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Self-Ordering of Pathology Tests in Nigeria: Implications for Medical Practice and Patients' Safety.

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Abstract

The global healthcare landscape is witnessing a significant shift towards patient autonomy, exemplified by the growing trend of self-ordering of pathology tests, also known as Direct Access Testing (DAT). This model, which allows individuals to request laboratory investigations without a physician's referral, is emerging in Nigeria amidst a complex healthcare system. This narrative review synthesized existing literature to explore the opportunities and challenges of DAT within the Nigerian context.

We examined the drivers, including digital health advancements, limitations in traditional healthcare access, and growing patient empowerment. Conversely, we critically analysed the profound implications for medical practice, including the potential for misinterpretation of results, overdiagnosis, unnecessary treatment, and the erosion of the clinician-patient relationship. The review also highlights specific systemic challenges in Nigeria, such as variable laboratory quality, the proliferation of quackery, and a weak regulatory framework. We argue that while DAT presents a potential avenue to improve healthcare access, its integration into the Nigerian health system requires robust regulatory oversight, stringent quality management systems in laboratories, extensive public education, and a collaborative model that preserves the essential role of medical guidance to safeguard patient safety.

Keywords: Direct Access Testing, Digital Health, Laboratory Quality, Nigeria, Pathology, Self-ordering.

1. Introduction

Traditional medical practice dictates that physicians evaluate patients and select various investigations, including pathology tests. This practice has been a cornerstone of medical practice for ages. [1,2] However, a global shift towards greater patient involvement in healthcare is fostering alternative models like Direct Access Testing (DAT) or patient self-ordering.[3, 4] DAT allows individuals to directly request laboratory investigations without a prior physician consultation, driven by factors such as consumer empowerment, digital health technologies, and a desire for convenience and confidentiality..[3, 4]

In most parts of the world, DAT and direct-to-consumer (DTC) tests, including home testing kits and

online services, are increasingly common, sparking debates on their clinical utility and ethical ramifications.[5-10] The landscape in Nigeria, however, is markedly different and characterized by a burdened public health system, significant out-of-pocket expenditure, geographic barriers to access, poor laboratory services, and a mix of formal and informal providers. The Nigerian context presents unique challenges and drivers for the adoption of self-ordering practices.[11-14]

While some private laboratories in Nigeria, particularly in urban centres, already offer some form of DAT, this practice exists in a regulatory grey area.[15] The National Health Act (2014) provides a framework for health service regulation, but its implementation, particularly concerning emerging models like DAT, remains nascent.[16] This review explores the phenomenon of self-ordering pathology tests in Nigeria, examining its drivers, the opportunities it may present, and the critical implications for medical practice and patient safety, drawing on lessons from global experiences and local constraints.

1.1 Justification of the Study

The Critical Problem in DAT is balancing Access and Safety of the patients at the same time.

The self-ordering of pathology tests is emerging in Nigeria as a response to severe systemic deficiencies. Nigeria's healthcare system is burdened by significant barriers, including geographical distance, excessive wait times, and high out-of-pocket costs, making DAT an attractive pathway for patient autonomy and rapid information retrieval.

However, the rapid and largely unregulated proliferation of DAT introduces profound public health risks. These risks include the potential for widespread misinterpretation of results, leading to unnecessary anxiety, dangerous self-medication, and delayed diagnosis of serious conditions. This danger is critically amplified by two existing local challenges: the highly variable quality of laboratory services and the pervasive presence of quackery within the diagnostic sector. Currently, DAT operates in a regulatory grey area, threatening patient safety and undermining the foundational principles of clinical practice.

Despite the increasing adoption of DAT by private Nigerian laboratories, there is a distinct lack of comprehensive, localized research that synthesizes its unique drivers and consequences within the Nigerian socio-regulatory context.

This narrative review is necessary because it systematically identifies and articulates the specific systemic risks posed by DAT in a low-resource setting with weak quality assurance (QMS), it establishes the urgent need for specific guidelines beyond the general provisions of the National Health Act (2014) to govern this emerging practice.

1.2 Benefits and Significance of the Study

The findings and recommendations of this review offer tangible benefits to public health, regulatory bodies, and clinical stakeholders:

1. Benefit to Regulatory and Policy Bodies

This study provides the evidence-based foundation required by regulatory bodies (e.g., MDCN and MLSCN) to draft specific and enforceable legislation for DAT. It defines which tests are appropriate for self-ordering and outlines the necessary accreditation and quality management standards that must be met by laboratories offering these services, thereby formalizing the practice and preventing unqualified providers from exploiting patients.

2. Benefit to Patient Safety and Laboratory Quality

By highlighting the dangers of variable laboratory quality and quackery, the review strongly advocates for widespread Quality Management System (QMS) implementation across diagnostic facilities. This directly contributes to reducing diagnostic errors and ensuring that the self-ordered results patients receive are reliable and clinically accurate, safeguarding them from misdiagnosis and inappropriate treatment.

3. Benefit to Clinical Practice and Continuity of Care

The review mitigates the risk of medical overuse and the erosion of the clinician-patient relationship by proposing a shared-access model. This model allows patients the convenience of ordering tests while mandating that results be reviewed by a professional for proper interpretation and counselling. This recommendation ensures that patient autonomy is supported by the essential safety net of medical guidance, preserving the continuity and quality of care.

4. Benefit to Public Health Education

The findings underscore the need for targeted public health education campaigns on health literacy. This will empower the Nigerian populace to understand the limitations of self-interpretation, recognize the dangers of self-medication based solely on laboratory results, and utilize DAT responsibly.

2.0 Methods and Materials

This study is a comprehensive narrative review conducted to synthesize and critically appraise the existing literature on self-ordering of pathology tests, with a specific focus on the Nigerian context. A systematic search was performed on electronic databases including PubMed, Google Scholar, African Journals Online (AJOL), and Scopus to identify relevant peer-reviewed articles, reviews, and reports. Search terms used included: Direct Access Testing, self-ordering, pathology, laboratory tests, Nigeria, patient safety, medical overuse, quackery, digital health, artificial intelligence, diagnostic error, and health regulation. The search was limited to publications from 2010 to 2025 to capture both foundational and contemporary perspectives.

Inclusion criteria encompassed studies discussing DAT models, laboratory quality in low-resource settings, patient self-referral, self-medication, digital health diagnostics, and regulatory policies. Exclusion criteria included grey literature that were not pair reviewed, unpublished materials that discussed the subject matter, Commentary, letters to the editor, or purely speculative articles that did not present original data , publication date outside our range, articles where the primary subject was unrelated to the core themes of DAT models, laboratory quality/accreditation, diagnostic safety, or Nigerian health regulation. Both global and Nigeria-specific studies were included to allow for comparative analysis. A total of 33 literature were selected for final inclusion based on their relevance to the core themes of this review: drivers of DAT, implications for practice and safety, laboratory quality challenges, and regulatory frameworks.

3.0 Results

A total of 33 articles were analysed for thematic synthesis. These articles comprised original research papers, review articles, and policy documents, addressing direct access testing (DAT), laboratory quality management, digital health adoption, and related patient safety issues.

1. Drivers of Direct Access Testing (DAT)

Studies consistently identified technological advancement, increased health literacy, patient empowerment, and dissatisfaction with traditional healthcare access as major drivers of DAT adoption. In Nigeria, factors such as long waiting times, shortage of medical personnel, and perceived high cost of consultations have led to a rise in patient-initiated laboratory testing and digital self-diagnostic platforms.[15,19,20,31,32]Worldwide, mobile health applications, wearable devices, and artificial intelligence–powered tools further accelerate this shift toward self-ordering and interpretation of laboratory tests. [7,9,21]

2. Patterns of DAT Utilization and Related Practices

Emerging evidence from Nigerian and other Low and Middle Income Countries (LMIC) contexts shows that DAT utilization is often informal and poorly regulated. Patients frequently access laboratory testing directly, without physician authorization, particularly in private laboratories with an emerging trend in public laboratories.[15,20,31]Similar patterns are observed globally with online or home-based test kits, especially for infectious diseases and genetic testing.[5–7,9] However, test selection and interpretation errors are common when professional guidance is absent, leading to diagnostic confusion and inappropriate self-treatment.

3. Laboratory Quality and QMS Implementation

Quality Management System (QMS) implementation remains inconsistent across Nigerian medical laboratories. While several institutions have successfully implemented ISO 15189–based systems, others still struggle with inadequate infrastructure, insufficient training, and weak regulatory enforcement. [13, 23,33] Studies highlighted that without an accredited QMS, the accuracy and reliability of laboratory results cannot be guaranteed. [13, 23, 25,29,33] Laboratories with functional QMS frameworks demonstrate improved turnaround times, traceability, and clinician confidence, underscoring the importance of system-wide adoption.

4. Regulatory and Policy Environment

The National Medical Laboratory Services Policy (2023) emphasized on the need for standardization and integration of laboratory services within Nigeria's health system.[30]

However, enforcement remains limited, with many laboratories operating without accreditation or regular audits. Regulatory gaps allow non-professional actors and unlicensed facilities to offer diagnostic services, increasing the risk of medical errors and patient harm.[11,17,20]

5. Human Resources and Professional Role

The effectiveness of laboratory services, including DAT models, depends largely on the professional roles

of pathologists, medical laboratory scientists, and technicians. Nigerian studies highlighted workforce shortages and underutilization of pathologist input in diagnostic decision-making.[24, 25,30] Integration of DAT without professional oversight risks undermining the interpretive and consultative roles that define laboratory medicine. [2, 28,29]

6. Health System Strengthening and DAT

Evidence indicates that laboratories with well-established QMS contribute significantly to broader health system strengthening through improved workflow efficiency, error reduction, and enhanced clinician confidence.[13,23,33] In Nigeria, QMS implementation in public health laboratories has shown measurable improvements in turnaround time, documentation, and regulatory compliance.[13,23,33] Accredited laboratories using ISO standards could promote safe expansion of diagnostic access through self-testing while reinforcing national health system resilience.[13 33]

7. Ethical and Patient Safety Concerns

The increasing use of self-testing and direct access diagnostics raises ethical issues surrounding patient autonomy, result interpretation, and potential harm from misdiagnosis.[5-8,11,15,18,22,27] In Nigeria, limited public understanding of laboratory test results and proliferation of unregulated diagnostic outlets heighten these risks.[15] Therefore, structured public education and patient safety frameworks are essential to guide ethical DAT integration and minimize misuse or harm. [5,6,15]

4. Discussion

4. 1 Drivers and Potential Benefits of Self-Ordering in Nigeria

Several factors specific to the Nigerian health environment could make DAT an attractive proposition for patients. A primary driver is the challenge of accessing traditional healthcare. Geographic distance remains a significant barrier to health facility utilization in rural Nigeria as many Nigerians are living in areas with poor access to quality healthcare services.[14] Furthermore, overcrowding in tertiary hospitals, where doctor-patient ratios can be as high as 1:4000, and long waiting times can make the process of seeing a doctor who will order medical tests seem inefficient.[17] DAT could potentially decouple diagnostic testing from physician consultation, offering a faster route to obtaining health information for time-pressed individuals or those living far from medical facilities.

Also, the advent of digital health technologies is creating new pathways for healthcare delivery in Nigeria as patients can now check their symptoms online.[3,4,15] Online health information, symptom checkers, and Artificial Intelligent -driven self-diagnosing platforms are empowering and compelling some patients to take a more active role in their health.[18, 19] This digital ecosystem naturally lends itself to DAT, where online platforms can be used to order tests directly. For educated and health-literate populations, DAT can satisfy a desire for autonomy and proactive health monitoring and interventions. [9]

Furthermore, in some cases, patients may seek DAT to bypass perceived inefficiencies or costs within the formal referral system. Studies on healthcare self-referral in Nigeria indicate that patients sometimes bypass primary care facilities for higher levels of care due to perceptions of better quality or a lack of trust in the initial point of contact.[20] DAT can be seen as an extension of this behaviour, allowing patients to directly access diagnostic information they believe is necessary.

4.2 Clinical Implications

Despite the potential benefits, the unregulated proliferation of DAT poses significant risks, magnified by the Nigerian context. In the first instance, pathology results are not absolute truths because they are clinical data that must be interpreted within the context of a patient's symptoms, and physical examination.[1, 2, 6] A result flagged as "abnormal" may be of no clinical significance (a false positive), or a "normal" result may provide false reassurance (a false negative) in a symptomatic patient. Without medical guidance, patients are prone to misinterpret results, leading to anxiety, unnecessary follow-up tests, or dangerous delays in seeking appropriate care, potentially resulting in wrong or delayed diagnosis.[2, 6, 21] This risk is exacerbated by low health literacy levels.

Also, DAT can facilitate overuse of medical resources. Patients may order batteries of unnecessary tests based on online research or anecdotal advice, leading to poor selection of pathology tests. [5, 21] This not only increases individual healthcare cost, it also adds to the already high increasing cost of medical treatment.

Furthermore, inappropriate self-medication practices are already prevalent in Nigeria, with study showing rates as high as 78% among university students. [22] DAT could exacerbate this by providing justification for self-prescribing of pharmaceuticals or even herbal

drugs with unknown interactions and toxicities, potentially leading to antibiotic resistance, adverse drug reactions, treatment of non-existent conditions, and exacerbation of existing health problems.

Another clinical implication is erosion of the clinician-patient relationship, as this is built on trust and collaborative decision-making. DAT can disrupt this dynamics. Studies show that while patients are curious about DTC tests, many still prefer their doctor's involvement for interpretation and guidance.[8, 10] However, when patients arrive with self-ordered results, it can shift the clinical dialogue from a collaborative process to a reactive one, potentially undermining medical authority and fracturing the continuity of care.[18] Furthermore, due to concerns over quality or relevance, physicians may be forced to repeat medical tests ordered directly by patients, leading to duplication of efforts, increased costs, and further strain on laboratory resources.

Furthermore, the Nigerian healthcare system contends with the serious challenge of quackery, which undermines quality care and patient safety. [11] The DAT model could be easily co-opted by unqualified practitioners and unregulated laboratories. Patient's eagerness for affordable and accessible testing may be lured by cheaper options from facilities operating without proper quality management systems (QMS). [11, 23] The consequences of inaccurate results from such sources can be catastrophic, leading to misdiagnosis and mistreatment, as the entire value of DAT hinges on the reliability of test results. In Nigeria, the quality of laboratory services is highly variable. [11, 23]

In a setting characterized by wide disparities, like Nigeria with different literacy level, socio-economic, cultural issues and comorbidities, these external factors often amplify the risks associated with self-management of health information. Pathology reports are written using technical language, patients with low health or even general literacy are prone to misinterpreting normal reference ranges, critical values, and clinical relevance. This can lead to excessive health anxiety over benign findings (false positives) or dangerous complacency regarding serious diseases (false negatives).[15,22] Socio-economic factors primarily influence access, choice, and post-testing action. While DAT can bypass consultation fees, the overall cost of tests remains out-of-pocket for most Nigerians. Patients with lower income may prioritize cheaper, potentially unregulated, or lower-quality testing facilities over accredited ones, exposing them to inaccurate results. [15, 18,26] Cultural beliefs and the complexity of existing health conditions further complicate the self-management model. Many individuals may default to traditional healers or self-medication (often using herbal remedies) immediately after receiving a test result, bypassing formal medical consultation altogether. [11,15] Patients living with comorbidities (e.g., hypertension, diabetes, HIV, chronic kidney disease) already require complex, integrated management. A self-ordered test result for a single parameter can be clinically meaningless or misleading without a physician's knowledge of the patient's complete medical history and current medication regime. Self-management in this population is exceptionally high-risk, increasing the likelihood of adverse drug interactions or misadjusted therapy. [8,18]

In view of these, the implementation of robust QMS in medical laboratories is a critical pillar for health system strengthening, including DAT integration into traditional medical practice. [1, 2] Studies within Nigeria have demonstrated both the feasibility and the challenges of establishing QMS in clinical laboratories. [13, 23] Without an accredited QMS, the accuracy, and reliability of test results cannot be guaranteed. Promoting DAT in an environment where many laboratories struggle with quality assurance puts patients at risk. [23]

Also, the effectiveness of any laboratory service, including DAT, depends on the expertise of pathologists, medical laboratory scientists and technicians. Their role extends beyond generating results to ensuring quality, interpreting complex cases, and providing consultative support to clinicians. [2, 23-25] A sustainable DAT model must therefore be integrated with professional laboratory medicine expertise to ensure results are not only accurate but also meaningful. [27, 28]

4.3 Way forward

For DAT to be safely integrated into the Nigerian healthcare system, a multi-faceted approach is required, centred on strong governance and system strengthening. This requires strengthening of laboratory services through effective policies and legislation.[13, 23-25] The National Health Act of 2014 provides a starting point, but specific guidelines governing DAT are urgently needed.[6] There must be proper legislation enacted to regulate this practice. Regulatory bodies like the Medical and Dental Council of Nigeria (MDCN), Medical Laboratory Science Council of Nigeria (MLSCN) in collaboration with ministries of health at both national and subnational levels must develop clear policies on which tests can

be self-ordered. For example, basic wellness panels can be ordered by the patients while complex diagnostic tests can only be requested by a physician. Also, laboratory facility offering DAT must meet stringent accreditation requirements and result reporting should include clear disclaimers on the necessity of physician interpretation.[27, 28] This requires a synergy among regulators of health services to create a cohesive and enforceable framework. [29, 30]

Concurrently, there is a need to strengthen referral system from primary to tertiary care to ensure that once a diagnosis is made through DAT, patients have a clear and efficient pathway for seeking professional treatment, thereby mitigating the risks of self-management.[17, 31]

Furthermore, extensive public health education campaigns are crucial to educate Nigerians on the appropriate use of pathology tests, the dangers of self-interpretation, and the importance of seeking professional medical advice.[32] Patients should be empowered to ask questions and participate in their care, but within a safe and guided framework. [6]

In addition, the foundation of any safe diagnostic service is a strength of the laboratory system. This includes nationwide scaling of QMS, continuous training, and adequate funding. [23, 25, 33] Furthermore, increasing capacity building in health sectors is required to address critical shortages of skilled healthcare professionals including pathology staff, which would improve access to qualified personnel for counselling and reduce the vacuum that DAT currently aims to fill.

In view of the above, a viable model for Nigeria could be a shared access approach. This involves DAT being offered by accredited laboratories with results automatically forwarded to a designated physician or a walk-in clinic for interpretation and counselling. [7, 25] This combines the convenience of direct access with the safety net of professional medical review, preserving the clinician-patient relationship and ensuring continuity of care.

5.0 Conclusion

The self-ordering of pathology tests is a double-edged sword for the Nigerian healthcare system. While it offers a potential solution to improve access and patient engagement, it introduces profound risks for medical practice and patient safety, including misinterpretation, increased costs, repeated tests, wrong diagnosis, and dangerous self-medication. These risks are amplified in a system still grappling with foundational issues of quality assurance, regulation, and human resource capacity.

Nigeria must not simply adopt DAT models from other contexts but must adapt them with extreme caution. The priority must be to strength the laboratory system through widespread QMS implementation and embark on capacity building. Thereafter, a carefully regulated framework for DAT, guided by proper legislation and synergy among regulators, can be explored. This framework must leverage digital health advancements while firmly retaining the essential guiding role of the healthcare professional within a strengthened referral system. Ultimately, the goal is not to restrict patient choice but to ensure that the pursuit of autonomy does not come at the cost of safety and quality care.

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Table 1: Summary of key findings from literature review (2010–2025)

Theme	References	Key Findings	Implications for DAT and Laboratory Practice
1) Drivers of Direct Access Testing (DAT)	3–9, 15, 19–21, 31,32	Growth of digital health platforms, wearable devices, and AI-based applications encourages self-testing and self-diagnosis. In Nigeria, long waiting times, healthcare cost, and limited access to physicians drive patient self-ordering of tests.	DAT expansion reflects patient empowerment but increases risk of misdiagnosis and medical overuse in weakly regulated systems.
2) Patterns and Utilization of DAT	5–7, 9, 15, 20, 31	DAT users often bypass physicians; frequent use for routine, infectious disease, and genetic tests. Misinterpretation and inappropriate self-treatment are common.	Need for professional interpretation and clinical context to prevent diagnostic errors and unsafe medical decisions.
3) Laboratory Quality	1,2,13,23,25,29,33	Implementation of ISO 15189-based QMS in Nigerian laboratories is uneven. Some centers demonstrate success, but have insufficient equipments, documentation, and training.	Sustainable DAT requires laboratories with accredited QMS to ensure result accuracy, traceability, and clinician confidence.

4) Human Resource and Professional Roles	2,24,25,28,29	Pathologists and laboratory scientists are essential for quality control, interpretation, and clinical correlation. Workforce shortage and under-recognition persist in Nigeria.	DAT should complement professional laboratory medicine expertise.Collaborative models are preferred.
5) Regulatory and Policy Environment	11,17,20,30,33	Weak enforcement of existing laboratory regulations, proliferation of non-accredited facilities and unqualified providers show poor regulation of pathology services. National Medical Laboratory Services Policy (2023) offers a framework but limited adoption	Stronger regulation and periodic accreditation audits are critical to prevent unsafe diagnostic practices.
6) Health System Strengthening and QMS	13,23,33	QMS implementation improves efficiency, reduces errors, and strengthens patient confidence. QMS is linked to overall health system resilience.	Integrating DAT within accredited laboratories can enhance diagnostic reach and system reliability.
7) Ethical and Patient Safety Concerns	5-8,11,15, 18,22,26	Self-testing raises ethical issues regarding result interpretation, anxiety, and misuse. Public misunderstanding and quack practices remain challenges.	Patient safety frameworks and public education must accompany DAT adoption to minimize harm.