, including healthcare providers, researchers, and policymakers. Its purpose is to evaluate their understanding, attitudes, and views concerning PGx and its application in clinical settings. The participants chosen for this study have some familiarity with PGx and have experience in Nigerian healthcare delivery. This selection ensures that the participants are well-versed to address the social, cultural, economic, ethical, and technical challenges related to the introduction of PGx at the point of care. Semi-structured questionnaires will be used to explore specific themes and get in-depth responses from respondents. The survey questionnaire was designed to complement the qualitative questions for the interview.

For the qualitative component, a separate group of stakeholders, who are not involved in the survey, will be invited for interviews. These interviews aim to delve deeper into the stakeholders' perspectives, understand their specific needs, and identify potential obstacles and strategies for implementing pharmacogenomics. The qualitative data gathered will enhance our understanding, aiding in explaining and contextualizing the results obtained from the quantitative survey.

2 Literature Review

2.1 Background

Nigeria is a country in West Africa with a population of over 200 million people and housing one-fourth of the African population, making it the most populous country in Africa. With over 300 ethnic groups, Nigeria has a diverse genetic pool due to the large number of ethnic groups and their distinct genetic backgrounds (Bolaji *et al.*, 2019). The three largest ethnic groups in Nigeria, the Hausa, Yoruba, and Igbo, have varying genetic characteristics and are known to have genetic variations that are different from each other and from other ethnic groups. There is also a significant amount of genetic diversity within each ethnic group due to various factors such as migration, intermarriage, and environmental influences (Bolaji *et al.*, 2019).

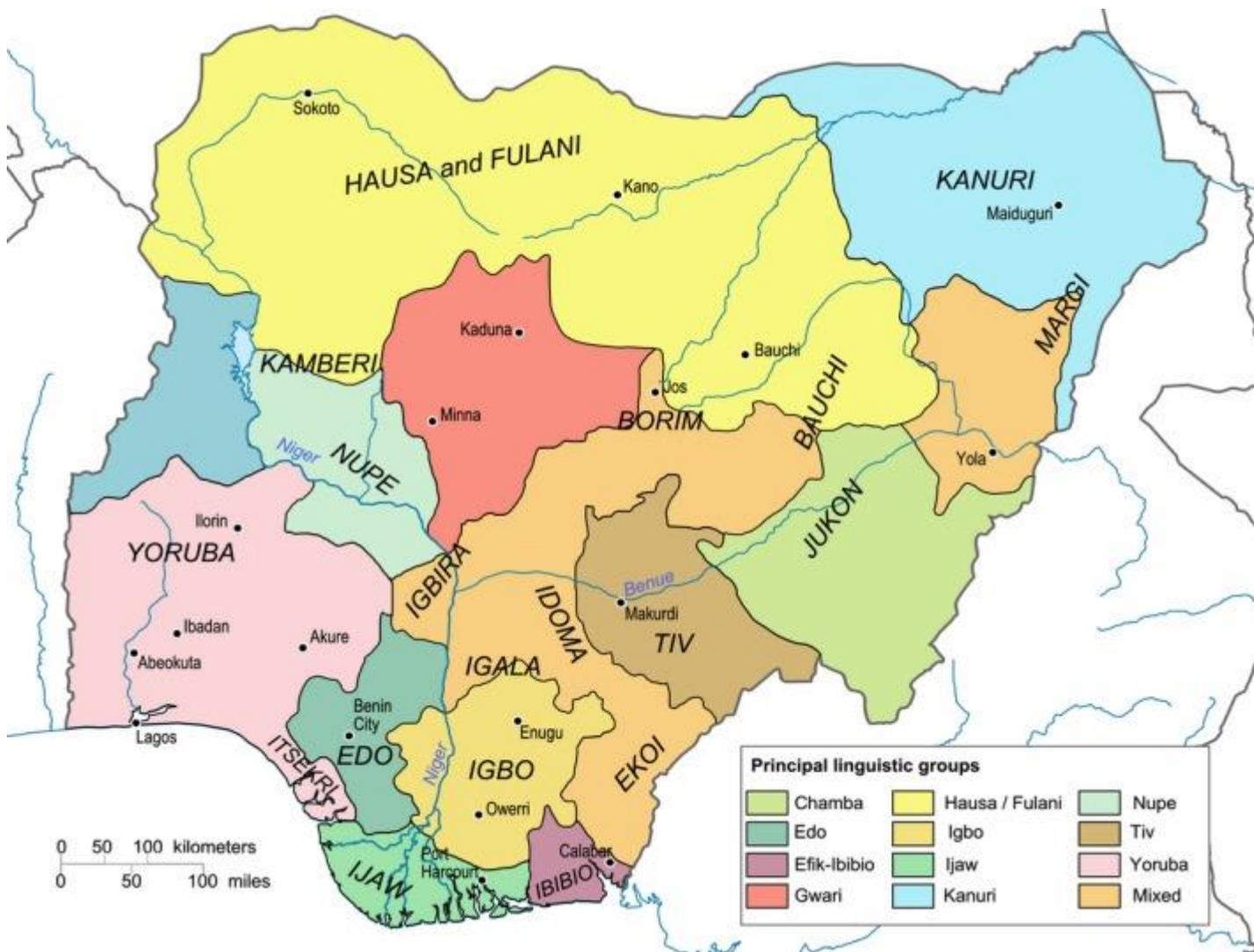


Figure 2.1 Ethno-linguistic map of Nigeria (Adeyemo *et al.*, 2018).

These variances may be more common in some ethnic groups, which may cause individuals from various ethnic origins to respond to medications differently. In recent years, studies have shown that the genetic diversity in Nigeria is among the highest in the world, these genetic differences can also increase the propensity to experience ADRs (Bolaji *et al.*, 2019) (Rajman *et al.*, 2017). Some of the some of the commonly used drugs in Nigeria like anti-malarials, antiretrovirals, anti-microbials and anti-tubercular they have been reported to have high ADRs which was not recorded in clinical trials.

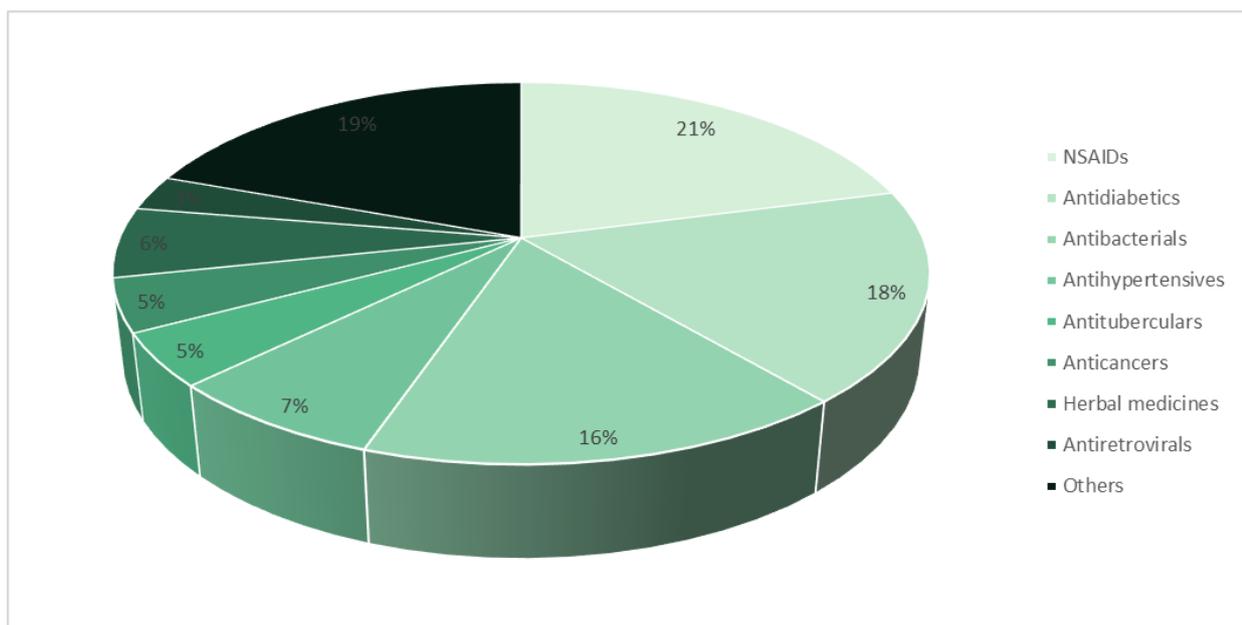


Figure 2.2: Most Implicated Classes of Drugs in Adverse Drug Reporting in Nigeria (Akhideno *et al.*, 2019).

The poor understanding of how medications affect the Nigerian population can be attributed to the lack of ADR reporting, underrepresentation of Africans in research and clinical trials as most clinical trials are conducted in North America and Europe; also the lack of genomic data on individuals of African ancestry which is about 3% of genome-wide association studies (GWAS) data (Titilayo *et al.*, 2018) (Dandara *et al.*, 2019) (Omotoso *et al.*, 2022). According to Bolaji, Adehin and Adeagbo (2019), strides have been made by the Human Heredity and Health in Africa (H3Africa) (<https://h3africa.org/>), 54gene (<https://54gene.com/>), African Pharmacogenomics Consortium (APC) and others, to sequencing more Africans genomes (including Nigerians), increasing research collaborations, and raising awareness for personalised medicines in Nigeria and other African countries. They also highlighted the need for having pharmacogenomics data on antimalarials, anticancer, antitubercular and antiretroviral drugs which are commonly used in Nigeria with reported high ADR.

There have been initiatives to create personalized medicine strategies that consider an individual genetic variation as well as to improve the representation of diverse populations in clinical trials in order to solve these problems. For people from various ethnic origins, these initiatives may result in safer and more effective medication regimens. PGx has the potential to revolutionize the field of personalized medicine (Hicks et al., 2016). By tailoring drug therapies to a person's unique genetic makeup, PGx can enhance treatment efficacy, reduce ADRs, and improve overall patient outcomes. However, the integration of PGx into clinical practice, particularly in resource-limited settings like Nigeria, remains a formidable challenge.

The inadequate programs designed to address the numerous health problems in Nigeria have led to the little improvement in our health status (Muhammad *et al.*, 2022). To enhance the health of the population in Nigeria and overcome these challenges, it's crucial to implement targeted, evidence-based interventions that specifically address the primary causes of poor health in the country (Angell *et al.*, 2022).

2.2 Drug Prescription and Current State of PGx in Nigeria

The National Agency for Food and Drug Administration and Control (NAFDAC) is responsible for regulating drugs in Nigeria. The National Agency for Food & Drug Administration & Control (NAFDAC) is the body responsible for providing guidelines for regulating drugs in Nigeria. NAFDAC work together with the Pharmacists Council of Nigeria (PCN) and National Drug Law Enforcement Agency (NDLEA), to uphold and enforce rational drug prescribing and dispensing, as well as to guarantee that best practices are followed when managing drugs in Nigeria. The standard for prescribing drugs in Nigeria healthcare system as required by the NAFDAC and NDLEA is that all drugs must be prescribed and dispense by qualified HCPs such as medical doctors, nurses, or pharmacists. The prescription process consists of various processes designed to ensure that patients' drugs are safe and effective (Animasahun *et al.*, 2019).

During consultation, the HCP evaluates the patient's medical condition through obtaining their medical history, doing a physical examination, and, if required, ordering diagnostic tests. A diagnosis is made by the HCP based on the information obtained. Once a diagnosis is determined, the HCP chooses the best drug for the patient's condition. They assess criteria such as the patient's medical history, current medications, potential drug interactions, and any contraindications. Then the healthcare practitioner chooses the right dosage and duration of treatment based on parameters such as the patient's age, weight, kidney and liver function, and the severity of the ailment being treated. The medical

professional and pharmacist are critical in teaching the patient about the recommended drug, how to use it properly, and the significance of adhering to the prescribed regimen. Follow-up appointments may be planned in some circumstances to monitor the patient's progress and make any required changes to the treatment plan.

Conversely, in Nigeria, self-medication is a widespread practice that is driven by issues like poor access to healthcare, expensive medical treatment, and inadequate health literacy. Without a prescription, anyone may buy over-the-counter (OTC) medicines, which can result in abuse, misuse, and possible drug interactions. Pharmacists are essential to the Nigerian drug prescription process because they guarantee the safe and efficient use of medicines. Their duties include prescribing, patient counselling, medication monitoring, and coordination with other HCPs (Oladipo *et al.*, 2022).

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2.3 Introduction to PGx

PGx is the field of study that explores how an individual's genetic composition affects their response to medications (Stevenson and Berenbrok, 2021). The field of PGx is an example of precision medicine that combines two branches of medicine; pharmacology, which examines the effects of drugs on the body, and genomics, which investigates the functions of genes, to study drug reactions, in order to deliver tailored medicine to an individual or group of individuals (Centres for Disease Control and Prevention, 2022).

Traditionally, most of the medicinal products produced in past years offer the promise of “one-size-fit-all” but do not offer the same efficacy, benefits and results in all patients as their response to drug cannot be predicted which can lead to adverse drug reactions (National Institutes of Health, 2022). Over the years, there have been many progressions in how healthcare is delivered to patients. Personalized healthcare/medicine is an advancing field which seeks to offer the best treatment for patients through targeted treatments based on the understanding of a patient’s demographic information, genomic information, and other relevant molecular information then used to combat diseases (Jain, 2019).

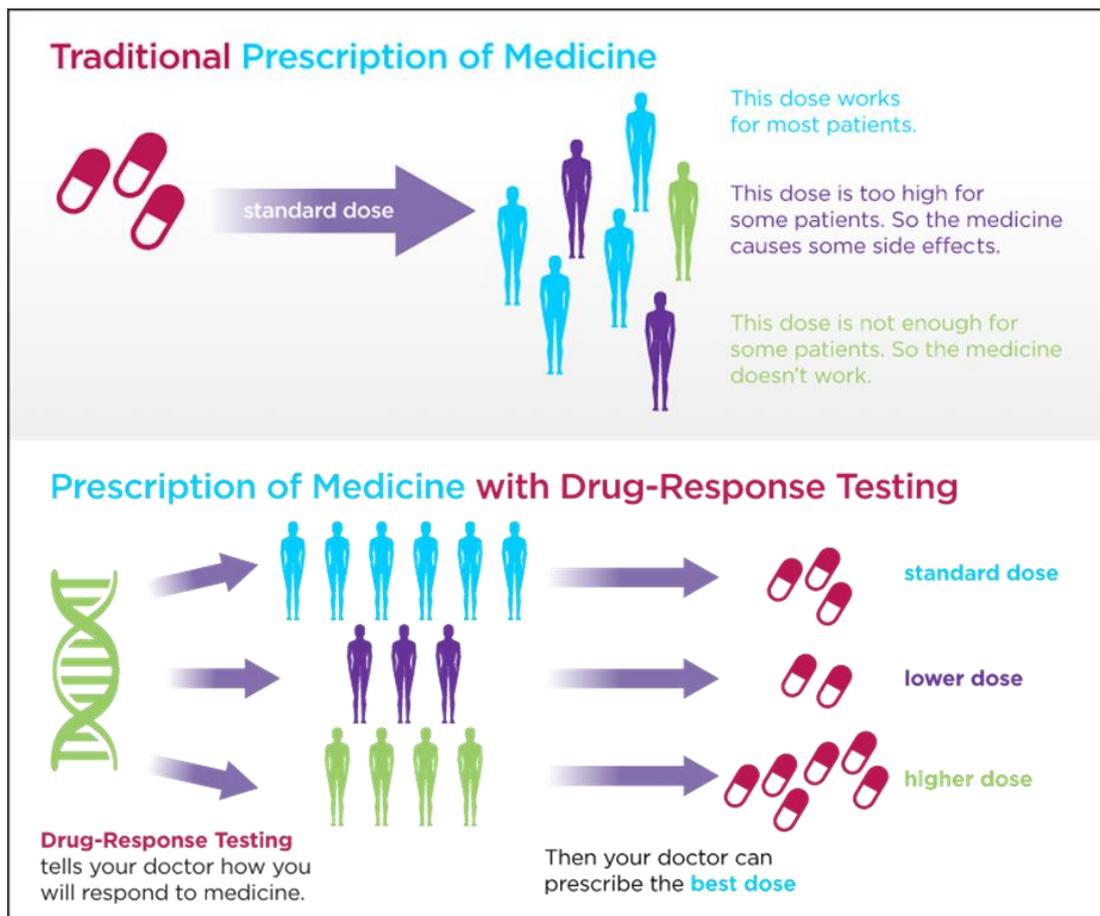


Figure 2.3: Comparison Between traditional Prescription of Medicine and PGx (Permanente, 2023).

The implementation of PGx in POC settings in Nigeria has the potential to improve patient outcomes and reduce healthcare costs save healthcare costs by enhancing medication efficacy and safety, rationalizing drug use, lowering the price of drug development, maximizing healthcare resources, and offering tailored drug therapies (Petry *et al.*, 2020). PGx testing is used to streamline the right medication for a patient by providing information on the suitable dosage to be taken, the efficacy and possible risks that may arise from a medication (Mayo Clinic, 2023). There are different approaches to carry out PGx testing, but the overall activities involved in the testing cycle is presented in figure 2.5.

PHARMACOGENOMIC TESTING CYCLE

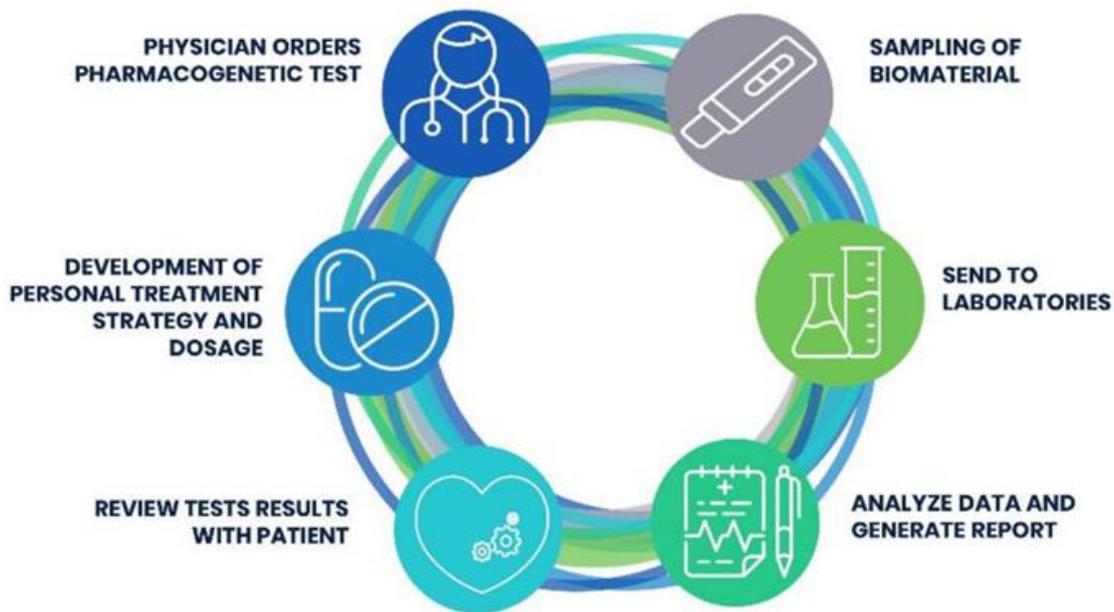


Figure 2.4: Schematic representation of PGx testing (Malsagova et al., 2020).

2.4 The need for PGx testing in Nigeria.

With Nigeria's unique genetic variations, implementing PGx in POC setting can hold great promise. Firstly, ADR are a major concern in healthcare worldwide, the majority of the reported cases were due to antibiotics, antimalarials, and antiretroviral drugs which are the commonly used drugs in the country (Akhideno *et al.*, 2019). PGx data on these drug groups are available and can that provide the accurate profile of medicinal products that can be used for the Nigerian population to provide an effective and safe therapy for these diseases, thereby reducing the incidence of adverse reactions to these drugs (Bolaji *et al.*, 2019).

Secondly, many medications have potentially dangerous side effects, especially when prescribed inappropriately. By incorporating PGx into clinical practice, doctors can identify patients who may be at a higher risk of experiencing adverse reactions to specific drugs. This information can help doctors make more informed decisions about which medications to prescribe and at what dosage.

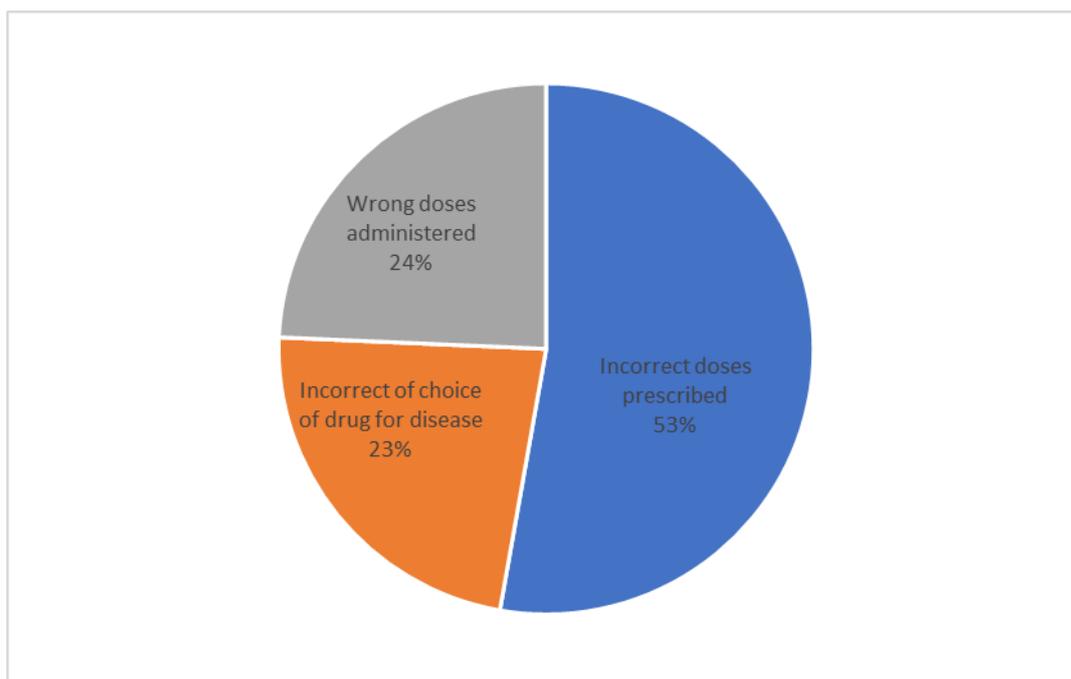


Figure 2.5: Incidence of medical errors in Nigeria (Ogunleye et al., 2016).

Finally, PGx has the potential to reduce the cost of healthcare in Nigeria. By prescribing drugs that are more likely to be effective, doctors can minimize the need for trial-and-error prescribing, reducing the number of failed treatments and the cost associated costs. This approach can also help minimize the need for additional medical interventions and hospitalizations, leading to significant cost savings.

Gene		Disease-associated alleles	Implicated diseases
CACNA1S	Calcium voltage-gated channel subunit alpha1 S)	3	Malignant hyperthermia, exercise-induced rhabdomyolysis, Statin-associated myopathy.
CFTR	Cystic fibrosis transmembrane conductance regulator)	40	Cystic fibrosis
CYP2D2	Cytochrome P450 2D6	310	Various diseases like brain diseases, cardiovascular, cancer and adverse drug reactions
CYP2B6	Cytochrome P450 family 2 subfamily b member 6	35	Hepatic diseases
CYP2C19	cytochrome P450 family 2 subfamily C member 19	34	Ischemic heart disease
CYP2C9	Cytochrome P450 family 2 subfamily C member 9	71	Cardiovascular diseases
CYP3A5	Cytochrome P450 family 3 subfamily a member 5	9	Hypertension
CYP4F2	Cytochrome P450 family 4 subfamily f member 2	3	Cardiovascular diseases and chronic obstructive pulmonary diseases.
DPYD	Dihydropyrimidine dehydrogenase	83	Cancer
IFNL3	Interferon lambda 3	2	Multiple sclerosis
NUDT15	Nudix hydrolase 15	20	Inflammatory bowel disease.
RYR1	Ryanodine receptor 1	49	Neuromuscular diseases
SLCO1B1	Solute carrier organic anion transporter family member 1B1	37	Cardiovascular diseases
TPMT	Thiopurine S-methyltransferase	46	Auto-immune diseases (lymphoblastic leukemia, inflammatory bowel disease, rheumatoid arthritis)
UGT1A1	UDP glucuronosyltransferase family 1 member A1	9	Gilbert syndrome
VKORC1	Vitamin K epoxide reductase complex subunit 1	2	Thromboembolic diseases

Figure 2.6 Brief information on selected pharmacogenes with plausible effects in African datasets (Oluwole and Henry, 2023)

In conclusion, PGx can help improve clinical practice in Nigeria by enabling doctors to prescribe medications that are more tailored to individual patients' genetic makeup, reducing the risk of adverse reactions, lowering healthcare costs, and reduce incidences from self-medication as patients' information will be available at their point-of-care.

2.5 Key stakeholders needed for the implementation of PGx testing in Nigeria

The implementation of PGx in Nigeria requires a coordinated effort among multiple stakeholders, including government regulatory bodies, HCPs, and researchers.

- **Government regulatory bodies:** The NAFDAC and the National Institute for Pharmaceutical Research and Development (NIPRD) are key stakeholders in the implementation of PGx in Nigeria. These bodies are responsible for regulating drug development and distribution, as well as promoting research and development in the pharmaceutical industry.
- **Healthcare providers:** HCPs, including doctors, pharmacists, and nurses, are responsible for implementing PGx in clinical practice. They must be trained on the appropriate use and interpretation of PGx tests and must communicate with patients about the potential benefits and risks of using these tests.

Research and academic institutions: Researchers and academic institutions play a critical role in advancing the science of PGx, they are responsible for conducting research and clinical trials to identify new PGx markers and drugs. There have been strives made by organizations like the Human Heredity and Health in Africa (H3Africa), 54gene and African Pharmacogenomics Consortium (APC) to sequencing more Africans genomes (including Nigerians), increasing research collaborations, and raising awareness for personalized medicines and PGx in Nigeria and other African countries (Bolaji *et al.*, 2019).

Point-of-care (POC) PGx testing can be conducted directly at or near the location where patient care is provided. POC tests are medical diagnostic tests that overcome the limitations of traditional laboratories by offering rapid test results and immediate availability of testing services. POC testing has become more rampart in Nigeria as it offers a fast and a more cost-effective way to disease diagnosis and monitoring. There have been studies that indicates that POC testing are more viable and favourable than the usual standard-of-care testing in diagnosis of diseases; like antigen test for Covid-19, lateral flow immunoassay (LFIA) for malaria, HemotypeSC for rapid test of Hb genotype in sickle cell patients and POC VL (viral load) testing for HIV (Kozel and Burnham-Marusich, 2017) (Olatunya

et al., 2021) (Chaplin *et al.*, 2023). POC testing is currently used in Nigeria in diverse capacity to improve diagnosis in diseases and offer the best option of treatment for patients within a time sensitive space HIV (Kozel and Burnham-Marusich, 2017). PGx testing at point-of-care, though indicate to offer tangible prospects, has not been realised in Nigeria.

2.6 The Theory of Change (ToC) framework

It is important to have a standardized way to evaluate digital health interventions so that decision-makers can determine how to integrate effective strategies into national health systems; the ToC framework is an approved model by the World Health Organization (WHO) that can be used for the monitoring and evaluation of approaches that is intended to be used for the implementation of strategies into healthcare (De Silva *et al.*, 2014). It allows for the layout of processes and rationale to assist in achieving a desired impact. A visual representation of the ToC map is used to depict the step-by-step pathways by which an initiative is expected to have an impact within the limitations of the setting in which it is implemented, while also revealing the key assumptions (Vogel, 2012).

The ToC addresses the question of ‘how’ and ‘why’ a hypothesised change or initiative would work when implemented through a step-by-step pathway that can be empirically verified. In order to examine the change(s) and how it occurs, the ToC is continually revised throughout the development and assessment process in partnership with stakeholders (De Silva *et al.*, 2014). For this study, the stakeholders are pharmacists, PGx scientists, NAFDAC and primary care physicians.

TOC as a model explains the expected outcomes and activities needed to achieve the desired change. Inputs refer to the resources used to develop and implement an intervention, while activities refer to the initiatives undertaken in delivering the intervention. Outputs are the direct products of these activities, which can include improvements in performance and user adoption. Developing a conceptual framework is important to understand project goals, objectives, and anticipated outcomes. Outcomes refer to the intermediate changes that occur as a result of inputs and processes in interventions and can be analysed at three levels: health systems, providers, and clients. Impact, on the other hand, reflects the medium- to long-term effects of an intervention, which can be both positive and negative and may not have been intended.

The ToC framework comprises several key components:

- **Interventions:** Interventions are the actions or strategies that will be implemented to address the challenges identified in the ToC framework. For example, investing in infrastructure upgrades, development of PGx guidelines, training HCPs in PGx, and establishing public-private partnerships to secure funding are all interventions that can help overcome the obstacles faced by the Nigerian healthcare system.
- **Outputs:** Outputs are quantifiable measures used to assess the progress and success of the interventions and preconditions. They enable stakeholders to track the effectiveness of the ToC and make data-driven decisions to adjust the interventions as needed.
- **Outcomes:** These are the intermediate preconditions that must be achieved to reach the long-term goal. In the context of PGx POC services, preconditions may include improved healthcare infrastructure, enforceable PGx guidelines, and sufficient number of skilled HCPs. Each precondition is linked to specific interventions that must be undertaken to achieve these intermediate outcomes.
- **Long-term goal:** The goal of implementing PGx POC services in Nigeria which will improve patient care and health outcomes through personalized medicine. This long-term outcome serves as the foundation upon which the entire ToC is built.
- **Assumptions:** These are the underlying beliefs or hypotheses about the causal relationships between the interventions, preconditions, and long-term outcomes. Assumptions need to be tested and validated to ensure that the ToC remains relevant and accurate throughout the implementation process.

By using the ToC framework, stakeholders can create a comprehensive roadmap for implementing PGx POC services in Nigeria. The framework enables a clear visualization of the complex relationships between challenges, interventions, and outcomes, facilitating collaboration and communication among various stakeholders (De Silva *et al.*, 2014).

The implementation of PGx in clinical practice has been a topic of discussion for quite some time, as it has the potential to improve therapeutic outcomes by tailoring treatment plans according to individual genetic makeup. Despite its promise, there are several barriers and challenges that need to be addressed to effectively incorporate PGx into clinical practice. One barrier to the implementation of PGx is the lack of clinical practice guidelines and algorithms (Ventola, 2011). Guidelines need to be robust, up to date, consistent, and flexible to allow for quick revision in response to new research findings. Collaboration between regulatory agencies, such as the FDA and healthcare professionals, is essential to facilitate developments in this field.

A case study within the IGNITE network focused on the implementation of a PGx intervention by utilizing a multidisciplinary team to guide the project, integrating PGx into the clinical workflow as smoothly as possible, and supplementing automated clinical decision support systems (CDSS) with opportunities for front-line clinicians to consult physicians with expertise in PGx (Rosenman *et al.*, 2017). This approach aimed to facilitate the integration of PGx testing in clinical practice and improve patient outcomes.

Another study highlights the potential of PGx in informing medical decision-making for a male patient with atypical psychosis and depression, along with attentional difficulties (Madan *et al.*, 2015). The patient's specific COMT polymorphism was taken into account, which helped tailor the treatment plan to his genetic profile, leading to improved therapeutic outcomes. To further advance the implementation of PGx, a multi-phased stakeholder study was conducted to define actions, roles, and responsibilities in primary care settings. Stakeholders, including pharmacists, primary care physicians, patients, scientists, and policymakers, were invited to discuss thresholds and opportunities for next steps in the implementation of PGx in primary care (Rigter *et al.*, 2020).

In line with the ToC framework, to suggest necessary roadmap for the effective deployment of PGx in POC, we derive the interventions from the existing conditions and demands of Nigeria's healthcare system, in addition to meeting the requirements outlined above. The proposed interventions are:

Intervention 1: Increased awareness and education about pharmacogenomics testing

Intervention 2: Development of Pharmacogenomics Guidelines

Intervention 3: Establish point-of-care testing in point-of-care in Nigeria.

Intervention 4: Train healthcare providers in Nigeria on how to carry out pharmacogenomics testing.

Intervention 5: Implement CDSS and Electronic Health Records (EHR) in the healthcare system in Nigeria.

Intervention 6: Collaborations with Pharmaceutical Companies to Develop Drugs

In conclusion, the implementation of PGx in clinical practice is an ongoing process that requires collaboration among stakeholders, the development of clear guidelines, and the integration of PGx testing into clinical workflows.

3 Research Methodology

3.1 Overview

Section No	Primary Data	Part A	Part B
1	Approach	Quantitative analysis	Qualitative analysis
2	Philosophy	Positivism	Interpretivism
3	Source	Questionnaire: Microsoft forms app online distributed via LinkedIn	Interview through Zoom
4	Population size (63)		
5	Structure	6 sections consisting of 21 questions	10 – 15 minutes audio
6	Subjects	Physicians Pharmacists Medical Laboratory Technicians Others	Physicians Pharmacists Medical Laboratory Technicians Others

3.2 Research Philosophy

Research philosophy is an essential component of research methodology. Research philosophical perspectives enables researchers choose the best strategy to use for their study and why, based on the research question. Due to the nature of this study, pragmatism research philosophy is the most appropriate as it is best for when a research begins with a problem and seeks to contribute functional solutions for future practices (Saunders *et al.*, 2019). Pragmatism is rooted in the belief that research methods should be driven by the research questions and the context in which the study is being conducted (Saunders *et al.*, 2019). In this study, pragmatism is chosen as the research philosophy because of its suitability for addressing the multifaceted challenges and opportunities related to incorporating PGx into POC in Nigeria. Pragmatism allows for flexibility in the choice of research methods and encourages the use of mixed methods to address complex research problems.

Pragmatism supports the use of mixed-methods research designs, as it recognizes that both quantitative and qualitative methods can provide valuable insights into a research problem (Creswell and Plano Clark, 2018). By integrating qualitative and quantitative data, a mixed-methods approach allows for a more comprehensive understanding of the phenomenon under investigation. In the context of this study, the use of a mixed-methods design enables the researchers to explore the complex interplay between individual perspectives, experiences, and contextual factors that influence the integration of PGx into POC in Nigeria.

The ToC approach is consistent with the pragmatist research philosophy, as it emphasizes the importance of understanding the underlying mechanisms and contextual factors that drive change (Vogel, 2012). ToC focuses on mapping the relationships between inputs, activities, outputs, outcomes, and impacts, as well as identifying the assumptions and external factors that may influence the success of an intervention. By adopting a pragmatist philosophy, the researchers can develop a ToC model that is grounded in empirical evidence and tailored to the specific challenges and opportunities related to incorporating PGx into POC in Nigeria.

Theoretical perspective will be used to provide a direction for this research using the theory of change framework, quantitative research will be used to develop a richer theoretical perspective, while qualitative research will be used to test it (Saunders *et al.*, 2019).

3.3 Research Approach

The research approach for this study will be an abductive approach. This approach is well-suited for mixed-methods research designs and is consistent with the pragmatic research philosophy (Saunders *et al.*, 2019). Abduction allows for the integration of both inductive and deductive reasoning processes in the research, providing a comprehensive understanding of the challenges and opportunities for incorporating PGx into POC in Nigeria. Abductive approach is best used when there is an abundant of information on a particular topic (sufficient availability of studies presenting significant clinical evidence of the benefits of PGx testing across different areas of healthcare), but less in the context for which a researcher wants to study (the potential of PGx has not yet been adopted within the Nigerian healthcare system and incorporation strategies have not been explored), giving the researcher the flexibility needed to make modifications to an existing theory (development of a framework that may be used for PGx testing implementation in Nigeria). Also good abductive approach is supported by pragmatism (Saunders *et al.*, 2019).

In the context of the study on incorporating PGx into POC in Nigeria using the Theory of Change, the author applied mixed-methods which combines both qualitative and quantitative research methods (survey and audio interview). This approach aligns with the pragmatist research philosophy, as it allows for the use of multiple methods to address the complex research problem and provides a comprehensive understanding of the challenges and opportunities related to incorporating PGx into POC in Nigeria.

The survey was distributed electronically to HCPs from different occupational background (physicians, pharmacists, medical laboratory technicians) and researchers who are the key stakeholders of PGx and were requested to take part in filling the survey questions. The semi-structured questionnaire was used to explore specific themes and gain a vast perspective of PGx and identify significant similarities among variants from respondents. The questions were aimed at assessing their knowledge, attitudes, and perceptions about PGx, and the use of PGx in clinical practice. The survey questionnaire was design to complement the qualitative questions for the interview.

For the qualitative approach, audio interview was conducted using Zoom to gain insights into stakeholder perspectives, identify their needs, and explore potential implementation barriers and interventions to implementation. Participants for the interview were highly qualified HCPs, researcher, and policymaker with good knowledge of PGx who best satisfies the research aims and have taken initiatives to promote the PGx research and practice in Nigeria. Qualitative research data will provide more insight and help explain and contextualize quantitative findings.

The extensive collection of data from diverse sources enables a comprehensive understanding of the research topic, facilitating an informed analysis and robust recommendations for integrating PGx into POC settings in Nigeria. The collected data was thoroughly analysed and compared with the findings from the reviewed literature, resulting in a comprehensive and conclusive study.

3.4 Research Strategy

The strategy of this research is to understand the current state of PGx, how it can be integrated into Nigerian healthcare settings and to identify the barriers and facilitators for its implementation in POC practice by gathering insights from multi-stakeholders their knowledge, awareness, and opinions on PGx. Based on the examined literature, it is evident that no studies have been conducted that specifically target multiple PGx stakeholders in Nigeria, with the intent to identify their needs, explore

potential barriers to implementation, and explore possible interventions for successful implementation in Nigeria.

Participants in this research were provided with comprehensive information about the study's purpose, including the fact that the author was conducting it as part of their MSc in Pharmaceutical Business and Technology degree requirements. The questionnaire was designed using clear and easily understandable language to facilitate participant understanding and response. It was distributed to more than 63 healthcare professionals with experience practicing in Nigeria.

3.5 Design of Questionnaire

The questionnaire consisted of six sections, containing a total of 21 questions designed at satisfying the purpose of the study. The questionnaire was designed using Microsoft Forms and distributed electronically to targeted individuals and the survey was completed independent of the author's views. This approach supports positivism, allowing participants to share their perspective freely without bias.

In order to obtain consent from participants, a shortened version of the patient information leaflet (PIL) was included at the beginning of the survey. This allowed participants to give their permission for their responses to be used as part of the research. Participants were assured that their data would be handled in compliance with the General Data Protection Regulation (GDPR) and that their responses would be kept confidential. It was mandatory for participants to answer the consent question before proceeding with the rest of the survey.

Participants who took part in the interview section were given the patient information leaflet (PIL) to help them understand the purpose of the research. They were then given an informed consent form (ICF) to sign, indicating their full informed consent to be part of the study. Semi-structured questions were used in the interview, this was to allow for flexibility in the interview process, allowing for discussion into specific subjects and encouraging open-ended responses from participants.

3.6 Data Collection Method

All questions in the questionnaire were directed towards gathering data on stakeholders' knowledge and perspective on PGx and its implementation in clinical practice. An overview of how primary data was collected is provided below:

Section 1: Focused on getting the demographics data of participants, the four questions in this section aimed at categorizing participants based on their level of education, field of work, and their work experience in Nigeria.

Section 2: This section contained questions directed at evaluating participants understanding of PGx and their foreseen benefits in clinical practice. It also gives insights on participants knowledge of regulatory guidelines in Nigeria and international PGx guidelines.

Section 3: For this section, the proposed theory of change was used to guide the questions. The 6 proposed interventions to implementation were presented to participants using Likert scale to gauge their opinion on it. The scale ranged from very important, somewhat important to not important.

Section 4: The outcome from the proposed interventions were presented in this section also using Likert scale ranging from agree, neutral, and disagree. This section aimed at getting a standpoint on what participants think of the proposed outcomes.

Section 5: In line with the theory of change framework, the assumptions and risks associated with the implementation of PGx in Nigeria proposed by author was presented in this section, with the aim of determining whether participants agree or disagree with these propositions.

Section 6: The final sections contained questions on the possible challenges and benefits of implementing PGx in point-of-care. Also, a question was also present to get data on participant expectations of PGx in clinical practice.

The interview was conducted to gather insights from highly experienced multi-stakeholders in order to comprehensively address the research question: "What are the key factors that influence the successful implementation of pharmacogenomics (PGx) in point-of-care (POC) settings in Nigeria?" The aim was to understand their perspectives on their specific needs, potential challenges that may impact implementation, and recommendations for achieving successful implementation of PGx in POC.

The interview was conducted via Zoom using open-ended questions, enabling the interviewees to freely share their opinions and perspectives.

3.7 Sources

Online survey and interview were both used to collect the primary data used in this research. The survey was developed based on the initial theory of change model developed, which is based on findings from literature review. The questionnaire was distributed among HCPs (physicians,

pharmacists, medical laboratory scientists) and researchers working in PGx, healthcare delivery, or healthcare policy in Nigeria. The survey was designed to understand their knowledge and attitudes towards PGx, as well as their interests with incorporating PGx into their practice.

3.8 Inclusion and Exclusion Criteria

Inclusion criteria for the qualitative interviews was professionals and stakeholders directly involved in PGx, healthcare delivery, or healthcare policy in Nigeria. Exclusion criteria from the study was individuals with no relevant experience or expertise in these areas.

For the quantitative survey, inclusion criteria for recruiting HCPs were that they are currently practicing in Nigeria. Exclusion criteria was HCPs who are not currently practicing or who do not have any experience with PGx.

3.9 Access and Ethical Issues

Before taking part in the research, all participants were given a brief introduction to the study, including its objectives and its relevance to the researcher's master's degree. The data collection methods employed ensured the confidentiality of participants, and each question was designed to align with the research objectives. Participants were informed of their right to withdraw from the study at any point, and their participation was entirely voluntary.

The information collected from questionnaires and interviews was treated with utmost confidentiality. The researcher made sure to schedule interviews at suitable times for the participants, ask only relevant research questions, and transcribe the interviews accurately. The study obtained ethical approval and adhered to the ethical guidelines set forth by the Griffith College Ethics Committee.

3.10 Summary

For this survey, quantitative approach was used. Twenty-one questions were structured and distributed across different HCPs and researchers in Nigeria via LinkedIn. In line with the qualitative method, an audio interview was conducted to better understand the respondent's views on the study. The primary data collected was analysed and compared with findings from existing literature. Further interpretation based on participant's answers is discussed in the next chapter.

4 Data Analysis

In this chapter, we'll examine the survey responses carefully to meet the goals of this study. The overall aim of this study is to explore the development of an operational model for the implementation of PGx in Nigeria by identifying key stakeholders and anticipating their needs. The research also examines the feasibility and impact of the proposed implementation model on patients' outcomes through the feedbacks from multi-stakeholders. By achieving these objectives, the outputs from this research study have the potential to be used to develop a comprehensive model for the implementation of PGx in Nigeria, which can be used to guide future research and policy decisions.

Reviewing the data from the surveys helped understand healthcare providers' overall knowledge, attitudes, and thoughts about PGx, and their expected use of PGx in clinical work. It also helped gain insights on the initiatives HCPs consider important when implementing PGx in POC in Nigeria. The data was sorted, coded, and analysed using Microsoft Excel. A total of 63 questionnaires were distributed electronically to HCPs and 31 responses were retrieved and analysed, only 27 participants met the inclusion criteria, making the response rate based on the sample size 42.86%.

4.1 Demographic Representation of Respondents

4.1.1 Distribution of Respondents

Table 1 Distribution of respondents based on their field of profession.

Profession	Frequency (Number)	Frequency (%)
Physician	6	22.2%
Pharmacist	6	22.2%
Medical Laboratory Scientist	7	25.6%
Researcher	4	14.8%
Clinical Research	3	11.1%
Regulatory	1	3.7%

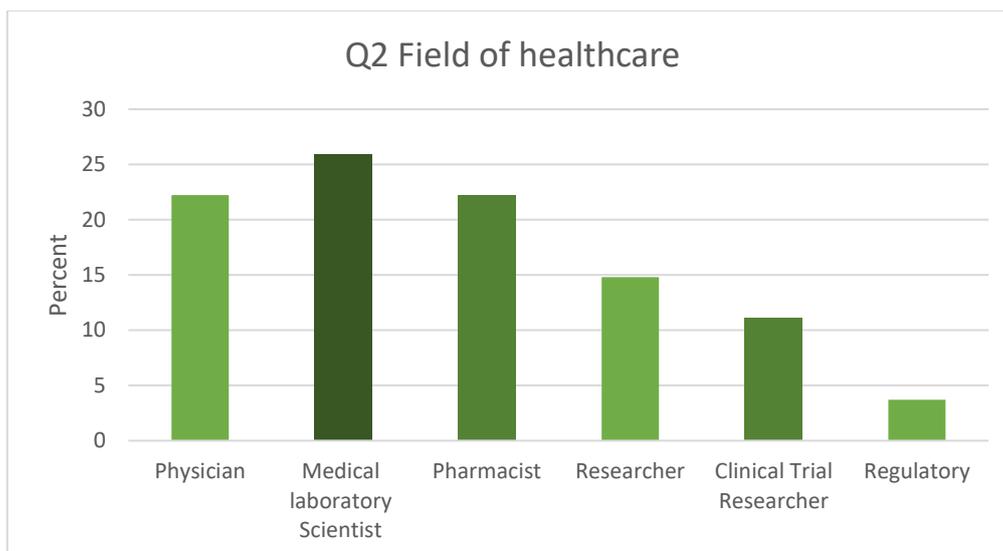


Figure 4.1: Q2 Field of healthcare

The distribution of the different HCPs that responded to the questionnaire were 7 Medical Laboratory Scientists (25.6%), 6 Pharmacists (22.2%), 6 Physicians (22.2%), 4 Researcher (14.8%), 3 Clinical Trial Scientist (11.1%), and 1 Regulatory (3.7%).

4.1.2 Educational Level of Participation

Table 2 Distribution of participants based on level of education.

Level of Education	Frequency (Number)	Frequency (%)
Bachelor's degree	17	63.0%
Master's degree	6	22.2%
Doctoral Degree	4	14.8%

Among the 31 respondents, 17(63%) held a bachelor's degree, 6 (22.2%) had obtained a master's degree, and 4 (14.8) had pursued their education to the doctoral level.

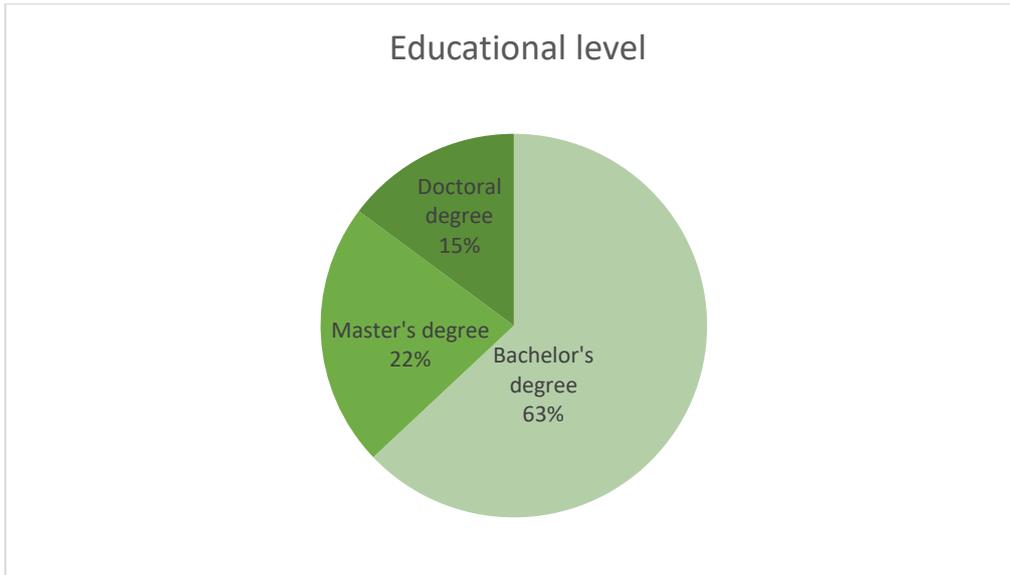


Figure 4.2 Pie char representing the distribution of respondents' level of education.

4.1.3 Distribution of work experience of respondents in healthcare system in Nigeria

Table 3 Work experience of the respondents.

Years of work experience	Frequency (Number)	Frequency (%)
0 to 5 years	19	70.4%
6 to 10 years	6	22.2%
11 to 20 years	2	7.4%

Among the 31 respondents, 19 (70.4%) have work experience of 0 to 5 years, 6 (22.2%) have within 6 to 10 years of work experience, and 2 (7.4%) had more than 11 years of work experience in the healthcare system in Nigeria.

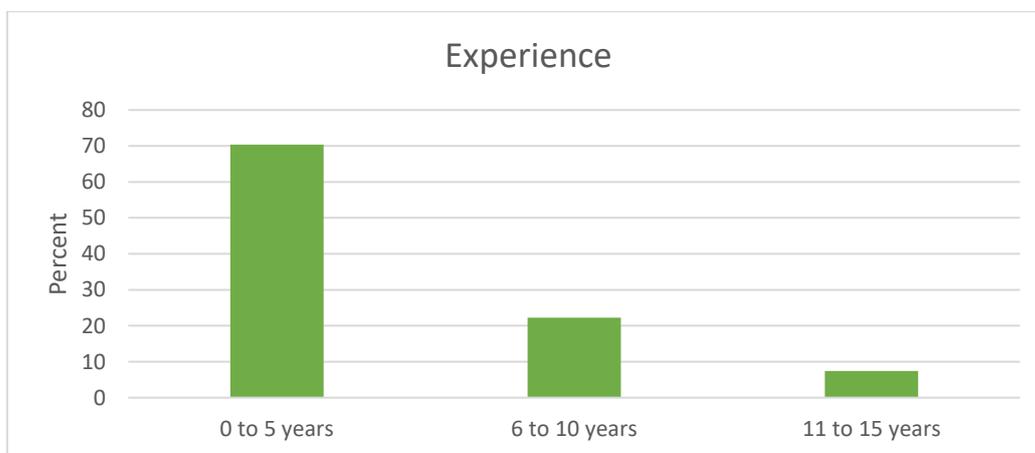


Figure 4.3 Bar chart representation of work experience of respondents.

4.2 HCPs Perspective on PGx in Nigeria (Question 6 to 15)

This section of the questionnaire was directed at assessing the knowledge of HCPs on PGx, its guidelines and their perspective towards PGx services testing in point-of-care.

Question 6, 7 & 8

This section of the questionnaire was designed to assess participants' knowledge of PGx and its application in clinical practice. 13 participants (51.9%) answered that they are very aware of PGx, while 14 (48.9%) said that they were somewhat aware. When it comes to the use of PGx in clinical practice, 19 (70.4%) said that if available they were willing to use it in their clinical practice, 23% were somewhat willing, while 4% was not willing at all.

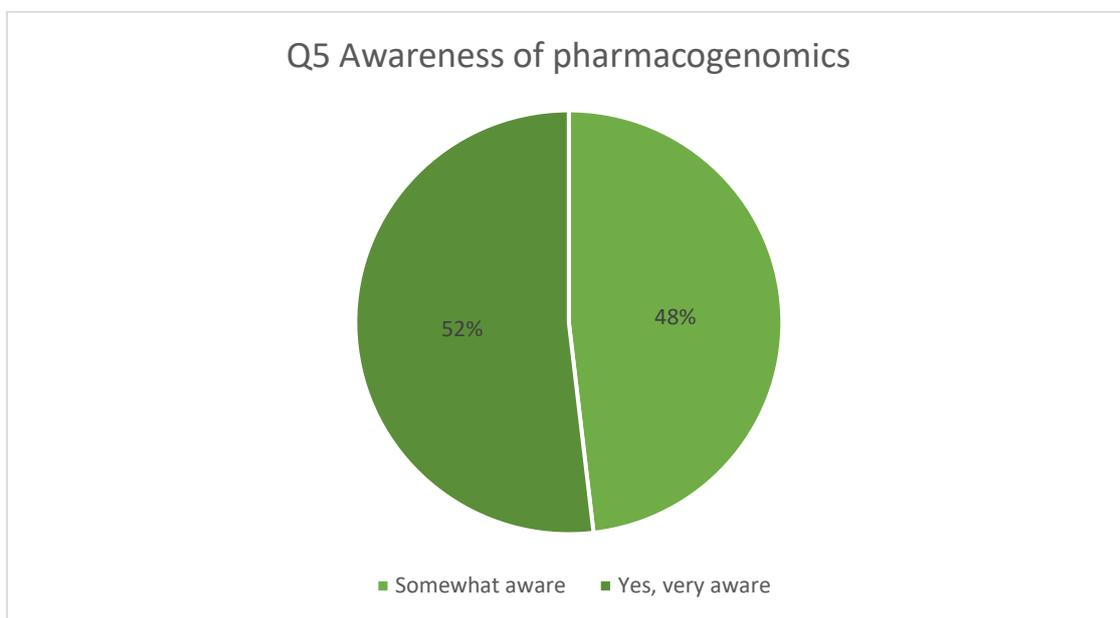


Figure 4.4 Participant's awareness of PGx

The table above demonstrates that HCPs (HCPs) from various backgrounds and educational levels are aware of the concept of PGx. Although one participant expressed reluctance to incorporate PGx into their clinical practice, the majority are open to embracing it. This receptiveness is beneficial for introducing and implementing PGx strategies in clinical settings.

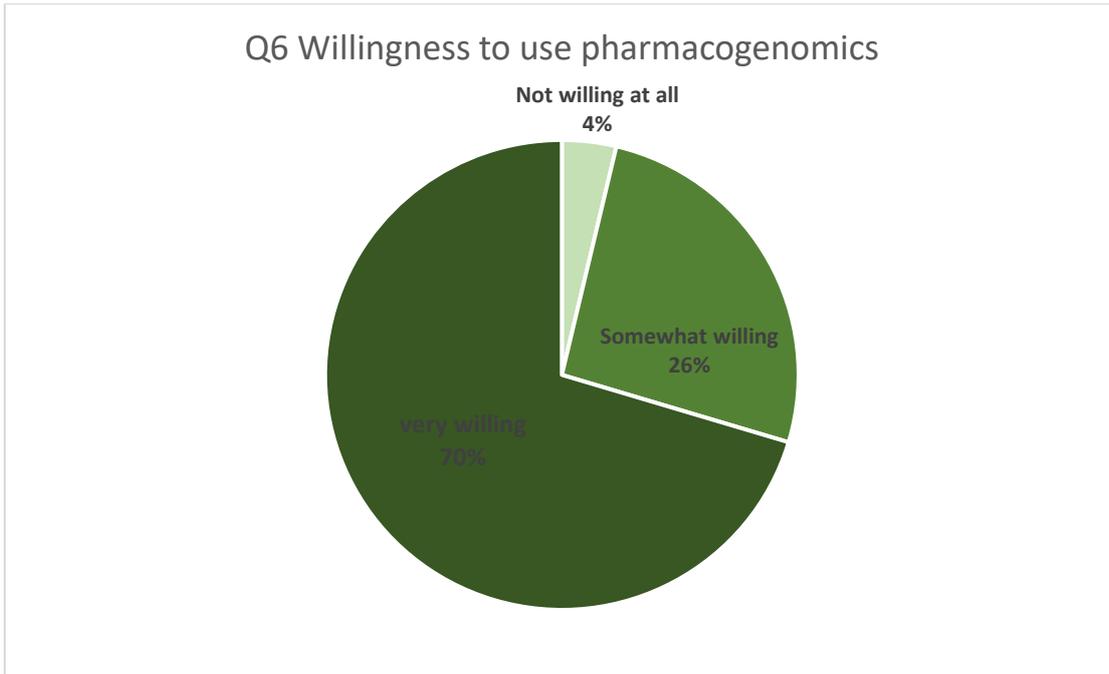


Figure 4.5 Participant's willingness to use PGx.

Question 8

This follow-up question aims to gather insights into the healthcare domains where participants envision the potential of PGx in Nigeria. The top areas identified were Oncology (37%), Infectious Diseases (22.2%), and Clinical Genetics (22.2%).

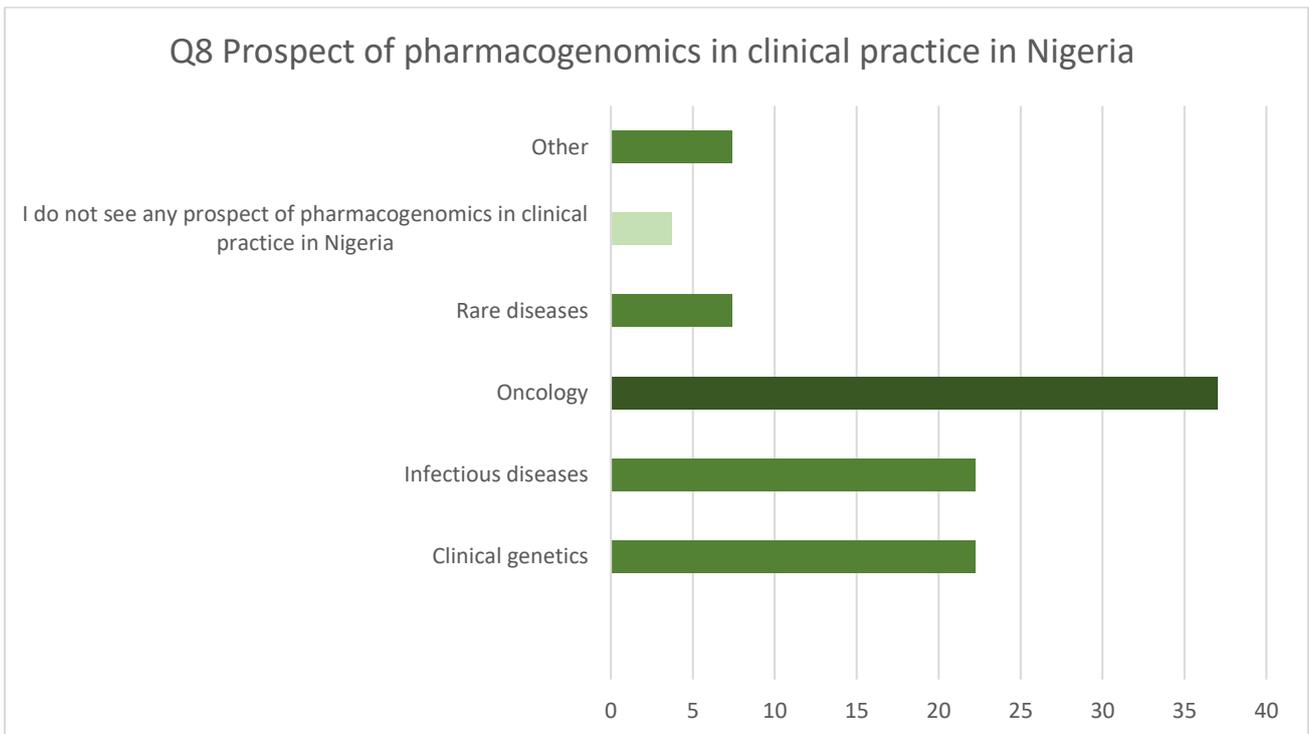


Figure 4.6 Respondents' prospect of PGx in clinical practice in Nigeria

Two respondents selected the 'other' option, with one specifying Psychiatry as a promising area, while the other stated:

“All of the above. Our genes influence how our bodies react to antigens, substances, and the environment in general, and so I believe that deploying PGx will influence the pathophysiology of diseases.”

Question 9 & 10

While PGx testing is not limited to pre-emptive and reactive testing, the questions presented in 9 and 10 was to determine if HCPs had a proper understanding of the basic targeted testing approaches used in PGX. Twenty-two respondents chose pre-emptive testing as their preferred approach, 4 selected reactive testing.

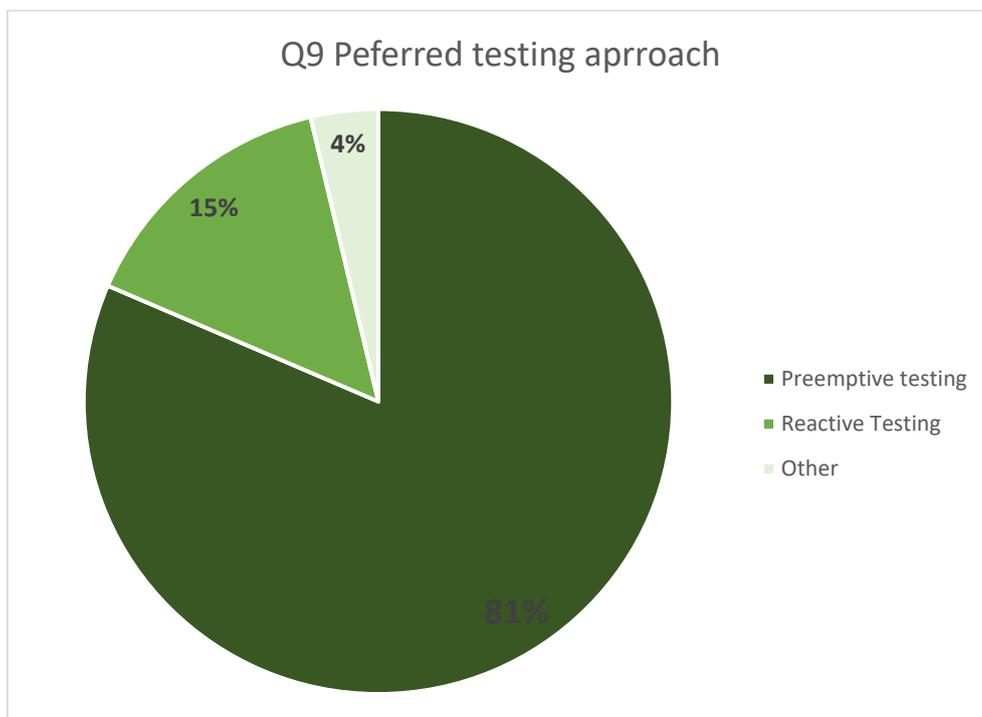


Figure 4.7 Respondents' preferred testing approach

Table 4.6 and 4.7 illustrate the prevalent themes among respondents regarding the reason for their selected testing approach, three participants however did not provide an explanation for their preferences.

Table 4 Q10 Themes – Reasons for choosing pre-emptive testing approach.

Code	Theme	Frequency
1	It is better than reactive testing	2

2	Allows for testing prior to disease development	11
3	Informed Clinical and therapeutic decisions	3
4	Prevention/ reduction of AE	7
5	Accuracy and Precision	3
6	Drug-gene interaction is put into consideration	3

Table 5 Q10 Themes – Reasons for choosing pre-emptive testing approach.

Code	Theme	Frequency
1	It is carried out based on the need for it	2

Question 11

This question was asked to ascertain the key factors that may substantially impact a HCP's decision to employ PGx in a POC environment.

Table 6 key factors that may influence HCPs to use PGx

Variables	Frequency (Number)	Frequency (%)
Regulatory requirement	5	18.5%
Standardization of PGx	6	22.2%
Compatibility with existing healthcare workflow	4	14.8%
Accuracy and Precision of test results	12	44.4%

The most crucial factor for 44.4% of respondents was the accuracy and precision of test results. The standardization of PGx (PGx) in clinical practice followed, with 22% of respondents selecting it. Next, 18.5% considered mandating PGx as a regulatory requirement, and finally, 14.8% prioritized compatibility with the existing healthcare workflow.

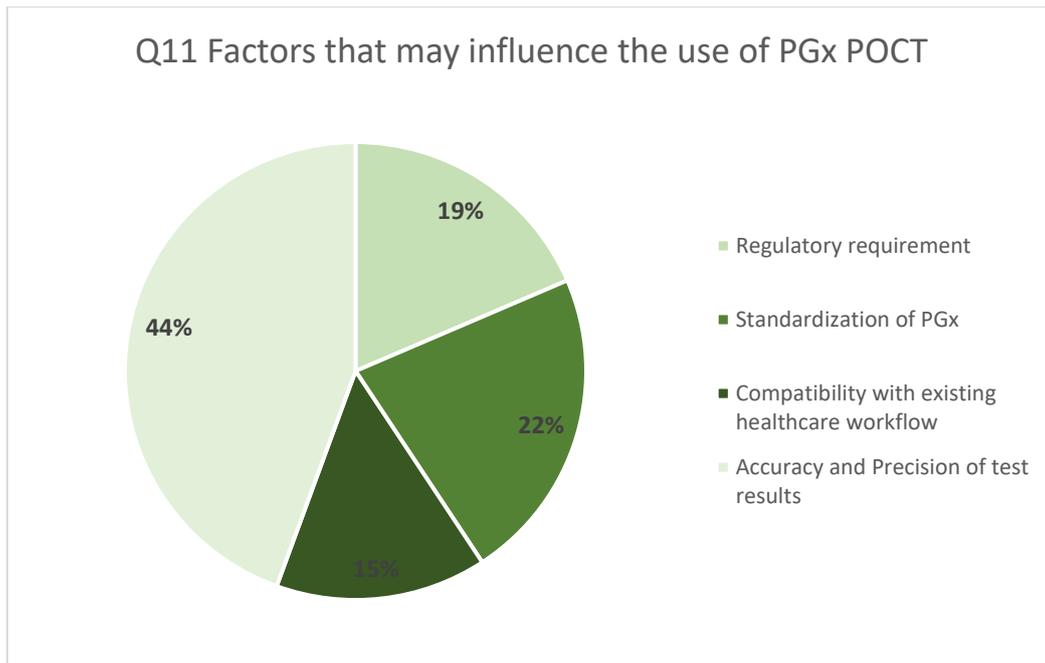


Figure 4.8 Pie chart representation of the HCPs response to factors that may influence the use of PGx POCT.

Question 12

Participants were inquired about their views on the potential benefits of introducing PGx in Nigeria. The goal of this question is to gain insights into the expected positive effects of integrating PGx into POC settings in the Nigerian healthcare environment.

Every participant acknowledged the possible advantages of incorporating PGx into POC settings, with their responses being nearly evenly spread. The most frequently anticipated benefit was enhanced drug efficacy and safety (27%), followed by better patient outcomes (26%), a decrease in adverse drug reactions (24%), and the development of personalized medicine plans (23%).

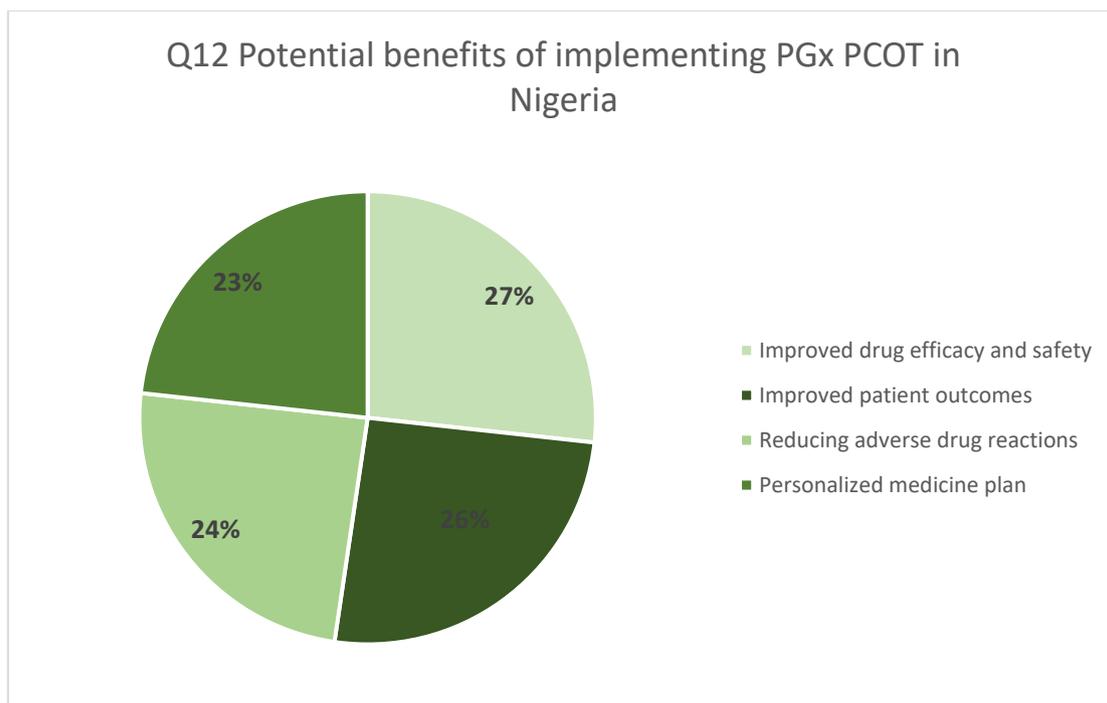


Figure 4.9 Pie chart representation of participants response potential benefit of PGx POCT

Question 13

This question was posed to determine whether participants are familiar with PGx resources and organizations and/or agencies that offer guidelines and materials for its clinical application.

Table 7 Pie chart representation of participants response potential benefit of PGx POCT

Which of these organizations provides resources for clinical PGx practice?	Frequency (N)	Frequency (%)
African PGx Consortium, Clinical Pharmacogenetics Implementation Consortium (CPIC)	7	26%
African PGx Consortium, Human Heredity and Health in Africa (H3africa)	2	7%
African PGx Consortium, PGx Knowledge Base (PharmGKB),	2	7%

Clinical Pharmacogenetics Implementation Consortium (CPIC), PGx Knowledge Base (PharmGKB),	5	19%
Clinical Pharmacogenetics Implementation Consortium (CPIC), National Agency for Food and Drug Administration and Control (NAFDAC)	5	19%
Human Heredity and Health in Africa (H3africa), PGx Knowledge Base (PharmGKB)	1	4%
Human Heredity and Health in Africa (H3africa), National Agency for Food and Drug Administration and Control (NAFDAC)	2	7%
National Agency for Food and Drug Administration and Control (NAFDAC), African PGx Consortium	2	7%
National Agency for Food and Drug Administration and Control (NAFDAC), PGx Knowledge Base (PharmGKB)	1	4%

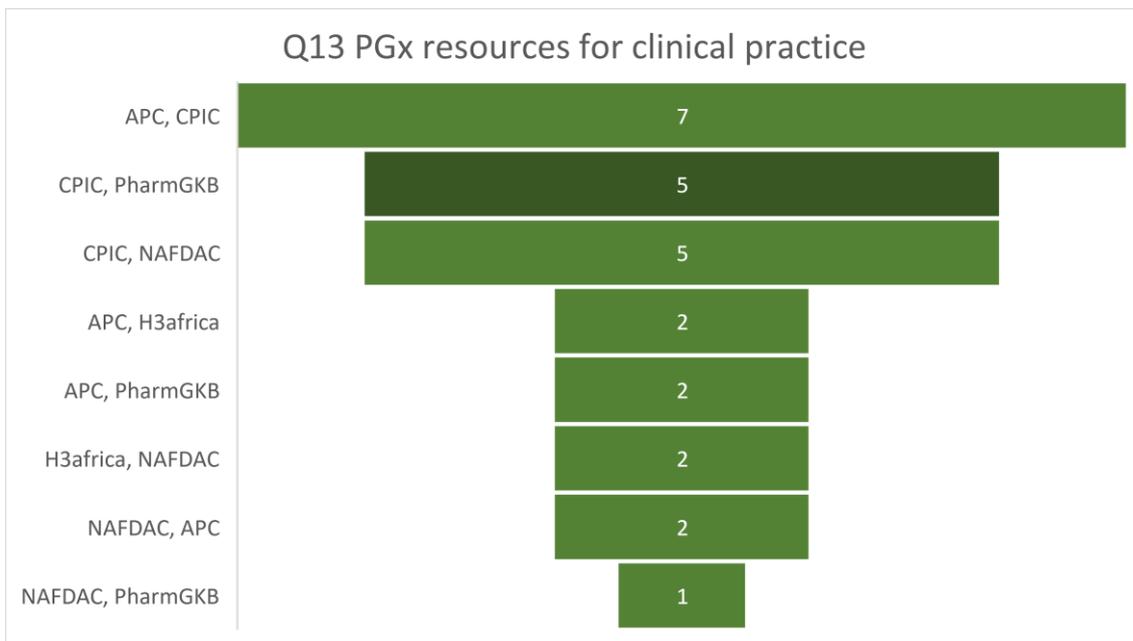


Figure 4.10 Funnel chart representation of participants choice of organizations or agencies

Table 4.8 and Figure 4 highlight the varied views among respondents regarding the agencies and companies that offer resources and guidelines PGx. A substantial portion, 26%, selected both the APC and CPIC, while 19% selected both CPIC & PharmaGKB and CPIC & NAFDAC respectively. APC

& PharmaGKB was chosen by 7% of respondents, the same percentage also picked APC & H3Africa, H3Africa & NAFDAC, and NAFDAC & APC. Lastly, 4% selected NAFDAC & PharmaGKB.

In terms of individual organizations, CPIC was recognized as a source of PGx clinical guidelines by 32% of respondents. APC followed, with 26% selecting it, then NAFDAC at 19%, PharmaGKB at 15%, and 8% for H3Africa.

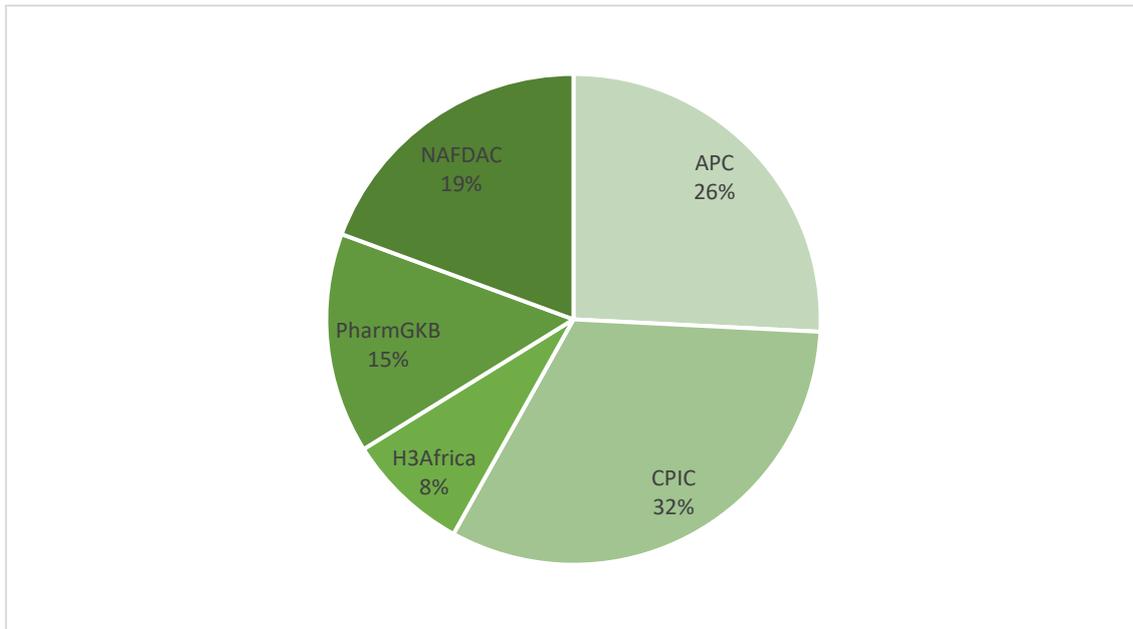


Figure 4.11 PGx resources for clinical practice.

Question 14

This follow up question was to determine respondents' awareness and participants' perspectives on the sufficiency of existing policies and guidelines in Nigeria concerning the clinical practice of PGx at the point-of-care. This is to reveal their opinion about the adequacy of the current regulatory framework and its effectiveness in supporting PGx application in clinical settings.

A significant portion of the respondents, 20 (74%), indicated that the existing guidelines and policies were insufficient to support PGx in clinical practice. Conversely, 2 (7%) found the current guidelines adequate. Meanwhile, 5 (19%) remained neutral, stating that they were uncertain.

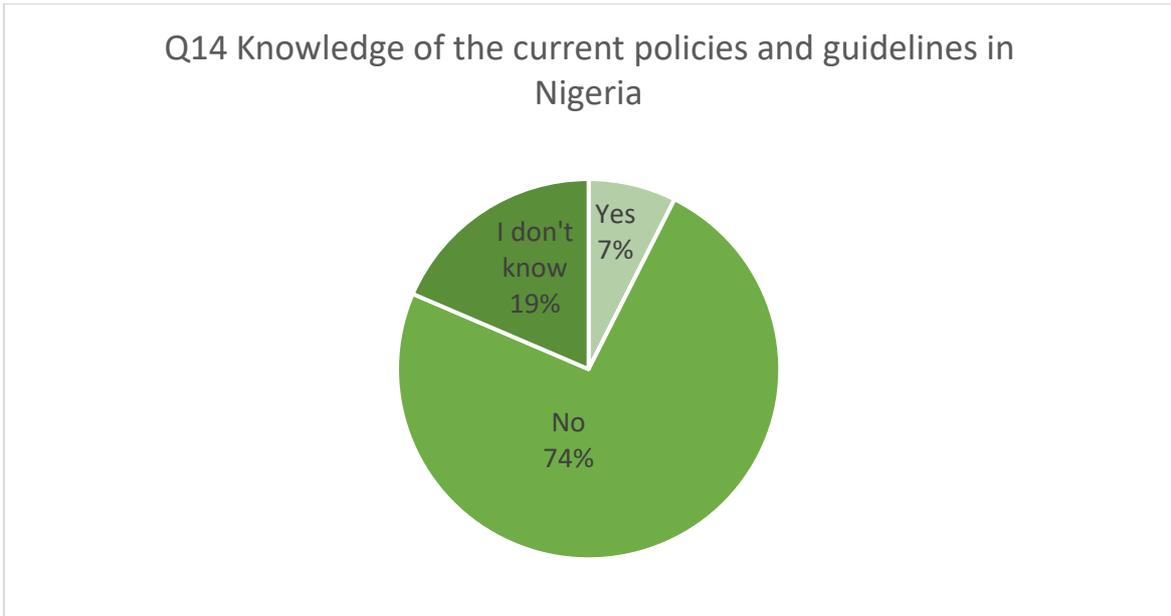


Figure 4.12 Respondents' knowledge of the current policies and guidelines in Nigeria

Question 15

The question presented here was to understand HCPs' perspectives on potential ethical issues that could emerge from the implementation of PGx in clinical practice. Understanding these views can provide valuable insights for addressing them in the development and application of PGx. **FIGURE 4** shows the opinion of respondents on this issue.

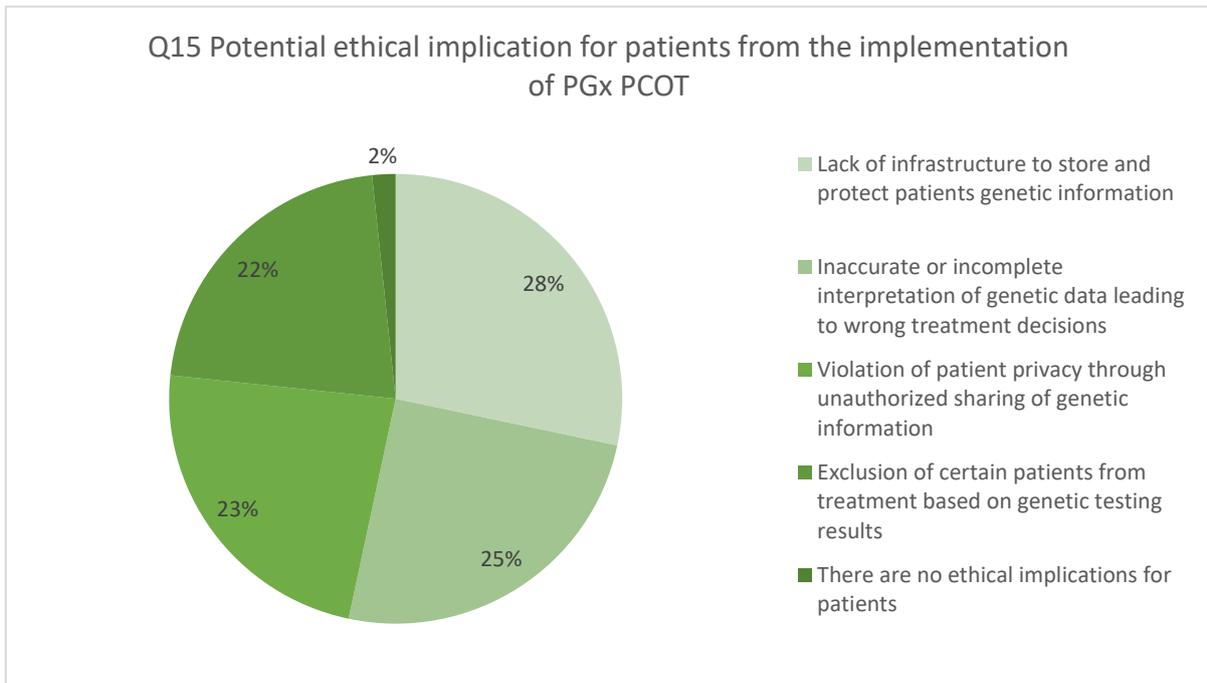


Figure 4.13 Potential ethical implication for patients from the implementation of PGx PCOT

Question 16 & 17

The questions presented to participants aimed to introduce the proposed implementation strategies and potential direct outcomes. This allowed stakeholders to determine which factors they deemed significant or insignificant for successful implementation. Figures 4.9 and 4.10 illustrate the opinions of respondents.

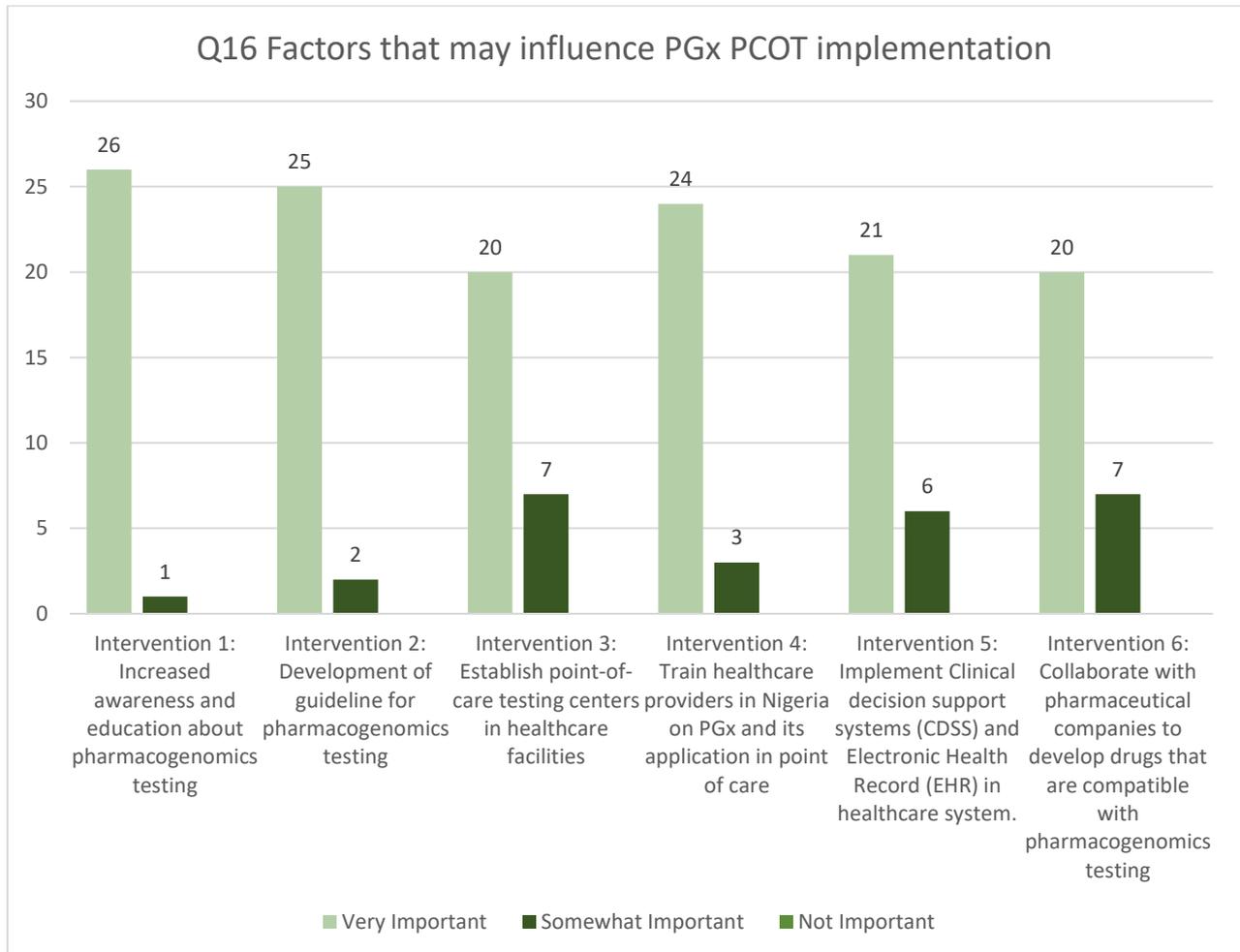


Figure 4.14 Factors that may influence PGx PCOT implementation.

The response gotten can also be used to prioritize the areas of implementation. Respondents' opinions determine which issues should be addressed first for the most effective implementation. This step is critical for the effective allocation of resources, ensuring that efforts and investments are directed where they are most needed. Based on the data, it can be inferred that Interventions 1, 2, and 3 are the most crucial for successful implementation.

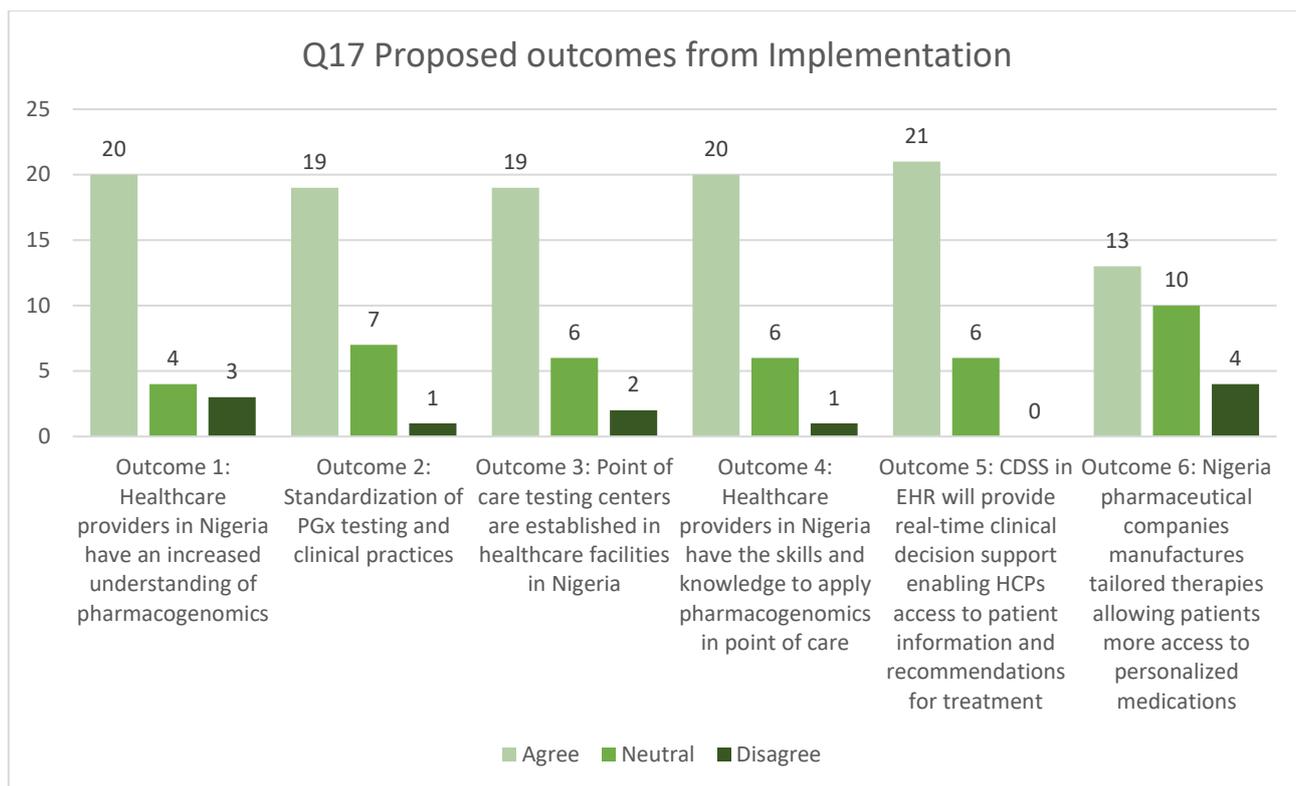


Figure 4.15 Proposed outcome from intervention

For the most part, respondents' perspectives on the proposed outcomes are clear - they largely agree with the anticipated results of the interventions. However, when it comes to outcome 6 from intervention 6, which advocates for collaboration with Nigerian-based pharmaceutical companies, the opinions are more varied. 44.4% of respondents agree with this proposed outcome, while 18.5% strongly disagree. Meanwhile, 37% of the respondents remain neutral on the matter.

Question 18

According to the question “Which of the following assumptions and risks could arise from the implementation of PGx in POC in Nigeria?”

The aim is to identify potential challenges or complications that might occur when introducing PGx into POC settings in Nigeria. This could include technical, logistical, ethical, or regulatory risks, as well as assumptions that may not hold true in the Nigerian context. By asking these questions, the survey is used to gather insights to better prepare for, and mitigate, these potential risks and challenges, thereby facilitating a more successful implementation.

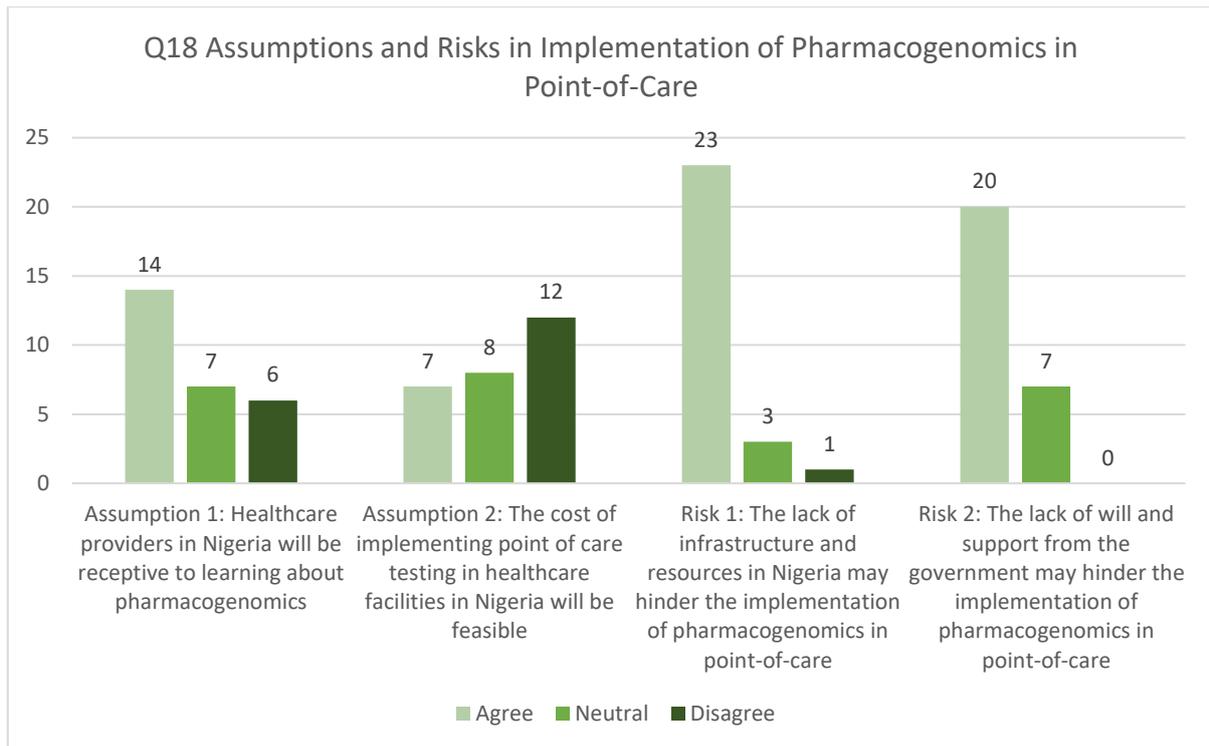


Figure 4.16 bar chart representation of the participants opinion about the proposed assumptions and risks in implementing PGx POCT

Figure 4.11 presents participants' perspectives on the proposed assumptions and potential risks that may be involved in the implementation process. Regarding Assumption 1, which presumes that HCPs in Nigeria will be open to learning about PGx, 51.9% of participants agreed, while 22.2% disagreed, and 25.9% maintained a neutral stance. In the case of assumption 2 about the feasibility of implementation costs, the opinions were mixed: 44.4% of respondents disagreed, 25.9% agreed, and 29.6% remained neutral.

Two risks were presented to the participants. The first suggested that inadequate infrastructure might impede the implementation of PGx at the point-of-care. A substantial 85.2% of respondents agreed with this risk, while a small fraction (3.7%) disagreed and 11.1% were neutral. The second risk proposed that lack of governmental support might also hinder implementation. Here, 74.1% of the respondents agreed, while the remaining 25.9% disagreed. There were no neutral responses for this risk.

4.3 Challenges and Future Outcome of PGx Testing Implementation in POC in Nigeria

The questions in this section were directed at getting comprehensive understanding of what the implementation could entail, what difficulties might be encountered, what results might be expected, thereby informing planning and decision-making for the implementation process.

Question 19

This question helped to understand the most significant obstacles or difficulties foreseen by the respondents in the integration of PGx into POC settings in Nigeria. From the options presented, 33% of participants identified the absence of regulatory guidelines for PGx in clinical practice as the most significant hurdle. Meanwhile, 30% highlighted potential ethical issues tied to the gathering, storing, and sharing of patient genetic data as their chief concern. Additionally, 22% expressed that reluctance among HCPs to adapt to and embrace new technologies could be the most pressing issue.

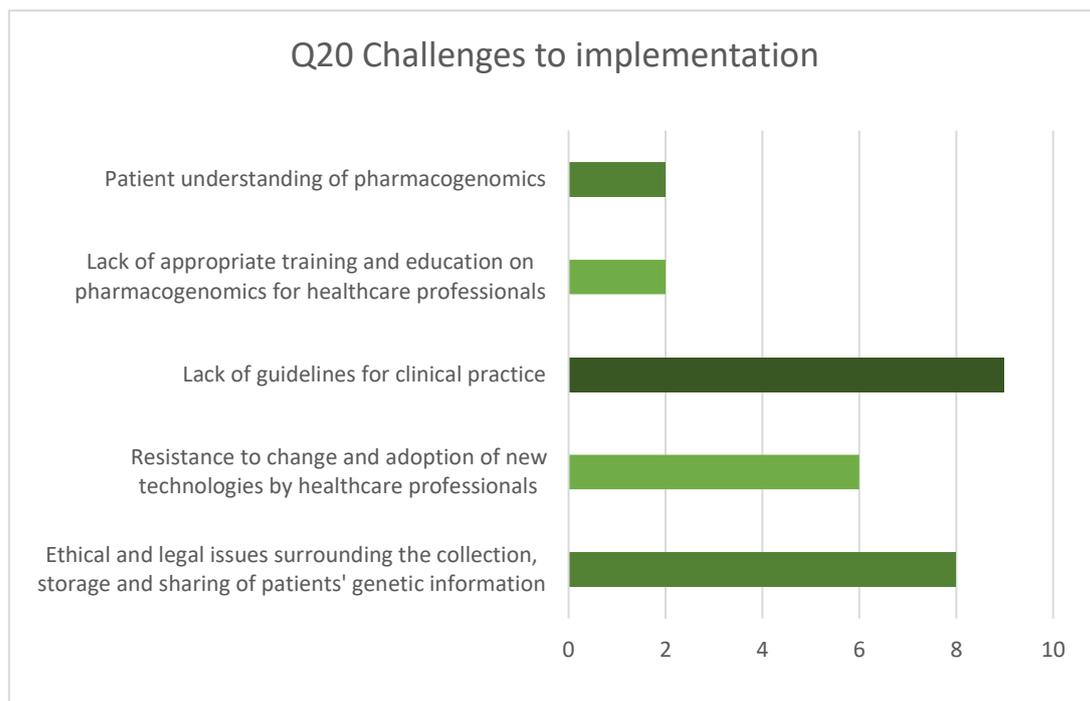


Figure 4.17 Bar chart representation of the participants opinion about challenges to the implementation of PGx POCT.

Question 20

The goal of this question is to understand respondents' perspectives on the key outcomes that should be assessed when determining the impact of PGx at the point-of-care. The insights gained from this question will help identify what aspects are considered most critical in evaluating the success or impact of PGx.

44% of respondents indicated that success should be linked with enhanced accessibility and availability of personalized patient care. 26% indicated that a better comprehension of the disease's genetic foundations within the population would be a robust measure of impact. Meanwhile, 22% selected a decrease in medication errors and an increase in patient satisfaction and trust in the healthcare system as indicators of success. 7% suggested that enhanced patient outcomes, like a decrease in adverse drug reactions, would be a fitting indicator of the influence of PGx in clinical practice.

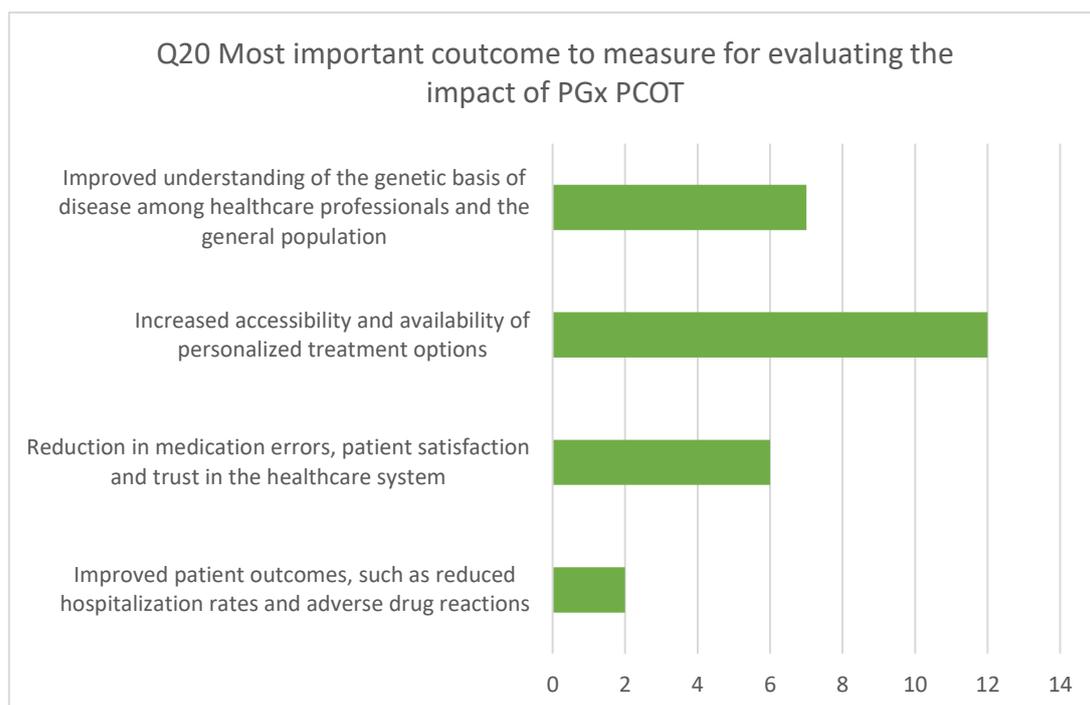


Figure 4.18 Participants perspective on measure for evaluating the impact of PGx PCOT

Question 21

“How do you see the future of PGx testing in Nigeria?”

This question was asked to gather opinions and perspectives about the potential trajectory and adoption of PGx testing in Nigeria. A significant majority of respondents, 63%, envision PGx as mainly restricted to research in Nigeria. Meanwhile, 33% anticipate its widespread adoption in clinical practice. However, a small fraction, 4%, does not see PGx as relevant in the context of the Nigerian healthcare system.

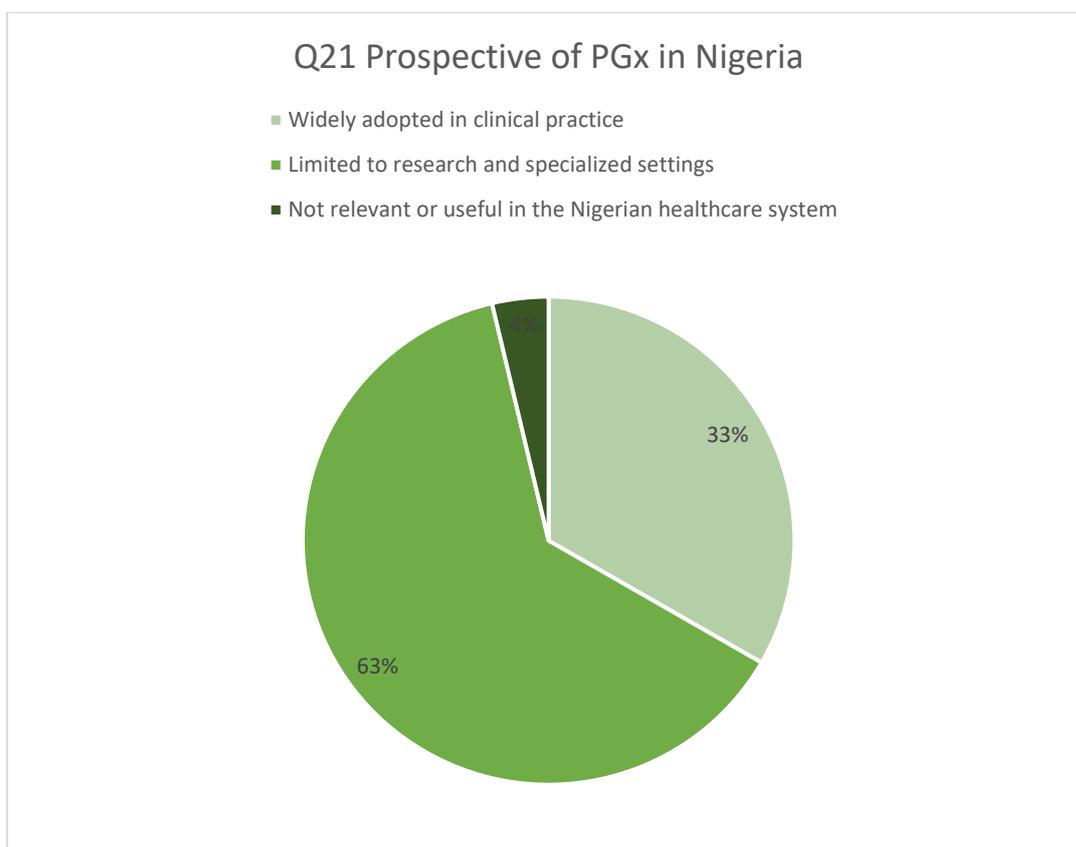


Figure 4.19 Participants perspective on PGx in Nigeria healthcare system

4.4 Qualitative Data Analysis

The data from the interview helped give more insights into the responses from the survey. By collecting data from such a wide range of sources, a thorough comprehension of the challenges and opportunities associated with the implementation of PGx in POC is attained. This comprehensive understanding

enables an informed analysis, leading to substantial recommendations for the effective integration of PGx into POC practices in Nigeria.

To accomplish this, interviews were scheduled with a total of 10 diverse stakeholders, 2 pharmacists, 2 physicians, 2 medical laboratory scientists, 2 research scientists, and 2 patients. However, only 5 participants were able to respond and engage in the interview sessions conducted via Zoom, resulting in a response rate of 50%. The distribution of the participants is presented in the table below.

Table 8 Description of participants

	Healthcare profession	Experience
Participant 1	Community pharmacist	5 years
Participant 2	Community pharmacist	3 years
Participant 3	Medical doctor	4 years
Participant 4	PGx scientist	5 years

Participant 5 was an individual who has lived and received treatment in Nigeria for 29 years.

The interview was structured with just four questions, every participant was asked the same question. This deliberate approach allowed for the exploration of variations and similarities in their responses.

4.4.1 Question 1

Can you describe the current state of PGx practice in Nigeria?

From the interview, according to all participants there is little to no PGx testing in clinical practice in Nigeria. **Participants 3 and 4** shared their perspectives on the application of PGx within hospital and clinic settings. **Participant 3** said:

“I'm currently practising in Lagos State, Nigeria and I think we should start with Lagos State first before we move up on to Nigeria as a whole. Pharmacogenetics practise in Lagos to start with, on a scale of zero to ten, I would give it a four. But for Nigeria as a whole, I can't exactly give you an accurate figure, but I've been to a couple of states, southern states and some northern states and it's even worse than what's happening in Lagos states. The knowledge and awareness, it's almost non-existent.”

Participant 4 gave more context to this:

“If I'm going to describe the current state of PGx in POC in Nigeria, then, I'll have to describe it based on if there is a clinic or hospital where they are use PGx testing, but right now I think

in Nigeria there are no clinics or institutions where you have PGx test as a POC treatment. But what you can see in Nigeria is probably if you have the money, you can request for the test, but as a routine practice in Nigeria, no, we don't have any institution or any clinic that is doing that.”

Participant 2 added that:

“...in rare cases where maybe it's a disease condition that is not common, maybe there will be from a PGx being used, but I don't think it's something that is prevalent right now in Nigeria.”

Participant 1 highlighted the underutilization of PGx in Nigeria. They emphasized that PGx remains largely untapped in the country, lacking comprehensive implementation and utilization:

“From the perspective of Community pharmacy practise, which is the most penetrative aspect of pharmacy practise in Nigeria, because penetrative in the sense that we get to interact with part a larger of the population compared to other aspects of pharmacy practise. I would say the current state of PGx in Nigeria is highly and heavily underutilised in the sense that it's all basic, it's still in its empirical state because the core tenets of PGx are not being utilised in the community space, meaning the only level of PGx that we utilise is interacting with patients and learning their family history of morbidity, comorbidities, and illnesses like; “does your father have a history of hypertension?”, “does your mother have a history of diabetes?” “does it run in your family?” as well as the case may be. So, I would say the current state of PGx in Nigeria is very underutilized.”

4.4.2 Question 2

“What do you think are the barriers limiting implementing PGx in POC practice in Nigeria, and how could they be addressed?”

After analysing participants' responses, several common themes emerged regarding the barriers that hinder POC PGx (PGx) testing. These barriers include, **lack of infrastructure, limited research funding, lack of knowledge and awareness, lack of training, inadequate data availability, cost of testing and the absence of government policies and regulations.**

Participants 1 stated:

*“The potential barriers are the barriers common to underdeveloped countries worldwide, which is the **lack of technology, poor technology use and poor sensitization** to the benefits of PGx and how it can improve patient treatment outcome”.*

He further elaborated:

*“How it can be addressed is well, first of all, in the **educational curriculum**, it is not a key component of what is taught in medical school. It is not taught as an option that should be explored, what is mostly in the curriculum is more of crude approach to pharmacotherapy and not a detailed overview of how genomics can be applied. Because the technology is not available it is not emphasized in training”. Emphasize PGx in training and no matter how little, expose the medical and pharmacy students to the technologies that performs these tests and let everybody see how much this can be beneficial to improving patient outcome”.*

While Participant 5 provided a different approach:

“I believe that PGx cannot be achieved alone by pharmacists. You would require the collaboration of other health professionals and researchers like doctors and geneticists to achieve this”.

*“One of the limitations would be **lack of research and funding** of this such projects then. Also **lack of institutional infrastructures** would be a limiting factor”.*

Participant 3 offered a distinct perspective by emphasizing the significance of patients and the broader community. This insight sheds light on the importance of involving and engaging patients in PGx initiatives. It highlights the need for **community-wide education, awareness campaigns, and patient empowerment** to promote the utilization of PGx in healthcare.

For barriers to implementation, **Participant 3** stated:

*“The main problem we have is the **awareness, knowledge, literacy of the people**. The people generally do not go to the hospital when they feel like something is wrong, either for drugs or for investigations. They would rather just go to the street chemists and get whatever drug they feel like is going to be good for them. So, the barriers in implementing the PGx in POC practise, first, I think is literacy”.*

“There are lots of people that sell drugs without knowing the side effects or how those drugs impact patients. Different drugs have different reactions in different body in different bodies, but these roadside chemists are not aware of this.

Community as a whole also encourages this because it's easier for them. Mostly they believe that when they come to the hospital, there's time wasting, and they spend a lot of money. Some fear that the hospital might insist on investigations, others do not want to be admitted assuming

their diagnosis requires admission, so they rather be treated at home. They rather self-medicate rather than going to get the proper care they require. If people are not coming to the hospital, like I said earlier, that means there is non-existent POC practise, and this will be very difficult in making the implementation of PGx possible”.

Speaking on what can be done to address this issue:

“Teaching people about the advantage of going to the hospital where there can be POC practise to start with, instead of just going to a nearby kiosk, where they call, themselves chemists”.

The issues presented by **Participant 2** were:

“...lack of data, there is need to collect a lot of data from patients. Also, the lack infrastructure, Nigeria is a developing country even the public or general hospitals are not currently state of the art”.

“There needs for more infrastructures to be built or maybe more healthcare being built that are of high standards that can now implement PGx”.

Participant 4 discussed broadly on this:

*“There are a lot of barriers looking at genomic in Nigeria, but I will just say the major is if you look at most developed countries where the PGx testing is already part of the healthcare system, you realise the government is fully involved. Hardly will you find in Africa generally, where there is a government funding or any kind of innovation that will foster PGx testing. So, our major barrier is finance, either **finance from the government or philanthropists**.*

*“...The current state of healthcare system in Nigeria will not even foster PGx testing in for example. Now if you look at our clinics or the hospital, there is **no electronic health record** there. It is difficult to track patients and record adverse events for a particular patient”.*

*“...For **human resources**, there are only few physicians or clinicians that know about PGx tests. Physicians should be able to talk about it and even counsel a patient about it. But they don't have much knowledge on it. We need more human resources regarding that. Incorporate PGx into any biomedical field or a course for physicians, pharmacists, and laboratory scientists...”.*

“These are the three major barriers to the implementation of PGx testing although there are more. A big finance towards PGx testing and precision medicine which I call ‘innovation

financing' in Nigeria, will go a long way for the implementation PGx testing in hospitals all over Nigeria”.

4.4.3 Question 3

“What specific actions or interventions do you think would be necessary or unnecessary to successfully implement PGx in POC practice in Nigeria?”

Participants were given proposed interventions to gather their perspectives and needs, allowing them the freedom to include or exclude interventions as they saw fit. The goal is to understand allow participants address their needs and identify opportunities to promote effective implementation of PGx in point-of-care. The information gathered will be used to develop interventions and strategies to overcome barriers and enhance facilitators. The common theme mentioned were, **government involvement, infrastructure building, HCPs education and training, patients outreach programs, fundraising and partnerships.**

Intervention 1: Increased awareness and education about PGx testing

Intervention 2: Development of PGx Guidelines

Intervention 3: Establish PGx testing centres in POC in Nigeria

Intervention 4: Train healthcare providers in Nigeria on how to carry out PGx testing.

Intervention 5: Implement Clinical decision support systems (CDSS) and Electronic Health Records (EHR) in the healthcare system in Nigeria.

Intervention 6: Collaborations with Pharmaceutical Companies to Develop Drugs

Participant 2 expressed their views on **Intervention 1**, stating that:

“There's need for increased awareness and education on PGx especially for both patients and healthcare itself”.

Participant 3 offered additional insights on **Intervention 1**, emphasizing the importance of its implementation. Furthermore, they highlighted the need for **Intervention 4** to address specific challenges:

“...the general population, they must be properly sensitised. They must be properly aware, properly educated about PGx. Creating awareness or creating some form of education for the for the public is more of a bone of contention than developing a guideline...if the community

gets sensitised and they go to these PGx PCOT centres and the HCPs there cannot carry out PGx testing, then it's all futile”.

“Most healthcare providers that’s the doctors, nurses, lab attendants, nutritionist, dieticians, everybody that work together to make the hospital run, do not know a lot of things outside their day-to-day routine. Most people have been doing the same thing for years and you know what they say about repetition, “you only know to do best what you do all the time... HCPs in Nigeria, if not all would need proper training on how to incorporate or how to carry out PGx testing”.

Participant 1 added that:

*“From an educational perspective, **re-educating the medical population** on the benefits associated of PGx and another necessary aspect would be integrating technologies into healthcare and POC in Nigeria. Technology integration is very important and healthcare providers need to be trained, you know on how to carry out PGx testing”.*

On developing PGx guidelines (**Intervention 3**) **Participant 2** simply stated:

*“The government need to take actions to **implement policies**”.*

Participant 4 elaborated on the challenges related to developing PGx guidelines, emphasizing the importance of focusing on creating guidelines specifically for Africa instead. He further suggested that caution should be exercised when utilizing existing guidelines in the African context.

“If we are looking at development of PGx guideline in Nigeria, we can develop when completion a comprehensive guideline for Africa is completed because right now, they have begun to generating data for Africa”.

“If you look at literature and you will find out that there are some African specific single nucleotide polymorphisms (SNPs) that are not there in the current PGx guidelines. What we might need to do is have something called an expensive mapping of African genome. So, after the extensive mapping of Africa or Nigeria genome, then we can develop on guidance. I think we should focus more on Africa first, then we can say “how can we extract from Africa?”

In addressing the idea of using current guidelines, **Participant 4** stated:

“Some of the population that was used to draft some of those guidelines are not based on African population, so it might not be able to address for all the gene. I can speak specifically for you for the guidelines that is available for DPYD on CPIC. It might be useful to some extent,

but we cannot depend solely on it, because you will find out that they are African specific polymorphism that are not represented on the guideline.”

*“There are some polymorphisms that you find in in European countries, you won't find in Africa population at all, and there are some in Africa you will not find them in the European western population. An example is CYP2C19*17, except you find it in African American you will not find it in European descent. It is starting point, but it will not address all the adverse events we are trying to prevent looking at PGx testing. Right now, we don't have any guideline for African specific population, but if we use this, it has to be translated with caution because you can't directly translate it”.*

Participant 3 and 4 both mentioned that for implementation, PGx data on the Nigeran population should be collected. **Participant 3** stated that:

“There will be need to collect a lot of data from patients”.

Participant 4 added:

*“There should be **generation of Nigerian PGx data** before developing guidelines. There are different types of data that can be collected, but it is more of SNPs, adverse event data generated via an observational or implementation study”.*

“Especially if you want to look at general PGx data, there are very different. You can group the data you want to, the one that has to do with polymorphism will be different. From that of polypharmacy. There are a lot of other data that we can actually generate that will help pharmacology implementation of PGx in Nigeria or in Africa”.

Regarding **Intervention 6** (collaborate with pharmaceutical companies to develop drugs), **Participant 2** stated:

“I don't think it would be easy to collaborate with pharmaceutical companies to develop drugs, because right now they are still feeding the majority of the population with the general medicines. It would be very expensive for them to start investing in personalised medicines”.

Participant 3 claimed that:

“Collaborating with pharmaceutical companies to develop drugs looks very farfetched because big pharmaceutical companies will not just develop drugs because of a particular phenomenon or a particular advantage that people are trying to get. Drugs are not just developed, they go through different trials, they go through different testing, which I know is

still part of what PGx is all about. But to help the cause instantly or within a short time, I don't think this sixth intervention is going to work”.

Meanwhile, **Participant 4** anticipates the prospects of this partnership:

“Collaboration with pharmacy pharmaceutical companies to develop drugs and all that is part of health system strengthening. More like even having a database to say we now have this database in Nigeria with 100,000 patients with different SNPs available, we can give it to let's say a pharmaceutical company or any research institutes with of course IP ownership being honoured. We can work with some of these SNPs that we've been able to identify genotyping data to develop drugs”.

Participant 1 provided more insights into the ethical issues that may arise as a result of dealing with patient's data:

“A lot of factors are involved when you talk about PGx that go beyond traditional Orthodox medicine. Whereby with PGx, we are dealing with genetic details of patients and there's a lot of ethical concerns in that topic so legally those concerns need to be addressed, and there need to be an at some level of assurance of patient data safety, patient data security before you now start talking about collaborating with pharma companies to come into the system and get access to patient's data, it's something that is a huge ethical dilemma”.

Although **Participant 3** expressed disagreement with **Intervention 6** but offered an alternative option:

“Instead of collaborating with pharmaceutical companies, I would say collaborate with the government. Collaborating with the government is going to cover the area of awareness to the community, training of HCPs at different arms of the health system from the tertiary institutions, secondary institution, primary health care centres, even private hospitals. Collaborating with the government at the state government level – state by state, before moving to Nigeria as a whole. At the state government level or even at local government level, which includes the primary health care centres, the government can help in in creating awareness, education, giving knowledge to the immediate community and if all local government starts doing that, assuming the collaboration works people become aware of PGx POC testing and even if they might have no good knowledge of it, over time they eventually would”.

Participant 4 provided a scenario of how the government can be involved in implementing PGx.

“... we need to have an innovative government in Nigeria that focuses on building infrastructure for PGx. Government must be fully involved in terms of PGx in Nigeria, besides just building these research institutions. It is very expensive for an individual to go into precision medicine, just a single experiment cost up to \$3000 and sometimes you spend more than that. Let's say you want to use a chip, you want to buy a cheap a chip right now from Thermo fisher, you can spend up to \$2500 as an average Nigerian, how do you want to get that? The government should have an infrastructure for PGx, set it up at a location and have students come in for training, a research lab that maybe attached preferable to a hospital or at a research institution”.

“Also, innovation of governments where you have national strategic plan for PGx in Nigeria working perfectly with public-private funding and also possibly reimbursement for some scholar from some scholars from the government”.

Participant 3 simply added:

*“...the government should find a way to **reduce the cost** of the POC testing”.*

4.4.4 Question 4

“What actions can be taken to sustain the implementation of PGx over time?”

Participant 1 stated:

“What I believe would help the sustainability would be the redesigning and integrating PGx into the curriculum at undergraduates, this is very important. The populace also needs to be educated, the National Orientation Agency needs to teach the public that this is a safe way or a safer way of approaching healthcare. If the curriculum is updated and HCPs are taught how to implement PGx, the technologies are available and the populace are afraid of this science and its intrusive nature, then the initiative is going to fail. The orientation needs to be done public to expose people to the tenets of PGx, how what it applies and the benefits”.

“The integration of better technology, availability, accessibility and distribution would be another way of ensuring sustainability. If PGx technologies are available and is only accessible in an urban setting in a centralised approach, this is still a very poor system because it is not going to benefit everybody. It has to be decentralised. Education, introduction and decentralization of this technology is one of the ways of employing sustainability of PGx therapy in Nigeria”.

Participant 3 provided another insight on how PGx can be sustained:

“At the Community level, create awareness, continuous education and all of that would work in sustaining implementation. At healthcare provider level; retraining healthcare providers on PGx. Then at the government level, sustaining the collaboration, government changing hands should not affect the collaboration towards this implementation”.

Participant 4 included:

“What we need majorly is to have an innovation ecosystem whereby we the government do their part, including the philanthropists. There’s partnership between institutions (that is universities/research institutions), and pharmaceutical companies, working together and independently on workforce and infrastructures. These four things will come together to bring innovative ecosystem for either precision medicine or PGx advancement in Nigeria”.

“If innovation financing and innovation government stands, there are some things that comes automatically, like workforce and infrastructure, strengthening of healthcare system, collaboration between educational institution and research institution. If there are funds available for an institution, definitely research will always go on”.

5 Conclusions and Recommendation

Introduction

In this chapter, the findings presented in Chapter Four are discussed. Based on the aim of this research study which is to explore the development of an operational model for the implementation of PGx in Nigeria using the ToC approach, the discussion will be categorized under three main themes to accomplish this; (1) Facilitators of implementation (2) Barriers to implementation (3) Outcome(s) to measure successful implementation of PGx in point-of-care.

Barriers Limiting Implementation

Based on the findings in question 2, it can be concluded that factors limiting the implementation of PGx in POC in Nigeria are lack of infrastructure, limited research funding, lack of knowledge and awareness, lack of training, inadequate data availability, cost of testing and the absence of government policies and regulations which is consistent with findings from secondary research.

Facilitators of PGx implementation

Based on the findings from questions 2, 3, and 4, it can be deduced that the integration of pharmacogenomics (PGx) into healthcare delivery at the point-of-care in Nigeria would be facilitated by several key factors. These include the presence of an innovative government, enhanced awareness and education on PGx, specialized training for healthcare professionals (HCPs) in PGx testing, the establishment of necessary infrastructure, the provision of technologies for PGx testing, and appropriate funding.

After considering the recommendations and requirements put forth by stakeholders, adjustments were made to the preliminary proposed actions. Taking into account solely the responses of participants, the following interventions are recommended:

Intervention 1: Innovative government

The commitment and support of organizational leadership is the first requirement for clinical implementation of PGx in any medical institution (Wang and Weinshilboum, 2019), the willingness and interest of the government and government agencies will also go a long way in endorsing PGx. This can involve incorporating technological advancements, fostering a culture of creativity and experimentation within government bodies, implementing policies that encourage research and innovation, citizen engagement. The aim of an innovative government is to better serve its citizens and adapt to evolving societal needs and challenges.

Government should put in place policies and guidelines that regulate PGx practices. The government has the capacity to establish a regulatory framework that not only ensures the safe and ethical use of PGx, but also encourages its growth. This could involve setting guidelines for PGx testing, data usage, and privacy, as well as creating incentives for public and private research institutes to develop and incorporate PGx solutions. The government should collaborate with researchers, Nigeria and African based PGx research organisations like 54gene, African PGx Consortium and H3Africa to develop or tailor guidelines relevant to Nigeria genetic data.

Next, government should direct significant investment towards research and development in PGx, by allocating funds for the exploration of new technologies and advancement of knowledge in this field. They should also develop strategies to lower the cost of PGx testing. This could be achieved by ensuring the efficient operation of the National Health Insurance Scheme (NHIS) or by devising alternative reimbursement methods to decrease the burden of out-of-pocket expenses.

Collaboration is another essential component of this strategy. Government should actively seek partnerships with academic and private research institutions, thereby increasing synergies across institutions. These collaborations can lead to an exchange of knowledge and resources, ensuring that research findings are applied practically, and that industry and healthcare needs are addressed in research. The government could also invest in necessary facilities such as high-throughput genomic sequencing laboratories and sophisticated data management systems. The development of telemedicine networks could also be prioritized to ensure broad access to PGx services. In managing the large genomic databases that PGx necessitates, the government should devise strategies to ensure data security and privacy. Striking the right balance would demand creative solutions, potentially involving the use of advanced data management and encryption technologies.

The transition of government leadership should not interfere with the implementation of PGx in point-of-care. An innovative government would remain adaptable throughout this process, continually evaluating and adjusting its strategies. As technology and societal needs evolve, so too must the government's approach to implementing PGx. By fostering a culture of innovation and creativity, the government can effectively navigate this complex landscape and make personalized medicine a reality for its citizens.

Intervention 2: Increased awareness and education on PGx

Creating awareness of PGx among HCPs and patients on PGx will enable an effective integration of PGx into clinical practice. For a successful implementation, it is paramount that all stakeholders: physicians, pharmacists, laboratories and patients are synergized in respect to their working knowledge

of PGx (Cicali *et al.*, 2022). Lack of knowledge of PGx service among healthcare professions in Nigeria is a major barrier to implementation (Abubakar *et al.*, 2022), HCPs need to have a thorough understanding of PGx and its applications in point of care. Information on how to identify clinical situations that may require PGx testing, how to identify the best PGx testing approach and how to collect and interpret genetic information and how to incorporate this information into patient care should be made available (Just *et al.*, 2019).

Educational materials should be developed and should cover various topics, including the fundamentals of PGx, the clinical significance of PGx, and the practical applications of PGx in point-of-care. Experts in PGx should be consulted in developing these materials and tailored to the specific needs of healthcare providers in Nigeria and presented in a language that is easily understandable to healthcare providers. It is also important to ensure that the educational materials contain up-to-date advancements in PGx. The information provided in the educational material should be able to bridge the gap between the available PGx guidelines and clinical reality; conferences can also be organized to provide HCPs with real-life learning experience with actual patient cases (Just *et al.*, 2019) (Petry *et al.*, 2020). There are available PGx resources like the IGNITE (Implementing Genomics in Practice) toolbox which provides educational guides for both HCPs and patients.

Public education and awareness are also paramount. To promote the acceptance and usage of PGx, the government could launch campaigns aimed at HCPs and the general public. These campaigns would communicate the benefits and implications of PGx, demystifying the concept and encouraging informed engagement with it. Moreover, the implementation of PGx would require robust infrastructure.

The success of Intervention 2 will depend on the availability and accessibility of the educational materials. The materials should be disseminated widely and made available in different formats to cater to the needs of healthcare providers with different learning styles. It is also essential to evaluate the effectiveness of the educational materials by collecting feedback from healthcare providers and incorporating this feedback into the development of future educational materials.

Intervention 3: Train healthcare providers on how to carry out PGx testing

The government could initiate training programs to build capacity among HCPs. With the requisite knowledge and skills to interpret and apply PGx data, these professionals could effectively integrate PGx into their practice.

Intervention 3 propose the training of healthcare providers in Nigeria on how to carry out PGx testing. This intervention is crucial as it will ensure that healthcare providers are equipped with the practical knowledge and skills required to perform PGx testing accurately and reliably. A comprehensive training program should be developed and should cover the principles of PGx, including genetic testing methods, laboratory techniques, data interpretation, and reporting, and how to integrate genetic information into clinical decision-making. The training should also provide HCPs with practical skills, such as how to use POC testing equipment, how to obtain and interpret genetic information, and how to use the information gotten to make informed treatment decisions. Ethical and legal issues related to PGx testing, as well as best practices for communicating with patients about their test results should be included in the training program. Practical translational programs that involve informal education via networks such as interdisciplinary teams and PGx advocates may offer hands-on learning and support needed to shift practice (Pearce *et al.*, 2022).

To ensure the success of this intervention, a system for monitoring and assessing the efficacy of the training program must be developed. This can be accomplished by frequent assessments of HCPs PGx testing knowledge and abilities, as well as surveys of patient satisfaction and health outcomes. It is also critical to establish a structure for continual professional development and continuing education to ensure that healthcare personnel are up to speed on the most recent advances in PGx testing.

Overall, training healthcare providers in PGx testing is a critical intervention that can aid in the improvement of patient care in Nigeria. By providing healthcare workers with the necessary knowledge and competencies, they will be better able to provide patients with tailored and effective care. It will also assist to guarantee that PGx testing is done correctly and consistently, resulting in improved health outcomes for patients.

Intervention 4: Establish Infrastructures and Supply the Essential Technologies for PGx Testing

The creation of an effective PGx testing system starts with well-structured infrastructure. This aspect involves the setting up of physical and organizational structures necessary for the execution of PGx testing. This could include building or repurposing laboratory facilities, establishing data centres for storing and analysing genetic data, and creating networks for the efficient communication and dissemination of PGx testing results.

In terms of physical infrastructure, this might involve the construction or renovation of laboratories to meet the specific requirements of PGx testing. These labs need to be equipped with the necessary

machinery, apparatus and reagents for performing genetic analysis. This includes but is not limited to PCR machines, DNA extraction systems, and sequencing equipment.

The organizational structure as well is also important. It should be designed to facilitate clear communication and smooth workflow among various stakeholders, including lab technicians, bioinformaticians, clinicians, and patients. This structure will provide the foundation for sample collection, testing, analysis, and reporting of results. The development of an efficient information management system is also crucial, the system should be able to handle and process a large amount of genetic data swiftly and securely.

In conclusion, the implementation of PGx testing on a broad scale requires specific, advanced technologies. These include high-throughput sequencing machines for genetic testing, sophisticated bioinformatics software for analysing and interpreting genetic data, and digital platforms for managing and sharing genetic information.

Intervention 5: Implement Clinical Decision Support Systems (CDSS) and Electronic Health Records (EHR) in the healthcare system.

The implementation of Clinical Decision Support Systems (CDSS) and Electronic Health Records (EHR) in the healthcare system in Nigeria can improve the quality of care and patient outcomes in PGx clinical practice (Crews *et al.*, 2012). CDSS can provide doctors with patient-specific recommendations based on an individual's genetic profile, ensuring that the most recent evidence-based recommendations are used to support clinical decision-making (Liu *et al.*, 2021) (Gottesman *et al.*, 2013). EHRs can facilitate the implementation and evaluation of PGx through POC clinical decision support (CDS). The adoption and implementation of CDSS and EHR in Nigeria may encounter a number of obstacles including shortage of laboratories with the necessary equipment and a lack of financing (Hicks *et al.*, 2016). As a result, integrating CDSS and EHR into the healthcare system calls for a comprehensive strategy that involves staff training, building a robust infrastructure, guaranteeing government commitment, and ongoing maintenance and support (Owusu-Obeng *et al.*, 2014) (Elewa *et al.*, 2015).

To implement CDSS and EHR in PGx clinical practice in Nigeria, the following steps can be taken:

1. Evaluate the current state of healthcare technology in Nigeria by taking into account technology and data management capabilities to determine what needs to be developed, outsourced, or improved (Wasylewicz and Scheepers-Hoeks, 2019).
2. Form partnerships with HCPs, researchers, information technology specialists and health informaticists to develop evidence-based CDSS models specifically suited to PGx (Mills, 2019).
3. Design and develop a CDSS that can be integrated with EHRs to help HCPs make educated decisions about PGx-based treatments (Sutton *et al.*, 2020). This system need to offer computerized physician order entry, order sets, templates, notifications, and reminders (Mills, 2019).
4. Integrate CDSS with EHRs. This step enables access to relevant patient data and real-time clinical decision-making support (Murphy, 2014).
5. Train HCPs how to effectively utilize the CDSS and EHRs for PGx practice.
6. Monitor and review the system that have been developed. Continually examine the CDSS and EHRs' performance, particularly their success in enhancing patient outcomes and reducing errors (Rubins *et al.*, 2019). Also take into account patients' feedback to continuously improve the system.
7. Ensure data security and privacy by putting effective data protection procedures in place to secure patient data while adhering to all relevant privacy laws.

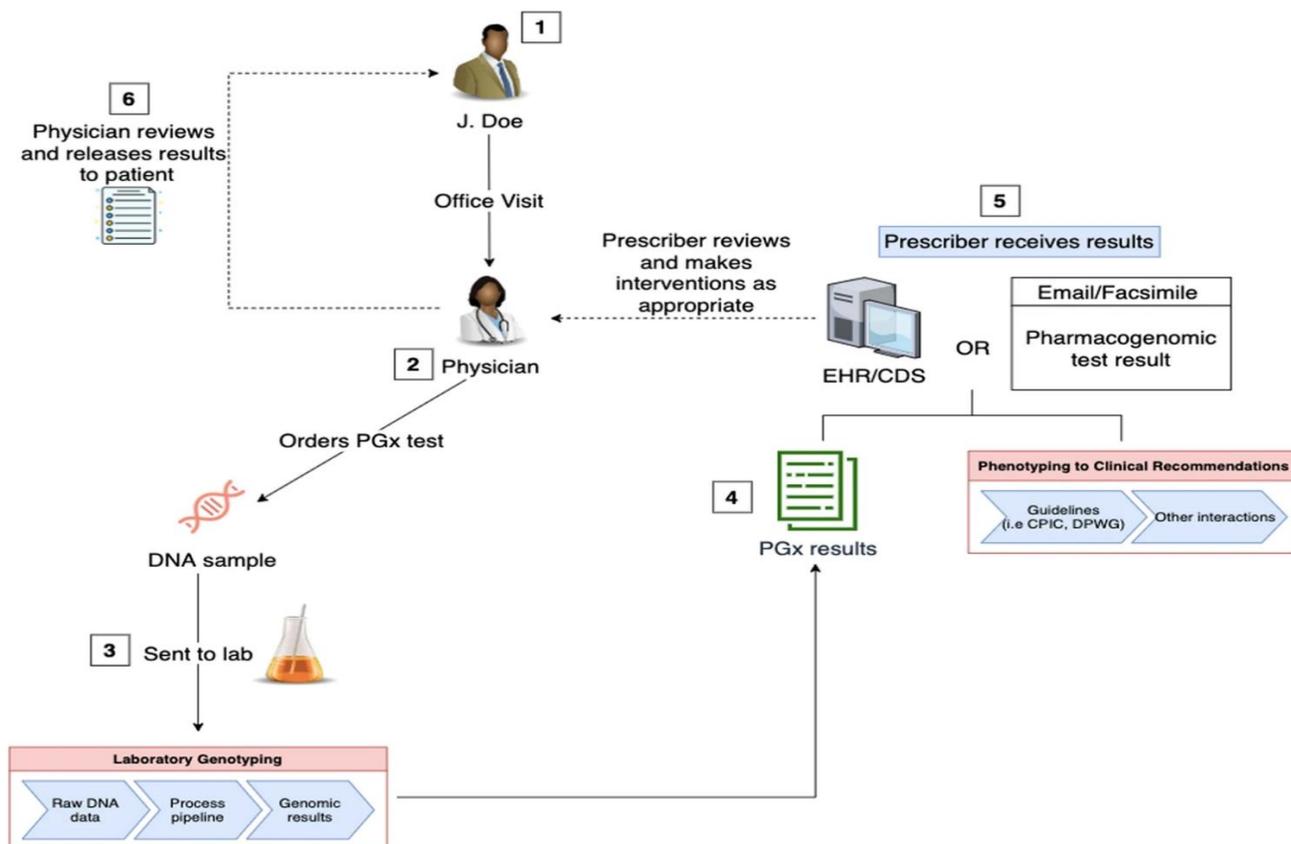


Figure 5.1: Workflow of a clinical PGx (PGx) test from ordering to reviewing (Roosan et al., 2021).

Intervention 6: Innovative finance

Innovative finance is about finding new and creative ways to get the money needed for a project. The implementation of PGx requires significant investment, and innovative financial strategies can play a key role in this process. These strategies involve non-traditional methods of raising and allocating funds, leveraging partnerships, and managing risks.

Blended finance approach can be used to generate funds for PGx. This is when public money (from the government) or donations (from philanthropist) are used to attract private money for projects with high social impact but might be too risky for businesses alone. In the case of PGx, government or philanthropic funds could be used to de-risk investments in research, infrastructure, and capacity-building initiatives. So, public money could be used to encourage businesses to invest in PGx.

Another way of strategically generating funds is by Social Impact Bonds and Development Impact Bonds. These are agreements where a private investor give money to a project, and if the project works well, a government or agency pays the investor back. These could be used for PGx projects, with payback based on improving people's health. Crowdfunding is another innovative finance option. This

will create an environment where researchers and organizations can appeal directly to the public for funds, enabling small-scale investors to contribute to PGx initiatives.

Through these various methods, innovative finance can significantly accelerate the adoption of PGx. By unlocking new sources of capital, reducing financial risks, and aligning financial incentives with health outcomes, these strategies can make PGx a more attractive and viable field for investment.

5.1 Outcome(s) to measure successful implementation of PGx in point-of-care

The initial long-term goal of this project was to improve healthcare outcomes through the implementation of PGx in point-of-care. However, considering stakeholders responses, the goal was subtly modified to align with stakeholders' presumptions. thus, the long-term goal is to improve healthcare delivery by increasing the accessibility and availability of personalized treatment options. With the generic ToC map, the long-term goal is to improve healthcare delivery in Nigeria with the implementation of PGx in POC based on the interventions and sustainability factors provided.

The proposed model, as depicted in Figure 5.2, represents potential actions for successful implementation of PGx at the point-of-care in Nigeria. This model is derived from the analysis of both qualitative and quantitative data gathered. By integrating these diverse sources of information, Figure 5.2 presents a comprehensive and actionable roadmap for integrating PGx into Nigeria's healthcare system, directly at the point-of-care, where it can have the most immediate impact on patient outcomes.

Impact	Increased accessibility and availability of personalized patient care					
Outcomes	Implementation of PGx testing in POC, generation of Nigeria genetic data set, and development of PGx testing guidelines.					
Outputs	Output 1: Educational materials on pharmacogenomics testing will be available to healthcare providers.	Output 2: There will be guidelines for PGx practice in Nigeria. This may also lead to the generation of Nigeria PGx data.	Output 3: Point-of-care testing centres established in Nigeria.	Output 4: HCPs are skilled on conducting pharmacogenomics testing.	Output 5: Implementation of CDSS and EHR in Nigerian healthcare facilities.	Output 6: Collaboration agreements with pharmaceutical companies for compatible drug development.
Activities	Activity 1 Support and allocate funds to PGx research and implementation. Reimburse genomics researcher to encourage more research. Set up payment plan to assist patients with the cost of PGx testing. Collaborate with researchers, Nigeria and African based PGx research organisations like 54gene and H3Africa to help tailor guidelines relevant to Nigeria genetic data.	Activity 2 Collaborate with the Ministry of Education to introduce PGx into health science curriculum. Develop and distribute educational materials on PGx for HCPs and Patients Set up continuous learning environment on PGx for HCPs and patients. Engage in community outreach to increase the awareness of PGx.	Activity 3 Train HCPs with practical skills, such as how to use point of care testing equipment, how to obtain and interpret genetic information, and how to use the results to make informed treatment decisions. Provide hands-on training for healthcare providers on PGx testing. Work together with various stakeholders, including physicians, pharmacists, laboratory scientists, and regulatory bodies, to understand their needs and identify areas where they lack so efforts can be made to bridge the gaps.	Activity 4 Evaluate the current infrastructure and resources in healthcare institutions. Determine infrastructural, equipment, and human resource shortages. Come up with a strategic plan for the establishment of PGx testing facilities, considering aspects such as location and target demographic. Get and install the necessary PGx testing equipment and technologies.	Activity 5 Partner with HCPs, researchers, information technology specialists and health informaticists to develop evidence based CDSS models suited to PGx use. Design and develop a CDSS that can be integrated with EHRs to help healthcare practitioners make educated decisions about PGx-based treatments. Continually examine the CDSS and EHRs' performance, particularly their success in enhancing patient outcomes and reducing errors, take into account patients' feedback to continuously improve the system. Ensure data security and privacy by putting effective data protection procedures in place to secure patient data while adhering to all relevant privacy laws.	Activity 6 Raise funds for PGx using: -Blended finance approach -Crowdfunding -Social Impact Bonds and Development Impact Bonds -Partnerships with private investors
Interventions	Intervention 1: Innovative government	Intervention 2: Increased awareness and education on PGx	Intervention 3: Train healthcare providers on how to carry out PGx testing	Intervention 4: Establish Infrastructures and Supply the Essential Technologies for PGx Testing	Intervention 5: Implement Clinical decision support systems (CDSS) and Electronic Health Records (EHR) in the healthcare system in Nigeria	Intervention 6: Innovative finance
Inputs	Government involvement		Infrastructure building	HCPs education and training, Patients outreach programs		Fundraising and partnerships
Assumptions	Healthcare providers in Nigeria will be receptive to learning about PGx. The cost of implementing point of care testing in healthcare facilities in Nigeria will be feasible.					
Risks	The lack of infrastructure and resources in Nigeria may hinder the implementation of PGx in point of care. The lack of political will and support from the government may hinder the implementation of PGx in point of care.					
Situation Analysis	Identify causes and consequences of the problem, and opportunities to address it.					
Problem statement	Limited knowledge and application of PGx in healthcare settings in Nigeria, leading to suboptimal treatment outcomes.					

- Inputs are the resources used to develop and implement an intervention
- Interventions are the actions taken or programs adopted to effect a desired result
- Activities refers to the initiatives required to deliver an intervention
- Outputs are the direct products of activities
- Outcomes are the intermediate changes that occur as a result of inputs and processes in interventions
- Impact reflects the medium- to long-term effects of an intervention

Figure 5.2: Proposed Implementation Model Using the Theory of Change (Toc) Framework

5.2 Recommendation

Based on the findings of this study, several recommendations can be made to support the implementation of PGx in point of care settings:

Invest in Infrastructure: Significant investments in healthcare infrastructure are necessary to ensure that facilities have the resources and capabilities to effectively deliver PGx POC services. This includes upgrading hospital and clinic facilities, improving transportation networks for sample and data transfer, and ensuring reliable electricity and internet connectivity.

Increase Funding: Policymakers should prioritize healthcare in budget allocations, with a focus on innovative medical technologies like PGx. Exploring public-private partnerships and other innovative financing mechanisms can also help mobilize the necessary resources for the integration of PGx into clinical practice.

Human Resource Capacity Building: A comprehensive capacity-building program should be developed to train HCPs in genetics, genomics, and PGx. This program should also include strategies to attract and retain skilled professionals within the country, contributing to a robust healthcare workforce.

Promote Interdisciplinary Collaboration: The successful implementation of PGx POC services requires collaboration among professionals from various fields, including genetics, pharmacology, healthcare, and public policy. Establishing platforms for knowledge exchange and collaboration can help drive innovative solutions and ensure a comprehensive approach to implementation. PGx will also help bring scientist like bioinformaticians, geneticists and biomedical scientists into the healthcare space.

Monitor and Evaluate Progress: Continuous monitoring and evaluation of the implementation process should be conducted using the indicators established in the ToC. By tracking these indicators, stakeholders can make data-driven decisions to modify the implementation strategy as needed, ensuring its continued relevance and effectiveness.

5.3 Limitation of Study

It is important to acknowledge limitations of this study and conduct further research to address the gaps. While this study endeavours to provide a robust pathway for the successful implementation of PGx PCOT in Nigeria, there are several limitations to consider:

- The extensive involvement of stakeholders in the development and revision of the ToC model could potentially have led to a bias towards desirability.
- Given the theoretical nature of this study, practical challenges may arise that can influence the feasibility and scalability of the interventions considered within.
- Since the findings from this study was based on the perspectives of mainly HCPs and researchers, future studies should include non-medical staff such as regulatory experts, government and patients to get their opinion which could be contrary to those presented in this study.
- The study does not extensively address the ethical issues associated with PGx implementation like informed consent, privacy, potential cultural and societal implications.
- While the study discusses the potential outcomes of the interventions, it does not provide a comprehensive evaluation plan or specific metrics to measure the effectiveness of the implementation.
- Future studies should explore the implementing PGx in Nigeria using the proposed model, identify implementation barriers and gather real-world data to inform evidence-based decision-making towards incorporating PGx in point-of-care.

5.4 Conclusion

In conclusion, this study has provided valuable insights into the current state of PGx implementation in POC settings and has identified key barriers and facilitators to its implementation. By understanding the challenges and opportunities surrounding the integration of PGx into clinical decision-making at the point-of-care.

The theory of change framework was an effective tool for fostering dialogue with stakeholders to provide a clear visualization of a comprehensive roadmap for implementing PGx in POC in Nigeria, outlining necessary steps, defining success factors and requirements, predicting long-term success, and establishing evaluation metrics.

The findings of this study highlight the importance of government involvement in PGx, increased public awareness, healthcare provider education and training, supportive policies and guidelines, implementation of CDSS and EHRs and advancements in technology for successful implementation of PGx in point-of-care. By addressing these factors, we can enhance the adoption and utilization of PGx, leading to improved medication management and better patient outcomes.

The insights gained from this study can guide future efforts in the field of PGx, enabling the development of effective strategies and interventions that support personalized medication management at the point-of-care. Hopefully these findings will contribute to the advancement of PGx implementation in clinical practice, ultimately leading to safer and more effective treatments tailored to individual patients.

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