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The applicability of a Finnish PROM point of care rapid test in the Nigerian market - market analysis and a proposal for market entry.

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Title
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Abstract

This study assesses the applicability and market potential of a Finnish point-of-care rapid test for PROM in Nigeria, a critical obstetric condition requiring prompt diagnosis to prevent complications. It identifies major birthing hospitals with private payer schemes, evaluating their capacity for adopting new diagnostic tests. The study examines current PROM diagnostic methods, analyzing whether rapid tests are in use or if traditional approaches (e.g., nitrazine tests, clinical examinations) still dominate. A competitive landscape analysis identifies existing PROM test providers and market positioning.

Key hospital decision-makers influencing test adoption, including Heads of Obstetrics & Gynecology, Procurement Officers, and Laboratory Directors, are explored. The study also investigates funding sources for PROM testing—whether through private insurance, out-of-pocket payments, or hospital budgets.

The study framework includes business environment analysis tools to assess market opportunities and competitiveness. Qualitative and quantitative methods, including questionnaire, interviews with industry professionals, and secondary data analysis, provide insights into Nigeria's healthcare sector. Findings from the questionnaire and interviews will inform market entry strategies for the PROM rapid test.

Language	Pages
English	Appendices
	Pages of Appendices

Keywords
Birthing centers, premature rupture of membrane (PROM), point-of-care testing (POCT), IVD regulation, Healthcare financing

Contents

1 INTRODUCTION

Premature rupture of the membrane (PROM) is a critical obstetric condition that explains the breakage of the amniotic membrane before the commencement of labour (Konar 2018, 1). About 15% of pregnancies worldwide result in PROM (Diriba, 2017, 164). The management of PROM is dependent on a precise diagnosis, timely, and appropriate intervention (Ng, Lim, Shafiee, Gbani, Ismail, Omar & Yassin, 2013). Early diagnosis Statistically, management of this condition in low- and medium-income countries is quite different from that in High Income Countries (HICs). There have been different methods employed for the management of PROM which have suffered some limitations. However, a noninvasive diagnostic tool fits perfectly as it should be able to differentiate between physiological fluids, detect rupture of fetal membrane (sensitivity) and produce a quick result (Ng, Lim, Shafiee, Gbani, Ismail, Omar & Yassin, 2013). Also, amniotic fluid contains very high concentration of binding protein called insulin-like growth factor binding protein – 1 (IGFBP-1) which is important for PROM Management in terms of sensitivity and specificity (Darj & Lyrenäs 1998, 296).

Companies intending to join in the fiercely competitive business world of today, must be knowledgeable about their choice of market (Edwards, Ketchen & Short 2014, 77). In addition, finding possible clients and having a working understanding of communication techniques to interact with them are essential (Bradley 2005, 15-16).

The study seeks to analyze the current diagnostic landscape, assess market entry challenges and opportunities, and propose a strategic plan for introducing the test in Nigerian healthcare institutions.

1.1 Maternal Health, PROM and Management

Maternal healthcare plays a pivotal role in global health, especially in developing countries where pregnancy outcomes can be greatly impacted by prompt and precise diagnoses. According to the World Health Organization, about ten million infants die before they clock one and about one percent is born preterm (World Health Organization 2014).

There has been significant effort in reducing maternal mortality between 1990 and 2015 with regards to care of pregnancy-related problems (WHO 2018). However, sub-Saharan African nations have had the slowest drop-in maternal morality rates (MMR) and has continued to have the highest MMR globally (Zureick-Brown, Newby & Chou 2013). In contrast to the worldwide average of 216/100,000 births, records from the sub-Saharan Africa area have seen significant increase of over 200% - 547/100,000 births (WHO 2015). Oluwasogo, Olalubi, Sebutu & Bello (2020) posits that there are over 800 maternal deaths in Nigeria for every 100,000 live births which placed her in the category of the world's poorest nations such as Somalia, Niger and Chad. With 14% of worldwide maternal mortality, the country with the highest number of maternal deaths behind India is Nigeria (Okonofua, Imosemi & Igboin 2017). Nigeria Demographic Health Survey (2018) estimates one in thirty-four women will die from maternal complications.

Hodgins & D'Agostinob (2014) says that maternal health is effective when antenatal care is received a minimum of four times, a marker for healthcare coverage worldwide (Hodgins & D'Agostinob 2014, 173).

Among several diagnostics challenges in the field of obstetrics currently is premature rupture of membranes (PROM). It happens when there is leakage of the fetal membrane prior to when labour begins. However, it is called Preterm PROM (PPOM) if it happens before the 37th week of gestation (Kuba & Bernstein 2018, 1163 - 4). According to Hnat, Mercer, Thurnau, Goldenberg, Thom & Meis (2005), about 10% experience premature rupture of the membrane during pregnancy (Hnat, Mercer, Thurnau, Goldenberg, Thom & Meis 2005, 164 – 8; Enjamo, Deribew, Semagn & Mareg 2022, 455 - 466).

Preterm birth rates range from 5 – 10% in Europe (Delnord, Blondel & Zeitlin 2015, 133-142). However, in Nigeria, preterm birth rates per 100 live births in 2020 range from 6 – 17 (WHO, 2023).

Several maternal risk factors have been linked to the aetiology of pre-labor rupture of membranes even though the precise cause of this condition is not well recognized. According to Odunsi & Oduntayo (2003), some of these risk factors include past cervical surgery (e.g., conization), uterine over-distension, cervical incompetence, bacterial vaginosis, poor nutrition, low socioeconomic level, connective tissue diseases (e.g., Ehler's-Danlos Syndrome), and history of PROM (Odunsi & Oduntayo 2003, 430-453).

Alexander & Cox (1996) highlights that PROM affects a humongous number of pregnancies which is usually fatal to both mother and child if proper diagnosis is not carried out or improper management is carried out (Alexander & Cox 1996, 369-74). According to Bigelow, Factor, & Miller (2016), PROM relates to a myriad

of neonatal diseases which include neonatal infection, necrotizing enterocolitis, and intraventricular hemorrhage which potentially raises serious concern in environments where there are insufficient facilities for neonatal care (Tranquilli, Giannubill, Bezzeccheri, & Scangnoli 2005, 759-763). Nigeria is one of the few countries around the globe that account for more than half of all maternal and newborn fatalities (Akinyemi, Bamgboye & Ayeni 2015, 2).

Dayal (2019) reveals that PROM complicates between 5 -10% and 2.3 – 30% of term pregnancies and preterm deliveries respectively (Dayal 2019). According to Wolke (2019), the major complication of PROM is prebirth which is linked with significant risk of death and morbidity (Wolke 2019, 69 – 92).

A study carried out by Emechebe Njoku Anachuna & Udofia (2015) in University of Calabar Teaching Hospital (UCTH) Nigeria aimed at reviewing the patterns of risk factors, gestational age at presentations, and fetal complications of PROM revealed that in contrast to around 25% of patients who reported with late preterm PROM (34–36 weeks), more than half of the study group had term PROM. (Emechebe et al. 2015, 1912-1917). In other study, there were 4.1% incidences of PROM in another health institution in Southwestern Nigeria (Suleiman Bello Tijani & Oluwasola 2021, 63) similar to another study carried out in Egypt (Abouseif Mansour & Hassan 2018, 99 - 107). However, there have also been researches which had between 7 – 20% in parts of other parts of Nigeria and Africa (Idrisa Pius & Bukar 2019, 15 - 20) which could be attributed to gestational age of viability and delivery centres in these places (Adeniyi & Atanda 2013, 1388 – 1397).

Eleje, Ezebialu, Umeobika, Eke, Ezeama & Okechukwu (2010) highlights that chorioamnionitis is the maternal complication of PROM (Eleje et al. 2010,10 - 14).

It rises with duration of rupture with about 10% recorded in mothers in the study made by Emechebe et al. 2015 suggesting that most of these mothers presented with prolonged PROM and could have had vaginal examination before presentation to the hospital as cases of infection increases with prolonged latency period more than 24hours (Dare, Middleton, Crowther, Flenady & Varatharaju 2006). The likelihood of chorioamnionitis with term PROM has been found to be below 10% and increase to 40% after 24hours of PROM (ACOG 2007, 1009). Therefore, the right management of PROM cannot be overemphasized.

The various effects of PROM can effectively be managed by early and accurate diagnosis (Emechebe et al. 2015, 1915) which is vital in making proper clinical decisions and improving maternal and neonatal health by health practitioners (National Institute for Health and Care Excellence 2022, 339). Tsakiridis Mamopoulos & Chalkia-Prapa (2018) also mentioned other ways of managing PROM which include use of antibiotics, stimulating labour and delivery (Tsakiridis, Mamopoulos & Chalkia-Prapa 2018, 371).

Management of PROM

According to Bunn & Sikarwar (2016), there are three useful methods for the management of PROM and they include the traditional, modern and quick diagnostic methods (Bunn & Sikarwar 2016, 4). Karat, Madhivanan, Knapp, Poornina, Jayanthi & Suguma (2006) collaborated the view of Bunn & Sikarwar. In addition, they mentioned that more sophisticated methods were used in developed areas of the world. For example, perinatal survival via amniotic infusion and sealing of rupture site (Karat, Madhivanan, Knapp, Poornina, Jayanthi & Suguma 2006, 284). However, in developing climes of the world, the story is quite different. For example, according to Suleiman et al. 2021, traditional methods are still employed in the management of PROM which include clinical examination e.g direct visualization of amniotic fluid egressing from the cervix,

diagnostic ultrasounds, Nitrazine paper tests, and the ferning test (Suleiman et. al. 2021, 65). Friedman & McElin (1969) opined that though these methods have been used for a long time, results from them could be unclear especially in patients presenting for obstetrical care moment after suspected PROM occurs (Friedman & McElin 1969, 545). In addition, El-Sayed, Mahdy, El-Bakry & Mohammed (2019) states that despite the Fern and Nitrazine tests being quick and simple, they might provide false positive and negative findings making it unreliable (El-Sayed, Mahdy, El-Bakry & Mohammed 2019, 621).

The management of PROM have continually been on the front burner in internally recognized obstetric groups but it has been faced with a myriad of challenges in low- and medium-income countries such as cost, lack of awareness of test, closeness to tertiary health centers (Shazly, Ahmed, Radwan, Abd-Elkariem, Ragab, Abouzeid, Shams, Ali, Hemdan, Menna, Nassr, AbdelHafez, Eltaweel, Ghoniem, El Saman & Thompson 2021, 5).

For the quick and precise diagnosis of ROM, there have been creation, approval and sale of a myriad of point-of-care immunoassay tests which identify alpha fetoprotein (AFP) in amniotic fluid and cervico-vaginal secretions in high and low concentration respectively (Mariona & Cabero 2012, 403).

According to Doret, Cartier, Miribel, Massardier, Massoud, Bordes, Moret & Gaucherand (2013), Insulin-like growth factor binding protein-1 (IGFBP-1, also known as placental protein 12 (PP12)) and placental alpha microglobulin-1 (PAMG-1) are the core of the first generation of monoclonal antibody approach test. (Doret, Cartier, Miribel, Massardier, Massoud, Bordes, Moret & Gaucherand 2013,1816). However, McQuivey & Block (2016) states that a combined immunoassay test made of monoclonal and polyclonal antibodies have been created to identify these proteins found in amniotic fluid in high concentrations.

(McQuivey & Block 2016, 70).

1.2 PROM POC Rapid Test

There has been some migration to the use of rapid diagnostic methods especially the point-of-care testing (POCT) which make use of immunoassay technologies. According to Warsinke (2009), POCT which is a rapidly area of clinical diagnostics, is a bedside test frequently performed at the patient care location (Warsinke 2009, 1393).

Von Lode (2005) notes that the testing can basically be carried out anywhere (Von Lode 2005, 592). According to Choi, Yong, Choi, & Cowie (2019), POCT has become more relevant than the traditional laboratory testing, which depends on isolating the bacterial or viral pathogen and carrying out extremely difficult assays. This method has swiftly determined a variety of disease agents and pathogenicity at the molecular level (Yager, Edwards, Fu, Helton, Nelson, Tam & Weigl 2006, 412).

According to Warsinke (2009), POCT is a quick testing which is made possible using immunoassay technologies such as agglutination, immunofiltration, and immunochromatographic assays (Warsinke 2009, 1395).

Rapid point-of-care tests, or PROMs, comprise of all quick, qualitative, point-of-care immunochromatographic assays created to identify amniotic fluid in women's cervico-vaginal secretions when there was a suspected membrane breakage (Senanayake 2013, 116). According to Von Lode (2005), the immunochromatographic assay has higher sensitivity and is easy to handle

making it universally accepted for diagnosis in the global healthcare market (Von Lode 2005, 594). Adebara & Adewara (2019) highlights that the use of Amnisure test in diagnosing PROM performed better in contrast to clinical methods in terms of sensitivity and predictiveness (Adebara, Ifarinola, Adewara, Adeniyi, Oni, Alayode, Busari & Kolawole Fasakin, 2019, 156).

The manufacturer's brand boasts of promptness, high sensitivity & specificity, reliability, used at any gestational age, non-interference with any other fluid of the body and global acceptance.

Diagnostic Devices

Peeling, Mabey, & Herring (2006) posits that a significant contribution to world health is made by diagnostic testing and are required to guarantee the proper use of medications and to direct treatment decisions (Peeling Mabey & Herring 2006, 1062). According to Mabey, Peeling & Ustianowski (2004), the use of diagnostics plays a pivotal role for the control of infectious diseases that require early detection to prevent transmission (Mabey, Peeling & Ustianowski 2004, 233). These tests are frequently lifesaving and result in complication if they are missed. Most diagnostic procedures that require patient's samples make use of In-vitro diagnostic medical devices (IVDs). They encompass a broad spectrum of technologies ranging from advanced apparatus for use in laboratories to a rapid test at the site of care. Because many patients do not reside within the confines of a working and furnished laboratory, access to diagnostic testing is commonly restricted in developing nations (Storla, Yimer, & Bjune 2008, 9). A new set of diagnostic tests made for use at the care site are created and do not require a laboratory. Spread of infectious diseases is reduced with this test (Peeling & Mabey 2010, 1064). According to McNerney & Daley (2011), it is important to

promote prompt access to these tests and their affordability in developing nations could increase access to appropriate healthcare (McNerney & Daley 2011, 206).

The table below provides a variety of diagnostic tests and their sensitivity and specificity percentages.

Test/references	Name of test	Cutoff	Sensitivity (%)	Specificity (%)
Nitrazine		Positive.Negative	90-97	16-70
Ferning and/or Pooling		"	51-98	70-88%
AFP	POM check	>30µg/L	90-94	95-100
Fetal fibronectin		>50µg/L	97-98	70-97
IGFBP-1	PROM test	>3µg/L	74-97	74-97
PAMG-1	Amnisure	>5.0ng/mL	98-99	88-100
IGFBP-1/alpha fetoprotein	Amnioquick duo^{+}		97.6	97.9

NOTE: AFP=Alphafetoprotein, β-hCG=beta-subunit of human chorionic gonadotropin, IGFBP-1=insulin like growth factor binding protein 1,

Table 1: Diagnostic PROM Test/references with their sensitivity and specificity percentages (Eleje et al. 2017).

Regulating Diagnostic Devices

The aim of medical items regulation is to ensure quality and safety with everyone. For a regulatory system to be effective, National Regulatory Authorities (NRAs) must exert their authority in all health sectors as demanded by law. New tests deemed unsafe, substandard are denied market access after an unbiased review

and safe products are approved and registered. Medical devices for the purpose of regulation include IVDs.

The acronym ‘ASSURED’ (Affordable, Sensitive, Specific, User-friendly, Rapid and robust, Equipment-free, and Deliverable to end-users) is a criterium used as a standard when deciding which diagnostic tests are best suited for environments with limited resources (Peeling Homes Mabey & Ronald 2006, 51).

However, these standards are general and must be adjusted for any diagnostic requirement. Certain regulatory standards must be met when launching a new diagnostic test.

When determining which diagnostic tests are most suited for environments with limited resources, the ‘ASSURED’ criteria can serve as a standard (Peeling, Homes, Mabey & Ronald 2006, 51) but these standards are general and must be modified for any diagnostic requirement. When introducing a new diagnostic test, there are specific regulatory requirements.

Rodriguez-Manzano, Sumithra, Subramaniam, Uchea, Katarzyna, Szostak-Lipowicz, Freeman, Rauch, Tinto, Heather, D’Alessandro, Holmes &, Awandare (2024) opined that innovators seek for regulatory clarity owing to the lack of direction on clinical gaps new treatments are required to fill (Rodriguez-Manzano, Sumithra, Subramaniam, Uchea, Katarzyna, Szostak-Lipowicz, Freeman, Rauch, Tinto, Heather, D’Alessandro, Holmes &, Awandare 2024, e934). Synergy between health organizations (such as World Health Organization in developing countries) in various climes is encouraged to create clear and evidence-based diagnostic tests. They also demonstrated how improved collaboration between lawmakers, Health Technology Assessment

(HTA) groups, doctors, and innovators may improve the design of tests diagnostic tools and maximize their potential impact.

Peeling & McNerney (2011) opined that most nations have a legal setup and a chosen body to control pharmaceuticals. However, medical devices regulation in developing nations is not commonplace. The National Agency for Food and Drug Administration and Control (NAFDAC) oversees medical device regulation, including invitro devices (IVDS). NAFDAC (2004) states that the manufacturing, importation, exportation, distribution, marketing, sale, and use of IVDs are all governed and overseen by the Federation of Nigeria's Act Cap N1 Laws. Before the product is used in the country, NAFDAC reviews IVD technical dossiers.

1.3 Healthcare Systems in Nigeria

With over 200 million inhabitants and known as the Nation in Africa with the highest number of persons, Nigeria consists of 36 states, a federal capital territory (FCT), and 774 local government districts. Nigeria is expected to rank fourth in the globe in terms of population with about 390 million people by 2050 (CIA 2020, 2). NBS (2018) states that most residents in Nigeria are between the ages of 0 and 14.

In addition to being a basic part of existence, healthcare is essential to the wellbeing of the community. According to Kerleau & Pelletier-Fleury (2002 210), using social, medical, and other resources to address individual needs in an area is one of the goals of healthcare system. In every community, a lack of essential health facilities and services is strongly linked to lower life expectancy, higher death rates, and poor productivity (Awoyemi, Obayelu & Opaluwa 2017).

In Nigeria, healthcare is categorized into first tier, second-tier and third-tier with each managed by the municipal, state administration and national government respectively. (WHO 2015). While the responsibility of the national Government is majorly confined to supervision of university teaching hospitals and federal medical centres, the State administration oversees general/specialized hospitals. The municipal government prioritizes Primary Health Care (PHCs) and overseen by National Primary Health Care Development Authority (NPHCDA 2018). Even though states control secondary hospitals, PHC regulation, and PHC technical assistance, PHC has historically been the responsibility of Local Government Areas (LGAs), providing health services such basic medical treatment, public health, hygiene, and sanitation through the ward health system (WHO 2015).

WHO (2018) states that fundamental human rights include good health as mentioned in her constitution. Consequently, every UN member is expected to ensure that her citizens and others living in their country have access to universal healthcare. According to WHO (2019), Primary Healthcare (PHC) is a wholistic methodology to health considering factors such as choices and characteristics of community dwellers.

Primary Healthcare Centres in Nigeria

WHO (1978) defines primary healthcare as practical and scientifically proven care made accessible to community dwellers via their involvement and affordable cost. According to WHO (1978), the Principles and Elements of Primary Healthcare include Equity, Community Participation, Intersectoral Coordination, Appropriate Technology and Support Mechanism Made Available as Figure 1 below illustrates. WHO (2025) posits that PHC addresses key health challenges in the community by offering preventive, therapeutic, and rehabilitation treatments.

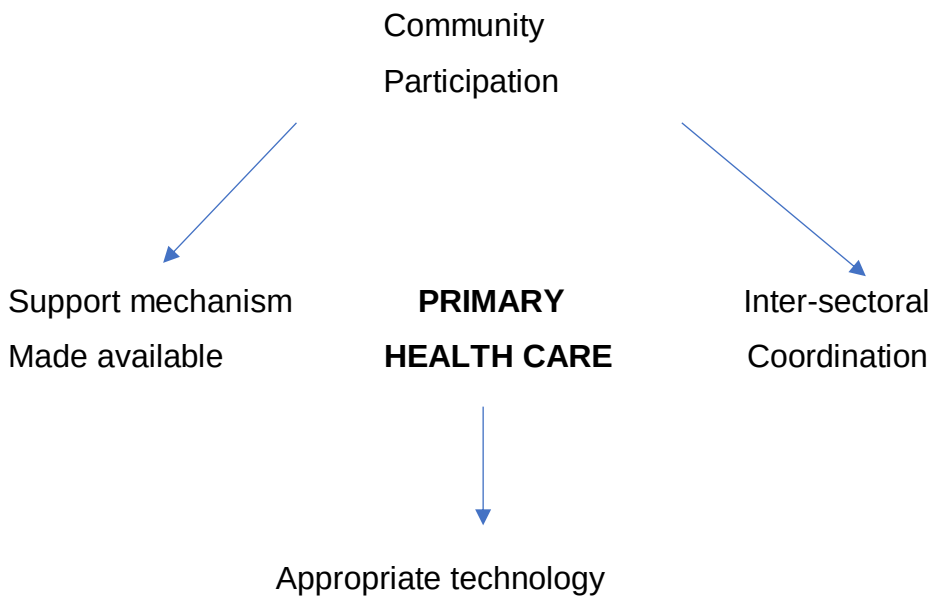

Figure 1: The four major pillars of the first-tier healthcare system.

Primary healthcare was formed as the core of the Nigeria health system by the National Health Policy of 1988 (FMOH, 2004) to improve equity in the availability and usage of necessary medical treatments. Nigeria's basic healthcare system has since undergone several developmental phases. Alonge (2020) highlights that PHC serves as the initial point of interaction for people, families, and the government health system. According to WHO (2018), the most important, unique, and pertinent part of Nigeria's three-tiered healthcare system is the primary healthcare system. According to Dunlop Howe Li & Allen (2020), PHC is responsible for more than 95% of all healthcare activities.

According to Ananaba (2018), Nigeria has very inadequate primary health care service delivery and continues to be among the poorest globally. Promotional, preventative, and basic care initiatives receive little coverage.

WHO (2023) posits that average life expectancy might increase by about 4years and save more than 50 million people by increasing PHC intervention in LMICs by 2030. Most of the required interventions for universal health care can be achieved using the PHC model.

Urban residents are served by second tier and third-tier health facilities in rural and suburban areas via government first-tier healthcare centres and faith-based clinics (WHO, 2018). Contrarily, primary healthcare is a deliberate and organized way to create healthcare systems to meet medical needs of less fortunate population. This system's price is also meant to be affordable and sustainable. However, Alonge (2020, 87) posits that primary healthcare should be accessible to all irrespective of their socio-economic rating.

Eboreime & Chukwuyem (2014) highlights that PHC aims to serve most of the population according to their needs by combining resources from within, outside the health field and use of technology irrespective of limitations due to finance or geography by development, management and evaluation of health programs (Eboreime & Chukwuyem 2014, 2260).

Badru (2003) states that primary health centres with the correct infrastructure, technology and necessary medication, must also perform tasks including health education, common disease diagnosis, and treatment (Badru 2003, 341). Oguntunde, Charyeva, Cannon, Sambisa, Orobaton & Kabo (2015) highlights that PHCs are essential in educating women about the warning signs of obstetric complications. Secondary general hospitals receive referrals from primary

healthcare centres for complex situations (Oguntunde, Charyeva, Cannon, Sambisa, Orobaton & Kabo 2015, 130).

Ademiluyi & Aluko-Arowolo (2009) points to Nigeria's colonial past, distribution effects and evolution of healthcare resources as the primary causes of underperformance of PHCs in contrast to hospitals in the country (Ademiluyi & Aluko-Arowolo 2009, 7). According to Central Bank of Nigeria (2005), most of the public healthcare funding, like government investment on general infrastructure, is allocated to secondary hospitals.

According to Alonge (2020), it is less likely that remote village dwellers seek healthcare in cities or other developed areas for myriads of reasons such as poverty, high cost of transportation, poor infrastructure etc. It is therefore important to offer fair and sustainable cost to individuals in distant places in terms of preventive and curative medical treatments (Alonge 2020, 89). Such a healthcare system must be established and made capable of providing treatment for a relatively small population. Primary healthcare, according to WHO (2019), is the most cost-effective way to accomplish this objective goal and meet holistic medical needs closest to the homes and communities of people.

Secondary Health Centres

Secondary health centres handle all forms of treatment and the management of mildly complicated conditions in addition to prevention. On the other hand, the most complex patients are sent to a tertiary hospital. The general hospitals and holistic health centres make up the Secondary Health Centres. The government owns and finances general hospitals, although private people or groups sometimes own comprehensive health centres (Ademiluyi & Aluko-Arowolo 2009, 107). Badru (2003) posits that areas for accident & emergency, X-ray & other diagnostic tools and pathology services are provided by the general hospitals

(Badru 2003, 340). In addition, the general hospital fulfills its function as a second-tier medical facility by integrating the primary healthcare institutions into their own. The Medical and Dental Council of Nigeria recommends that second-tier health centers have a minimum of three licensed physicians who can provide pediatric, obstetric, and surgical services in addition to other medical treatment.

Tertiary Health Centres

The tertiary health centres offer comprehensive primary and first referral treatment to their patients in most metropolitan areas (World Bank 1994, 45). Tertiary healthcare services, the apex cadre of health care in the country, are provided by highly specialized institutions and offer highly specialized treatments (Polsa, Spens, Somoye & Antai 2011, 20–21). University teaching health facilities, federal health facilities, and other nation-wide specialty health facilities are some examples of such institutions.

About nine-tenth of Nigeria's total health facilities are primary health centres and table 1 below shows the distribution in Nigeria.

Health Centres	Public	Private	Total
First-tier Centres	21,808	8,290	30,098
Second-tier Centres	969	3,023	3,992
Third-tier Centres	76	10	86
Total	**22,853**	**11,323**	**34,176**

Table 1: Health centres in Nigeria (National Health Accounts 2017)

Makinde, Sule, Ayankogbe & Boone (2018) states that governed owned health facilities outnumber those privately acquired (67% vs 33%). Also, they posit that most secondary healthcare institutions are privately held, and the northern region of Nigeria has a far larger proportion of public to private healthcare facilities than the southern region (Makinde Sule Ayankogbe & Boone 2018, e1179).

Obansa and Orimisan (2013) confirm that Nigeria's health sector has faced turbulent events with related negative effects with her large population notwithstanding the abundance of health centres and technological improvement (Obansa and Orimisan 2013, 222). Additionally, particularly in rural areas, the country's medical facilities, including medical institutions, personnel, and equipment—are inadequate (HERFON 2006). This, of course, explains why the mortality rate for moms, babies, and even adults have been so high throughout the years. In Nigeria, more than 15% of kids never reach their fifth birthday.

Structure of the Healthcare System (Public vs Private Hospitals)

Nigeria has an extremely varied system of health care delivery, including both traditional and conventional methods. Both the public and private sectors provide orthodox healthcare services (Oyibocha, Irinoye, Sagua, Ogungide – Essien, Edeki & Okome 2014, 36). However, healthcare in Nigeria remains the responsibility of all tiers of government.

There are visible differences in healthcare quality provided by private and public health providers in Nigeria. Obi, Abe & Okojie (2013) concluded that private health institutions are more service-ready than public ones (Obi, Abe & Okojie 2013, 33). The socioeconomic growth of the northern and southern parts of Nigeria differs significantly from one another. Majority of people in northern Nigeria are Muslims, and their culture is in tandem with those from the Arab states

in North Africa and Middle East. In contrast, Christianity is the prevalent in religion in the southern region of Nigeria (Osaghae & Suberu 2005, 7). According to Osaghae & Suberu (2005), residents of southern Nigeria are more educated and more likely to adopt western lifestyles, which is significant given their religious tendency, which was mostly brought about by foreign missionaries (Osaghae & Suberu 2005, 8). Babalola & Fatusi (2009) mentioned that distinctions in healthcare services demand and the ways in which families seek medical attention are two ways that the sociopolitical, ethnic, economic, and religious distinctions that now exist between northern and southern Nigeria affect health disparities Babalola & Fatusi 2009, 2).

Healthcare facilities in Nigeria are randomly distributed and particularly lacking in staff and infrastructure in rural regions (Asuzu 2004, 2). The private sector uses both conventional and contemporary western hospitals and clinics to fill the void and have the most influence on the primary healthcare system. Although they are typically local, regions of jurisdiction cover a wide variety of services.

Nigeria Demographic and Health Survey (2018) says Nigeria has about 40% professional birth attendance rate with about 25% and 15% of deliveries carried out in public and private institutions respectively. This means most women in Nigeria give birth at home stressing the need for devices that can be used for the management of PROM anywhere. This potentially contributes to high maternal death rate in Nigeria.

The Federal Capital Territory, Abuja has three (3) third-tier health centres, fourteen (14) second-tier health centres, two hundred and sixty-five (265) first-tier health centres and over a thousand (1000) private hospitals.

Birth Rate in Nigeria

Figure 2 below reveals Nigeria's birth rate from 2012 to 2022.

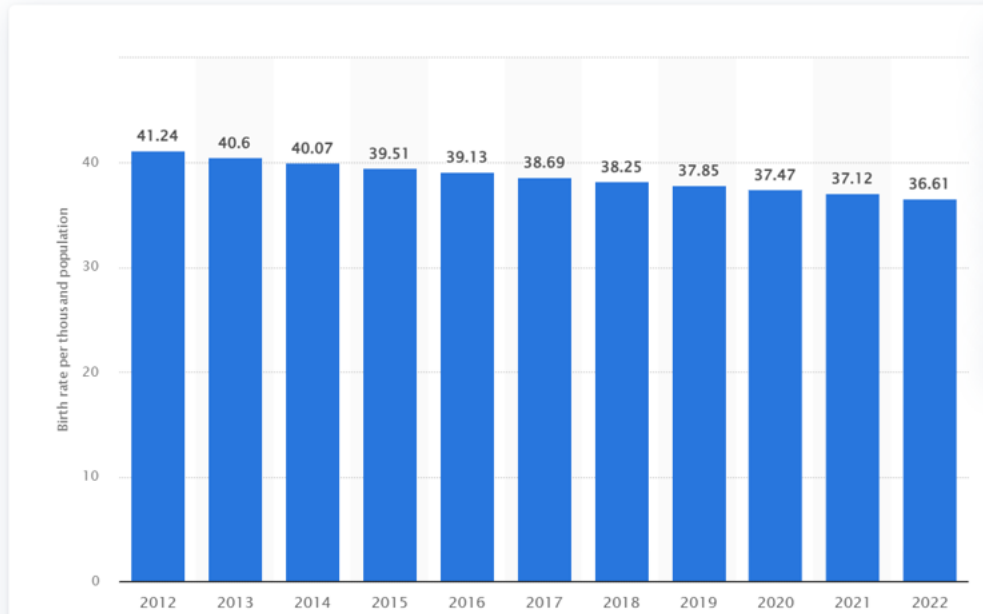

Figure 2: Birth rate in Nigeria from 2012 – 2022 (per 1000 inhabitants)

Decisions in Choosing Birthing Centres

Effectively managing the phases of labor during pregnancy and the potential difficulties that may arise is one of the most significant factors in lowering maternal fatalities, particularly in settings with limited resources. In underdeveloped nations, adolescent women's pregnancy and delivery complications are the main cause of maternal fatalities. According to Nigeria demographic and health survey (2013), One key tactic to lower maternal fatalities is to increase the proportion of births that are delivered in medical facilities. The survey also revealed that only about one third of births in Nigeria occur in a medical institution and the other fraction giving birth at home.

There are several obstacles that prevent pregnant women from using medical facilities as birthing places. Ononokpono & Odimegwu opined that women's choice of delivery location is influenced by a few variables, including service costs, transportation to the facility, their capacity to make decisions, cultural & religious customs, educational attainment and the area in which they live (Ononokpono & Odimegwu 2014).

According to Ashimi & Amole (2015), high frequency of home births was facilitated by the sudden beginning of labor late at night, the lack of transportation, and the restricted alternatives for delivery positions (Ashimi & Amole 2015, 120). Knowledge, women's attitudes and understanding of labor outcomes, community views, and prior birth experience were among the variables identified in recent qualitative research as discouraging women from giving birth in facilities (Nyakang & Booth 2018, 4).

Eluobaju, Okonofua & Weine (2023) opined that women-centred approach must be adopted to boost prenatal care to childbirth in health facilities transition. Furthermore, they opined that women would have the option to deliver in a helpful

manner by retraining professional birth attendants and incorporating safe cultural practices (Eluobaju, Okonofua & Weine 2023,7).

Strata of Healthcare Institutions

Healthcare in Nigeria have three levels and they include first-tier, second-tier and third tier. By policy structure, the first-tier Health Care falls within the Local Government and arguably the initial center for the sick and injured. Mild health related issues are handled here such as malaria, fever, cold and nutritional disorders.

Primary healthcare centres send complex situations to secondary centres. With the aid of right technology and drugs, primary health centres undertake duties such as awareness, identification and management of usual diseases (Badru 2003).

The duties of secondary health facilities include managing, treating, and preventing less complicated cases. However, more complex situations are handled by tertiary centres. General hospitals funded usually by the government and Comprehensive health centres usually owned by private individuals make up the secondary centres.

Along with other services, general hospitals also provide exits for accident, emergency, and diagnostic units (Badru 2003). The Medical and Dental group in Nigeria proposed at least three doctors as part of the standard of being a second level of healthcare centre.

A third-tier health centre mostly specialists and teaching hospitals oversee complicated situations from the general hospitals or direct admission and has accident & emergency, diagnostic, wards and treatment units.

1.4 Healthcare Financing

WHO (2014, 228) defines Health care financing as the creation, distribution, and utilization of financial resources within the healthcare system. According to Obansa & Orimisan (2013), the goals of health finance include making funds accessible, ensuring less expensive treatments are picked and bought with suitable financial benefits for providers in addition to quality healthcare for all.
Three key roles are covered by health financing. These include the acquisition of health services, risk sharing, and revenue collection. The process of healthcare support via raising money from diverse areas is known as revenue collection, purchasing is giving the pooled monies to the health care providers so they may offer health services to the populace and risk pooling is the method used to manage income received (Asante, Wasike, & Ataguba 2020, 750).

According to World Health Organization (WHO 2000), Nigeria ranked 187th out of 191 members of the organization in terms of health system performance. The foundation of the national health system, primary health care (PHC), is still in a state of complete paralysis because of severe underfunding, poor management, unethical behavior, and a lack of ability at the local government level.

Gottret & Schieber (2006, 324) highlights tax-based financing, donors, out-of-pocket payments (OOPPS) and health insurance (private, public, and community) as the most often used methods globally to support healthcare. These sources can alternatively be categorized as private, quasi-private, and public (Ichoku & Fonta 2009, 300).

Olakunde (2012, 8) posits a combination of taxes, out-of-pocket expenses, international donations, and health insurance are currently also employed to finance healthcare in Nigeria.

Figure 3 below illustrates funding sources in Nigeria's healthcare system with over 60% from individuals.

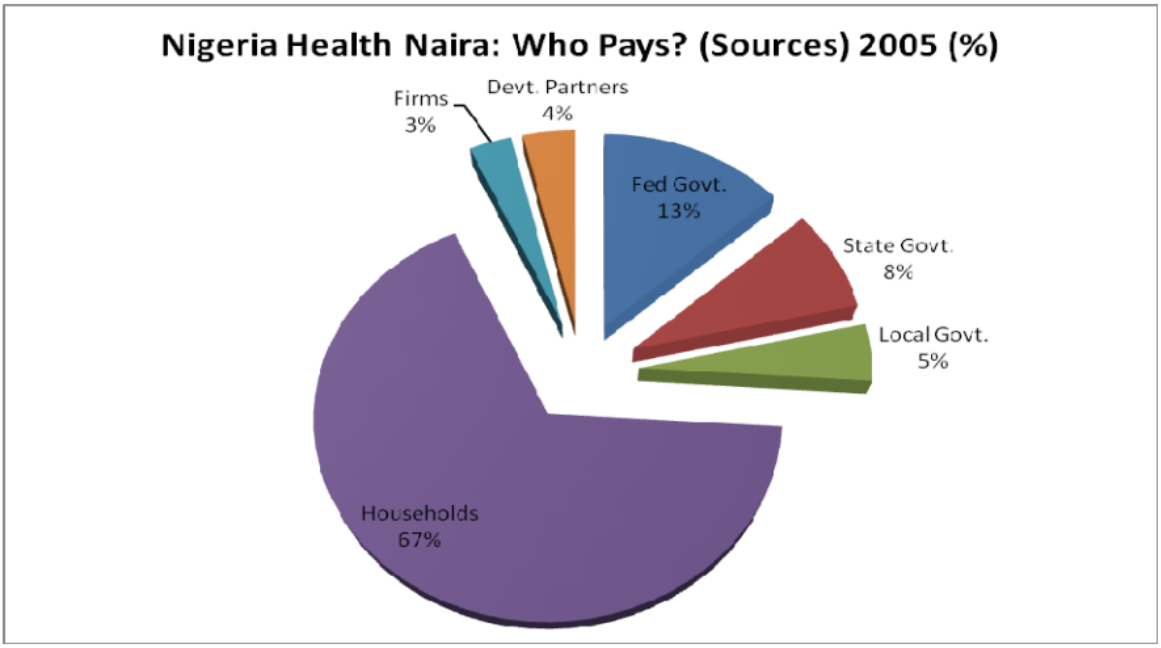

Figure 3: Health Financing Sources in Nigeria Source: NHA 2003–2005

Out-of-pocket payments (OOPPS) are payments made directly by a patient to healthcare providers and are often made at the point of service. They are also referred to as user fees. The range of user fees is adaptable and consists of an aggregate of admission and consultation costs in addition to medical pricing and medical material charges (Lagarde & Palmer 2006). According to International Journal of Technology assessment in health care, OOPS accounted for over 70% of Nigeria's overall health spending in 2018.

According to Health Reform Foundation HERFON (2006 10-12,130,191), it is estimated that 4% of families in Nigeria spend most of their earnings on healthcare, while 12% of them spend a quarter of their earnings which is quite staggering and poses a major burden for the country given that 7 out 10 Nigerians are poor (National Bureau of Statistics 2010). High OOP has forced low-income households to put off getting medical care, hire quack health practitioners, and self-medicate. Puteh & Almualm (2017) highlights that families and individuals may experience catastrophic health expenditures due to out-of-pocket payments which may worsen poverty.

More than 90 million globally are plunged into poverty yearly owing to paying for their medical treatment out of pocket (WHO 2014, 228). Therefore, health care globally can be enhanced by adequate funding of public healthcare (Chan 2006, 11).

Notwithstanding its significance, some research has shown that health finance does not improve health outcomes in some nations (Nathaniel & Khan, 2019), while other studies have showed that it helps (Kulkarni 2016; Edeme Emecheta & Omeje 2017, 98).

Tax revenue health financing system or Beveridge system

Savedoff (2004) mentions the government as the main source of funding for medical expenses in this system of health financing and it is the main source of funding for public health facilities in Nigeria. Typically, the federal, state, and local governments use the health system's funding from the federal account. States and local government areas get an additional 20% from internally generated revenues via taxes, fees, and levies. According to WHO (2004), the federal resources formula is set as 48.5%, 24%, 20% and 7.5% to national, state

administration, municipal and special tasks respectively by the revenue mobilization, allocation, and fiscal commission. The sources of federal government revenue include proceeds from exported crude oil and gas, royalties and different taxes (Obansa & Orimisan 2013). According to Health Reform Foundation (2006), health care in Nigeria is funded by about 5% of her gross domestic product as against the US$35 recommended by the Commission on Macroeconomics and Health (Health Reform Foundation 2006, 130). However, the country made a pledge in 2001 alongside other forty-three African nations to allocate 15% of their yearly budget to public health (Obansa & Orimisan 2013).

Health Insurance in Nigeria

Health Insurance is part of Nigeria's pooling arrangement with different forms viz a viz public/social health insurance, community-based health insurance, and private health insurance. 2005 saw the implementation of the Nigeria National Health Insurance Scheme (NHIS). A study by Uzochukwu Ughasoro, Etiaba, Okwuosa, Envuladu & Onwujekwe 2015) revealed that most Nigerians who enrolled in the scheme are mostly in formal establishment (Uzochukwu, Ughasoro, Etiaba, Okwuosa, Envuladu & Onwujekwe (2015, 440). They also opined that a paltry 5% of Nigerians are covered by the scheme. Their view was also collaborated by Chukwu Garg Eze (2016, e37). They mentioned that majority of health insurance subscribers are government workers.

According to Nigeria Demographic and Health Survey (2018,) Only 3% of individuals between the ages of 15 and 49 have health insurance. Figure 4 below illustrates the findings by Akokuwebe & Idemudia about the health insurance ownership in Nigeria and South Africa. They shared 98% of Nigeria's population are not part of health insurance and about 87% of South Africa's population are not insured.

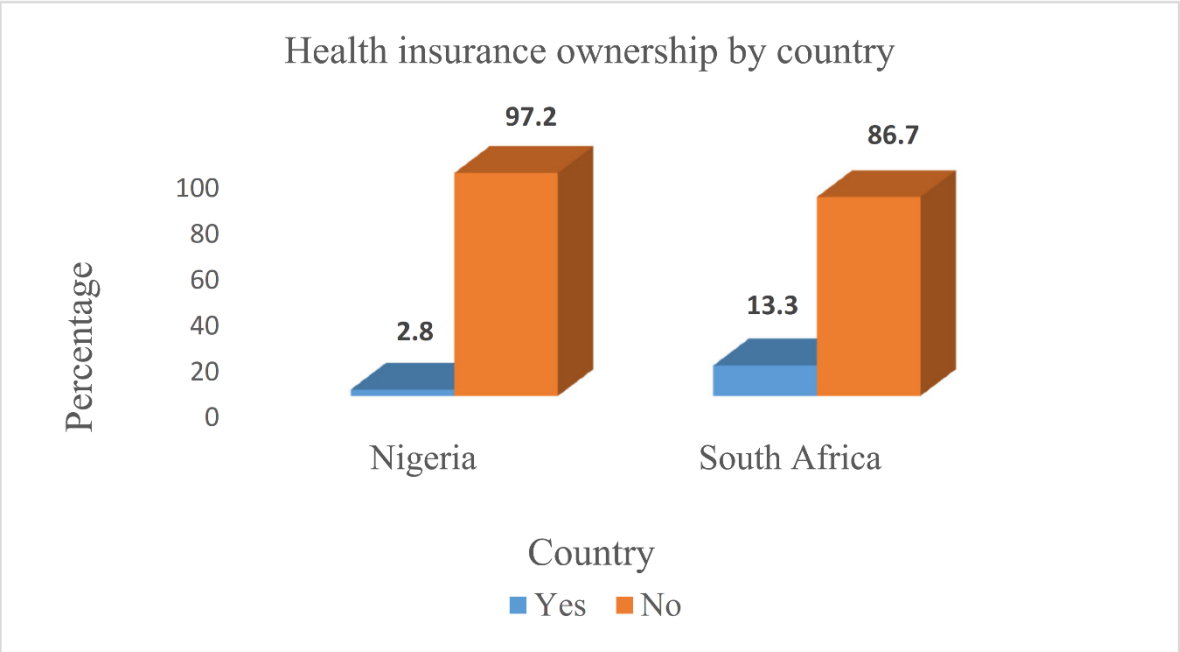

Figure 4: Health Insurance Ownership in Nigeria and South Africa (Akokuwebe & Idemudia, 2022)

Figure 5 below illustrates how subscribers of health insurance by gender in Nigeria and South Africa are shared. According to the figure, the male gender had a higher percentage in both countries (about 4% in Nigeria and about 14% in South Africa). The female gender had about 3% and 13% in Nigeria and South Africa respectively. However, there was a decrease in health insurance ownership among Nigeria's male and female respondents in contrast to South Africa.

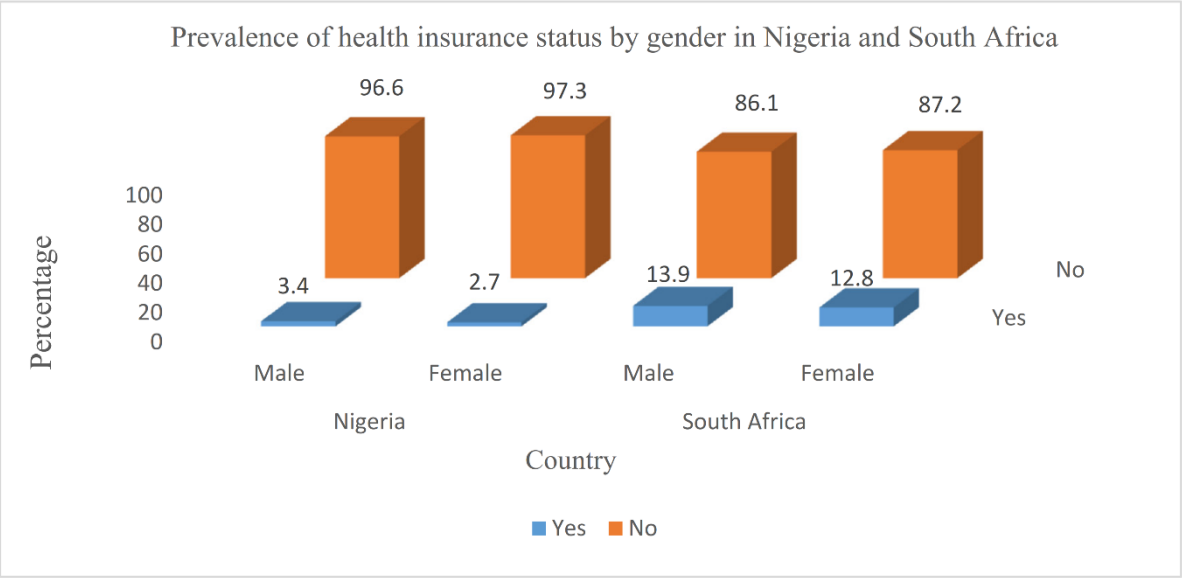

Figure 5: Health Insurance Subscribers by Gender in Nigeria and South Africa (Akokuwebe & Idemudia, 2022)

Purchasing medical devices in medical centers or health institutions in Nigeria

Howitt, Darzi, Yang, Ashrafian, Atun & Barlow (2012, 510) says provision of health services is hampered, patient outcomes are subpar, and there are significant hazards to the health system and national security when there are no secure, efficient, and functional medical devices and equipment (MDEs). According to Lartey, Puplamou, Ayegua, Seneadza, Oliver-Commey & Amoah (2012, 5), delays in emergency response is precipitated by deficiency in protective wears necessary to prevent infection and laboratory equipment which helps in fast and correct diagnosis.

According to estimates, 40–70% of MDEs in environments with limited resources are malfunctioning, underutilized, or unsuitable (Perry & Malkin 2011, 720). This

problem is exacerbated by indiscriminate procurement practices, a mismatch between technological design and demand, exorbitant pricing, and difficulties with deployment, maintenance, and human resource training (WHO 2010).

Decision Making in Health Systems

According to Desai, Griffith, Woodbury, June, Ratcliffe & Schwarz (2022, 113), decision making in health systems are varied depending on the type of decision. for example, in a study contacted in Odisha, India; when it came to hiring and promoting employees, the Odisha Department of Health had the most power among all PHCs and SCs. The decision-making power for facility maintenance decisions, such as ordering medications, maintenance, and finance allocation, typically reside within the centre though certain decisions are under the control of central authorities.

Figure 6 below shows the sharing of decision-making authority in first-tier centers in Odisha, India.

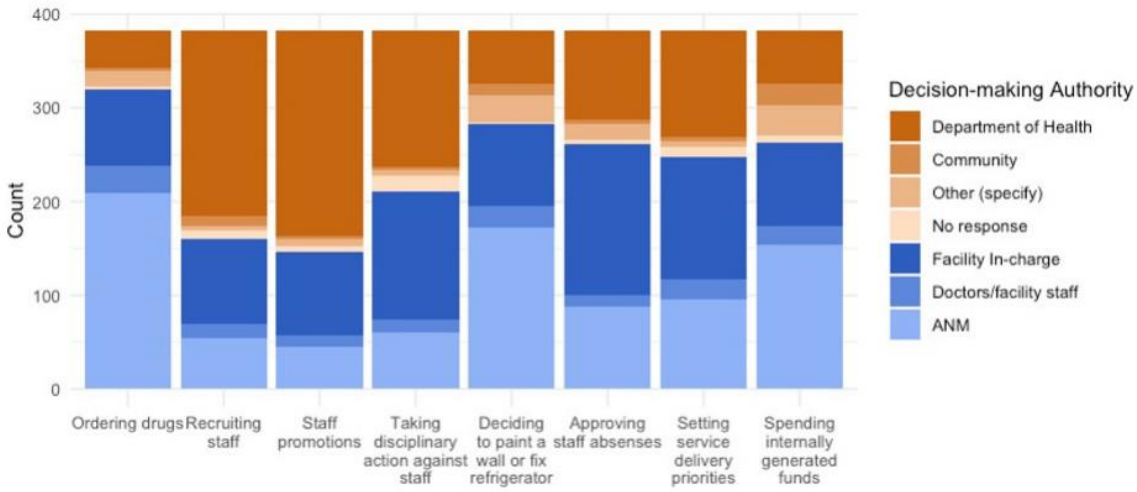

Figure 6: Decision-making authority distribution in first-tier centers in Odisha, India. (Desai, Griffith, Woodbury, June, Ratcliffe & Schwarz 2022)

1.5 Thesis Aim

Research questions (RQ) for the study are itemized below:

RQ1: What are the commonly used methods for diagnosing PROM in Nigerian hospitals?

RQ2: Are point-of-care rapid tests currently in use, or do hospitals rely on traditional diagnostic methods (e.g., nitrazine tests, clinical examination)?

RQ3: Who is/are the existing competitor(s) in the market for PROM testing in Nigeria?

RQ4: Who is the key decision-makers responsible for adopting new diagnostic tests in Nigerian hospitals (e.g., Heads of Obstetrics & Gynecology, Procurement Officers, Laboratory Directors)?

RQ5: What factors influence their decision to adopt a new PROM test?

RQ6: How is PROM testing funded in Nigeria (e.g., private health insurance, out-of-pocket payments, hospital budgets)?

RQ7: What is the willingness of hospitals and patients to pay for an additional PROM rapid test?

RQ8: What are the regulatory requirements (e.g., NAFDAC approval, CE marking, FDA clearance) for introducing a new PROM test in Nigeria?

RQ9: What are the barriers to market entry, such as cost, local product preferences, or extensive product evaluation processes?

RQ10: Are there any clinical guidelines in Nigeria that influence the adoption of PROM rapid tests?

RQ11: What strategies can be implemented to successfully introduce the Finnish PROM test into the Nigerian market?

A closer look and overview of above research questions will provide viable information about the Nigerian Market and offer useful market entry strategy into the Market.

1.6 Research Process & Method

In this thesis, a mix of qualitative and quantitative approaches is employed with a view to providing more understanding to the above listed questions. It further reflects the market environment and competitiveness in Nigerian healthcare system for the manufacturer. Qualitative research encompasses the assembly, creation & explanation of data which comprises of text, images, videos which is useful in the discovery of complicated subjects providing insight into the behaviour of people. Conversely, the quantitative research analyses numerical data using statistics and most often data from market conditions and rivalry in the Nigerian healthcare market (Johnson & Onwuegbuzie 2002). Combination of both methods potentially offers a greater understanding of the market and competition within (Kandel 2022).

The research will begin with a series of meetings and discussions between the author and the commissioning company to determine a suitable and relevant research topic. Following these discussions, specific research questions will be developed and structured into a questionnaire aimed at collecting primary data. This questionnaire (multiple-choice, open-ended questions, close ended questions, scale-based questions etc) written in English Language, will be

administered to a range of maternal healthcare professionals in Abuja, including obstetricians/gynaecologists, nurses, midwives, and other relevant practitioners.

In addition to the questionnaire, the author plans to conduct a semi-structured interview with a consultant in obstetrics and gynaecology who practices in Abuja. This interview will be conducted in English language and virtually via Google Meet to ensure convenience and accessibility with consent obtained from the interviewee.

The responses obtained from both the questionnaire and the interview will form the basis of the data analysis. No personal data will be obtained in the questionnaire. Hence, a consent form will not be needed. However, Quantitative data from the questionnaires will be analyzed using the Statistical Package for the Social Sciences (SPSS) software to identify trends, patterns, and insights relevant to the research objectives. Factors that show the viability and profitability of Finnish PROM point-of-care when compared to other brands, is revealed to the manufacturer of the product.

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1.7 Research Outline

Chapter 1 of this thesis gives an introduction of the topic and research's aim identified where the study questions are mentioned. Methodology employed in this research is also explained.

The theoretical framework is embedded in Chapter 2 where some tools used for analysis of market environment, evaluation of a competitive environment, market potentials, and risk control structure are explained. The business environment of

the target country where all factors that plays significant role in manufacturer's operation in the Nigeria healthcare market.

Chapter 4 brings to bear result from the interview conducted with a consultant in obstetrics and gynaecology in a secondary facility in Abuja, Nigeria and responses from the questionnaire shared as analyzed using SPSS software. The manufacturer obtains a better understanding of the market situation in terms of economy, business, legal implications using the information provided. Discussion stemming from responses from the questionnaire is evaluated in Chapter 5 and this would include opportunities for Company X in the Nigerian market.

2 THEORETICAL FRAMEWORK

The thesis theoretical framework employs tools such as PESTEL analysis, SWOT analysis and Porter's Five Forces for an understanding of the external & internal environment in addition to competition within the environment.

A vivid discussion of these tools is employed in this session offering support and guidance to the manufacturer in making policies in a competitive world.

Possible business opportunities are discussed using the above-mentioned tools, understand Nigeria's competitive landscape while mentioning possible risks that could be faced whilst doing business in Nigeria.

Useful information pivotal in making strategic plans and arrive at important decisions for having business in Nigeria is gained with this study.

2.1 Market Environment

Market Environments speaks of institutions, forces, and variables that entrepreneurs must contend with, to accomplish their goals constitute market environment (Gandhi 2014, 99).

Market environment is analysed using a variety of approaches. The PESTLE analysis was chosen for this thesis because it best suits the goals and purposes of the study. The acronym “PESTLE” or “PESTEL” refers to the political, economic, social, technological, environmental, and legal environment of the business. According to Johnson, Scholes & Whittington (2002), businesses may employ the use of the tool to methodically evaluate outside factors that may have an impact on their operations and market positioning (Johnson, Scholes & Whittington 2002, 55). There has been agreement by several authors that business environment is affected by factors already mentioned above (Bunoa, Nadanylova & Hraskova 2015, 425). Figure 7 below illustrates PESTEL analysis.

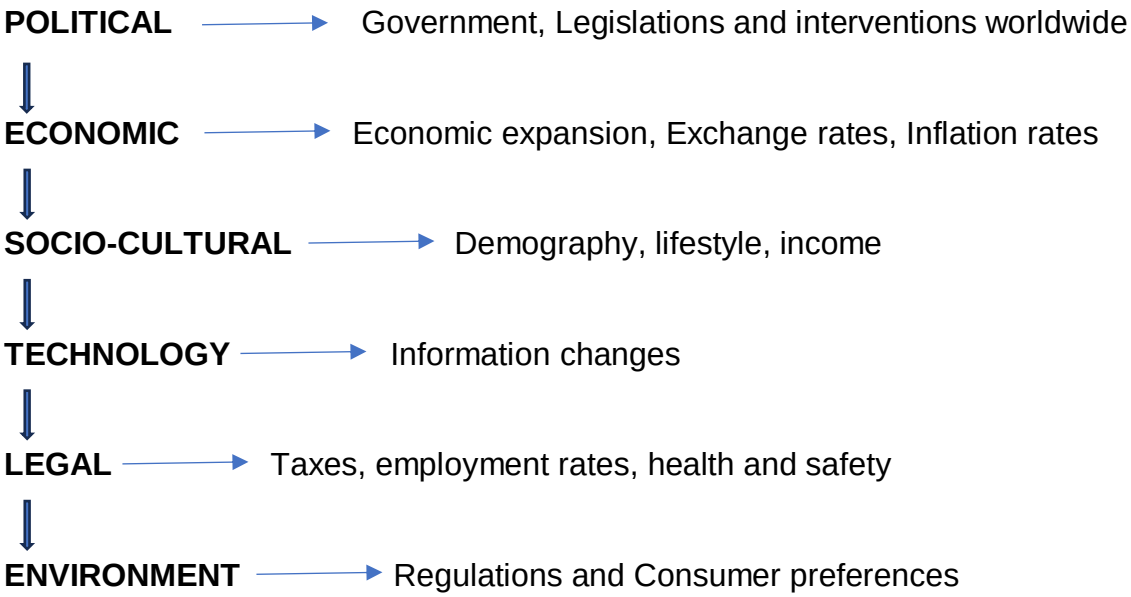


Figure 7: PESTEL Analysis

Political Factors

Political factors have an influence on the quality of business environment which greatly impact on the behaviors of investors (Grosanu & Bota-Avram 2015, 60). Regulations, taxes and government policies make up this factor (Shatskaya, Samarina & Nekhorosheva 2016, 47).

The unpredictability nature of the political parts of a nation have been its greatest undoing (Kobrin 1982, 114-117). It may be in the shape of changes in rules of government which in the long run changes trade rules and taxation (Perera 2020, 8-9). The onus then lies on businesses or organizations to ensure proper system to examine the risks associated with such changes and according to Hollensen (2014), these risks can be reduced if not eradicated via skilled adaptation and management (Hollensen 2014, 237).

Economic Factors

Business environment is shaped by economic factors such as macroeconomic environment, monetary policies and population (Havierniková & Kordoš, 2019). GNP (Gross National Product), GDP (Gross Domestic Product) and CPI (Consumer Price Index) are some of the economic measurements that reveals how well a country is doing (Brezina 2012, 5 – 12) and have an impact on consumers' purchasing power, spending habits, and ability. (Kotler et al. 2008, 197). Economic environment components are interest, exchange, currency conversion & unemployment rates and inflation. These elements potentially affect organization’s profitability (Yusop 2018, 35 - 36).

Socio-Cultural Factors

Socio-Cultural factors play a pivotal role for businesses or organizations wishing to do business abroad. According to Trehan & Trehan 2019; socio-cultural factors

include culture, language, religion, level of education, customer preferences and attitude of the society that affect foreign trade (Trehan & Trehan 2019, 53). These factors are uncontrollable by business representatives in most cases and must be properly understood for marketing purposes (Hollensen 2014, 263).

Technological Factors

Factors that influence company's functions are known as Technological Factors (Blaschke, Demel & Kotorov 2021). According to Kotorov, Krasylnykova, Demel & Blaschke (2023), these factors include modernization levels, research & development etc. Organization's success is hindered by both external and internal technological sources (Yasar, Paul & Waad 2011, 650).

Environmental Factors

Factors that include effects of climate, weather & pollution on the environment fall under this category in addition to Organization's actions to these effects and laws addressing environmental implications such as waste, water & forest control, biodiversity conversation, carbon emission and land use planning (Falade & Babatunde 2018, 63).

Raimi et al. (2019) posits that there must be proper use and management of natural resources as health and welfare of individuals/employees depend largely on them. Productivity can go south because of health disorders occasioned by any form of pollution (Xue, Zhang & Zhao 2021, 1).

Legal Factors

According to Yasar et al., 2011, there is a positive correlation between the organization's success and the quality of a nation's legal system. Businesses or

companies are encouraged when there is high quality of political institutions (Autio & Fu 2015, 70). Lim, Morse, Mitchell & Seawright (2010) opined that organization's choice to commence a business is bolstered by environment with consistent regulation, financial system and education.

2.2 Evaluation of a Competitive Environment

The decision-making process of an organization is enhanced by a collective knowledge of demand, cost information and competitive environment (Hill 1989**,** 183)**.**

A competitive environment exists when companies within a particular market compete to draw customers for trading purposes by employing different strategies such as pricing, promotions and distribution network.

According to Porter (1979), in the quest for market share, competition is not shown among other rivals but in its own economics. Competitors may include customers, suppliers, possible rivals and other substitute goods (Porter 1979,2).

Understanding industry's competition can be done using an essential model known as Porter Five Forces (Michaux, Cadiat & Probert 2015, 6).

Porter Five Forces Industry Analysis

The tool was originally published in the Harvard Business Review in 1979 and developed by Professor Michael Porter. According to Johnson, Scholes, and Whittington (2008), the five forces structure is effective for defining forces in line with businesses when used from an outside-in viewpoint.

The tool offers businesses better understanding of distribution of profit among the five forces in a particular sector and the most influential player within the industry regarding legal operations. The framework identifies five microenvironmental dynamics that fuel competition and endanger an organization's capacity to achieve success.

In addition to providing an overview of the industry at certain times, the framework helps to better illuminate the variety of industry dynamics and potential future changes (Bruijl 2018, 2).

Figure 8 below illustrates the five key forces that affect the level of competitiveness within a sector which are supplier power, competitive rivalry, buyer power, the threat of substitution, and the threat of new entrants, albeit they are not listed in any order (Porter 1979, 1–6).

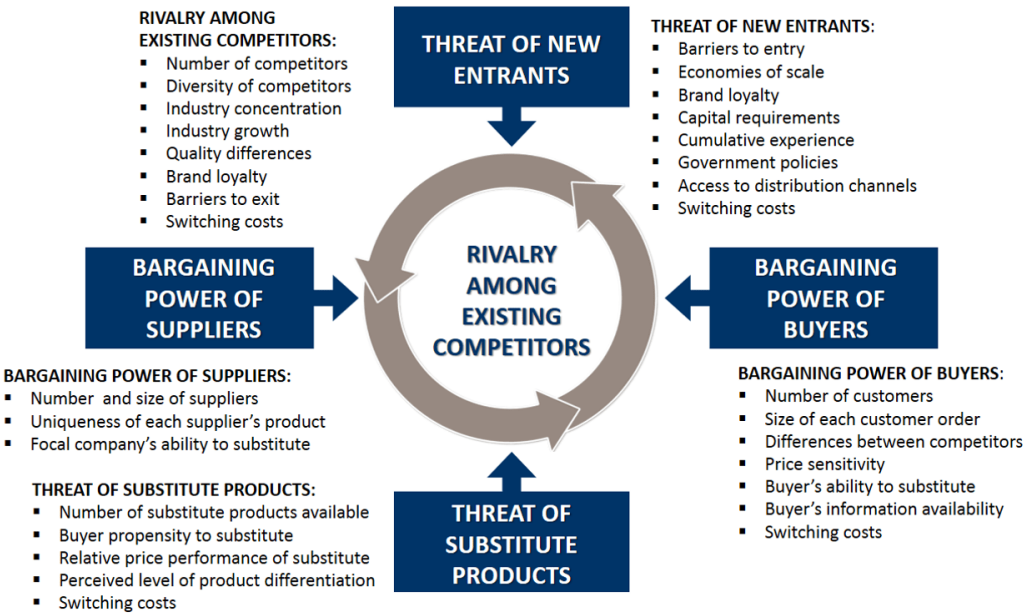


Figure 8: The five factors that shape industrial competition (Pringle & Huisman, 2011)

Competitive Rivalry

The competition a company faces from competitors in its industry has a big impact on its performance (Khan 2015, 74). This concept is what Porter referred to as 'jockeying for position' employing strategies such as pricing, product introduction and adverts (Porter 1979). However, the level of rivalry and the ways in which the industry is affected by variables like industry growth rate, storage and fixed costs, the number of organizations in competition, differentiation, exit barriers, and switching costs between competitors depends on the frequency of the events (Hubbard & Beamish, 2011).

Little rivalry exists in a completely competitive market where there are many consumers and sellers, and the product is the same for everyone. It is also the same situation in a monopoly market where there is only one participant and a single product type. However, competition may be strong under oligopoly or monopolistic competition where there are few firms, and the market conditions allow them to distinguish their goods and services (Gerry & Kevan 2004).

The Buyer Power

Powerful consumers can increase their own worth by using their power to demand more services at the same price or to push down prices (Harvard Business School 2023; Porter 2008, 30; Magretta 2011, 41-42). A strong bidder might reduce the seller's potential profit and increase industry competitiveness. On the other hand, a weak buyer is an organization that depends on the seller for pricing, quality and cost; this reduces industry rivalry and increases the seller's profitability (Edwards and colleagues, 2014, 109).

When there is a monopolistic market, customers who are big and have the freedom to easily move to fewer other providers have the most negotiating leverage (Slater & Olson, 2002).

Supplier Power

Industry's profitability can be negatively impacted since suppliers may threaten businesses by raising good and services cost. Cost will be passed on to their own pricing if businesses fail to recoup. There is a myriad of factors considered as strong bargaining power for suppliers. Alternatively, bargaining strength can be influenced by the number & size of suppliers and the presence of other choices (Slater & Olson, 2002).

Threat of New Entrants

According to Porter (1985), new entrants to an industry bring new capacity and desire to gain market share that puts pressure on prices, cost, and the rate of investment necessary to compete (Porter 1985, 8) but the threat of entry primarily depends on the number of firms in the industry and the level of entry barriers (Johnson et al., 2008).

Additionally, new competitors might directly impact on the competitive advantages of incumbent businesses in each industry. When demand is neither rising nor falling, a greater supply of products or services will result in lower profit margins for market players. New competitors may also directly affect the competitive advantages of incumbent businesses in each industry. When demand is neither increasing nor decreasing, a greater supply of goods or services will result in lower profit margins for market players.

Analyzing entry barriers and anticipating potential retaliation measures from competitors is a crucial responsibility for organizations before entering a new

industry and overcoming these entry barriers without opposing industry's profitability (Porter, 1985).

Threat of Substitute

Finding alternatives is looking for goods or services that can serve the same function as those produced by the industry under consideration. A buyer's addiction to purchasing substitutes or the expense of switching between industrial items and replacements are two factors that might affect the threat of alternative goods and services (Hubbard & Beamish 2011).

A company may gain a thorough grasp of the elements influencing industry profitability by analyzing all five competitive forces. Early identification of game-changing developments may allow an organization to swiftly capitalize on them. Additionally, opportunities to overcome profitability constraints or even realign these forces to one's benefit will be found (Porter 2008, 24).

2.3 Market Potentials

SWOT Analysis

Organizations utilize SWOT analysis as a tool for strategic management and planning (Gürel, 2017). According to Thompson, Strickland & Gamble (2007), SWOT tool is a simple and sure technique in evaluating company's strength and weakness, market possibilities and external risks that impedes growth (Thompson et al., 2007, 97).

STRENGTH

According to Thompson & Strickland (1989), an organization's strength is something it excels in or a quality that endows it with a significant capacity. "Strength" in this sense refers to a resource, skill, or other advantage in comparison to rivals and the needs that an organization serves or anticipates serving (Thompson & Strickland 1989, 109).

WEAKNESS

A weakness is a circumstance that places an organization at a disadvantage or something that it lacks or does badly compared to others (Thompson & Strickland 1989, 113). Here, "weakness" refers to a capability, skill, or resource shortage that significantly hinders an organization's ability to function effectively. It is just as crucial for the organization to understand its shortcomings as its strengths.

An organization is weaker at the organizational level when its current existence and capabilities are inferior to other organizations and rivals. (Gürel, 2017, 997).

OPPORTUNITY

An opportunity for a business or company speaks of benefit(s) to the company either within or outside the business and this happens businesses take advantage of environmental factors to their profit.

THREAT

Threats are external environmental elements that have negative consequences in the company. According to Gürel (2017), threats are circumstances that arise because of modifications to a company's primary or remote environment and are harmful to the business (Gürel 2017, 998). These situations may make it impossible for the company to stay in operation or result in it losing its competitive advantage. They may impede the company's progress and cause irreparable

harm. Examples include harm to the business's reputation or a potential decline in trust. (Sarsby 2016, 10).

2.4 Risk Control Structure

The economic, operational, and financial operations of every business include some degree of risk (Dionne 2013, 147). Risk management is the process of identifying, tracking, and controlling possible hazards to reduce the potential they might bring to a company which includes network system failure, reputational harm, data loss, cyberattacks, breaches of security protocols, and many other unforeseen circumstances. According to Mema & Al-Thani (2008), an effective risk management system will help identify the risks that pose the greatest threat to a business and will also offer expert advice on how to respond and handle the situation (Mema & Al-Thani 2008, 2-3).

This framework component are identification, assessment, prioritization, Mitigation, Monitoring and communication.

Identification

A business team looks at all project characteristics as they arise from the standpoint of unconnected risk groups when identifying hazards. It determines the hazards that might negatively impact company operations (Cervone 2006, 259).

Assessment

According to Stern & Arias (2011), the purpose of this step is to evaluate or compute the possible probability and magnitude of a loss or injury (Stern & Arias 2011, 62).

Prioritization

To ensure that the most important risks are addressed first, risks can be assessed and then rated based on their effect and likelihood (Cervone 2006, 259).

Mitigation

This step involves the development and implementation of solutions that reduce or eliminate the likelihood or effect of identified hazards (Cervone 2006, 260).

Monitoring

This comprises tracking the project's progress in addressing risk concerns and taking the required action to address them as needed (Stern & Arias 2011, 61).

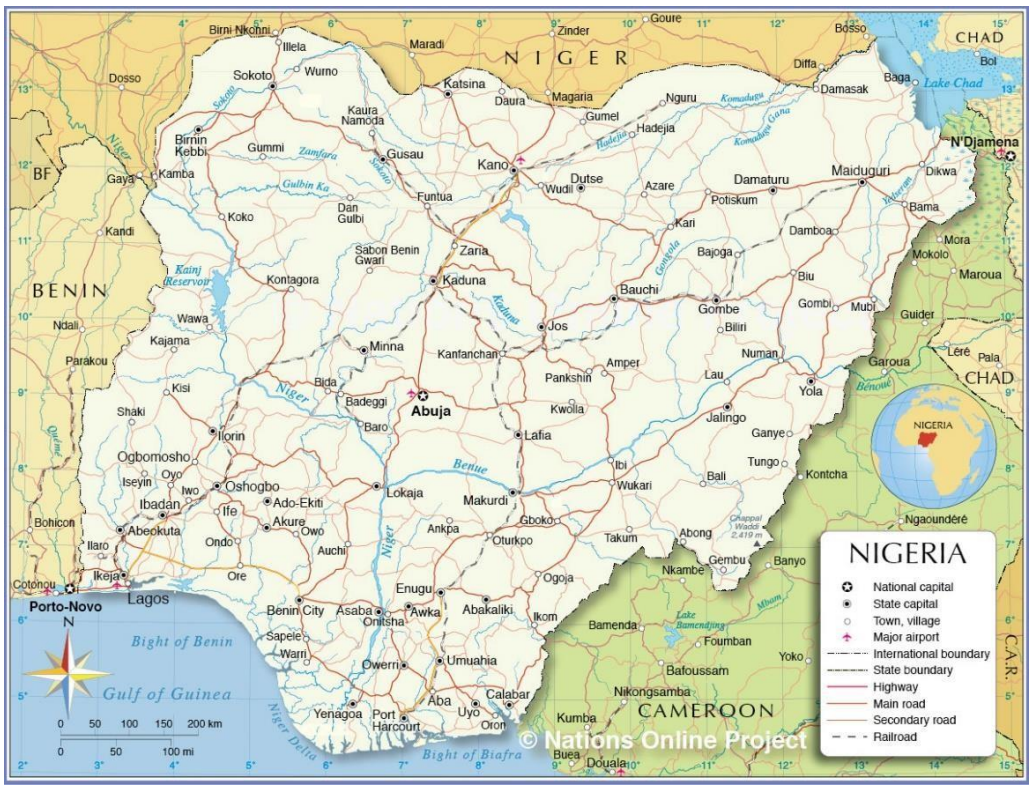
Communication

According to the World Health Organization (2023), risk communication is the immediate sharing of information, ideas, evaluations, and expertise between specialists and people who are at risk or have suffered a loss.

One of the most effective ways to lower risk on any project is to keep lines of communication open with stakeholders and project partners (Cervone 2006, 261).

3 THE BUSINESS ENVIRONMENT OF NIGERIA

Nigeria, which is in western Africa, is formally known as the Federal Republic of Nigeria (Nigerian Constitution 1999). Niger, Chad, Cameroun, Benin are neighbouring countries to Nigeria in the North, East, West and South respectively (Federal Republic of Nigeria 2018) as shown in Map 1 below:



Map 1: Map of Nigeria showing national capital and neighbouring nations (The Federal Republic of Nigeria 2018, 11; Nations Online 2021).

Every country's flag is its most conspicuous symbol (Pai 2009). Figure 9 shows the three components of the Nigerian flag, which are green on either side and white in the centre. White stands for peace and harmony while green symbolizes the nation's richness and prosperity as well as its many natural resources. The Nigerian flag was first hoisted at the country’s independence October 1, 1960 (The Federal Republic of Nigeria's Embassy, Tel-Aviv, Israel, 2023).

Figure 9 below illustrates the colours of Nigeria flag.

Figure 9: The map of Nigeria (Freepick Company 2023)

The Nigerian Naira is the nation's official legal tender and is issued by the Central Bank of Nigeria (CBN), which also regulates the money supply to support monetary and price stability. The Nigerian Security Printing and Minting (NSPM) Plc, which is mostly owned by the government, produces the money in Lagos and Abuja. On occasion, a few chosen overseas companies also mint the naira. Quality assurance and receipt of completed currency are preserved by the CBN (CBN 2023).

3.1 Political Factors

Government policies, regulatory frameworks, and political stability all have a big impact on how businesses operate. According to Chukwuma & Adeyemi (2022), political unpredictability in developing nations has a detrimental impact on investment and growth (Chukwuma & Adeyemi 2022, 33). A study by Aisen & Veiga (2013) posits that there is a link between political instability and GDP growth for over 150 nations from 1960 to 2004. They found that Growth rates are inversely correlated with political instability (Aisen & Veiga 2013, 152).

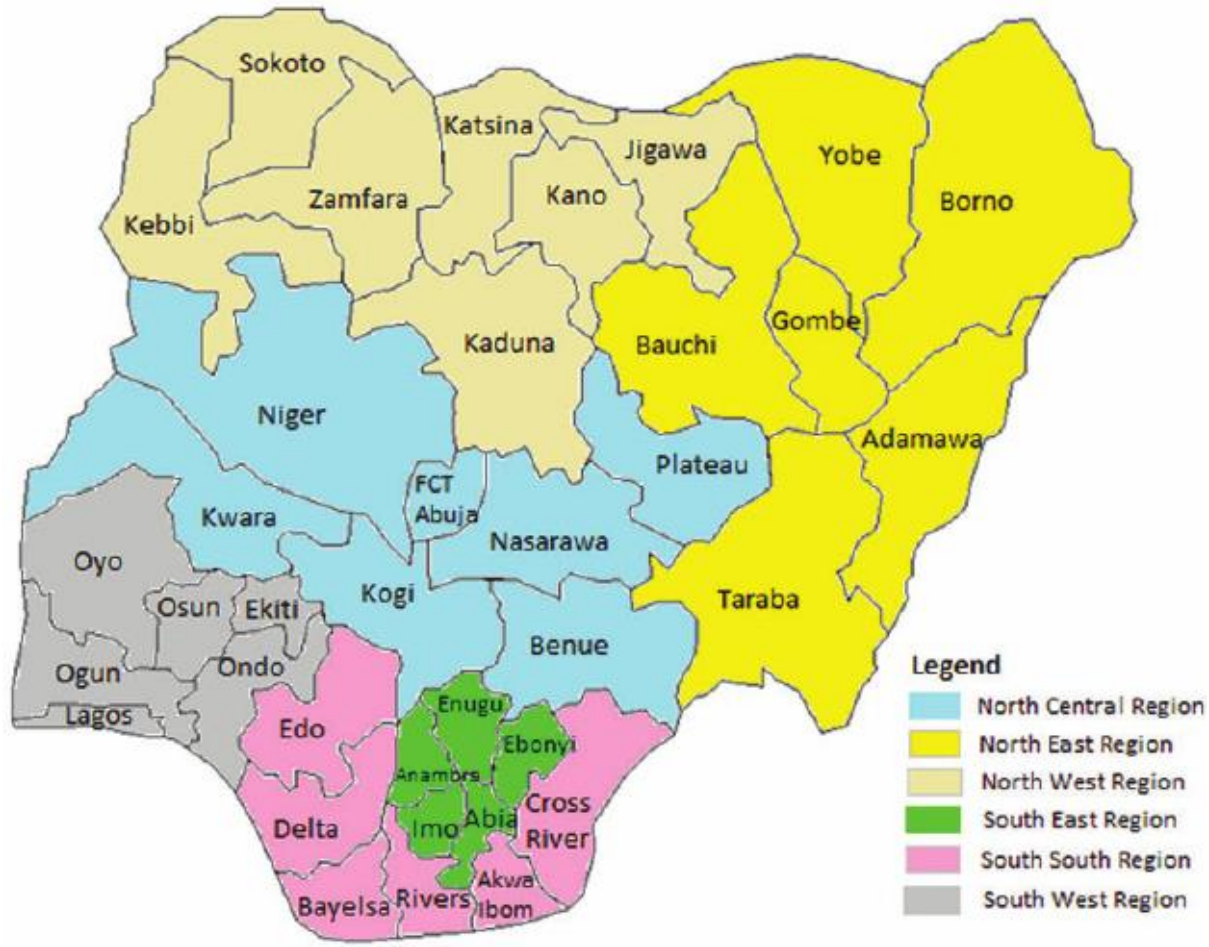
Favorable trade policies promote foreign direct investment (FDI), whereas inconsistent ones may hinder supplier chains and market access. Adetayo &

Smith (2021) posit that multinational corporations in Africa were shown to be more likely to lower risks and take advantage of government incentives when they actively engage in policy advocacy (Adetayo & Smith 2021, 45).

The Nation Nigeria consists of different groups and rich cultures (Philip & Terzungwe 2012, 42). Nigeria has had both civilian and military presidents since gaining independence on October 1, 1960, and the final military handover of power to civilian governance in 1999. (Adejumobi 2002, 49). The last election was held on February 25, 2023 (INEC, 2022) and usually, the duration for the presidential election is four years. In other words, winners are expected to rule for a period of four years and can show interest in running again for a second term. Despite being under military administration until 1999, the nation has had a stable democratic system of governance since then. According to Oluwole (2016), the country's political situation is stable despite the challenges of terrorism in the North and groups agitating for their rights to oil revenue in the south.

Manufacturers of medical devices in Finland can take advantage of the bilateral investment treaties (BITs) signed between Finland and Nigeria on June 22, 2005, which went into effect on March 20, 2007. Among other things, it covers the nonbiased protection of investment in each other's territory and the promotion of economic cooperation between the two countries.

Map 2 below shows the map of Nigeria with the states and Abuja (FCT) citing the various regions in the country.



Map 2: Map of Nigeria showing the 36 states and Federal Capital Territory (FCT), Abuja.

3.2 Economic Factors

Nigeria has the largest population in Africa. According to UN estimations, Nigeria's overall population is projected to reach around 401.31 million by the end of 2050. Nigeria will have more than 728 million people by the year 2100 if current trends continue (worldpopulation 2025).

Population in Nigeria is predicted to exceed United States in 2047 with about 400 million (Worldpopulation 2024). With those numbers, Nigeria would become the world's third most populated country. Nigeria's population is growing primarily due

to high birth rates, early marriages, and limited access to family planning. According to worldpopulation (2025), there are around 37 births for every 1,000 people living in Nigeria.

The Central Bank of Nigeria reports that the inflation rate is 24.48%. The Central Bank of Nigeria's graphic representation of this rate is shown in figure 10 below.

Figure 10: Central Bank of Nigeria - Inflation Rate (CBN 2025)

There has been a forecast of a further reduction in inflation rate in 2026 and 2027 as captured in the figure 11 below:

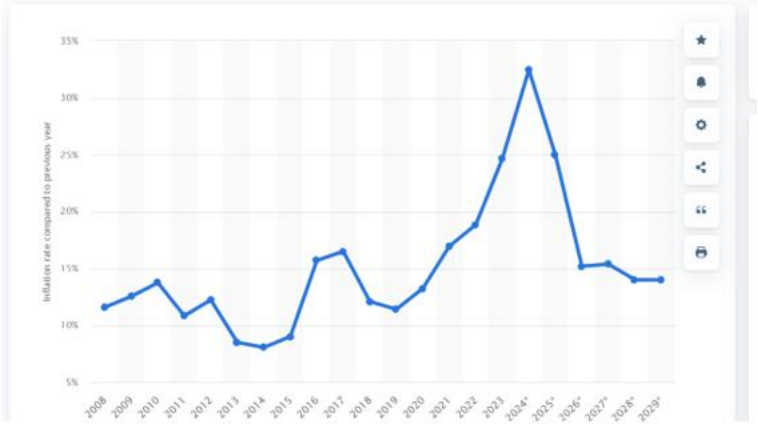


Figure 11: Inflation rate in Nigeria from 2008 to 2029 (Statista, 2025)

Gross Domestic Product in Nigeria

According to Statista (2025), Nigeria's Gross Domestic Product (GDP) in 2022 was 476.47 billion US dollars. Significantly, there was a nosedive in 2023 with GDP 363.83 billion US dollars which could be because of change in government and policies.

Figure 12 illustrates the country's Gross Domestic Product (GDP) in current prices from 1999 to 2029.

Figure 12: Gross Domestic Product (GDP) in current prices from 1999 to 2029 (Statista 2025)

Unemployment in Nigeria

A study by Mohammed Okoroafor & Omoniyi (2015) reveal that inflation and unemployment have an inverse relationship with economic growth in Nigeria (Mohammed Okoroafor & Omoniyi 2015, 103). The GDP's erratic growth rate made the unemployment rate worse and put more pressure on consumer prices. Over the years, Nigeria's economy has consistently experienced weak economic development, despite its abundant natural and human resources. This has unintentionally had a bad effect on the country's unemployment and inflation

rates. According to Okeowo (2023), the unemployment rate might decrease as the output of goods and services increases, in contrast to other macroeconomic indicators that have a positive link with economic development (Okeowo 2023, 109.

Different studies believe that unemployment, inflation, and economic growth in Nigeria are negatively correlated (Mohammed Yelwa & Okoroafor 2015; Madito & Khumalo 2014; Hjazeen Seraj & Huseyin 2021) suggesting that while the overall level of prices will decrease, a gain in GDP will lead to increases in employment, household consumption, saving, gross capital creation, and investment. However, Okowo (2023) discovered that unemployment and inflation had a beneficial impact on Nigeria's economic growth, defying Okun's thesis that unemployment and economic growth had a negative relationship (Okeowo 2023, 109).

The National Bureau of Statistics (2025) reports that the employment-to-population ratio fell 1.5% to 75.6% in Q3 2023 compared to Q2 2023. There was about 90% increase in the rate of unemployed and underemployment dependent on time in later half of 2023 when compared to the second part of the year. In Q3 2023, the unemployment rate for young people (15–24 years old) and those with post-secondary education was 7.8% and 8.6%, respectively, 1.4% higher than the second quarter of 2023 (NBS 2025).

3.3 Socio-Cultural Factors

Socio-Cultural factors encompass all aspects of individual’s society and cultures. Characteristics, age, origin, religion, morals, attitudes, lifestyles, language, educational attainment, and associates are some of these factors (Weatherly 2011). Socio-cultural environment refers to everything that is not included in the political or economic system. Understanding sociocultural effects is necessary to

create effective policies, programs, and interventions that can address issues related to social development, education, and health.

A people's or community's sociocultural and religious beliefs have a significant impact on their women's reproductive outcomes because they shape their behavior when seeking health care. Culture is defined as a set of easily identifiable beliefs and practices that a group of people share and that systematically guide their decisions, thoughts, and actions. Culture and tradition also include religion, food, social customs, beliefs, music, and the arts.

There are three major languages and over 250 ethnic groups in Nigeria with Hausa in the North, Yoruba in the West and Igbo in the east. The official language in the country is English (BBC Africa 2023; Carmona et al. 2022).

Guerrier, Oluyide, Keramarou & Grais (2013) conducted observational research on maternal and newborn mortality in Northern Nigeria and discovered that "the youngest age groups had a greater burden of maternal death than other age groups" (Guerrier, Oluyide, Keramarou & Grais 2013, 496). The low marriage age, which is common in rural northern Nigeria, might be the cause of this (Rai, Singh & Singh 2012, e408). High maternal mortality, unfavorable pregnancy outcomes, and early childbearing have all been linked (Omar, Hasim, Muhammad, Jaffar, Hashim & Siraj 2012, 221; Rashed & Abdelmonem 2011, 22). To lower maternal mortality, community-based family planning initiatives, women's education, and postponing pregnancy seem to be top priorities.

According to Ibeh (2008), examining maternal death rate is hindered by poor reporting and dearth of right methods to measure actual maternal mortality rate (Ibeh 2008,133). Factors linked to poverty and malnutrition include low socioeconomic status, poor healthcare system and non-utilization of healthcare

delivery services which contribute to maternal and neonatal mortality in developing countries. Olusegun, Ibe & Ikorok (2012) collaborated same opinion as Ibeh's (Olusegun, Ibe & Ikorok 2012, 34).

Nigerian Women in the southern area of the country are more likely to give birth in a medical institution in contrast to their counterparts from the northern region. In addition, they posit ethnic diversity was negatively linked to the delivery of health facilities, living in neighborhoods with a high fraction of women with secondary and higher education dramatically boosted the likelihood of giving birth in facility (Ononokpono and Odimegwu 2014).

Akokuwebe & Okafor (2015) in their study attributed poor maternal health to factors such as finance, education status, access to healthcare pregnancy disorders anaemia (Akokuwebe & Okafor 2015, 2). They stated that Nigeria's current maternal health system cannot bring about long-lasting change because of the country's extreme corruption, misaligned priorities, and neoliberal policies, which cause families to be uprooted socially and economically and result in widespread poverty.

Ogu, Agholor & Okonofua (2016) state that key interventions are needed to mitigate the impact of negative sociocultural practices that increase maternal mortality (Ogu, Agholor & Okonofua 2016, 62). For example, some cultures frown at giving birth via Caesarean section and as a result, women have decided to rather give birth in front of traditional birth attendants (TBAs). Therefore, there is a need for collaboration between TBAs, skilled attendants and referral facility personnels. Maternal health is enhanced when there is unhindered access to professional care before and after pregnancy (Miller & Smith 2017).

Business Etiquette and Culture in Nigeria

Understanding the cultural norms and expectations is crucial when doing business in Nigeria. Being on time for meetings is crucial in Nigeria, where being on time is highly regarded. It is also important to engage in small talk before getting down to business. Dressing professionally demonstrates regard for the meeting and those in attendance. Listening is a huge skill in meetings and refrain from cutting people off in the middle of their discussion. Additionally, it is customary to show respect by referring to them by their titles, such as "Dr." or "Chief." At the conclusion of the meeting, it is traditional to exchange business cards and send a thank-you email or letter to show gratitude for the chance to meet. Nigerians are open to negotiation, compromise and this should be considered when doing business with them.

Furthermore, there are some issues that are termed “taboos” that anyone planning to do business in Nigeria must not be seen to do or be involved in. They include being disrespectful to elders, stealing, homosexuality etc.

3.4 Technological Factors

Nigeria faces several information technology-related challenges, including those related to modern (digital) devices and infrastructure, institutional structures, teaching methods, a steady supply of electricity, and technological literacy (Nigerian Communications Commission 2021, 12). Nonetheless, ever-changing work skill has made the sector distinct in Nigeria. It provides opportunities for increased productivity, economic growth, and job creation due to its dense population.

3.5 Environmental Factors

Orisakwe (2017) defines the environment as the sum of living and non-living surroundings necessary for sustainability and life. These components of the environment which are crucial to health and life, are greatly impacted by the status of the environment.

According to the World Health Report, environmental factors account for 26% of child fatalities and 23% of all deaths worldwide, including up to 4 million deaths of children under five annually (WHO 2017). In addition, over 80% of 102 diseases are impacted by environmental factors (WHO 2018).

Numerous additional environmental issues, such as deforestation, desertification, wind erosion, floods, and climate change, are present in Nigeria (Pona, Xiaoli, Ayantobo & Tetteh 2021). Recent years have seen significant improvements in the environmental situation in Nigeria. Many companies and businesses in Nigeria are quickly migrating into oil exploration and industrialization. Nigeria's rapid population increase has led to issues with the environment (Amegah & Agyei-Mensah 2017). Many people are migrating to cities due to poor rural development exacerbating challenges associated with the environment (Babanyara Usman & Saleh 2010).

Urban areas in Nigeria are affected by ecological challenges. According to Institute for Health Metrics and Evaluation, numerous health hazards, including cardiovascular illnesses, respiratory disturbances, heart diseases are connected to air pollution in Nigeria making her one of the top five countries in the world with very high mortality rate (IHME 2020).

Akpodiogaga & Odjugo (2010) posits that climate change have been a phenomenon in all regions in Nigeria with more floods in the southeast & north

central areas and less rainfall in the northeast and south in addition to increased temperature in the entire country (Akpodiogaga & Odjugo 2010, 48).

The status of the environment has changed significantly on a global scale. Numerous natural calamities, including ice melting, floods, tsunamis, air pollution, and the spread of infectious and non-communicable illnesses, have affected by climate and greenhouse effect, posing a threat to human health (Farooq & Meraj 2019).

Nigeria’s challenges transcends both health and environment. They include maternal mortality, infectious illnesses, inadequate sanitation and hygiene, disease surveillance, road traffic accidents, disease control management, environmental risks and the lack of basic human requirements. However, the country's health challenges have not been adequately addressed by the programs that were established, and the increase in health status has been modest (Abdulraheem, Amodu, Saka, Bolarinwa & Uthman 2012).

3.6 Legal Factors

Over the years, the federal government has ratified numerous international declarations on reproductive health, and maternal health has been a key component of national health pledges and strategies made by succeeding governments. However, some of these initiatives and commitments have proven to be more aspirational than practical.

For seven years, a National Health Bill that, among other things, allocated 2% of Nigeria's substantial oil earnings to basic healthcare was stalled in the National Assembly. Despite strong opposition from the Nigerian Medical Association and other health professional bodies, it was eventually approved by the legislature in May 2011 and then rescinded by the president's office (Hope for Health in Nigeria

2011). Although it was submitted in October 2012, it has yet to be fully enacted in its entirety.

There are several governmental and administrative organizations that oversee the healthcare industry. One significant player in this field is the National Agency for Food and Drug Administration and Control (NAFDAC) that establish guidelines to safeguard the public from health-related problems. It is crucial to understand that without the health statutory body's consent, no medical equipment may be manufactured, imported, traded, advertised, sold, or transported into Nigeria. Medical equipment imports into the nation are subject to certain requirements set by the government, but an application must be made to enroll the medical device. (NAFDAC 2016, 1).

The Standard Organization of Nigeria (SON) is another significant organization. The organization's mandate includes, among other things, creation of products, measurements, materials & other processes standard and promotion of same at all levels (SON 2025).

Nigeria is one of the countries that is said to have pre-market control (WHO 2016).

Community health initiatives to reach the great majority of Nigerians outside of the formal sectors are still ineffective, and a national health insurance program has started to gain traction in the formal sector but has not yet reached a critical mass. Shiffman & Okonofua (2007) states that more encouraging developments have been sparked by the Ministry of Health's dynamic leadership as well as civil society organizations that have gained more clout and support since military rule ended, including the National Council of Women's societies, the Partnerships for Safe Motherhood, and the Society of Gynaecologists and Obstetricians of Nigeria (SOGON) (Shiffman & Okonofua 2007, 128).

4. RESULT

This includes an interview response with Dr. Osagie Osayande - Consultant, Obstetrician/Gynaecologist in Wuse District Hospital, Abuja and from questionnaires administered to medical practitioners (maternal healthcare) such as Obstetrician/gynaecologists, nurses, midwives, etc. in Abuja. Ethical approval was obtained from the Health Research Ethics Committee, Abuja.

4.1 Interview with Consultant

Dr. Osagie Osayande, a Consultant Obstetrician and Gynecologist with over 24 years of experience, practices at Wuse District Hospital, which manages approximately 1,000 births annually. The current method for diagnosing premature rupture of membranes (PROM) relies on sterile speculum examination—an approach he noted as low in accuracy, uncomfortable for patients, and incapable of reliably distinguishing amniotic fluid from other discharges.

Despite the clinical need, Wuse Hospital lacks point-of-care PROM diagnostics. Dr. Osayande emphasized cost as a major barrier, with 90% of patients paying out-of-pocket. However, the hospital already uses several point-of-care devices, indicating readiness to adopt new technologies if affordable and approved. The table shows some of these devices already being used in the facility.

S/NO	TEST	BRAND
1	Bilirubinometer	BILIDx by Hadleigh Health Technologies
2	Haemoglobinometer	DiaSpect by DiaSpect medical GmbH
3	Glucometer	Accu-Check (Instant)

Table 2: Some point-of-care tests and brands used in the secondary facility.

Procurement of diagnostics is managed centrally through the Abuja Central Medical Store, post-NAFDAC approval. While the regulatory process is described as straightforward, procurement delays are common.

Dr. Osayande highlighted that introducing a bedside PROM test would be beneficial and welcomed, especially in referral centers like Wuse. He recommended pilot testing with subsidized pricing to promote acceptance among healthcare providers and patients.

4.2 Responses from Questionnaire

RQ1: What are the commonly used methods for diagnosing PROM in Nigerian hospitals?

The data indicates that ultrasound is the most used method for diagnosing Premature Rupture of Membranes (PROM) in Nigerian hospitals, as reported by 48.1% of the respondents. Other significant diagnostic methods include clinical examination, which is used by 37% of respondents, followed by Nitrazine paper test and point-of-care tests, both used by 14.8% of the respondents. This suggests a reliance on diagnostic methods like ultrasound and clinical examination, with some hospitals also utilizing other tools, though ultrasound seems to be the most widely accepted method for diagnosing PROM.

RQ2: Are point-of-care rapid tests currently in use, or do hospitals rely on traditional diagnostic methods (e.g., nitrazine tests, clinical examination)?

Point-of-care rapid tests are not yet widely used in Nigerian hospitals, as per the data. Traditional methods, such as clinical examination and nitrazine tests, remain predominant for diagnosing PROM. The analysis reveals that point-of-care tests are used by 14.8% of respondents, which is significantly less than 48.1% using ultrasound and 37% using clinical examination. Furthermore, barriers to adopting point-of-care rapid tests, such as lack of awareness or training (40.7%), high costs (18.5%), and extensive and costly evaluation processes (18.5%), are cited, which indicates that these tests are not yet widespread in practice.

RQ3: Who is/are the existing competitor(s) in the market for PROM testing in Nigeria?

The data does not specifically list competitors by name for the PROM testing market in Nigeria as many facilities do not have PROM rapid test in use. However, a brand of rapid test for PROM - Actim was mentioned by two respondents. Also, based on the data regarding the sources of payment and suppliers, it can be inferred that a variety of authorized distributors (77.8%) and direct manufacturers (37.04%) are involved in the provision of other diagnostic tests/rapid tests. Additionally, hospitals may procure tests from government-approved medical laboratories and other suppliers, as indicated by responses about alternate purchasing channels. Given the varied sources, it seems that the market for

PROM testing involves both local suppliers and manufacturers, as well as possible international competitors, particularly through authorized distributors.

This analysis, combined with respondents mentioning government-approved laboratories and pharmaceutical distributors as purchasing channels, suggests a competitive landscape where multiple stakeholders are involved in providing PROM diagnostic solutions.

RQ4: Who is the key decision-maker responsible for adopting new diagnostic tests in Nigerian hospitals?

The key decision-makers responsible for adopting new diagnostic tests for PROM in Nigerian hospitals are predominantly the Heads of Obstetrics and Gynaecology, who are cited by 77.8% of respondents as having the final say in the diagnostic test selection process. Additionally, hospital management/administration (33.3%) and heads of laboratories (18.5%) also play important roles in decision-making. The presence of alternative answers from respondents regarding “Other” decision-makers, such as laboratory scientists and consultants, suggests a level of involvement from various stakeholders in the hospital environment. However, the overall trend points to the Heads of Obstetrics & Gynaecology being the most influential in this decision-making process.

RQ5: What factors influence their decision to adopt a new PROM test?

The adoption of new PROM tests is influenced by several key factors, as outlined in the rankings provided by the respondents. Performance (sensitivity, specificity, etc.) is considered the most important factor, with 59.3% of respondents ranking it as the top priority. Following this, alignment with established guidelines comes in second, with 22.2% of respondents ranking it first. Cost is another significant factor, with 14.8% ranking it as the most important, while ease of use is ranked

fourth by 3.7% of respondents. This suggests that decision-makers prioritize tests that offer high diagnostic accuracy (sensitivity) and adhere to clinical guidelines, while also considering the financial implications and usability of the test.

RQ6: How is PROM testing funded in Nigeria?

PROM testing in Nigerian hospitals is primarily funded through out-of-pocket payments by patients, which is the case for 88.9% of respondents. This indicates that most patients pay for their PROM diagnostic tests directly. Other funding sources include hospital budgets (7.4%), which are likely sourced from public health systems or government resources, and other schemes such as the National Health Insurance Scheme (NHIS) (3.7%). This suggests that, while there are some alternatives, a significant reliance on patients' personal funds to cover the costs of diagnostic tests, including those for PROM, exists in the country. The availability of private payer schemes in some hospitals (29.6% of respondents) further reflects the possibility of insurance-based coverage, although this is not the dominant method of funding.

RQ7 What is the willingness of hospitals and patients to pay for an additional PROM rapid test?

The data indicates a complex and constrained willingness to pay. While point-of-care rapid tests are used (14.8%), the primary method remains ultrasound (48.1%) and clinical examination (37%). Most rapid tests are funded through out-of-pocket payments (88.9%), and only 29.6% of facilities report having private payer schemes, with another 29.6% unsure of their existence. These figures suggest a cautious or limited willingness to pay for additional testing, especially when considering high costs are already listed as a barrier to adoption (7.4%) and a concern in open responses.

RQ8 What are the regulatory requirements (NAFDAC approval, CE marking) for introducing a new PROM test in Nigeria?

According to respondents who provided specifications for private payer schemes, regulatory requirements include clearance from institutional ethics boards and registration/compliance with Nigerian regulatory bodies. Specifically, the Medical Laboratory Science Council of Nigeria (MLSCN) and NAFDAC are identified as the principal regulatory agencies that mandate registration and adherence to standards. This suggests that, in addition to global certifications like CE or FDA, local regulatory approval (NAFDAC, MLSCN) is mandatory for diagnostic test introduction in Nigeria.

RQ9 What are the barriers to market entry such as cost, local product preference, or extensive product evaluation process?

Several barriers to market entry were identified:

- Lack of awareness or training (40.7%) is the most frequently cited barrier.
- Extensive and costly evaluation processes (18.5%) are also a significant hurdle.
- Preference for locally produced products (18.5%) may limit acceptance of foreign diagnostics.
- High test costs (7.4%) and exclusion of rapid tests from current guidelines (7.4%) further complicate entry.
- Open responses reinforce that manufacturing scale, distribution challenges, and affordability concerns reduce uptake and benefit.

RQ10 Are there any clinical guidelines in Nigeria that influence the adoption of PROM rapid tests?

According to responses from the questionnaire, 77.8% of respondents affirmed the existence of guidelines that influence the adoption of point-of-care rapid tests, indicating that such frameworks are actively shaping diagnostic decisions in Nigeria. While 18.5% were unsure and only 3.7% denied the existence of guidelines, the dominant affirmative response suggests that clinical practice is indeed guided by formal recommendations. Furthermore, 92.3% of respondents followed WHO guidelines for PROM diagnosis, with only a small minority referencing UK guidelines (7.7%). These findings confirm that international guidelines, especially WHO's, are the primary standard, although local adaptation and enforcement are likely in place.

RQ11: What strategies can be implemented to successfully introduce the Finnish PROM test into the Nigerian market?

Based on cumulative evidence, the following data-driven strategies are recommended:

1. Regulatory Compliance: Ensure the Finnish PROM test is registered with NAFDAC and MLSCN, as these were explicitly mentioned as required from analysis of the data obtained from the questionnaire. Local ethical clearance may also be needed.
2. Training & Awareness: Address the most cited barrier—lack of awareness or training (40.7%,)—by organizing clinical workshops, continuous medical education (CME) programs, and product demonstrations.
3. Evidence of Performance: Emphasize the sensitivity and specificity of the test, as performance is ranked the most important factor in test approval (59.3% ranked it #1).

4. Cost Management: Offer flexible pricing models to accommodate the high out-of-pocket payment burden (88.9%,) and limited presence of private insurance schemes (only 29.6% confirmed availability).
5. Aligning with Guidelines: Seek endorsement or inclusion of the test in updated national or WHO-aligned clinical guidelines, as guidelines are a key influence in test adoption and are considered the second most important approval factor (22.2% ranked it #1).
6. Engage Decision-Makers: Target the Head of Obstetrics & Gynaecology (77.8% of decision-making cases), along with hospital management, to champion adoption.
7. Strengthen Distribution: Collaborate with authorized distributors (preferred by 77.8%), and ensure consistent supply, which was the second-most influential supplier factor (71.4%).
8. Address local Preferences: Navigate preference for locally produced products (18.5%) by exploring local partnerships or contextual adaptation of marketing materials and packaging.

5 DISCUSSIONS

5.1 Opportunities for Company X in the Nigerian Market

The Nigerian healthcare landscape offers a convincing opportunity for the introduction of a point-of-care diagnostic test for Premature Rupture of Membranes (PROM) which would in no small measure improve maternal health in the country. Currently, PROM diagnosis in health facilities in Abuja employs speculum examination, ultrasound and other traditional methods. While some of these methods are accepted by international standards, it has some limitations as highlighted from the questionnaires which include causing discomfort amongst patients and inaccuracy in distinguishing between amniotic fluid and other fluids

such as urine or secretions which can have adverse effects on results. This kind of situation brings to bear the dire need for a rapid and reliable PROM diagnostic test.

Nigeria's demography makes this opportunity even juicer with the number of births annually and high cases of maternal and neonatal morbidity and mortality. Responses obtained from the questionnaire shows that there is near absence of any standard point-of-care PROM testing, offering significant advantage to company X going into Nigerian Healthcare market establishing it as benchmark for PROM diagnosis across the country's healthcare institutions.

Diagnostic solutions are more likely to be embraced in Nigeria among policy makers and global contributors as the country aims to reduce maternal neonatal mortality in line with the United Nations Sustainable Development goals.

Interestingly, health practitioners are receptive to adopting new technologies (especially one that enhance diagnostic accuracy, ease of use, comfort among patients and cost sensitive) as typified from responses from the interview and questionnaire. This is clearly seen as some facilities were already using some other point-of-care devices such as bilirubinometers, glucometers, and haemoglobinometers. Therefore, integration of the PROM diagnostic test is made easier with such previous knowledge.

The Nigerian healthcare system boasts of a unique feature - centralized procurement mechanism. For example, procurement of medical supplies in Abuja is coordinated by a central agency called Abuja Central Medical Store. Orders are sent to them from facilities, and they are subsequently given by the agency. Approval of the use of medical supplies is usually obtained from the National

Agency for Food and Drug Administration and Control (NAFDAC). With this framework, market entry logistics are greatly simplified.

Furthermore, company X has the chance to make a clear distinction by offering training support in addition to the diagnostic test. This would position the company strategically in collaborating with healthcare institutions to establish clinical practices centred around PROM diagnosis and contribute substantially in improving maternal healthcare promoting long-term trust and loyalty rather than just suppliers.

In Nigeria, obtaining regulatory approval is also quite easy. Although all medical products need to be approved by NAFDAC, if all product data and documents are properly presented, the approval procedure is usually simple.

In conclusion, all indices presented above points to fact that Nigeria is a highly promising country for the introduction of a point-of-care PROM diagnostic test. Clinical need, market size, regulatory accessibility, institutional receptivity to innovation, and alignment with public health priorities all work together to produce an environment that is conducive to the successful adoption of new products and their long-term effects on improving maternal health outcomes.

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Selected responses from questionnaire

Selected responses from the questionnaire that was sent out to obtain certain information such as type of healthcare, facility, role of the interviewee, number of years they have worked in maternal healthcare, number of births per year occurred in their facility, guidelines they follow in the diagnosis of PROM, number of times pregnant women visit their facility for ante-natal care, method they currently use for the diagnosis of PROM and challenges they encounter, decision-making on usage of diagnostic tests, factors they consider when approving a new test, factors influencing choice of supply of diagnostic test, preferred channels for purchasing diagnostic test, who typically pays for diagnostic tests, barriers in adopting point-of-care rapid tests for PROM etc.

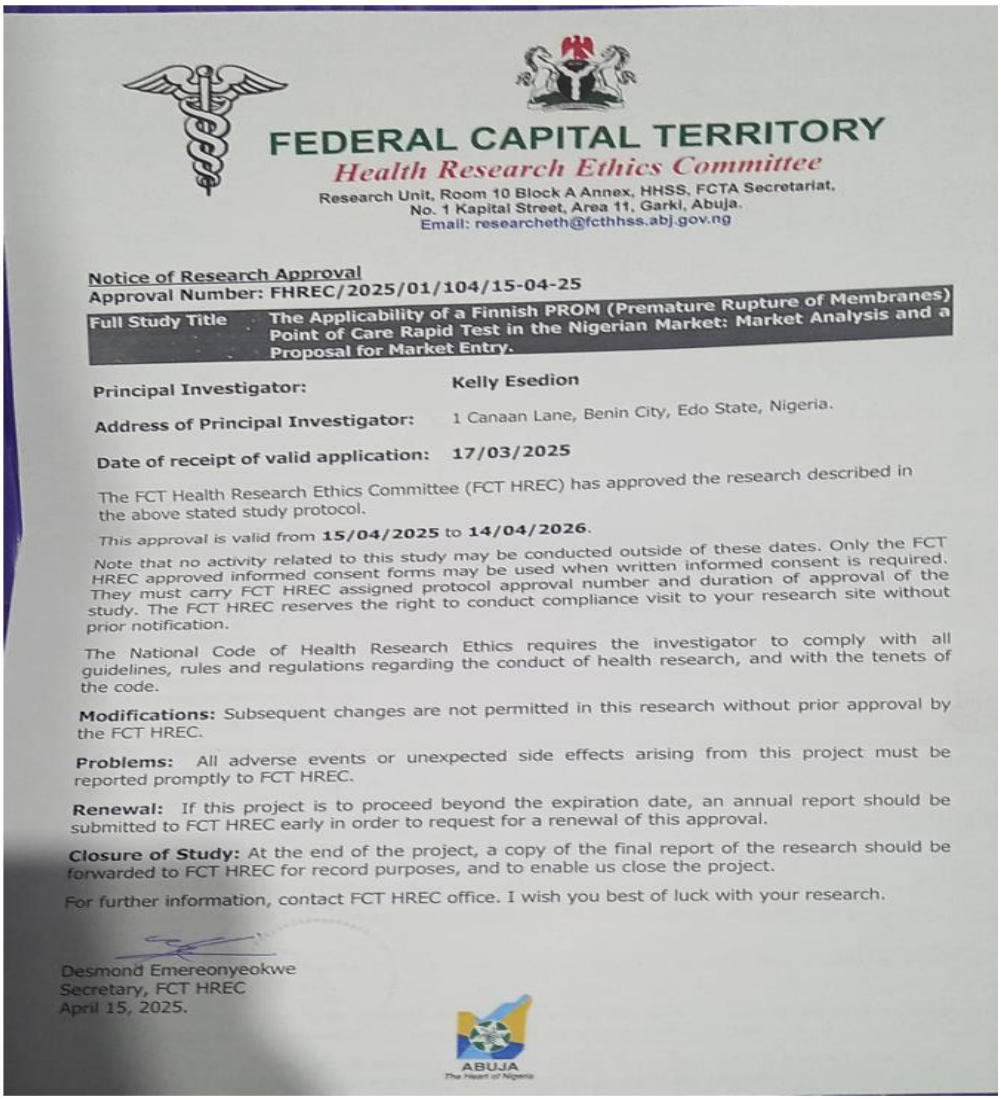
G	H	I	J	K	L
What type of healthc	If you have selected (	The Facility is a	If you have selected (	What is your role in t	If you have selected (
Public Hospital		Secondary Health Center		Other	Medical Laboratory scie
Public Hospital		Secondary Health Center		Nurse	
Public Hospital		Secondary Health Center		Administrative Staff	
Private Hospital		Tertiary Health Center		Other	Anaesthesia assistance
Private Hospital		Tertiary Health Center		Nurse	
Maternity		Primary Health Center		Midwife	
Public Hospital		Secondary Health Center		Nurse	
Private Hospital		Primary Health Center		Nurse	
Public Hospital		Tertiary Health Center		Midwife	
Public Hospital		Tertiary Health Center		Nurse	
Public Hospital		Secondary Health Center		Midwife	
Public Hospital		Secondary Health Cente	nill	Obsetrician/Gynaecolog	nill
Public Hospital	nill	Secondary Health Cente	nill	Midwife	nill
Public Hospital		Tertiary Health Center		Nurse	
Public Hospital		Secondary Health Center		Obsetrician/Gynaecologist	
Public Hospital		Secondary Health Center		Midwife	
Private Hospital		Secondary Health Center		Nurse	
Public Hospital		Primary Health Center		Midwife	
Public Hospital		Secondary Health Center		Obstetrician/Gynaecologist	

M	N	O	P	Q	R	S
How many years hav	Approximately how r	On an average, how r	In the diagnosis of Pr	If you have selected (	What method does y	If you have selected I
ie Less than 1 year	1,000 - 5,000	8 - 9				
1 - 5 years	1,000 - 5,000	8 - 9	WHO guidelines		Clinical Examination	Hospital admission for
6 - 10 years	1,000 - 5,000	8 - 9	WHO guidelines		Ultrasound	Ultra Sound method is
e Less than 1 year	Less than 1,000	6 - 7	WHO guidelines		Clinical Examination	Collecting a sample of f
1 - 5 years	Less than 1,000	8 - 9	WHO guidelines		Ultrasound	Ultrasound
Less than 1 year	Less than 1,000	4 -5	WHO guidelines		Clinical Examination	Did not select Point of C
1 - 5 years	1,000 - 5,000	4 -5	WHO guidelines		Ultrasound	Nill
1 - 5 years	1,000 - 5,000	8 - 9	WHO guidelines		Ultrasound	Ultrasound
6 - 10 years	More than 5,000	6 - 7	WHO guidelines		Clinical Examination	Nill
6 - 10 years	More than 5,000	4 -5	WHO guidelines		Ultrasound	Nil
1 - 5 years	1,000 - 5,000	4 -5	WHO guidelines		Nitrazine Paper Test	nill
1 - 5 years	Less than 1,000	4 -5	WHO guidelines	nill	Nitrazine Paper Test	nill
1 - 5 years	Less than 1,000	4 -5	WHO guidelines	nill	Point-of-care	Actim
More than 10 years	1,000 - 5,000	8 - 9	WHO guidelines		Ultrasound	Ultrasound
1 - 5 years	Less than 1,000	4 -5	WHO guidelines		Nitrazine Paper Test	Nil
6 - 10 years	1,000 - 5,000	8 - 9	WHO guidelines		Clinical Examination	Nil
6 - 10 years	Less than 1,000	6 - 7	WHO guidelines		Ultrasound	Nil
Less than 1 year	Less than 1,000	6 - 7	WHO guidelines		Clinical Examination	Nil
6 - 10 years	Less than 1,000	4 -5	WHO guidelines		Point-of-care	Actim

Z	AA	AB	AC	AD	AE
What factors are con	What factor(s) influe	If you have selected (	Through which chan	If you have selected (	Who typically pays fo
Cost;Ease of Use;Alignm	Price;Reliability of supply;Quality of products ;D		Direct from manufacturers ;Authorized distribut		Patients (Out-of-pocket)
E Alignment with guidelin	Price;Delivery time;Quality of products ;Reliabili		Authorized distributors	Goverment approved M	Patients (Out-of-pocket)
Cost;Performance (Sens	Quality of products ;Price;Reliability of supply;Al		Authorized distributors	Authorised distributor a	Patients (Out-of-pocket)
Performance (Sensitivity	Reliability of supply;		Authorized distributors	Authorized distributor	Patients (Out-of-pocket)
Performance (Sensitivity	Price;Reliability of supply;Delivery time;		Direct from manufactur	Nil	Patients (Out-of-pocket)
Performance (Sensitivity	Reliability of supply;Quality of products ;Price;		Online medical supplier	Did not select other.	Public systems e.g. Hosp
a Alignment with guidelin	Price;Reliability of supply;Supplier reputation;		Other;	My department is not ir	Patients (Out-of-pocket)
Performance (Sensitivity	After-sales support;Delivery time;Supplier reput		Direct from manufactur	H medix	Patients (Out-of-pocket)
Performance (Sensitivity	Quality of products ;Del	Non	Direct from manufactur	Non	Patients (Out-of-pocket)
Performance (Sensitivity	Quality of products ;		Direct from manufactur	Nik	Patients (Out-of-pocket)
Alignment with guidelin	Price;Reliability of supply;Quality of products ;Su		Authorized distributors	nill	Patients (Out-of-pocket)
Performance (Sensitivity	Price;Quality of product	nill	Authorized distributors	nill	Patients (Out-of-pocket)
Performance (Sensitivity	Price;Reliability of suppl	nill	Authorized distributors	nill	Patients (Out-of-pocket)
Performance (Sensitivity	Reliability of supply;		Direct from manufactur	Direct from manufactur	Public systems e.g. Hosp
Performance (Sensitivity	Price;Quality of product	Nil	Authorized distributors	Nil	Patients (Out-of-pocket)
Cost;Alignment with gui	Reliability of supply;Quality of products ;Price;		Authorized distributors	Nil	Patients (Out-of-pocket)
Alignment with guidelin	Price;Reliability of suppl	Nil	Authorized distributors	Nil	Patients (Out-of-pocket)
Alignment with guidelin	Price;Reliability of suppl	Nil	Authorized distributors	Nil	Patients (Out-of-pocket)
Performance (Sensitivity	Price;Reliability of suppl	Nil	Authorized distributors	Nil	Patients (Out-of-pocket)

T	U	V	W	X	Y
Sensitivity	Specificity	What challenges do y	If you have selected (	Who typically decide	If you have selected (
				Head of Obstetrics and	Head of department
or c Somewhat effective		Limited Availability of Resources;		Head of the Laboratory;	In Abuja, the Nigerian E
is u Very effective	Somewhat effective	Limited Availability of Resources;		Hospital Management/	The Hospital manageme
of fl Neutral	Neutral	False Positive Results;		Head of Obstetrics and	Head of obstetrics and g
Very effective	Neutral	Time Consuming;False Positive Results;		Head of Obstetrics and	Nil
of C Somewhat effective	Somewhat effective	Limited number of training personnels;		Head of Obstetrics and	Did not select other.
Very effective	Neutral	Limited number of training personnels;		Head of the Laboratory;	The head of OBS norma
Very effective	Very effective	Time Consuming;		Head of Obstetrics and	The consultant
Very effective	Very effective	Time Consuming;Limited number of training per		Head of Obstetrics and	Non
Neutral	Neutral	Time Consuming;Limited number of training per		Head of Obstetrics and	Nil
Very effective	Neutral	False Positive Results;		Head of Obstetrics and	nill
Very effective	Very effective	False Positive Results;	nill	Head of Obstetrics and	nill
Very effective	Very effective	High Cost;	nill	Head of Obstetrics and	nill
Very effective	Somewhat effective	Time Consuming;		Head of the Laboratory;	Head of laboratory
Very effective	Very effective	False Positive Results;		Head of Obstetrics and	Nil
Neutral	Neutral	Limited number of training personnels;		Hospital Management/	Nil
Very effective	Neutral	Limited Availability of Resources;Time Consumir		Head of Obstetrics and	Nil
Neutral	Neutral	Time Consuming;Limite	Nil	Hospital Management/	Nil
Very effective	Very effective	High Cost;		Head of Obstetrics and	Nil

Ethical approval from Health Research Ethics Committee in Abuja, Nigeria



FEDERAL CAPITAL TERRITORY

Health Research Ethics Committee

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No. 1 Kapital Street, Area 11, Garki, Abuja.
Email: researcheth@fcthhss.abj.gov.ng

Notice of Research Approval

Approval Number: FHREC/2025/01/104/15-04-25

Full Study Title : **The Applicability of a Finnish PROM (Premature Rupture of Membranes) Point of Care Rapid Test in the Nigerian Market: Market Analysis and a Proposal for Market Entry.**

Principal Investigator: **Kelly Esedion**

Address of Principal Investigator: 1 Canaan Lane, Benin City, Edo State, Nigeria.

Date of receipt of valid application: **17/03/2025**

The FCT Health Research Ethics Committee (FCT HREC) has approved the research described in the above stated study protocol.

This approval is valid from **15/04/2025** to **14/04/2026**.

Note that no activity related to this study may be conducted outside of these dates. Only the FCT HREC approved informed consent forms may be used when written informed consent is required. They must carry FCT HREC assigned protocol approval number and duration of approval of the study. The FCT HREC reserves the right to conduct compliance visit to your research site without prior notification.

The National Code of Health Research Ethics requires the investigator to comply with all guidelines, rules and regulations regarding the conduct of health research, and with the tenets of the code.

Modifications: Subsequent changes are not permitted in this research without prior approval by the FCT HREC.

Problems: All adverse events or unexpected side effects arising from this project must be reported promptly to FCT HREC.

Renewal: If this project is to proceed beyond the expiration date, an annual report should be submitted to FCT HREC early in order to request for a renewal of this approval.

Closure of Study: At the end of the project, a copy of the final report of the research should be forwarded to FCT HREC for record purposes, and to enable us close the project.

For further information, contact FCT HREC office. I wish you best of luck with your research.

Desmond Emereonyeokwe
Secretary, FCT HREC
April 15, 2025.

ABUJA
The Heart of Nigeria