Designing for Neglected Tropical Diseases: Co-creating digital diagnostic devices for Low-Resource Settings

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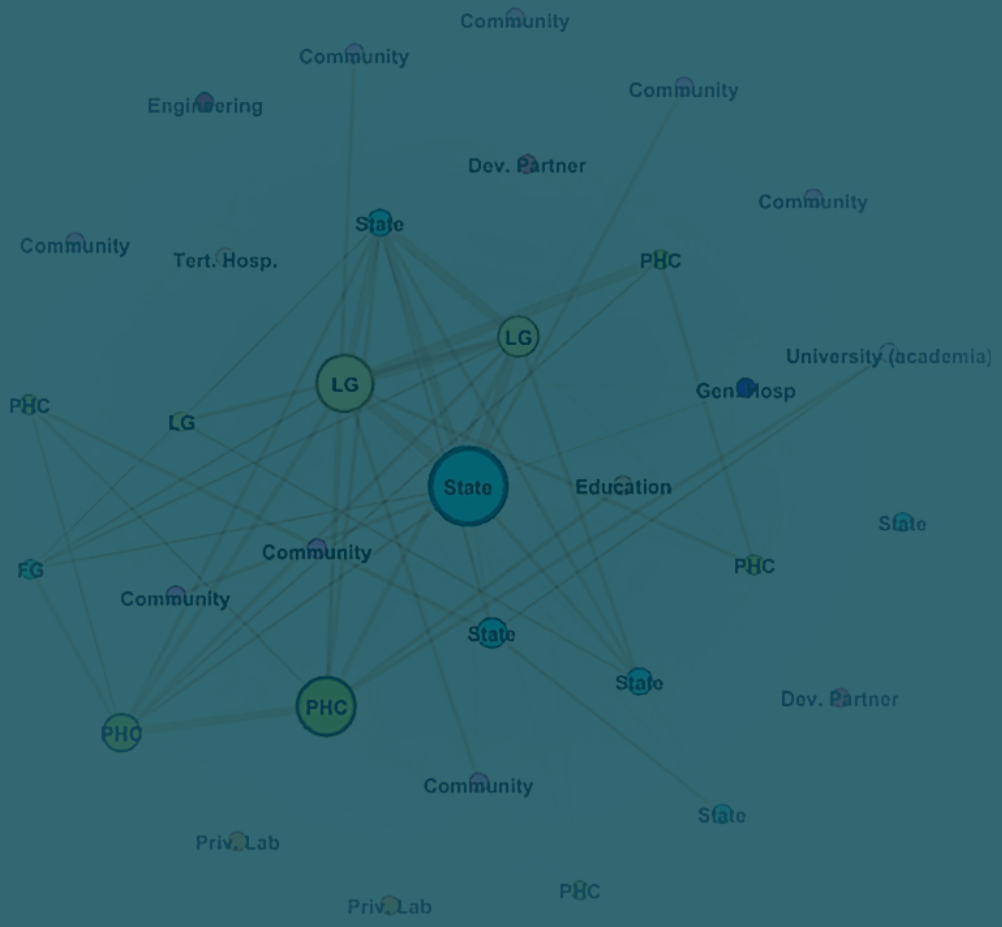

ADEOLA ONASANYA

Designing for Neglected Tropical Diseases: Co-creating digital diagnostic devices for Low-Resource Settings

Dissertation

for the purpose of obtaining the degree of doctor
at **Delft University of Technology**
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Designing for Neglected Tropical Diseases: Co-creating digital diagnostic devices for Low-Resource Settings

The first section gives an overview of the thesis. It begins with an introductory chapter that situates the thesis within a body of design, social and public health research. It further introduces the rationale for the study and methodology. Thereafter, the result section answers the research questions based on the result of the various studies carried out during the course of the PhD. Finally, the discussion section addresses the implications of the research questions on the several themes highlighted in the introductory chapter.

Chapter

1

INTRODUCTION

This chapter gives an overview of Neglected Tropical Diseases (NTDs), makes a case for designing digital diagnostics for NTDs, situates the research within the systemic design framework, states the research approach and methodology and presents a summary of the research findings.

1.1. NEGLECTED TROPICAL DISEASES

Neglected Tropical Diseases (NTDs) are a group of infections that primarily affect populations in the world's tropical and subtropical regions (WHO, 2023). They are referred to as "neglected" because they disproportionately affect the poorest and most marginalised communities and have historically been overlooked by the global health community compared to more well-known diseases such as malaria or HIV/AIDS (Engels & Zhou, 2020). Apart from a few outliers, NTDs are mainly caused by parasites, bacteria, fungi or viruses and spread by vectors such as mosquitos, flies, and snails, or by contaminated water and soil (WHO, 2023). The term 'parasite' is broad and includes organisms such as helminths, protozoans, mites and larvae.

The World Health Organization (WHO) recognizes 20 different NTDs (Table 1.1) (WHO, 2023). The most prevalent NTDs include schistosomiasis, soil-transmitted helminthiasis, lymphatic filariasis and onchocerciasis (World Health Organization, 2020a). NTDs can cause a variety of symptoms, such as stunted growth, chronic pain, disabilities, blindness, cancer and even death. They can also have long- term effects on economic productivity and social development because they disproportionately affect the most vulnerable and marginalised populations, such as children and women (Dean et al., 2019; WHO, 2023).

Table 1.1. List of Neglected Tropical Diseases

Category	Disease
Helminth infections	1. Schistosomiasis 2. Lymphatic filariasis 3. Onchocerciasis 4. Taenia solium (neuro) cysticercosis/Taeniosis 5. Soil-transmitted helminthiases (ascariasis, Hookworm diseases, trichuriasis, strongyloidiasis) 6. Dracunculiasis 7. Echinococcosis 8. Foodborne trematodes
Bacterial infections	9. Leprosy 10. Trachoma 11. Buruli ulcer 12. Yaws
Protozoan infections	13. Leishmaniasis 14. Human African trypanosomiasis 15. Chagas disease
Viral infections	16. Rabies 17. Dengue and chikungunya fever
Fungal infections	18. Mycetoma, chromoblastomycosis, deep mycosis
Ectoparasitic infections	19. Scabies, Myiasis
Venom	20. Snakebite envenoming
Source: Abdela et al. (2020)	

Despite their significant burden, NTDs are frequently overlooked in the research and development of new diagnostics, medications and vaccines (Engels & Zhou, 2020). To eradicate or manage NTDs, more funding and attention have been given in recent years in the form of interventions such as Mass Drug Administration (MDAs); Water Sanitation and Hygiene programs (WASH) and vector control with some regions making some progress in reducing the disease burden (Casulli, 2021; World Health Organization, 2020a). The WHO has also set a target of eliminating or controlling the most common NTDs by 2030 and has outlined coordinated strategies through cross-cutting initiatives based on

1. Accelerated actions aimed at reducing the NTD burden through scientific advances, new interventions, and effective, standardised, and affordable diagnostics.
2. Mainstreaming NTD interventions into national health systems in the context of universal health coverage and improving coordination between stakeholders and related programmes.
3. Modifications to operating models and culture to enable countries to take ownership of their NTD programmes (World Health Organization, 2020a).

Achieving these aims requires collaboration among a wide range of stakeholders. Ideally, developing innovative ways to diagnose, treat, and prevent these diseases should involve country-based stakeholders.

Although there is a wide range of NTDs and several pathways to reduce disease burden, this thesis will focus mainly on helminthic NTDs specifically schistosomiasis with minor references to lymphatic filariasis and the co-designed digital diagnostic devices that detect both diseases. This is based on the disease burden, ease of sample collection for testing and ease of sample processing for testing both diseases (Fimbo et al., 2020; Utzinger et al., 2015).

1.1.1 Schistosomiasis

Schistosomiasis also known as bilharzia is a parasitic illness caused by infection with blood flukes of the genus Schistosoma. Individuals and communities are infected when they interact with water sources infested with a specie of water snail that serves as the parasite's host (World Health Organization, 2020b). The disease is prevalent in developing countries, especially in Sub-Saharan Africa and parts of South America, Asia, and the Caribbean (Adenowo et al., 2015; World Health Organization, 2020b). According to the World Health Organization (WHO), about 230 million individuals worldwide are affected with schistosomiasis, with about 120 million in need of treatment (World Health Organization, 2020b). Long-term infections with one of the species, Schistosoma haematobium, are implicated

in significant morbidity and mortality including kidney failure, infertility, and bladder cancer in adults; and growth and learning difficulties in children (Adenowo et al., 2015; Aula et al., 2021; World Health Organization, 2020b) leading to social and economic loss.

Diagnosis for schistosomiasis can be broadly grouped into 3: clinical, sonography-based and laboratory methods (Hoekstra et al., 2021). Clinical diagnostic methods include observation for clinical markers, signs and symptoms such as haematuria, fever, muscle pains etc. Sonography-based methods focus on the use of ultrasound in diagnosing urinary schistosomiasis in experimental studies. Laboratory- based methods are the mainstay of schistosomiasis diagnostics and include a wide range of optical, antigen-based, antibody-based and molecular-based tools using a variety of sample sources including blood, serum, urine, and stool (Table 1.2).

In reality, schistosomiasis diagnosis is made at the primary level of care, which has its financial and human resource limitations. It is clear that several tests for Schistosoma haematobium infection either demonstrate poor specificity or are expensive or too laborious for use in endemic countries, creating a need for more sensitive, cheaper and easy-to-use devices with extensive diagnostic capabilities. There is also a need for smart optical diagnostics which can be integrated into the monitoring and evaluation system for schistosomiasis control.

Table 1.2. Overview of schistosomiasis diagnostic methods

Diagnostic method	Compo-nent	Technology type	Usage	Skill level	Cost	Pros/ Cons
Clinical *(Carbonell et al., 2021)*	Signs and symptoms	-	The first step in diagnosis	High	Medium	**Pros:** cheap, readily available **Cons:** Low specificity and sensitivity
Sonography *(Hoekstra et al., 2021; Kaminstein et al., 2019)*	Sound waves	Ultrasound	Experimental-based	High	High	**Pros:** Novel **Cons:** Low specificity and sensitivity, expensive
Laboratory *(Hinz et al., 2017; Meulah, Bengtson, et al., 2022; Utzinger et al., 2015)*	Optical	Optical lens based only	Microscopes: Mainstay of diagnosis	High	High	**Pros:** Highly specific **Con:** High cost, variable sensitivity
		Digital plus optical lens (smartphone-based, computer-based)	Experimental and undergoing development	Low	Unknown	**Pros:** Optimizable to detect several helminths, easy to use, Data management potential **Cons:** Cost unknown
	Antigen	POC-RDT (POC-CCA)	Commercial kits available	Low	Low	**Pros:** Low cost, easy to use **Cons:** low sensitivity and specificity
		POC-RDT (POC-CAA)	Emerging use/undergoing development	Low	Low	**Pros:** Easy to use, low cost **Cons:** can only detect schistosomiasis alone
		Others	Commercial kits undergoing development	Medium	Unknown	**Pros:** High Sensitivity/specificity **Cons:** can only detect schistosomiasis alone
	Antibody	ELISA	Commercially available	Low	Low	**Pros:** Easy to use, low cost **Cons:** Early infections not easily detected
		IHA	Commercially available	Low	Low	**Pros:** Easy to use, low cost **Cons:** Early infections not easily detected
	Molecular	PCR	Specialised labs	High	High	**Pros:** High sensitivity and specificity **Cons:** Expensive

1.1.2. Lymphatic Filariasis

Lymphatic filariasis (LF), also known as elephantiasis, is a painful and severely deforming condition endemic in tropical and subtropical regions of Asia, Africa, and the Pacific (World Health Organization, 2022). It is caused by an infection with parasites known as nematodes (roundworms) of the family Filariodidea, which are spread via mosquito bites. Larvae spread by mosquitoes are deposited in the host blood when mosquitoes bite (CDC, 2021). The transmission cycle is then continued as the larvae migrate to the lymphatic vessels where they mature into adult worms. In communities where LF is prevalent, all ages are affected. Although the infection may be contracted in childhood, its visible symptoms, like limb oedema and disfigurement, may develop later in life and result in either temporary or permanent disability (Cano et al., 2014; World Health Organization, 2022).

Lymphatic filariasis has a significant social and economic impact in areas where it is endemic. Around 120 million people are projected to be infected and more than 1 billion people are at risk of infection (Cano et al., 2014; Fimbo et al., 2020; World Health Organization, 2022). Although there is currently no cure for LF, there is supportive treatment to manage the symptoms. The use of protective clothing, mass drug administration campaigns, and mosquito control measures are all part of the prevention efforts aimed at reducing disease incidence (World Health Organization, 2022).

Similar to schistosomiasis, LF can be diagnosed by a range of laboratory-based methods, including optical devices such as microscopes, antigen-based, antibody-based and molecular-based tests. Unlike schistosomiasis, blood samples collected at a specific time of day or night are required (World Health Organization, 2022). For LF, early detection of the parasites means that treatment can be quickly administered reducing future complications and disease burdens within the community.

1.2. DIGITAL DIAGNOSTICS FOR NTDS

Digital diagnostics refers to the application of technology to disease diagnosis. Artificial intelligence and machine learning algorithms can be used in digital diagnostics to analyse medical data thereby supporting disease diagnosis. Digital diagnostics aims to increase the efficiency and effectiveness of the diagnostic test and process as well as increase patient accessibility and convenience (Cunnington & The Digital Diagnostics for Africa Network, 2022; Ward et al., 2022).

In recent years, several new digital-based optical diagnostic tests for helminthic NTDs have been developed which can be broadly classified into smartphone-based and computer-based diagnostic technologies (Meulah et al., 2022). These tests are superior in that they rely on direct

observation of the parasites using digitally supported optical tools which can easily be verified by an expert. Both technologies are similar in that they can identify and determine the presence of parasites in urine, stool, blood or skin samples. By automating the counting and identification of the parasites or eggs, these systems can contribute to increasing the accuracy and effectiveness of the diagnostic procedure. However, smartphone-based diagnostic technologies may be limited by the phone processing capacity and optical capacity of the phone's camera (Diehl et al., 2020).

Although digital optical diagnostics can support the early diagnosis and treatment of helminthic NTDs and enhance access to healthcare in the regions where the infection is common, the mainstay of diagnosis for most parasitic NTDs is the microscope which is either not readily available at the primary level of care in needed settings or requires expertise which may be lacking by health workers at that level of care (Aula et al., 2021; Onasanya et al., 2020). There is a need to develop affordable, easy-to-use NTD diagnostic devices for diagnosis, prevention of long-term complications and easy monitoring and evaluation of disease control progress Designing these products requires an understanding of the context of use (social and healthcare) wherein the product fits, which is best accessed by identifying and collaborating with stakeholders in the use setting.

1.3. DESIGNING DIGITAL DIAGNOSTICS FOR NTDS: THE LOW RESOURCE CONTEXT

Low Resource Settings (LRS) are predominant in developing countries and are characterised by limited resources which do not meet accepted standards (Goldstuck, 2014; Zyl et al., 2021). These limitations apply to both social and healthcare resources. Incidentally, developing countries and low-resource settings are also the main regions/countries affected by NTDs (Casulli, 2021; World Health Organization, 2020a).

Designing for LRS requires a broad understanding of the context exclusive to these settings and differences unique to particular regions or countries to ensure product fit and eventual use adoption. As such, designing digital diagnostics for NTDs requires awareness, assessment and accommodation of the effects of financial, material, technical, infrastructural, human resource and cultural factors on the design process, the diagnostic device design and the use context.

1.3.1. The design process

The design process is discursive and consists primarily of 5-steps namely: empathize, define, ideate, prototype and test (Aranda Jan et al., 2016; Brown, 2008) which can be applied to the healthcare product design process. Empathizing requires understanding the disease context to

aid the identification of peculiar needs. It is important to understand the population's unique needs in the developing countries where the diagnostics will be applied and includes understanding the disease's prevalence and geographic distribution, including the current healthcare system, social context and available resources.

The second step in the design process is defining user needs. Defining user needs requires research to determine the best diagnostic methods and technologies for the particular disease and population by identifying gaps and challenges with current diagnostic methods (Chamorro-Koc et al., 2004).

The third step in designing diagnostics requires ideation which challenges assumptions and creates ideas by brainstorming and conceptualizing a diagnostic product based on user needs. Ideation requires co-creation with stakeholders (Saidi & Douglas, 2022). Co-creation can be described as a "transparent process of value creation in an ongoing, productive collaboration with, and supported by all relevant parties, with end-users playing a central role" (Jansen & Pieters, 2018). Co-creation enables collaboration between relevant groups that may normally not be involved in the product's design, leading to a common understanding of the disease process and raising awareness of the challenges and opportunities within the current diagnostic landscape. Co-creation fosters ease of adopting newly designed devices.

The fourth step in the design process is prototyping wherein different prototypes of diagnostic devices are created and validated with stakeholders iteratively (Coulentianos et al., 2020).

The final step is testing the diagnostic product (Wang et al., 2023). This will include technical testing based on engineering parameters, performance testing (lab and field-based) for assessing precision and reliability, and user testing for assessing user experience, usability and acceptability (Bailey et al., 2009; Wang et al., 2023). At each test level, the diagnostic device will be optimised to ensure population, social context and healthcare contextual fit.

1.3.2. The diagnostic device design

The diagnostic device design requires input on 5 key areas which are iterative and benefit from co-creation with stakeholders. These are the design and evaluation of:

1. The diagnostic device in general
2. The software system
3. The hardware system
4. The structural composition, specification and style of the diagnostic device
5. The product manual (Wang et al., 2023)

The design and evaluation of the diagnostic device in general situate the design of the diagnostic device within policies and regulations, industry standards, and regulatory documents both broadly at the global level and locally at national or regional levels. For diagnostic devices for NTDs, guidance is available in the form of product specifications created by the developers to guide the design process, medical device development guides developed by the International Standard Organization (ISO) which is a regulatory body (International Organization for Standardization, 2019), and Target Product Profiles (TPPs) created by the World Health Organization (WHO) (WHO, 2021; World Health Organization, 2023), developmental organizations (PATH, 2015) or research groups (Fongwen et al., 2022; Sluiter et al., 2020). In general policies, regulations and standards guide the product's design specifications, testing procedures, test principles, structural elements, functional indicators, performance index, main workflow, modular structure design, cost budget, etc (Center for Devices and Radiological Health, 2020; International Organization for Standardization, 2016, 2019; Wang et al., 2023).

The software system design and evaluation are the core of the diagnostic device design. For the development of the digital diagnostic devices for NTDs, the components include the Artificial Intelligence (AI) technology based on various AI models for detection of parasitic NTDS, operating system and other system functions, the software's interface design, security requirements and user module requirements (Agbana et al., 2020; Oyibo et al., 2022; Ward et al., 2022).

The design and evaluation of the hardware system are important for a functional diagnostic device for NTDs. The components of this process include the design of the structural, mechanical, control and electrical parts including the structure and layout of these parts within the device (Ates et al., 2021; Shrivastava et al., 2020; Wang et al., 2023).

The structure, specifications, and design aesthetic of the final diagnostic device shape are largely determined by the structure and size of individual components of the device. A robust design form can contribute to lower production costs, positive user experience and acceptability of the diagnostic device (Coulentianos et al., 2020; Saidi & Douglas, 2022). As a result, the design form is an important discursive process in diagnostic device design.

The product manual gives a thorough explanation of the diagnostic devices' design, structural elements, key technical indicators, the layout and structure of each component, the necessary software support, the performance index, the operating environment, the functions to be implemented and workflow (Saidi & Douglas, 2022; Ward et al., 2022). The product manual serves as a guide for end users and biomedical engineers who may be involved in

diagnostic device repairs.

1.3.3. The use context

The use context refers to the environment where the diagnostic device will be used. It is a complex system wherein the physical, social, cultural, and environmental setting broadly interacts with healthcare organizational goals, policies, workflow tasks, resources and users (Aranda Jan et al., 2016; Chamorro-Koc et al., 2004; Gjestsen et al., 2017). For NTD diagnostic devices, the broad context of use is a low-income/ developing country context, and designing for this context cannot occur in isolation. In addition, this context cannot be detected in detail from a distance and there is a need to engage relevant stakeholders within this context. Relevant stakeholders may include local communities, end-users, healthcare professionals, researchers, regulatory and policy makers etc.

To ensure that the diagnostic device for NTDs is population and culturally-appropriate, it is crucial to involve stakeholders from the use context in the design development process and the diagnostic device design (Chamorro-Koc et al., 2004). One way to ensure diagnostic device fit within the context of use is to co-create with stakeholders. Co-creation enables collaboration with the stakeholders during the design development process and the development of the diagnostic device design (Frow et al., 2016; Jansen & Pieters, 2018; Peng et al., 2022). This fosters ownership of the diagnostic device development process, its use and contributes to the overall acceptability of the diagnostic device.

Successful co-creation with stakeholders will require prior mapping, identification and grouping of stakeholders, alongside an understanding of relational dynamics between these stakeholders (Fusco et al., 2023; Jansen & Pieters, 2018; Laurisz et al., 2023). Mapping and identification of stakeholders for NTD diagnostic device design would require an in-depth study of the healthcare and social system in the use context including a) an appraisal of existing NTD programmes, policy documents, research papers on NTDs and the healthcare system within this context, and b) interviewing stakeholders identified through various approaches (Greenhalgh et al., 2016; Onasanya et al., 2020).

Stakeholder grouping can be undertaken to understand the stakeholder characteristics and categories, their interest in NTD diagnostic devices based on perception, and the power they may have over NTD policy making, healthcare organizational goals and patients (Onasanya et al., 2020; Reed et al., 2009). Studying the relational dynamics between these stakeholders is critical to understanding the interaction between stakeholder characteristics, power and interest (Reed et al., 2009). Stakeholder relational dynamics can

be studied through Social Network Analysis (SNA).

SNA is a study of social networks between stakeholders. Social networks are known to be multi-layered and dynamic with different relationships overlapping between stakeholders based on characteristics of the individual stakeholders, healthcare organization and the social and healthcare system or organization wherein they function (Barabasi, 2003). SNA can give insight into the specific relationship dynamics that can affect the operations of individuals and consequently the healthcare system as a whole (Celik, 2018). SNA can also reveal other stakeholders within the healthcare context which may not normally be mentioned during regular interviews (Valente et al., 2015).

Overall, it is possible to design new digital diagnostics for NTDs that are efficient, appropriate, and affordable for use in developing countries and low-resource settings by taking into account these crucial factors and collaborating closely with local stakeholders.

While the broad context of use is important, it is crucial to situate the use context locally in specific regions and countries for several reasons. First, designing diagnostic devices cannot be done in isolation (Saidi & Douglas, 2022). Second, stakeholders required for co-creation should be situated locally within a region or country (Aranda Jan et al., 2016; Coulentianos et al., 2020). Third, there is a need to demonstrate proof of concept within a locality first before the diagnostic device can be adopted by other countries or regions (Coulentianos et al., 2022). Lastly, for NTDs, choosing the sub-Saharan region in Africa is important due to the disproportionate burden of NTDs within this region (Aranda Jan et al., 2016; Aula et al., 2021).

Sub-Saharan Africa is a large landmass compromising of several countries with different cultures, social, political and environmental characteristics giving rise to multiple contexts of use. This research will focus on the Nigerian context, which has one of the largest disease burdens of schistosomiasis and lymphatic filariasis (LF) in the world (Cano et al., 2014; Ezeh et al., 2019; Federal Ministry of Health, 2023; Fimbo et al., 2020). The country currently has a policy targeting the reduction of its schistosomiasis and LF burden (Federal Ministry of Health, 2023). However, there are currently gaps and constraints within this system (Onasanya et al., 2020; Van et al., 2020) allowing the newly developed diagnostic devices to fill this need.

1.4. GENERAL OBJECTIVE AND RESEARCH QUESTIONS

The main objective of this thesis is to investigate how smart optical diagnostics for NTDs can be created for endemic countries by integrating local experience and knowledge leading to local system uptake.
It specifically addresses the following research questions:

1. What is the social and healthcare context as regards NTD diagnosis?
2. What are the opportunities, constraints, and dynamics within the social and healthcare context?
3. Who are the key stakeholders within this context, why are they important, and how do they interact?
4. What are the context-specific product specifications for the device?
5. In what ways can the designed product be used in this context?
6. How can we develop an adoption plan for the diagnostic device?

1.5. RESEARCH APPROACH, METHODS AND RELEVANCE

Based on the research questions and objectives, this research uses a systemic design method as the best approach to the thesis. Systemic design is a method that incorporates elements of systems thinking with human-centred and social-centred design to address complex problems (Battistoni et al., 2019). Systemic design is focused on 5 pillars: human-centeredness, gathering stakeholders, dialogue, iterative inquiry and multiple design actions over time (Battistoni et al., 2019; Jones, 2014). Systemic design ‘builds on the analytical strengths of systems thinking and the action-oriented strengths of design’ (Bijl-Brouwer & Malcolm, 2020).

At the research context level, an instrumental case study approach was used focusing on the Nigerian context. This allows an in-depth, multi-faceted exploration of complex issues in their real-life settings in other to gain a broader appreciation (Aranda Jan et al., 2016; Cowan & Murdoch, 2006; Petkovic et al., 2020) of the NTD diagnostic landscape in Nigeria.

A mixed methods approach to data collection is taken. Qualitative methods used for data collection include key informant interviews, in-depth interviews, focus group discussions, expert recommendations, observations, and document analysis. Qualitative research methods offer a rich source of data that reveals the complexities and depths of what can be abstracted for stakeholder analysis. The quantitative aspect of the research was limited to the use of ranking product specification and implementation strategies using a Q-methodology tool. Q methodology is a semiquantitative technique used to study people’s viewpoints and examine how people think about a topic (Churruca et al., 2021). Q methodology is interactive and requires respondents to sort cards on a topic into an order of preference on a grid by considering decisions and choices between the statements (Alderson et al., 2018).

A mixed-method approach to data analysis was used in which all data are triangulated to give a clear picture of the context. Quantitative data analysis methods used include: approaches used include context mapping, thematic analysis and graphical Social Network Analysis (SNA). Quantitative data analysis focused on the use of descriptive and inferential statistics.

The output of this research is relevant at global and local levels both now and in the future. It is widely accepted that smart diagnostics have a role to play now and in the future of medicine. This research will contribute to a better understanding of the context of use leading to the creation of cheaper and more efficient devices that can reduce healthcare costs and disease morbidity in resource-limited settings.

At the global level, targets have been set to eliminate or reduce the burden of schistosomiasis and LF in both the Sustainable Development Goal 3 (SDG 3) and the roadmap for the elimination of Neglected Tropical Diseases. This involves a coordinated approach with treatment on a large scale with safe and effective drugs and at regular intervals. Since diagnosis is important for evaluating targets, this research will contribute to an understanding of the contextual factors affecting the elimination of parasitic NTDs in low-resource settings.

At the local level, in this case, Nigeria, the research will contribute insights into the context-specific problems regarding NTD control and elimination programme in Nigeria, and develop strategies which may be more applicable to disease elimination within the country. The research will contribute to an improved practice of co-creating with stakeholders in low-resource settings using a knowledge transfer model to reduce co-creation costs and redundancy. In addition, the process orientation in co-creation will contribute to increased stakeholder ownership of the diagnostic device being created leading to greater trust and more sustainable relationships between the different stakeholders involved.

The PhD research is situated within the NWO WOTRO INSPiRED (INclusive diagnoStics for Poverty RElated parasitic Diseases) project which aims to develop easy-to-operate smart optical diagnostics devices for parasitic diseases which are integrated (include sample preparation and diagnosis), inclusive (co-creation with relevant stakeholders), and thoroughly tested in the laboratory as well as field settings in endemic countries.

1.6. THESIS OUTLINE AND SUMMARY OF FINDINGS

The outcomes from this research in answer to the research questions is addressed in two parts as illustrated in Table 1.3. In Section1, Chapter 1 is the introduction to the thesis and gives an overview of NTDs, makes a case for designing for NTDs, situates the research within the systemic design framework, states the research approach, methods, rationale, objectives and research questions and gives a summary of the results. This is followed by chapter 2 where the main outcomes of the research based on the research questions are discussed. Chapter 3 includes a general discussion of the research implication, its implications, methodological considerations

and recommendations for future research and stakeholders. The second section shows publications from the research and starts with chapter 4 which examines the context of the use of NTD diagnostic devices in Nigeria with a particular focus on schistosomiasis. Chapter 5 assesses the NTD stakeholders' relationships and perspectives on new diagnostic devices for schistosomiasis in Nigeria. Chapter 6 investigates the co-creation method for developing TPPs for schistosomiasis diagnostic devices, identifies challenges with the available TPPs and recommendations for the TPP development process and content. Chapter 7 discusses the results of user testing of the designed diagnostic devices within the Nigerian context. Chapter 8 examines pathways to device adoption by identifying innovative use scenarios and recommendations for meeting NTD elimination plans beyond the current strategies.

Table 1.3. Thesis outline

Section 1: Main thesis
1. Introduction
2. Overall findings
3: Discussion
Section 2: Publications
4. The Stakeholder context *Publication 1: A Stakeholder Analysis of Schistosomiasis Diagnostic Landscape in South-West Nigeria: Insights for Diagnostics Co-creation.* *Publication 2: Improving Access to Diagnostics for Schistosomiasis Case Management in Oyo State, Nigeria: Barriers and Opportunities*
5. Stakeholder assessment *Publication 3: Social Network Analysis of the Schistosomiasis control program in two local government areas in Oyo State, Nigeria: Insights for NTD elimination plans* *Publication 4: Stakeholders' Perspectives on the Application of New Diagnostic Devices for Urinary Schistosomiasis in Oyo State, Nigeria: A Q-Methodology Approach*
6. Co-creating with stakeholders *Publication 5: Developing Inclusive Digital Health Diagnostic for Schistosomiasis: A Need For Guidance Via Target Product Profiles* *Publication 6: Target product profiles for devices to diagnose urinary schistosomiasis in Nigeria*
7. User research *Publication 7: Designing for Neglected Tropical Diseases: User Experience of a novel diagnostic device for multiple diseases* *Publication 8: A usability study of an innovative optical device for the diagnosis of schistosomiasis in Nigeria*
8. Towards an adoption plan for NTD digital diagnostics *Publication 9: Rethinking the Top-Down Approach to Schistosomiasis Control and Elimination in Sub-Saharan Africa* *Publication 10: Diagnostic Task shifting for NTDs: Outcome of a preliminary quasi-experimental study for microfilaria detection using a novel diagnostic device in Nigeria*
Section 3: Pictural overview of diagnostic devices
9. The Schistoscope device
10. The AiDx Device

Based on research outcomes, a summary of the research findings is itemized below to give insight into the overall thesis outcome. However, in-depth discussion of research outcomes and their implications can be found in chapters 4-8 of this thesis.

1. The social context in low-resource settings is broad and includes demographics, social norms, culture and socialization, social networks and structures, power, history, political, economic and environmental context.
2. The social context influences three interdependent and interrelated arenas: individual, community and institutions.
3. The social context affects the awareness, and interest in prevention, diagnosis and treatment; availability, accessibility, affordability, accommodation and acceptability of resources for NTD diagnosis and diagnostics usage at the individual, community and institutional levels.
4. The healthcare context exists within the social context and both interact and influence each other.
5. The healthcare context of NTD diagnosis is broad ranging from the micro at the patient level to the highest macro at the global level.
6. There are many different stakeholders within the healthcare context of NTD diagnosis with various interests and viewpoints including affected persons and communities, healthcare providers, Non-Governmental Organisations (NGOs), governments and international organisations including developmental partners.
7. Collaboration and coordination among stakeholders is important for resource allocation, alignment with national and international strategies and development of new diagnostics.
8. There is a lack of adequate diagnostic tools and laboratory infrastructure and a scarcity of skilled healthcare professionals which are limitations to meeting NTD elimination targets.
9. Stakeholders within the healthcare context are important for the development of product specifications and the design process.
10. Successful product specifications development for NTD diagnostic devices requires input from technical, regulatory, manufacturing and use context-based stakeholders.
11. Three different product use scenarios for NTD diagnostics identified within the Nigerian healthcare setting include screening programmes, monitoring and evaluation programmes and point-of-care testing.
12. Undertaking monitoring and evaluation of diagnostics in different use scenarios can help identify areas for improvement and ensure the diagnostics' long-term use and viability.
13. The adoption of NTD diagnostics in low-resource settings will require constant collaboration and co-creation with context-based stakeholders throughout the product development life cycle.

Chapter

2

OVERALL FINDINGS

This chapter discusses the thesis level findings for the systemic design process and evaluation of 2 NTD digital diagnostic devices in a low-resource setting. The overall findings will address each research question theme based on the practicalities observed from this research.

2.1. THE SOCIAL AND HEALTHCARE CONTEXT OF NTD DIAGNOSIS

Neglected Tropical Diseases (NTDs) are a group of infections that affect about 2 billion people worldwide, with the majority of cases occurring in low-income African, Asian, and Latin American countries (Engels & Zhou, 2020). In Africa where NTDs are dominant, the social and healthcare context wherein NTD diagnosis takes place is complex and multidimensional.

The term “social context” is by consequence broad, and covers a variety of domains that affect both individual and group experiences and behaviour. These include demographics, social norms, culture and socialization, social networks and structures, power, history, political, economic and environmental context influencing three interdependent and interrelated units: individual, community and institutions (Burke et al., 2009; Cowan & Murdoch, 2006).

The social context of NTD diagnosis is broad and ranges from the micro at the patient level to the highest macro at the global level. The social context affects the awareness, and interest in prevention, diagnosis and treatment; availability, accessibility, affordability, accommodation and acceptability (Van et al., 2020) of resources (human, infrastructural and material) at the individual, community and institutional levels.
The healthcare context exists within the social context and both interact and influence each other (Braveman & Gottlieb, 2014). Studying the healthcare context of NTD diagnosis in Africa shows that a lack of adequate diagnostic tools and laboratory infrastructure, as well as a scarcity of skilled healthcare professionals, are limiting factors to meeting NTD elimination targets. (Adenowo et al., 2015; Aula et al., 2021; Davies et al., 2017; Petti et al., 2006; Tchuem Tchuenté et al., 2017).

2.2. THE EFFECT OF THE SOCIAL AND HEALTHCARE CONTEXTUAL DYNAMICS ON NTD DIAGNOSIS

The social and healthcare dynamics surrounding NTD diagnosis is complex, and it differs depending on region and disease. Table 2.1 below shows how the social context at the micro, meso and macro levels affects the awareness, interest, availability, accessibility, affordability, accommodation and acceptability of healthcare, NTD diagnosis and diagnostics usage (Onasanya et al., 2020; Van et al., 2020).

Table 2.1. Mapping the context of diagnostic gaps for NTDs

Social context level	Key actor	Social context theme	Diagnostic gap
Micro 1	Patient	Self (beliefs), social norms, socialization, environment, economic	Awareness, interest, availability, accessibility, affordability, accommodation, acceptability
Micro 2	Community members	Culture, social norms, socialization, environment, social structure, history, resources	Awareness, interest, availability, accessibility, affordability, accommodation acceptability
	Primary health care officers	Resources (material, infrastructural, human), power, environment	Awareness (disease), interest, availability, accommodation acceptability
Meso 1	Local government: NTD officer, DSNO, MOH	Power, politics, economics, Resources (material, infrastructural, human), social network and structure (healthcare and governance)	Interest, availability, accessibility
Meso 2	State government: State NTD officer, State DSNO, Commissioner for Health, governor	Power, politics, economics, resources, social network and structure (healthcare and governance)	Interest, availability, affordability
	Secondary and tertiary healthcare workers	Structure (healthcare)	Interest
Macro 1	Federal Government: National NTD officer, National DSNO, NCDC, Minister for Health	Politics, power, economics, resources, social network and structure (governance)	Interest, availability, affordability
Macro 2	Global: International NGOs, other developmental partners, WHO, funders	Economic, power and politics	Interest

For parasitic and helminthic NTDs, a general lack of awareness about these diseases including symptoms and available treatment is predominant in prevalent areas resulting in misdiagnosis or a delay in diagnosis (Aula et al., 2021; Van et al., 2020). This lack of awareness affects patients, community members and healthcare workers (Wiegand et al., 2017). This is particularly common in rural, hard-to-reach and conflict-prone areas where healthcare may not be available based on environmental, political and economic factors.

At the micro level, the awareness of NTDs, beliefs about NTDs and the healthcare systems, cultural practices, interests, social norms, socialization, physical environment, social structure, history, available resources including economic activities and available finances (Banda et al., 2021; Dean et al., 2019; Engels & Zhou, 2020; Van et al., 2020) can affect access to healthcare and may conceal the true need for diagnostics for NTDs.

For instance, at the individual and community level, the stigma and discrimination linked to some NTDs (Anagbogu et al., 2022; Fimbo et al., 2020; Gouvras, 2018) is one of the social constraints to NTD diagnosis. This may cause delays in receiving diagnosis and treatment. Patients with female genital schistosomiasis, for instance, may be stigmatized by their communities, making access to medical care a challenge (Engels et al., 2020; Kukula et al., 2019). Persons with bloody urine may assume to have sexually transmitted diseases which is a source of stigma (King, 2018; Onasanya et al., 2020).

Within the healthcare system, there is a shortage of trained healthcare workers, limited access to diagnostic tools and medicines and inadequate healthcare infrastructure (Davies et al., 2017; Petti et al., 2006; Van et al., 2020). For instance, without specialized laboratory equipment, which might not be accessible and available in many rural areas or areas with challenging topography, diagnosing some NTDs may be difficult.

At the meso level, the power structure and interaction between meso 1 and 2 levels, availability of resources, accessibility to financing and support and affordability of preventative and treatment options for NTDs may affect the diagnosis of NTDs broadly. Increasing interest, availability, accessibility, and affordability of infrastructural resources like digital diagnostics can improve the diagnostic capabilities of healthcare workers for detecting NTDs. At the macro level, interest, availability and affordability are the main themes. Interest is a dominant theme because it sets digital diagnostics as an option for policy inclusion.

It is known that funding and political support for NTDs both locally within the healthcare and social context and in the global context is challenging (Dean et al., 2019; Onasanya et al., 2020). It can be difficult to obtain funding and political support because many NTDs affect the poorest and most marginalised communities (Banda et al., 2021) making these diseases literarily invisible to prominent stakeholders and actors within both the healthcare and social contexts.

2.3. STAKEHOLDER DYNAMICS FOR NTD DIAGNOSTICS DEVELOPMENT

NTD diagnosis involves a wide variety of stakeholders across different strata and sectors, including affected persons and communities, healthcare providers, Non-Governmental Organisations (NGOs), governments and international organisations including developmental partners (Onasanya et

al., 2020). This means that the stakeholder dynamics for diagnosing NTDs is intricate and involves a range of interests and perspectives.

Two significant stakeholders in the diagnosis of NTDs are the patients and the affected communities. They are involved in community-based approaches to NTD control and may provide insights into the sociocultural factors that influence NTD diagnosis (Onasanya et al., 2020; Van et al., 2020). Engaging patients and communities is important for ideating the needs for NTD diagnosis and NTD control programmes.

Medical professionals, such as doctors, nurses, and laboratory technicians, are also important stakeholders in the diagnosis of NTDs. They diagnose and treat patients with NTDs and are important for ideating new diagnostics for NTDs (Bengtson et al., 2022; Sluiter et al., 2020). However, particularly in remote or rural areas, it may be difficult to guarantee that these levels of healthcare professionals are available (Egan et al., 2017). There is a need to involve other healthcare stakeholders such as Community Health Extension Workers (CHEWs) in the diagnosis, use of diagnostics and treatment of NTDs (CDI study group, 2010; Egan et al., 2017; Onasanya et al., 2023).

NGOs play a significant role in the diagnosis of NTDs by engaging in community-based work promoting NTD awareness, supporting healthcare infrastructure, and offering diagnostic and therapeutic services (Onasanya et al., 2020). Additionally, they support greater political and financial support for NTD programmes by liaising with governments and other international developmental partners (Odoch et al., 2022; Ogongo et al., 2022; Onasanya et al., 2020). However, coordinating the efforts of various NGOs and aligning with national and international NTD control strategies is critical to NTD control. It is important to engage NGOs during the development of diagnostics for NTDs due to their strong networks with communities and the government.

Governments, both national and sub-national are crucial to NTD diagnostics acceptability because they formulate policies and allocate funds for NTD prevention and treatment initiatives. They also allocate health infrastructure, human resources and material resources that support disease management including NTD diagnosis (Onasanya et al., 2020; Van et al., 2020). While funding for NTD control programmes may be limited due to competing interests, political support for NTD programmes can vary by country and there is a need to ensure more visibility for NTD diagnosis (Onasanya et al., 2020). In addition, governments are needed for the development of new diagnostics for acceptability and incorporation into programmes and healthcare workflow.

The World Health Organization (WHO) and other developmental partners are important in NTD diagnosis. They coordinate global efforts to eradicate NTDs and offer technical support and direction for NTD control programmes (Ogongo et al., 2022; Onasanya et al., 2020). The priorities and strategies of international organisations are important and each country should situate such guidance within their context. These organizations also set the need for diagnostics through the development of Target Product Profiles (TPPs) and they can influence national governments in accepting new diagnostics.

Overall, there are many different stakeholders with various interests and viewpoints involved in the stakeholder dynamics of NTD diagnosis. Collaboration and coordination among stakeholders are important for resource allocation, alignment with national and international strategies and development of new diagnostics leading to effective NTD control programmes.

2.4. PRODUCT SPECIFICATIONS FOR NTD DIAGNOSTICS

The product specifications for NTD diagnostics depend on the specific disease being diagnosed and the use context including user profile. Product specifications can be broad-based and also context-based.

Broad-based specifications include technical, regulatory and business specifications. Technical specifications can be divided into 2: manufacturing and performance-based. Manufacturing specifications are related to product materials, electrical and machinery (Wang et al., 2023) needed to give the product a form and function while performance-based specification is related to functionality in action with particular specifications such as sensitivity, specificity and speed (Bengtson et al., 2022; Onasanya et al., 2023).

Regulatory specifications are related to the standards set by regulatory bodies such as the International Standards Organization (ISO) and other bodies such as the World Health Organisation (WHO) (International Organization for Standardization, 2016; WHO, 2021, 2022). These specifications are related to the technical specifications and can also address some context-based specifications such as cost.

Business-based specifications relate to financing and business use case comparing new diagnostics to current models of diagnosis. Manufacturing specifications have a strong influence on the business case for new diagnostics especially when funding for NTDs is not a priority in most endemic countries (Diehl et al., 2020).

Context-based specifications are associated with contextual factors that may affect user experience, usability and acceptability within the context of

use (Onasanya et al., 2023). The contextual factors include social, economic, political, and environmental factors the and availability of human, material and infrastructural resources, Context-based specifications can influence manufacturing and business specifications. For instance, diagnostics for NTDs should be easily used by the lowest level of health worker which is the Community Health Extension worker in the Nigerian context (Egan et al., 2017). This means these devices should have a simple interface, require few steps to complete tasks and output should be easy to interpret. In the Nigerian context also, electricity supply is irregular giving the rise to need for diagnostics that either do not need electricity, can store electricity or can use alternative sources of power for functioning. Other contextual specifications that need to be taken into cognizance include the effect of weight, size, dust, temperature and humidity on the manufacturing specifications and performance specifications.

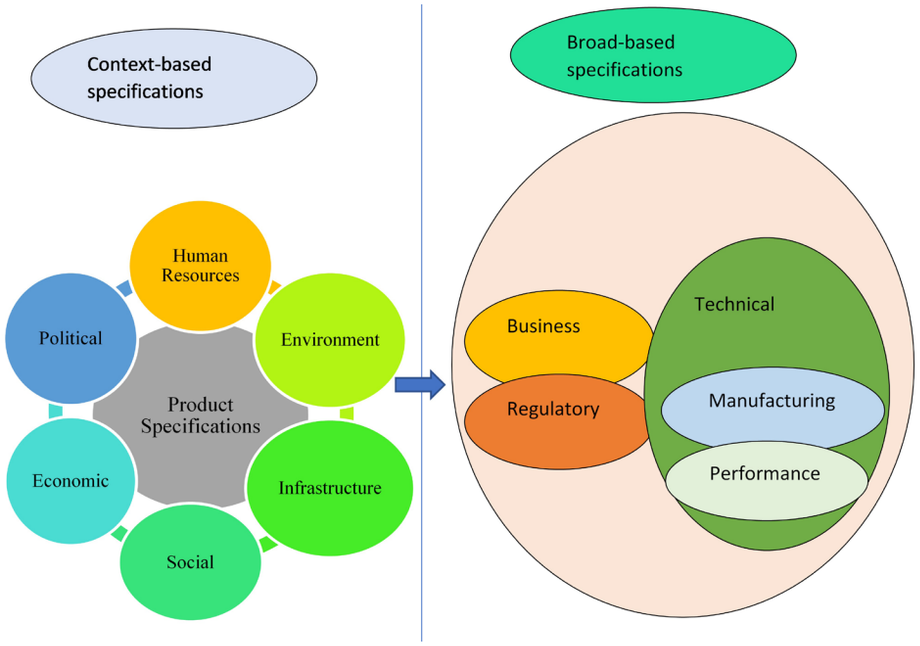

Figure 2.1. Relationship between broad-based and context-based specification

In general, product requirements for NTD diagnosis in limited resource settings should take into account the unique needs and difficulties of the region, including contextual factors especially environmental and economic and available resources (human, infrastructure and material) beyond performance metrics.

2.5. USE SCENARIOS FOR DESIGNED PRODUCTS

There are different product use scenarios for NTD diagnostics depending on the specific disease being diagnosed and the use context. Product use scenario planning requires a study of the WHO agenda for NTD control and its alignment with country-based social and healthcare contextual factors including available resources (Hoekstra et al., 2021; World Health Organization, 2020a). In the Nigerian context, 3 potential use scenarios for new NTD diagnostics: screening programmes, monitoring and evaluation and point-of-care testing (Sluiter et al., 2020).

Screening programs may use newly developed NTD diagnostic tests in large populations, especially in endemic regions. These programmes which are either community-based or school-based can involve NGOs and other stakeholders in collaboration with the government as part of mapping activities and needs assessment.

Monitoring and Evaluation (M&E) programmes may need new diagnostic tests to evaluate the success of NTD prevention programs. Digital diagnostic devices can be used to track and map the prevalence rates in a population or the outcomes of Mass Drug Administration (MDA) programs.

Point-of-care testing is important in the case management of NTDs at the primary level of care. This is especially important for remote or resource-limited settings where access to laboratory infrastructure is constrained (Petti et al., 2006).

2.6. ADOPTING NEW DIAGNOSTICS IN LOW-RESOURCE SETTINGS

A multifaceted strategy involving cooperation between stakeholders at various levels can positively affect the adoption of NTD diagnostics in low-resource settings. The following are some possible strategies to best ensure device adoption:

1. Engaging local stakeholders and communities early before and during the product development cycle is critical to fostering an understanding of the value of new NTD diagnostics (Onasanya et al., 2020). Engaging the community can help identify regional needs and concerns as well as raise awareness of NTDs and new diagnostic devices.
2. Encouraging collaboration between national and sub-national governments, non-governmental organisations, research institutions, and the private sector can reduce challenges with NTD diagnosis, and ideate potential use scenarios for new NTD diagnostics (Onasanya et al., 2023). Utilizing available resources and expertise can lead to the development of diagnostic tests that are contextually fit, useful and acceptable leading to an uptake in the local context.

3. Providing adequate training and support to healthcare workers on diagnostic techniques, result interpretation, and device integration into the current healthcare systems workstream. This increases disease awareness and gives rise to an opportunity for the introduction of new diagnostics (Bengtson et al., 2022; Onasanya et al., 2023).
4. Addressing regulatory and policy barriers early by collaboration with national regulatory authorities before device development and at different times during the product development cycle (Agbana & Onasanya, 2021) can aid country-level adoption.
5. Undertaking multiple proof of concept studies under different use scenarios in partnership with NGOs and the government for legitimacy(Agbana & Onasanya, 2021; Meulah, Oyibo, et al., 2022) is important to testing contextual fit.
6. Undertaking monitoring and evaluation of diagnostics used during implementation in different use scenarios can help identify areas for improvement and ensure the diagnostics' long-term use and viability (Onasanya et al., 2023).

Chapter

3

DISCUSSION

This chapter discusses the practical and experiential implications of the thesis's main findings, methodological considerations for the social network analysis and recommendations for NTD stakeholders and future research.

3.1 MAIN DISCUSSION

This thesis provides an answer to the main enquiry that guided the investigation for this thesis: how can smart optical diagnostics for NTDs be created for endemic countries by integrating local experience and knowledge leading to local system uptake? It uses a systemic design approach in assessing the stakeholder context for NTDs, evaluating stakeholder relationships, co-creating product specifications with stakeholders, evaluating user experience with end-users and planning towards NTD diagnostics adoption.

3.1.1 The stakeholder context for NTDs

A stakeholder is an entity (person or organization) with interest and/or connection to an organization, project or programme, and can influence or be influenced by it (Dwivedi, 2021; Reed et al., 2009). Stakeholders are crucial to the design process for NTD diagnostics because they represent the diverse viewpoints and interests that have an impact (Dwivedi, 2021) on the device design, device design process and use context. They can make significant contributions to the design's objectives and goals while identifying constraints, and ensuring that the final design meets the criteria of all relevant parties (Dwivedi, 2021; Freeman, 1984). Involving stakeholders in the design process can also help to increase project support and ensure that the final design is accepted and adopted (Neil, 2009; Petkovic et al., 2020).

Various types of stakeholders may participate in the design process for NTD diagnostic devices. They include:

1. End users: They are stakeholders for whom the service or product is being built. They can offer insightful feedback on the usability, user experience, and design needs. In the context of healthcare, they can include community members, and healthcare workers (Onasanya et al., 2020; Van et al., 2020).
2. Subject matter experts: These are stakeholders with in-depth knowledge or experience about the project. They can offer insightful opinions on the design's technical needs and limitations(Agbana & Onasanya, 2021; Sluiter et al., 2020). They include engineering teams, medical experts, policy experts and design experts etc.
3. Business/funding stakeholders: These stakeholders contribute significantly to the design process' budget, project schedule and timeline, and return on investment (van Limburg et al., 2015). They can also be involved in buying the end product for use in healthcare systems.
4. Regulatory stakeholders: They offer insightful guidance on the restrictions and design needs relating to accessibility, safety, and environmental effects (International Organization for Standardization, 2016; WHO, 2022). They include the International Standardization Organization (ISO), World Health Organization (WHO).

5. Suppliers and other partners: They are involved in the development and supply of materials, device parts or services. They can offer insightful commentary on the design specifications and limitations pertaining to materials, procedures, and logistics. These include biomedical engineers and manufacturing companies (Coulentianos et al., 2019, 2020, 2022).
6. Policy and governance stakeholders: These stakeholders are involved in the needs assessment for the healthcare system globally or locally. For NTDs, they are involved in the development and implementation of policies. They are critical to setting the agenda for diagnostics development including diagnostics need assessment and use case (Onasanya et al., 2020). These include National and sub-national government representatives involved in NTDs, Local and International Non-Governmental Organizations (NGOs) and developmental partners such as WHO.

While there are many different stakeholders, not all of them need to be involved in every stage of the design process, and the level of their involvement may vary depending on the specific needs and the design process's stage (Coulentianos et al., 2020; Leviton & Melichar, 2016). However, all relevant stakeholders must be considered, and their participation in the design process must be maximised to ensure eventual device adoption.

The term "stakeholder context" refers to the settings and circumstances in which stakeholders (people or organisations) operate (Chamorro-Koc et al., 2004; Cowan & Murdoch, 2006). It includes specific traits that define a given person, group, community or society. The term is broad and it involves several interrelated factors including structural and situational contextual factors, such as culture, norms, beliefs, education and resources among others, all of which interact concurrently (Adedokun et al., 2017; Gjestsen et al., 2017; Sabot et al., 2018). Understanding the larger context is critical to ensuring that stakeholder engagement efforts are relevant, build on previous experience, are responsive to stakeholder needs and sensitivities, and do not duplicate other activities (Neil, 2009; Petkovic et al., 2020).

3.1.2. Evaluating stakeholder relationships

The process of evaluating the people or groups who are impacted by a project, programme, or organisation is known as stakeholder assessment (Neil, 2009; Reed et al., 2009). Typically, this process entails identifying stakeholders, evaluating each stakeholder's interests, needs, and expectations, and determining how the project or programme will affect them(Gjestsen et al., 2017; Leviton & Melichar, 2016).

Stakeholder assessment is a crucial component of project management and strategic planning for diagnostics development because it enables the

leadership team to find potential opportunities and risks, gather support for their initiatives, and interact meaningfully with stakeholders (Franco-Trigo et al., 2020; Leviton & Melichar, 2016; Neil, 2009; Reed et al., 2009). This means the diagnostic development team can accomplish their objectives by adjusting their activities, plans and communication in line with their stakeholders' needs and expectations. Assessing stakeholder relationships is critical to evaluate the positional and relational dynamics relationships between stakeholders within the local context of use, and their viewpoints on novel diagnostics, product features, and disease elimination pathways.

There are several ways of assessing stakeholders depending on project needs and stakeholder contextual factors. These include power-interest matrices, Q-methodology, social network analysis etc (Masefield et al., 2021; Mitchell et al., 1997; Reed et al., 2009). In the context of this research, stakeholders were identified using various methods (Onasanya et al., 2020). Thereafter, the assessment of the power and interest of each stakeholder was mapped based on the transcript from interviews and observational data. Further assessment was carried out using Social Network Analysis (SNA) to understand the dynamics of stakeholder relationships.

Social network analysis is a technique for identifying and elucidating the connections among various stakeholders in a project, programme or organisation (Valente, 2010). It can be used to identify important stakeholders for diagnostic device design, evaluate the stakeholder network's power dynamics, and identify possible gatekeepers and influencers (Valente et al., 2015). It can also help the design management team to identify potential communication channels and find ways for the stakeholder group to cooperate or communicate (Celik, 2018; De Brún & McAuliffe, 2018). SNA aids in understanding stakeholder group dynamics and the potential consequences of actions and decisions on various stakeholders, detecting potential conflicts and opportunities for cooperation, and developing a strategy for engaging with stakeholders based on the analysis (Muthathi et al., 2021; Purington et al., 2020; Smit et al., 2020; Valente et al., 2015). The result of the SNA for the stakeholder network involved in the NTD diagnostic device design showed gaps within the NTD network in Oyo state, Nigeria. National and sub-national policy and governance stakeholders were dominant. Other actors such as NGOs and the private healthcare sector had little or no role to play in NTD control (Onasanya, Engelen, et al., 2023).

Assessing stakeholders' perspectives is crucial to the design process for diagnostics because it offers insightful contributions to users' needs and preferences including practical considerations and project constraints (Samenjo et al., 2022). This contributes to a more inclusive and user-centred design, leading to stakeholder buy-in and project success. Additionally,

considering the perspectives of stakeholders can help identify potential issues or challenges early in the design process, facilitating more effective problem-solving and decision-making. One method of analysing stakeholder perspectives is the use of Q-methodology.

The Q-methodology is a type of discourse analysis that is grounded in the empirical analysis of stakeholder perceptions rather than theoretical perspectives. Discourse analysis reveals the various viewpoints and points of agreement among individuals, as well as how people think and discuss a topic (Churruca et al., 2021; Reed et al., 2009). Based on these shared perceptions and commonalities, the Q methodology is then used to classify people into 'social discourses. (Reed et al., 2009). The Q-methodology has been proposed as a method for studying priorities and setting priorities in healthcare (Alderson et al., 2018; Churruca et al., 2021).

In this project, Q methodology was used to assess stakeholder viewpoints on the use case, infrastructure, product requirements and rollout strategy for a newly developed diagnostic device for diagnosing schistosomiasis. The outcomes showed that stakeholders formed a consensus on 4 ideas. First, new diagnostic tools for NTDs should be developed for use in remote settings. Second, diagnostic tools or devices should fit within local settings with minimal infrastructural support. Third, new diagnostic devices should be cost-effective. Finally, diagnostic devices should be used to identify and confirm schistosomiasis infection status before treatment (Samenjo et al., 2022).

3.1.3. Co-creating product specifications and target product profiles

Co-creation is the process of integrating resources through interactions and activities with collaborators to achieve mutual benefits (Frow et al., 2016; Peng et al., 2022). It can be used to create or improve products, services and systems (Sanders & Stappers, 2008). Co-creation is crucial to the NTD diagnostic design process because it enables active involvement and input from all stakeholders, including end users resulting in creativity, innovation, user-centred designs, user acceptance and adoption (Fusco et al., 2023; Greenhalgh et al., 2016; Peng et al., 2022). Additionally, co-creation can help identify potential issues or problems early, leading to more effective and efficient design choices and less resource waste.

Co-creation can be used either as a method of creating new ideas with stakeholders or as a process of continuous engagement with stakeholders (Fusco et al., 2023; Laurisz et al., 2023; Sanders & Stappers, 2008). In the context of this project on digital diagnostics for NTDs, co-creation is seen as a process involving the overall interaction and activities with stakeholders throughout the project lifecycle.

Co-creating product specifications with stakeholders is a continuous process that requires open dialogue, attentive listening and a readiness to modify and revise prototypes based on feedback (Laurisz et al., 2023; Mandolfo et al., 2020). Involving and engaging stakeholders in the product development process is crucial in meeting user needs. Co-creating product specifications with stakeholders require stakeholder identification, stakeholder assessment and engagement and iterative stakeholder interaction with prototypes until a consensus on product specification is achieved.

Technical product specifications provide a detailed description of the goal, functionality, features, and behaviour of a product (Sluiter et al., 2020; WHO, 2022). They play a crucial role in the design process because they specify the requirements that the product must meet to be successful. They usually contain details about the materials, dimensions, weight, performance requirements, and any other pertinent information required for the creation of the product (International Organization for Standardization, 2016; Saidi & Douglas, 2022). Product specifications are used to make sure that the product satisfies both the manufacturer's, regulatory and the end-users' requirements (WHO, 2017). They also act as a point of reference for quality assurance during production.

Creating product specifications for neglected tropical diseases is part of a range of tools to support the development of improved diagnostic devices. Guidelines for the development of product specifications for neglected tropical diseases have been developed by research groups and organizations in the form of Target Product Profiles (TPPs) (Cocco et al., 2020; Donadeu et al., 2017; Fongwen et al., 2022; PATH, 2015; Sluiter et al., 2020; World Health Organization, 2023). Besides, the World Health Organization (WHO) established the Diagnostic Technical Advisory Group (DTAG) to support the development of diagnostics and is in a position to establish product profiles targeted at specific NTDs.

Target Product Profiles (TPP) are documents that outline the qualities of a novel product to meet an unmet clinical need (Cocco et al., 2020). TPPs are different from product specifications because they outline the need, performance metrics and context the of use of new products in addition to technical requirements (WHO, 2022). TPPs are broadly used to match the development team's objectives with those of the market and regulatory bodies. There are several steps involved in developing TPP involves determining product goals, product features, target audience, performance objectives and context of use. These are assessed by a 3-step process involving scoping reviews, drafting new requirements and consensus building with stakeholders (Cocco et al., 2020; WHO, 2021). TPPs are not permanent and can be updated as new information becomes available.

3.1.4. User Scenario Testing

A user scenario is a thorough description of the user in relation to the product (goods, services or systems) within a particular context (Chamorro-Koc et al., 2004). It describes the steps and actions a user will take to accomplish a particular task or reach a particular goal (Center for Devices and Radiological Health, 2016; Russ & Saleem, 2018). To understand the user's perspective on digital diagnostics for NTDs, designers, developers, and stakeholders can use user scenarios to identify potential issues or areas for improvement. In user-centred design and usability testing, user scenarios are frequently used to guide the development process and ensure that the final product meets the needs of the intended users.

User testing involves having actual users interact with a system, product, or service and provide feedback to evaluate it. User testing aims to find usability problems, collect user experience feedback, and gather information on how users interact with the product (Chamorro-Koc et al., 2004; Zarour & Alharbi, 2017). User testing can take place at various stages of the development process and can be done in a variety of ways, including in-person testing, remote testing, or online surveys (Russ & Saleem, 2018). There are different types of user testing methods including usability testing, A/B testing, user acceptance testing, field testing and surveys (Bailey et al., 2009; Center for Devices and Radiological Health, 2016; International Organization for Standardization, 2016). Depending on the product or service being tested, user testing can also be conducted by various user types, including experts or representative users.

In the context of this project, user scenarios were developed based on stakeholder interviews, observation and validation. The outcome indicates 3 scenarios for NTD diagnostic device use: screening programmes, Monitoring and evaluation programmes and point-of-care testing (Sluiter et al., 2020). The outcome of the user testing on laboratory technicians, scientists and Community Health Extension Workers (CHEWS) shows that the devices were easy to use and acceptable to these groups of stakeholders (Agbana & Onasanya, 2021; Bengtson et al., 2022; Onasanya et al., 2023).

3.1.5. Adopting NTD diagnostics in low resource settings

The process of adopting new diagnostic devices varies depending on the type of device and the healthcare context in which it will be used. The process involves several stakeholders and typically entails several steps including research and evaluation, training and education, implementation and integration, monitoring and evaluation, support and maintenance, device evaluation and improvement and scale-up (table 6.1).

Table 3.1. Stakeholders' Involvement in the adoption stage

	Adoption stage	Stakeholder						
		End user	Healthcare manager (hospital-based)	Healthcare manager (system-based)	Developer	Financing	Regulatory	Policy
1	Research, development and evaluation	√	√	√	√	√	√	√
2	Education and training	√	√	√	√			√
3	Implementation and integration	√	√	√	√			√
4	Monitoring and evaluation	√	√	√	√			√
5	Support and maintenance	√	√	√	√	√		√
6	Device evaluation and improvement	√	√	√	√	√		√
7	Scale-up			√	√	√		√

Digital diagnostics adoption for NTDs requires an understanding of context and contextual factors at all adoption stages. The context refers to both social systems and characteristics of the environment in which an intervention will be delivered. This context is broad and it involves an awareness of an interplay of contextual factors affecting the use context, workplace culture, openness to innovation, information-sharing practices, medical products contracting, and policies among other factors, beyond the intrinsic value of the product (Aranda Jan et al., 2016; Cowan & Murdoch, 2006; Gjestsen et al., 2017; Mielke et al., 2022). In addition, it is important to note that the adoption process including scale-up of use is complex, nonlinear and often political and iterative (Ben Charif et al., 2022; Franco-Trigo et al., 2020; Shaw et al., 2018).

Understanding the context and contextual factors is important in designing an adoption process for digital diagnostics for NTDs in developing countries for several reasons. First, resources are scarce in many developing countries and healthcare managers may have to determine needs based on available resources (Oleribe et al., 2019; Peabody et al., 2006). Second, infrastructural support, for instance, power supply, may be unavailable or inconsistent in some of these contexts (Oleribe et al., 2019). Third, political instability may affect adoption and scale-up (Mhazo & Maponga, 2022; Odoch et al., 2022). Finally, cultural differences may affect how why and if a device will be adopted.

Therefore, it is important to conduct a thorough needs analysis to identify the unique difficulties within the developing context, understand product fit within the cultural context by involving culturally-aware stakeholders and undertake a cost and feasibility analysis including local production capacity, required infrastructure and available resources.

The diagnostic device and its implementation process both have a dynamic relationship with the context (Gjestsen et al., 2017; Li et al., 2018). At the research and evaluation stage, it is important to include an assessment of the perceived need for the innovation to be implemented, its potential compatibility with existing routines and an assessment of user expectations, apart from product technical-based metrics such as sensitivity and specificity (Ben Charif et al., 2022; Hinrichs-Krapels et al., 2022; Roback et al., 2007; Saidi & Douglas, 2022).

After the device has been assessed and found to be effective, the end-users must receive training on use, implementation and integration into their workflow in tandem with other supporting stakeholders such as biomedical engineers (Chamorro-Koc et al., 2004; Onasanya et al., 2023).

To ensure the device tool is being used correctly and product output it is accurate and trustworthy, it is critical to monitor and evaluate device usage and result output. Support and maintenance are critical and should be specified in the product-service contract (Hinrichs-Krapels et al., 2022; Saidi & Douglas, 2022).

Within the Sub-Saharan African context, helminthic NTD elimination requires a systemic design approach involving zooming in and out of the context of use, design process and diagnostic device design while managing and co-creating with stakeholders to ensure the development and adoption of newly developed digital diagnostic devices for NTDs.

3.2. METHODOLOGICAL CONSIDERATIONS

During the process of this research, various methods of data collection and analysis were used. These include observations, interviews (quantitative and qualitative), document analysis, Social Network Analysis (SNA) and Q-methodology. While most of these methods can and were validated before and during data collection, SNA results can only be validated after analysis is completed.

Validating the SNA result is critical to result in fidelity. Social network analysis alone cannot provide all the context or details surrounding the data. It has to be triangulated with information from select stakeholders and interpreted with other contextual data.

The social network analysis results and conclusions were discussed with two dominant stakeholders based on the result of the SNA. These stakeholders could oversee the entire system based on their multiplicity of roles, backgrounds, and occupations. These stakeholders serve as key players in multiple networks and can provide clarity on the reliability and coherence of the data and analysis findings.

3.2.1. Procedure and result

After analysis of the SNA data, the two stakeholders were approached with the graphical representation of the three networks including the key for deciphering the stakeholders. The result of the validation is discussed below.

Stakeholder 1 (Urban LGA)

Stakeholder 1 is a civil servant who was dominant in the contact, resource sharing and collaboration networks. Regarding their position, stakeholder 1 acknowledged his position across all three networks as correct. He attributed his prominence in these networks to his role and the multiplicity of duties he performed. In the contact and collaboration networks, he was one of the key linkages to other stakeholder clusters. In the resource-sharing network, he was the major contact point for resources to be shared.

Regarding network completeness, stakeholder 1 stated that the sociogram was complete and encompassed all stakeholders related to schistosomiasis control. He stated that all important stakeholders were mentioned. Regarding stakeholder contribution to NTDs, he stated that the private hospital/lab stakeholders contributed minimally to schistosomiasis control. In addition, the developmental partners were only relevant when invited for monitoring purposes.

Regarding the research conclusion, stakeholder 1 related the density of the networks to the incidence of schistosomiasis within the LGA. Since schistosomiases cases were few, the contact, collaboration and resource-sharing network data reflected the low incidence of the disease. He further mentioned that developmental partners like the WHO gave support and resources when the need arises.

Stakeholder 2 (State level/Rural LGA)

Stakeholder 2 is a civil servant at the state level who was dominant in the contact, resource sharing and collaboration networks. The stakeholder was the key actor in the rural LGA regarding NTDs before he was promoted to the state level. This means he has insights into both the rural LGA context and the state-level context.

Regarding their position, stakeholder 2 admitted that his position across all three networks was correct. Stakeholder 2 found his position across all three networks as usual based on his long civil service work history and his current position. At the state level, he was the major contact point for both the local government and national-level programmes.

Regarding network completeness, stakeholder 2 stated that the sociograms were generally very comprehensive. However, some stakeholders such as schools and community leaders were absent. He remarked that this absence may signify low priority assigned to these schistosomiasis stakeholders within this period because of the Covid-19 pandemic.

Regarding the research conclusion, stakeholder 2 commented on the density of the three networks as correct for both urban and rural LGAs. Based on his position and work history in the NTD programme, he believed that collaboration and contact density will vary based on NTD programmatic plans and policies. In addition, he believed that the resource-sharing network sparsity is linked to the limited resource availability due to competing healthcare priorities beyond only NTDs.

3.2.2. Discussion

In general, the reliability and coherence of the findings and the data collection were confirmed during the validation exercise. The outcome of the stakeholder's validation was valuable, and the majority of the network analysis's conclusions were confirmed. By combining the outcomes seen in the network graphs with their observations, the experts also offered some extra insights.

On the actors, roles, and relationships in general, the stakeholders were in consensus. The stakeholders confirmed the reliability of the results and were pleased with the overall accuracy by looking at their positions and relationships. One stakeholder mentioned the absence of schools and community leaders in the three networks while also suggesting the likely effect of the Covid-19 pandemic and competing priorities on connections with these stakeholders. Another stakeholder mentioned the absent collaboration with private sector stakeholders but did not elaborate on the reason for this absence.

The stakeholders acknowledged density concerns across the networks and particularly the resource-sharing network. Explanations for this varied, ranging from disease prevalence to limited resources and competing interests. By highlighting a few patterns, the stakeholders provided fresh perspectives on the research.

3.3. RESEARCH IMPLICATION

There are several implications of this research on NTD control and elimination, the development of new NTD diagnostics and health product development for low-resource settings.

First, a multifaceted strategy is needed to address the social and healthcare dynamics that influence NTD diagnosis in Africa. This entails raising public awareness and providing more information about NTDs, enhancing access to diagnostic tools and healthcare infrastructure, and funding the education of healthcare professionals and communities using a variety of methods (Dean et al., 2019; Engels & Zhou, 2020; Onasanya et al., 2020; World Health Organization, 2020a). Supporting NTD programmes also needs political commitment and funding, especially in the poorest and most marginalised communities.

Second, for NTD elimination control and elimination at both global and national levels, the development and use of diagnostic tools will have a significant impact on current efforts on disease control and improve health outcomes. In addition, early disease detection and treatment requires easy-to-use diagnostics devices that can fit into different use scenarios and are contextual fit for use. Digital diagnostics for NTDs are important as it supports both disease management and evaluation of NTD programmes by giving real-time data on NTDs.

Third, the specific disease being diagnosed, the environment in which the tests will be used, and the national NTD policies will all influence the product use scenarios for NTD diagnostics. Effective NTD diagnostic devices should be developed while taking into account the contextual factors influencing the needs of the populations being tested. In addition, these diagnostic devices use should be maximized to have the greatest impact on disease control and elimination programmes.

Fourth, for the development of new NTD diagnostics multidisciplinary and multi-sectoral collaboration is key. Health product development for low-resource settings requires a fine balance of innovation, technological progress, cost-effectiveness and contextual fit. Fostering country and contextual ownership and co-creating with stakeholders are strong determinants of acceptability. In addition, the possibilities for commercialization should be explored early and throughout the product development cycle.

Fifth, performance-based parameters are important but there is an increasing need for incorporating and factoring the effect of contextual factors on the user experience, usability and acceptability of new devices. For instance, the best-performing devices may be useless if they are not portable and

cannot be used by the lowest healthcare worker.

Finally, using the WHO TPP is a starting point for contextual factors but there is a need for developers to look beyond the TPP during product development.

In conclusion, ensuring the uptake of NTD diagnostics in low-resource settings requires an extensive and in-depth collaboration that includes interacting with communities, cultivating partnerships, creating user-friendly diagnostic devices, offering adequate training and support, addressing regulatory and policy barriers, and overseeing and evaluating implementation.

3.4 RECOMMENDATIONS FOR STAKEHOLDERS AND FUTURE RESEARCH

The outcome of this research shows that the successful design and adoption of new diagnostics for NTDs requires cross-cutting collaboration across different sub-contexts within the national context. In addition, the National NTD policy has revealed some gaps that need to be addressed. Recommendations for NTD stakeholders include:

1. Prioritize diagnosis at the sub-national level including local government by partnering with the private sector for support.
2. Encourage local governments to actively seek support from other sectors beyond funding from the national level.
3. Incorporate the private healthcare sector in the monitoring and evaluation of NTDs.
4. Utilize Community Health Extension Workers in the case management and surveillance for NTDs.

Based on the exploratory and contextualized research, it is important to implement similar research within other low-resource settings, especially within regions with high NTD endemicity. There is a need to validate the results of the Social Network Analysis (SNA) within other sub-national contexts in Nigeria and other high-endemic countries. There is also a need for operations research on the use of new NTD diagnostic devices within different use scenarios within the same and across different contexts and countries. Finally, it is important to conduct cost-effectiveness studies on the newly developed diagnostic tools.

SECTION 2

Publications

The second section showcases publications from the research. It begins with a publication on the context of the use of NTD diagnostic devices in Nigeria with a particular focus on schistosomiasis. Thereafter, other themes such NTD stakeholders' relationships and perspectives on new diagnostic devices, co-creation methods for developing TPPs for diagnostic devices, challenges with the available TPPs and recommendations for the TPP development process and content, user testing and pathways to device adoption are showcased in different chapters.

Chapter

4

THE STAKEHOLDER CONTEXT

In this chapter, two papers will highlight the stakeholder context where the Schistoscope device will be situated. The first paper explores the results of stakeholder identification, mapping and analysis to determine stakeholders important at every stage of the design cycle for the Schistoscope medical device in the Nigerian context. The second paper explores the results of the contextual mapping for diagnostic barriers and the potential of gaps and opportunities for new diagnostics for Schistosomiasis within the Nigerian context.

4.1. A STAKEHOLDER ANALYSIS OF SCHISTOSOMIASIS DIAGNOSTIC LANDSCAPE IN SOUTH-WEST NIGERIA: INSIGHTS FOR DIAGNOSTICS CO-CREATION.

Citation: Onasanya, A., Keshinro, M., Oladepo, O., Van Engelen, J., & Diehl, J. C. (2020). A Stakeholder Analysis of Schistosomiasis Diagnostic Landscape in South-West Nigeria: Insights for Diagnostics Co-creation. *Frontiers in public health,* 8, 564381.
https://doi.org/10.3389/fpubh.2020.564381

Abstract

Background: Schistosomiasis, one of the neglected tropical diseases, is a water-based parasitic disease of public health importance. Currently, tests for Schistosoma haematobium infection either demonstrate poor specificity, are expensive or too laborious for use in endemic countries, creating a need for more sensitive, cheaper, and easy to use devices for the diagnosis of schistosomiasis. To ensure engagement during the process of device development; and effective acceptance and use after the introduction of diagnostics devices for S. haematobium, there is a need to involve stakeholders with varying power, interest, and stakes in device co-creation, as well as those relevant for later use situation in the diagnostic landscape. The main goal of this study is to identify and analyze relevant stakeholders for co-creation using a power-interest matrix.

Materials and Methods: The study was based on an action research methodology using a case study approach. A contextual inquiry approach consisting of 2 stages: stakeholder identification and interview; and stakeholder analysis was used. The field part of the study was carried out in Oyo State, Nigeria using a multistage cluster purposive sampling technique based on the category of stakeholders to be interviewed predicated on the organizational structure within the state and communities. A mix of qualitative research techniques was used. Identified themes related to power and interest were mapped and analyzed.

Results: We identified 17 characteristics of stakeholders across 7 categories of stakeholders important for schistosomiasis diagnostics. Most of the stakeholders were important for both the co-creation and adoption phase of the device development for diagnostics. However, not all stakeholders were relevant to co-creation. Key Stakeholders relevant for diagnostics co-creation demonstrated significant social power, organization power, and legitimate power bases. Most of the stakeholders showed significant interest in the device to be created.

Discussion: The power and interest of these stakeholders reveal some insight into how each stakeholder may be engaged for both co-creation and device usage. The involvement of relevant actors who will also be important for co-creation and implementation, will simplify the engagement process for the critical stakeholders, increase the ability to manage the process, and increase diagnostic device acceptability.

Keywords: schistosomiasis, stakeholders, co-creation, diagnostics, power, interest

BACKGROUND

Schistosomiasis, one of the 20 Neglected Tropical Diseases (NTDs), is a water-based parasitic disease of public health importance. The disease, which currently affects over 250 million people, is endemic in Sub-Saharan Africa (1, 2). There are five different types of species causing schistosomiasis infection: Schistosoma haematobium affecting the urinary tract; Schistosoma mansoni, Schistosoma japonicum, Schistosoma intercalatum, and Schistosoma mekongi affecting the intestine. S. haematobium and S. mansoni infections are common in Africa (2, 3). Of these species, S. haematobium is the most prevalent parasite in Nigeria affecting an estimated 30 million people yearly (1, 4). S. haematobium infection is endemic in many rural and agrarian communities in Nigeria that interact with water through subsistence farming, fishing, washing activities, and water recreational activities (5, 6). The constant contact with water containing S. haematobium cercariae released from the Bulinus snail, which occurs regularly, often results in re-infection with the disease, and this impacts on the data on disease prevalence (1, 3–5). Since adult worms have been documented to live in humans for as long as 30 years, most long-term residents of endemic areas become infected or re-infected with schistosomes at some point in their life (7) leading to a vicious cycle within the communities. Besides, depending on the stage of the infection, a wide range of clinical symptoms may occur, many of which are hard to distinguish from several other diseases.

(5). However, it is a notable cause of morbidity with many infected persons experiencing hematuria, dysuria, bladder-wall pathology, and hydronephrosis (8). Although Nigeria has one of the largest schistosomiasis disease burdens in the world, currently, there is no accurate national data on the prevalence of the disease (1). While the country currently undertakes a large-scale deworming exercise of school-age children in endemic zones with praziquantel (9), addressing diagnosis among adults who are not covered by mass administration of praziquantel is a challenge to the disease control.

Nigeria currently tackles schistosomiasis through a 2-step approach: case management and a control program (1, 10). In the case management

approach, cases are diagnosed at the primary care level. For the control program, Nigeria has a schistosomiasis control program wherein school-aged children are given praziquantel for the treatment of schistosomiasis. Schistosomiasis is common among children with the highest intensity of infection found in children between ages 5 and 15 years (11), but it is also known that women and men carry a high risk of urinary schistosomiasis due to social and occupational activities such as farming and washing, especially in areas with poor water, and sanitation services (1). In this respect, there are concerns about missed diagnosis for several reasons. First, several persons do not pass bloody urine which is characteristic of the disease (12). Second, the current control program does not include adults in mass drug administration (1, 9) which means that several adults are likely to have schistosomiasis and are not being treated. Third, S. haematobium infection is mainly diagnosed currently using microscopy to detect parasite eggs in urine specimens which is not sensitive in detecting light infections of <50 eggs per 10 mls of urine (13), is labor-intensive, and sensitivity of diagnosis depends on the skill of the laboratory personnel (5, 6, 12). Also, egg excretion in urine varies daily and can be complicated by interaction between the host and the parasite (14). Other tests for detecting S. haematobium infection either demonstrate poor specificity, high cost, or painstaking logistics for use in endemic countries (6, 15). Besides, some of these tests are more useful during the elimination phase of the control which has not been reached by a large number of countries (16). As such, there is a need for more sensitive, cheaper, and easy to use devices for the diagnosis and control of schistosomiasis.

To address these issues, the project INSPiRED—Inclusive diagnoStics for Poverty RElated parasitic Diseases in Nigeria and Gabon, was initiated to explore ways to create a new device for the diagnostics of S. haematobium infection within the context of countries with a high disease burden such as Nigeria using a human-centered approach. The project aims to design easy to use, affordable, and reliable diagnostics devices which may deliver the most effective and efficient step toward schistosomiasis control, aligned with the country's model of care. The device to be co-created is a smart optical device for the diagnosis of schistosomiasis (17) which will be developed from a sustainability point of view and not a profit point of view (18, 19). We regard sustainability in the context of ecological, financial, and social consequences of the device to the society which is most visible through a continuous process of improvement exemplified by the co-creation process (20). The devices will eventually be locally manufactured using locally available materials and components. This will reduce the cost of production, reduce dependence on imports, will enable local and maintenance, and contribute to the economy of countries that are willing to adopt the device.
A crucial first step in the designing of the new device is the proper

understanding of the schistosomiasis diagnostics landscape in the context of use for several reasons. First, prompt, accurate, and timely diagnosis is important for schistosomiasis control. Since treatment with praziquantel is cheap and readily available, easy to use diagnostics appears to be critical to schistosomiasis control.

Second, a diagnostic device is only effective if it is designed for its context, and this context is complex and deserves an in-depth study. In this situation, several factors such as the people, process, technology, customer requirements, and innovation need to be addressed (21) through multi-stakeholder input at all stages of development, testing, evaluation, and advocacy for adoption. This implies that stakeholders need to give insight into the process and context-of-use of the technology, including device requirements and the innovation context. The alternative to this co-creation process is a top-down approach focusing on the technology itself which has been reported to have limited successful outcomes due to variation between contexts of use and the design context (22). Besides, the complexity of the context, in this case, the social and healthcare context, cannot be detected in detail from a distance. Since the social context is a critical influencer of the stakeholders' outlook, the stakeholders within this social context can be viewed as both static in terms of the operational arrangement of stakeholders (network structure); and dynamic in terms of stakeholder roles, interactions, flows, and interdependencies (23, 24) which have to be taken into consideration during co-creation. Since stakeholders also vary in background, power, interest, and stakes; the complexity of the stakeholder co-creation process must be effectively managed to achieve the expected outcome. Consequently, there is a need to understand how the actors or stakeholders in this context interact through both stakeholder identification, and understanding of the stakeholder network structure and dynamics. As such, it is important to involve stakeholders in the entire device development process.

Third, there is a multiplicity of stakeholders with this context. Initially influencing and involving them in designing the new diagnostic device seems to be a proper approach to co-creation (23–26). Co-creation has a large role to play in the generation of new knowledge and ideas, development of new insights into existing interventions, and concept development (27, 28). To ensure that diagnostic devices are useful in the context for which they are created, it is critical to involve end-users and other important stakeholders through the entire co-creation process. Such involvement will likely lead to increased uptake of the created product. It has been reported that stakeholders perceive a sense of ownership through active participation in the development of diagnostic devices leading to a more efficient solution to achieving positive societal changes (29). To co-create a robust solution,

there is a need to identify the stakeholders who are likely to interact with the product. Identification of stakeholders who are important for this process, and understanding their characteristics can help address the gaps and challenges that can impact on device development. Besides, the fact that stakeholders have different views on the problem of schistosomiasis diagnostics and differing solutions means that stakeholders will have different important insights to contribute (30). Although it appears that the government is the most visible stakeholder, it is important to note that other stakeholders such as health workers and patients can impact on the design and use of a diagnostic device for schistosomiasis.

After the stakeholder identification, it is important to analyze the stakeholders using key characteristics that are useful during the process and life cycle of device development. Stakeholder analysis is a process that defines aspects of a phenomenon affected by a decision or action, identifies individuals, groups, and organizations affected by or that can affect those parts of the phenomenon; and prioritizes these individuals and groups for involvement in the decision-making process (31). Stakeholder analysis is useful for assessing their knowledge about the schistosomiasis diagnosis as well as their interests and power. Consequently, our study aims to describe how to effectively identify, select, and analyze important stakeholders for co-creation, as well as identify potential stakeholders for the adoption and implementation of a schistosomiasis device for large scale use.

Although there exists a need to involve important stakeholders when addressing the schistosomiasis diagnostic landscape, there is little information on the required techniques to do so (30). Moreover, in the field of NTDs, it appears that there are no studies on the involvement of stakeholders in the co-creation of a device or the context for design specifically for S. haematobium, to the best of our knowledge. There are, however, several studies on NTDs that involve stakeholder analysis (32–38). For these studies, stakeholders are usually identified through purposive sampling (32–35, 37). Most of the studies involved stakeholders at the macro-level (32, 34, 37, 38) with a few studies involving stakeholders at the community level (33) or both (35). However, using purposive sampling alone for stakeholder identification means that some stakeholders who are not in the same network with the identifying stakeholders might be missed.

We also did not find any framework for stakeholder identification and analysis fully tailored for NTD research. Also, we did not find any guidelines or frameworks for the co-creation of diagnostic devices for schistosomiasis. In this paper, we will present a framework for stakeholder identification based on our understanding of the healthcare system and schistosomiasis context in Nigeria, and a contextual inquiry framework (39) used by Van

Woezik et al. (30). We will present the results of applying this framework to a stakeholder identification process during the process of co-creation of services, devices, and policy with stakeholders. We will also present our analysis of relevant stakeholders' power, interest, and stakes for device co-creation using a power-interest matrix. We will close the paper by discussing how such a strategy might help to identify relevant stakeholders within a specific field of study and to develop ways of engaging and co-creating with stakeholders based on the outcome of the analysis.

METHODS

The study used an action research methodology with Oyo State, Nigeria, as a case study. Qualitative data collected include key informant interviews, in-depth interviews, focus group discussions, expert recommendations, and document analysis. The qualitative method of data collection is rich and reveals the complexities and the depths of what can be abstracted for stakeholder analysis.

Research Approach

We used a contextual inquiry approach, similar to work done by Van Woezik et al. (30). This consists of 2 stages: stakeholder identification and interview; and stakeholder analysis using the qualitative data to create a power-interest matrix.

Stakeholder Identification

We defined a stakeholder as any person, group, or organization who should be or is involved in schistosomiasis diagnosis based on Freeman's definition of a stakeholder (39). The first stage of the process consists of 3 levels of inquiry using a mixed approach into the context of stakeholders important to the research (Figure 1).

1. Literature scan: First, we identified stakeholders based on the literature on NTD research (4, 40–42) as well as policy documents on schistosomiasis in Nigeria (9, 11).
2. Expert panel recommendation: After identifying stakeholders from literature, we involved 2 experienced experts from public health research and clinical medicine, respectively to validate and make suggestions on other stakeholders who were important to the diagnostic landscape in Nigeria.
3. Snowballing: We used a snowballing technique in which we asked all interviewed stakeholders to identify other stakeholders that might be important to schistosomiasis diagnosis in Nigeria.

The outcome of the first two steps of the contextual inquiry process led to the creation of stakeholder categories based on the conceptualization of the

demand and supply aspect of healthcare diagnostics for schistosomiasis using stakeholder characteristics (Table 1). The final list of interviewed stakeholders was validated through a 2-step process. First, all identified stakeholders were selected based on meeting at least 3 of the following criteria which were developed from the research question in Figure 1: (1) suggestion by experts and/or stakeholders, and/or literature (2) having a clear stake in schistosomiasis diagnostic landscape, and/or (3) being a potential end-user of the to-be-developed diagnostic device, and or (4) having a strong influence on the demand of the to-be-developed diagnostic device. Second, the generated list was finally reviewed by 2 experts from public health research and clinical medicine, respectively using a binary approach of Yes/No. The final stakeholder categories of stakeholders and a list of important stakeholders were agreed upon by all members of the team.

Study Setting and Sampling Approach

Based on stakeholder categories in Table 1, the field part of the study was carried out in Oyo State, South-West Nigeria. The state has a moderate prevalence of schistosomiasis infection (1, 4). For category 1–3 stakeholders, we used a multistage cluster purposive sampling technique. Two local government areas (LGA); urban and rural, respectively were selected based on ecological factors such as closeness to rivers which were known reservoirs of S. haematobium infection. One ward from each local government structure was also selected based on ecological factors. Based on information available from the local governments on recently treated schistosomiasis cases (category 1 stakeholder), we selected and interviewed category 2 and 3 stakeholders based on geographical proximity to the area of residence of category 1 stakeholders. Category 4–6 stakeholders were sampled using purposive sampling. The sample size is difficult to determine a priori because of the explorative nature of this research. However, our final sample size was considered sufficient when it met the following criteria: (1) a minimum of 30 interviewed stakeholders based on recommendations by Marshall et al.(43); (2) when theoretical saturation is reached by no new mention of stakeholders from the snowballing technique. A respondent was considered a good fit when he/she met the criteria in Table 1 and was validated by the 2-step process described earlier.

Stakeholder Interview and Analysis

We carried out qualitative (In-depth and Key informant) interviews and Focus Group Discussions (FGD) with stakeholders. The questions asked depends on the stakeholder background and experience. However, questions asked include normative ideas on S. haematobium infection, interaction with formal and informal health care, current diagnostic landscape, and diagnostic challenges and limitations. Consent was given before the interviews. Ethical approval for the study was obtained from the Ethical Review Committee of

the College of Medicine, University of Ibadan, Nigeria (NHREC/05/01/2008a). Interviews were transcribed and translated where applicable. Transcripts were reviewed by two researchers, entered into atlas.ti version 8.4 and coded using the deductive thematic analysis method. A researcher coded the interviews and created a coding manual. Two other researchers validated this.

All researchers within the team independently validated the identified themes related to power and interest. Power was defined as "the level of influence a stakeholder has in the diagnosis of S. haematobium infection" (30). The sources of power could include: political, economic, social, cultural, historical, and/or organizational factors (26, 44). The expression of these sources of power (power bases) includes reward, coercion, information, legitimate, expert, and referent which can be derived from political, economic, social, cultural, historical, and/or organizational factors (26, 44). Interest was defined as "value abstraction to the new diagnostic device for the diagnosis of S. haematobium infection" (45). Interests could either be "expressed" or "implied/ manifested" in direction and willingness-to-use magnitude (46).

Based on the results of the analysis, stakeholders were further categorized into four levels of analysis of stakeholders based on the four-level model of the healthcare system, which was adapted from Reid et al. (47). The themes were analyzed based on the level in which stakeholders fall into. Thereafter, stakeholders were ranked based on their power and interest, which were valued on a scale of 1–5, with 1 meaning low level and 5 meaning the highest level of power and interests, respectively similar to the ranking by Hyder et al. (48). The results of these analyzed stakeholders were mapped to identify stakeholders who were important to co-creation into players, context setters, crowds, and subjects (49).

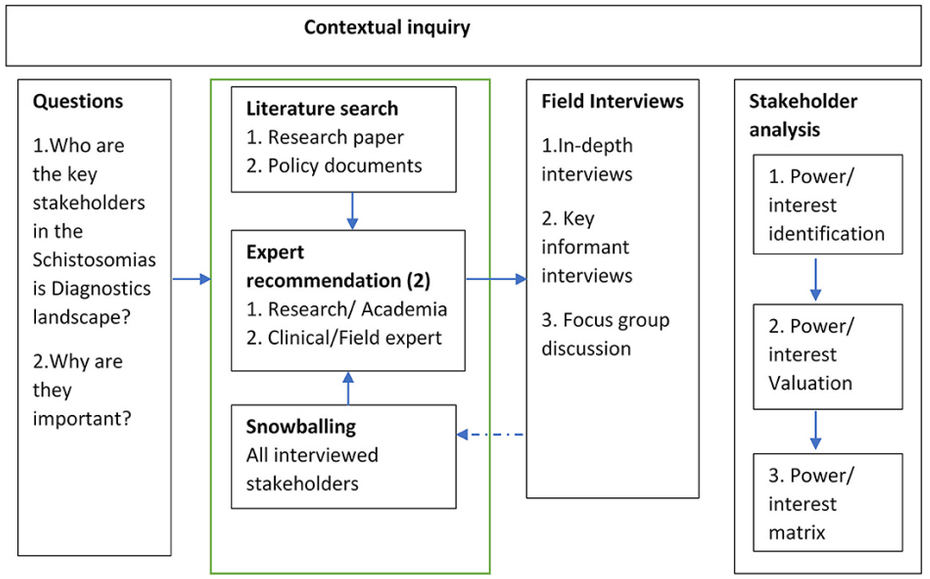

Figure 1. Process map of contextual inquiry into the schistosomiasis diagnostics landscape

Table 1. Stakeholder categorization for diagnostics co-creation.

Catergory	Characteristics
1.	Persons/parents of children who have been previously diagnosed and or treated for *S. haematobium* infection within the last 3 years.
2.	Stakeholders within the community that can impact the patient's decision to access care (diagnostics, and or treatment).
3.	Stakeholders within the formal health system (both public and private) who can diagnose and or treat patients with schistosomiasis.
4.	Stakeholders within the government who are in charge of programs/processes to identify, and or treat schistosomiasis.
5.	Stakeholders in Non-Governmental Organizations (NGOs) that contribute to schistosomiasis diagnosis, and or treatment within the state.
6.	Stakeholders in academia who are working in the Neglected Tropical Disease field.
7.	Stakeholders that finance diagnosis and or treatment of Neglected Tropical Diseases.

RESULTS

Stakeholder Characteristics

A total of 17 stakeholder characteristics were identified across the 7 categories (Table 2). This yielded a total of 36 stakeholders to be interviewed. Thirty-three stakeholders were interviewed. One stakeholder (religious body) was not interviewed based on the large variance in types and modes of operation of religious bodies, 2 other stakeholders (State Disease Surveillance and

Notification Officer (DSNO) and Federal NTD officer) were not available for interviews.

As can be seen from Table 2, the literature scan identified 6 stakeholder characteristics, 5 stakeholder characteristics were identified by experts and by snowballing, respectively.

Figure 2 has a breakdown of the number of stakeholders according to the location. Twenty stakeholders performed a singular role, 13 stakeholders performed 2 roles, while another 2 stakeholders performed 3 roles concurrently. At the local government level, the location of the community (rural or urban) did not significantly determine the multiplicity of roles.

Stakeholders' power and interest in schistosomiasis diagnostics were further analyzed by categorizing stakeholders into four levels which were adapted from Reid et al. (47). Based on this level of analysis (Figure 3), Stakeholder categories 1–2 falls within the micro-level or community level, stakeholders within category 3 fall into the health care level; stakeholders in category 4 fall within the organizational level. and category 5–7 stakeholders fall into policy/economic environment. Some stakeholders fall within 2 or more categories based on their multiple roles. Stakeholders relevant for diagnostics co-creation had significant social power, organization power, and legitimate power bases at each level of analysis. All stakeholders were influenced both by other stakeholders within their level and by the next level of stakeholder within the lower and higher concentric circle (Figure 3).

Table 2. Stakeholder characteristic and identification for co-creation.

Stakeholder category	Role	Method of identification	Number interviewed
1.	Parent/guardian of children with schistosomiasis	Literature review	5
2.	Community leader	Expert	1
	Patent Medicine Vendor (PMV)	Expert	1
	Traditional healer	Expert	1
	Community mobilizer	Snowballing	1
3.	Doctors	Literature review	1
	Community Health officers	Snowballing	1
	Laboratory scientist/Technician	Literature review	5
	Community Health Extension Workers (CHEW)	Literature review	2

Stakeholder category	Role	Method of identification	Number interviewed
4.	Primary health care (PHC) coordinator	Literature review	2
	NTD officer	Literature review	3
	Disease surveillance and notification Officer (DSNO)	Snowballing	2
	Teachers	Snowballing	2
5.	NGO	Literature review	1
	Community-based organization (CBO)	Expert	0
6.	Academia	Literature review	3
7.	Financing	Expert	1
*One interview was an FGD.			

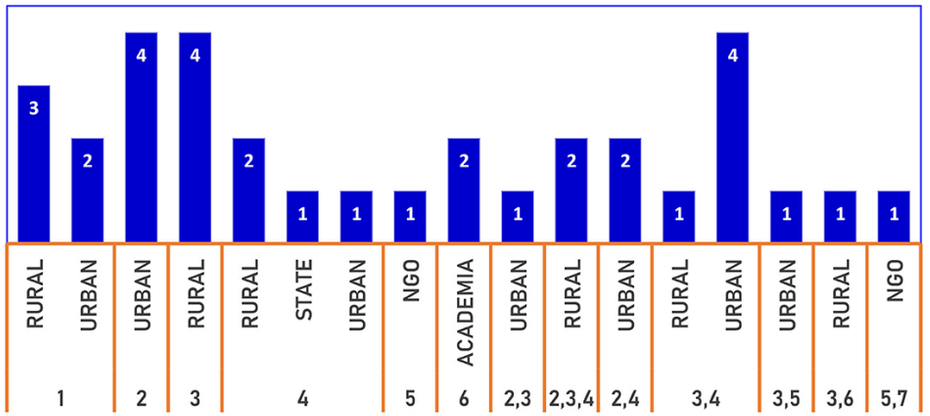

Figure 2. Stakeholder characteristics.

We also found stakeholders that were important for both co-creation and adoption of technology. Although the initial focus was on diagnostics co-creation, we were also able to identify some stakeholders from the interview transcripts who did not fall into the diagnostic co-creation categories but may be important for the adoption of the device based on the 2- step validation process for all stakeholders. However, these do not show the complete extent of stakeholders for adoption and implementation (Table 3).

Table 3. Stakeholder characteristics and stage of device lifecycle.

Characteristics	Stage of the Device development lifecycle
Parent/guardian of children with schistosomiasis	Implementation/adoption
Community members	Co-creation and Implementation/adoption
Community leader	Co-creation and Implementation/adoption
Patent Medicine Vendor (PMV)	-
Traditional healer	-
Market associations	Implementation/adoption
Community health committee	Implementation/adoption
Community mobilizer	Co-creation and Implementation/adoption
Doctors	Co-creation and Implementation/adoption
Community Health officers	Co-creation and Implementation/adoption
Laboratory scientist/ Technician	Co-creation and Implementation/adoption
Community Health Extension Workers (CHEW)	Co-creation and Implementation/adoption
Primary health care (PHC) coordinator	Co-creation and Implementation/adoption
Primary health care board director	Implementation/adoption
NTD officer (State and LGA)	Co-creation and Implementation/adoption
Disease surveillance and notification Officer (DSNO) (State and LGA)	Co-creation and Implementation/adoption
Teachers	-
NGO	Co-creation and Implementation/adoption
Community-based organization (CBO)	Co-creation and Implementation/adoption
Academia	Co-creation and Implementation/adoption
Financing	Co-creation and Implementation/adoption
Biomedical Engineer	Co-creation and Implementation/adoption
National Center for Disease control	Implementation/adoption
Media	Implementation/adoption
Politicians	Implementation/adoption
Equipment suppliers	Implementation/adoption
Federal Ministry of Health	Co-creation and Implementation/adoption
World Health Organization	Co-creation and Implementation/adoption

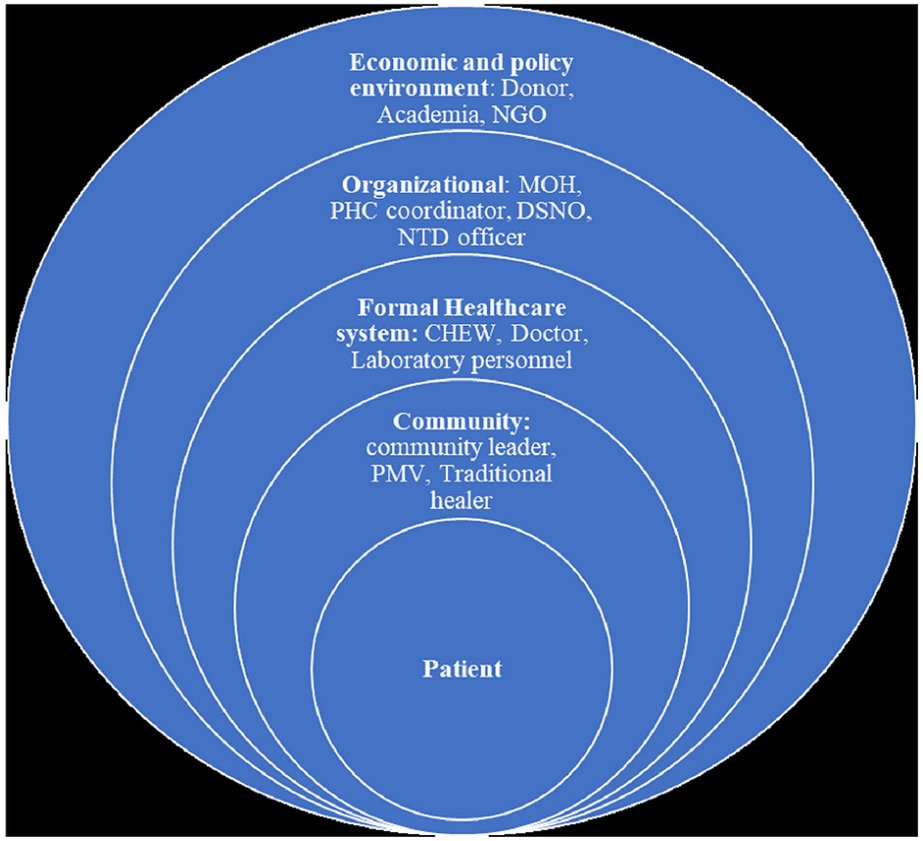

Figure 3. Stakeholder categorization within the health system.

Stakeholder Power/Influence Thematic Analysis

All the important stakeholders that were interviewed, demonstrated varying types and levels of power. A summary of this can be found in Table 4.

Community-Level Stakeholders

Community-level stakeholders demonstrated varying levels of power. These stakeholders consist of individuals: patient's parents/guardians, traditional healer, community leader, community mobilizer, and Patent Medicine Vendor (PMV), all embedded within the same community network.

Patient

All the patients or their guardians individually did not demonstrate any significant power. However, collectively, they have a great source of social power which determines the demand for healthcare. The decision to access healthcare was made based on either financial situation, social relationships,

trust and or ease of access to the formal health system (CHEW or Doctor) or other sources of healthcare (PMV, traditional healer). This social power is important to drive the use and demand for diagnostics. This power did not significantly differ between rural and urban areas. However, guardians in the urban areas were more likely to use a hospital as a first step than using other sources of treatment.

> *"Mummy (referring to community mobilizer) asked him to go to the hospital and she also informs his dad because she is closer to him, so they take him to the hospital and he was treated and they ensure that he is okay before he traveled."* Patient's guardian, male, urban area.

For rural areas, the patient was more likely to take some other steps, before accessing healthcare

> *"When that illness started with the child, he was running temperature and we gave him herbs but it was not effective. . . We gave him paracetamol and yet there was no difference, . . . later saw him urinate and sighted blood in his urine. . . We waited for our husband to come back. When he comes back he took him to daddy (referring to CHEW) at. . . we did not know about the disease, and he took care of it."* Patients' parent, female, rural area.

Traditional Healer

The traditional healer demonstrated some degree of power over patients seeking care. Power was based on cultural and social factors. A traditional healer could also demonstrate referent power by referring non-improving cases to the hospital.

> *". . . so I gave him traditional herbs, they are what we had previous knowledge of and when he drank it, he was cured." Apart from that one, he also brought his boss to me, we treated his boss with the same herbs we used to treat him. So when he was okay I told him to go for further treatment at the hospital and to check if you are totally cured'* Traditional healer, male, urban area.

The traditional healer also mentioned the patient's autonomy in seeking diagnosis and treatment

> *'People in those days (in the past) listen to advice but nowadays people do not take advice anymore'* Traditional healer, male, urban area.

Community Leader

The community leader demonstrates some form of legitimate power over

the community but this power is limited to giving advice. The inherent power source of the community leader may likely impact on power demonstrated as those with cultural/ historical power source may demonstrate more power.

> *"so when such a thing occur we normally advise the parents to carry such children to the hospital"* Community leader, male, urban area.

Community Mobilizer

The community mobilizer demonstrates some form of social power based on relationships and could also demonstrate expert power depending on training.

> *"the way we interact, you can see that as I got here now, they started greeting me. . . because of the relationship I have with them. . . and clinically we diagnose them I mean we treated them clinically because there is no laboratory to confirm it"* Community Health Officer and Community Mobilizer, male, rural area.

> *"yes we serve as the interface between the government and the people of this community, so we usually sensitize them about their health, their environment. . . those (patients) that can manage to go (to the hospital) without any problem and has an assistant, I ask them to go, and those that are too weak to go by themselves like (an) emergency, I followed them."* Community mobilizer, female, urban area.

PMV

The patent medicine vendor's (PMVs) source of power came from social relationships, expertise, and had the power to refer patients to seek care. There are two types of PMVs: mobile and resident. Resident PMVs have more power over the patient's care and access to diagnosis

> *"If they are ill and it is body temperature that just started, so I will give hem drugs for two days, sometimes if there is no changes we refer them to the health center"* PMV, female, urban area.

> *"I usually greet and ask them about their health when they pass by my shop, sometime some will thank me for the drugs I gave them the day before and that it's effective while another may come to report that the medicine was not effective and request for another kind."* PMV, female, urban area.

Resident PMVs viewed their power over disease diagnosis to be limited to what was acceptable by law. Due to their presence within the locality, they could easily be identified and liable to the law.

". . . so far it won't affect us, you know there is nothing that the police don't investigate, so if it won't affect us and the police won't disturb us, no problem" PMV, female, urban area.

Health Care Level Stakeholders

This level of Stakeholders includes Doctors, Nurses, Community Health Officers (CHO), Community Health Extension Workers (CHEWS), Laboratory Scientists/Technicians. They work within the clinical aspect of the health care system.

CHEWS/CHO/Doctors

The CHEWS/Doctors are the first level of entry into the healthcare system. Due to the limited number of personnel within the healthcare system, CHEWS/CHOs are in charge of smaller primary health care centers and health posts that are close to the communities, while Doctors were in Charge of larger health centers. The CHEW, CHO, and Doctor demonstrated power as experts. However, the CHEWs also demonstrated social power based on their continuous residence within the community leading to the formation of relationships with members of the community.

". . . I have more information, so they really do not have a lot of options than to follow my instructions; this is not in all cases but it happens most the time. . . If I tell them that I want to admit them, then they do not have a choice. If they refuse to stay, this is not a prison and they can leave. It depends on how you talk to them anyway" Doctor, male, urban area.

".. (Patient)came into the clinic with complaints and then he followed my boss (Senior CHEW) into town for proper diagnosis where tests were carried out on him. After everything, my boss told me they got drugs and that it was schistosomiasis" Junior CHEW,

Health Center, Rural area

"...At times if I want to go and I run into people passing by going toward the area with their bikes, they often assist me." Junior CHEW, Female, rural area.

"I think I might have seen about two to three cases (of schistosomiasis). When this happens, the first thing we do after noting their complaints is to refer them to the MOH(medical officer of Health)." CHO, female, urban area.

Laboratory Personnel

Laboratory personnel demonstrated power as experts with technical knowledge. Their power over patients was limited and they only had contacts

with patients through a referral from doctors. That did not have power over treatment or what diagnostic test to carry out.

"Yes, at that point you, whatsoever analysis is requested from the physician, at the end of my own analysis once I see a result, I have that privilege to also recommend... suggestive. So, it now depends on the physician by the time the patient reports back to the physician" Laboratory scientist, male, NGO, urban area.

"our job is to analyze the specimen and report. Then the doctor decides on how to act on our result. . . they get referred by doctors to here from various hospitals... and people come here on their own. . ..But mostly they are referred here by doctors" Laboratory scientist, male, private lab, urban area.

"we first go for microscopy and if there is schistosomiasis, we refer them to the doctors for treatment" Laboratory technician, female, Health Center, urban area.

Organizational Level Stakeholders

Organizational level stakeholders were those in charge of programmatic parts of schistosomiasis control as well as gathering and using information about schistosomiasis for program planning. These include the Medical Officer of Health (MOH), Primary Health Care (PHC) coordinator, Disease Surveillance and Notification Officer (DSNO), and the Neglected Tropical Disease Officer (NTD) and teachers.

Primary Health Care (PHC) Coordinator/MOH

The PHC coordinator /MOH is in charge of primary care at the local government levels demonstrated legitimate power because of their position within the organization part of the healthcare system, as well as expertise based on training.

"by virtue of my position can relate with other line ministries, department, and agencies, international organizations. . . that want to partner with the local government on health matters to implement any program as far as the health system of the local government is concerned."I get referrals and at the same time, I do refer people, depending on the case that presents itself. My staff can refer patients to me or invite me to manage a case at the facility level' MOH and PHC coordinator, male, urban LGA.

"I see to the affairs of the PHC department in general. I also coordinate the staff in terms of their duties, supervise them, and then if there is any

need for recommendation for any of them from the state government, I will make those recommendations" PHC coordinator, female, rural LGA.

However, the level of power of these officers to address schistosomiasis and recommend a line of action is limited by other stakeholders that do not have a direct relationship with schistosomiasis diagnostics.

> *"There are enough skilled people outside but the government did not recruit them. I cannot recruit them by myself, they are usually recruited by the State Primary Healthcare Board."* PHC coordinator, female, rural LGA.

> *"It takes a collaborative effort of my office, the office of the political officeholders. The politicians are the ones who initiate policies and they decide if they want to expand and add more to the existing facilities. They determine the felt need of the people in the community that they serve. When they go to the people and the people tell them that they need a healthcare facility, they work on it. Then, they will refer to me. The process goes from top to bottom, it rarely goes bottom-up."* MOH and PHC coordinator, male, urban LGA.

NTD Officer

The NTD officer is primarily in charge of the programmatic aspect of the schistosomiasis control. They demonstrate technical power because of their position. They were also in charge of the School-based deworming day targeting school-age children for treatment for schistosomiasis. They also have ties with the community and could leverage social connections within the community.

> *"We only currently handle kids from ages 5 to 14, adults are also prone to the risk and we have seen cases of adults passing blood in urine. This is why several adults have been asking when we will carry out a program like this for them. So, it is necessary for both adults and not the children alone. . . Maybe the next time we have a meeting with the state, we would bring up that they should extend the range of reach to cater for people 15 years and above because they also swim in the rivers and they can end up infecting the ones we've treated if they are not included"* NTD officer, female, urban LGA.

> *"We do surveillance. We try as much as possible to pass messages to the community leaders so that they will be aware of it, so whenever they see signs, they will be able to call on me to inform me about the cases, and then, there will be a linkup between myself and the community."* NTD officer, male, rural LGA.

The State had legitimate organizational power over the schistosomiasis control program. However, the Federal government determined the overall strategies for schistosomiasis control based on policy.

> *"because the state does not have the authority to that (address schistosomiasis through policy). It always comes from the federal level. The guidelines we use are from the federal level and our hands are tied without the federal ministry of health."* State NTD Officer.

Table 4. Stakeholder power and interest ranking.

Stakeholder category	Role	Power type	Power rank	Interest rank
1.	Parent/guardian of children with schistosomiasis	Social, coercion	2	2
2.	Community leader	Social, legitimate	2	1
	Patent Medicine Vendor (PMV)	Social, referent	2	1
	Traditional healer	Social, cultural	2	1
	Community mobilizer	Social, informational, referent	3	3
3.	Doctors	Expert, referent	3	3
	Community Health officers	Expert, referent	3	3
	Laboratory scientist/Technician	Expert, referent	3	4
	Community Health Extension Workers (CHEW)	Social, Expert, referent	4	5
4.	Primary health care (PHC) coordinator	Organizational, Expert, legitimate	3	3
	NTD officer	Organizational, informational, social	3	3
	Disease surveillance and notification Officer (DSNO)	Organizational, legitimate, Expert, social, informational	4	4
	Teachers	Informational	1	1
5.	NGO	Organizational, legitimate, informational	3	3
	Community-based organization (CBO)	-	-	-
6.	Academia	Expert, informational	3	5
7.	Financing	Organizational, informational	5	4

Disease Surveillance and Notification Officer (DSNO)

These officers are in charge of monitoring and reporting notifiable diseases including schistosomiasis. They directly work with health facilities and demonstrate strong legitimate power over health facilities, both private and

public, and at all levels of care (primary, secondary and tertiary healthcare) within their jurisdiction.

> *"We have weekly and monthly reporting. Whenever they see something of such nature such as blood in the urine, they will send a text message notifying me that there is a case of this nature and on monthly basis, they will sum all the activities for the weeks and send it to me. I have a column that indicates schistosomiasis. Whenever such a case has been reported to me, I must go and investigate in all health facilities. . . I have to contact the higher authority which is the state disease, surveillance officer. Then we go together and make verification."* DSNO, male, urban LGA.

> *"The health workers there will treat the patient and document it. We will then send the record to the state."* DSNO, female, rural LGA.

Teachers

Teachers only featured strongly within the treatment aspect of the schistosomiasis control program. They, however, have limited powers overtreatment and no power over the diagnosis of schistosomiasis.

> *"we announce it to them that there is deworming, some of them came some did not come to school and some who came like one he was always tapping me that her mother said she should not take any medicine"* Primary School Teacher, Urban area.

> *"then it depends on the condition if it one that requires an immediate attention. For example, a kid that has a cut and was injured and he is bleeding several of them have been taken to private clinics around here, the principal pay for their treatment, teachers raising money taken to him, to attend to them at that first day. . . there were children that have been rushed to hospitals by the school, the parents will come, meet them in the hospital where they were taken to so it depends on what happens.. that will determine. . . "* Participant 3, FGD, Secondary school, urban area.

Policy/Economic Environment Stakeholders

These stakeholders have a wider level of impact and they interphase with more than one level of the health system simultaneously. These include interaction with both the community level, local Government, State Government, and or at the Federal government level. They include academia/researchers, Non-Governmental Organizations (NGOs), financing/donor organizations.

Non-Governmental Organizations (NGO)

We identified three main NGOs. One of the NGOs [Association of Reproductive and Family Health (ARFH)] worked within disease diagnostics and the second, the World Health Organization (WHO) performed a technical function. While the third (Evidence action) provided technical function as well as funding support. The WHO function appeared to have stronger legitimate powers by performing supervisory roles. The WHO did not have a state-based NTD officer. This was only present at the national level. However, other officers within the state office filled the gap when needed.

> *"This may be due to the fact that I do not really look into it but in my supervisions, I have barely seen cases of schistosomiasis. . . I think the surveillance is poor for schistosomiasis. With good surveillance system, I think we will easily pick up quite a number of cases. Many of the factors that might predispose to schistosomiasis is present"* WHO state technical officer.

Financing

Financing appeared to be one of the greatest sources of power. Financiers had legitimate power as well as the power to coerce the state and the federal government to address schistosomiasis diagnostics. One NGO primarily performed some financing activity targeting schistosomiasis control through the school- based deworming exercise. The NGO also has informational power to bring about change.

> *"I do not think that schistosomiasis is really prioritized and there is probably no funding line for it. Funding is also a big issue. No matter the charges, the funders have their interest. If they insist that they want to fund a certain disease, other diseases will suffer."* WHO state technical Officer.

> *"we basically provide technical assistance for the government to be able to carry our deworming.. . It involves anything from policy, advocacy, planning and collection and distribution of the drug, monitoring the program and. . . so we supply, we provide funding for them, we also provide the technical know-how, working with the state. . . well, we went to the government to say we would have to work with them to carry out a state-wide deworming program so in a way should I say we initiated it but it's the government program. . . and we do not, we are not the one that provide the drugs, the drugs are provided by the federal ministry of health, it's a free donation. . . through WHO and WHO is the source of supply"* Country Director, Evidence Action.

Academia/Research

We found three persons in Research and who all performed dual roles. Two were both doctors and researchers, while one was as both a researcher and a laboratory scientist. Researchers exhibited powers as experts based on technical knowledge and could identify other stakeholders as well as reach out to these stakeholders. As such, they had some form of informational power.

> *". . . based on the report we had, what we did was to get the NGOs working in those areas to get to their local health authorities to let them know of the problem of schistosomiasis because the cases found here were actually from the local health authorities who gave us the medications for free."* Researcher and Doctor, male.

> *"I think the program covers all local government what I now do not know is if they've been able to identify some high-risk regions in the state and have intensified program in those regions as compared to the places with low risk,. . . but I know the program, the NTD program is state-wide thing"* Researcher and Doctor, female.

> *"I want to talk about one, political will, because there are a lot of politics that go around which—you have planned something and because of one thing you don't they just stop it all of a sudden."* Researcher and Laboratory scientist, male.

Stakeholder Interest Thematic Analysis

Most of the interviewed stakeholders were interested in the device and its use for the diagnosis of schistosomiasis. Table 4 shows the grading of their level of interest.

Community-Level Stakeholders

Members of the community did not show a strong interest in the device due to a lack of understanding of how the device works, low level of awareness of the disease, and also because they looked up to the health workers to make certain decisions about diagnosis and treatment. However, other stakeholders were able to give insight into the patients' perspectives on this device.

> *"yes, you need sensitization because if you don't sensitize them, they will not know the value of this"* CHO and Community Mobilizer, female, rural area.

> *"If the government provides equipment that can bring out result instantly"* Guardian, female, urban area.

Healthcare Level

Medical personnel appeared to be interested in the device improving the diagnostic process and increasing efficiency, especially in hard-to-reach areas.

> *"I think that's a good idea, and it will be a good development like in the case of malaria. . . so, it's just a welcome idea"* CHO and Community mobilizer, rural LGA.

> *"I know that you people are always moving forward, so I look forward to whatever advances you can make you know to make life easy for us here"* Laboratory scientist, Private lab.

> *"If such a device is brought to this healthcare facility, I think it will be easier for us to diagnose patients if such a case is brought to us."* CHO, Health center, urban LGA.

Organizational Level

At the organizational level, the PHC coordinator and NTD officers were interested in the device easing workflow and improving diagnosis, thereby helping their output.

> *"If you can innovate one that can be appropriated for the ease of local use without microscopy, it will be good since it will be something easy to work with"* PHC coordinator and MOH, male, urban LGA.

> *"Yes. This is because some will not give you the consent to take their children's urine. We need to convince them totally before samples can be taken. . . Connecting with the DSNO and going to the UCH (tertiary hospital) takes a very long time. The result also takes time to arrive. It will be better if the diagnosis is done at the PHC level".* PHC coordinator, female, rural LGA.

For the NTD officers, the introduction of the device would increase the effectiveness of their work and reduce waiting times for the conformation of cases from secondary and tertiary hospitals.

> *"There is no machine. We do have labs but we are limited to some tests to be carried out at the LGA level. We have to take the samples to UCH (tertiary hospital) to test if it is schistosomiasis. . . We have lab scientists at the LGA now but the materials they need are not available. If there are materials and equipments to use, they should be able to work"* NTD officer, male, rural LGA.

"It should let us know people that are coming down with schistosomiasis..." NTD officer, male, urban LGA.

Policy/Economic Environment Level

At this level, all stakeholders were interested in the device improving schistosomiasis diagnosis and reducing the impact of disease within the state.

"Diagnosis is key. For example, tuberculosis control starts with diagnosis before anything can be done. To do this properly, we have to strengthen the labs as the diagnosis and the confirmation of the cure end in the lab. We are advocating point of care devices that could make a diagnosis of some of the public health diseases without a lot of sophistication" WHO state technical officer.

"but I think it's...it's potentially a game-changer as to how we do field surveys for Schisto and STH so it's something personally I would really like to get involved in" Country Director, Evidence Action.

Researchers mentioned the importance of the device's input in quick diagnosis and its importance as a quick screening tool for those with infection or highly endemic regions.

"They will get the buy-in. If it is for schistosomiasis, the private facilities in places where they have a high burden of that will be interested" Researcher and Doctor, male.

"People will embrace it. I'm so sure of that. . . In fact, already I'm falling in love (with the device)" Researcher and Laboratory scientist.

"So if there are better diagnostic test or methods or stuff, that might be able to help so that there are no missing cases, there are obviously missing cases, and I feel that even the few, the ones that we see, they can be picked earlier before it gets to the stage of frank haematuria. They can be picked earlier if we have easy-to-use diagnostic or screening test kit." Researcher and Doctor, female.

Stakeholder Classification and Ranking

Based on the stakeholder power base, and interest evidence available from the interviews, 2 interviewers/researchers read through the transcripts and ranked stakeholders for co-creation according to their power and interest independently (Table 4). Any differences in the ranking were resolved by a more senior researcher.

Stakeholder Power/Interest Matrix

Based on the ranking of the stakeholder power and interest, stakeholders for co-creation were mapped into a power interest matrix to identify stakeholders who were important to co- creation. Stakeholders could fall into the following categories (Figure 4): players, context setters, crowds, and subjects (49).

From our analysis, the stakeholders important for co-creation clustered into two categories: "crowd" and "key players." The "crowd" stakeholders are characterized by low power and low interest. This category is predominantly made up of community- level stakeholders within stakeholder categories 1 and 2. They may have a high impact if they act together toward a goal.

The "key players" stakeholder group consists of category 3– 7 stakeholders except for the community mobilizer who falls under category 2 stakeholder. These stakeholders demonstrate high power and high interest. These stakeholders also fall within the organizational, healthcare, and policy/ financial environment levels of the healthcare system. Although these players appear to have a high influence/power, these do not necessarily mean high impact since they cannot enforce acceptance by the patients and the community. No stakeholder fell within the category of stakeholders with high interest and low power (subjects) or those with high power and low interest (context setters).

DISCUSSION

This study assessed and mapped stakeholders' interest, influence/power, and position within the schistosomiasis diagnostics landscape concerning the development of a device for improved diagnosis of schistosomiasis. Engaging and co- creating with stakeholders in diagnostic device development and adoption is known to be important for successful deployment and use of diagnostic devices. We improved upon an existing framework for stakeholder identification and applied it to the stakeholder identification process for co-creation. This framework can also be used to identify implementing stakeholders. We also analyzed relevant stakeholders' power, interest, and stakes for device co-creation using a power- interest matrix. This strategy will help to identify relevant stakeholders within the field of study and develop ways of engaging stakeholders based on the outcome of the analysis. To the best of our knowledge, this is the first study using a three-stage stakeholder approach to co-creation for a device for S. haematobium.

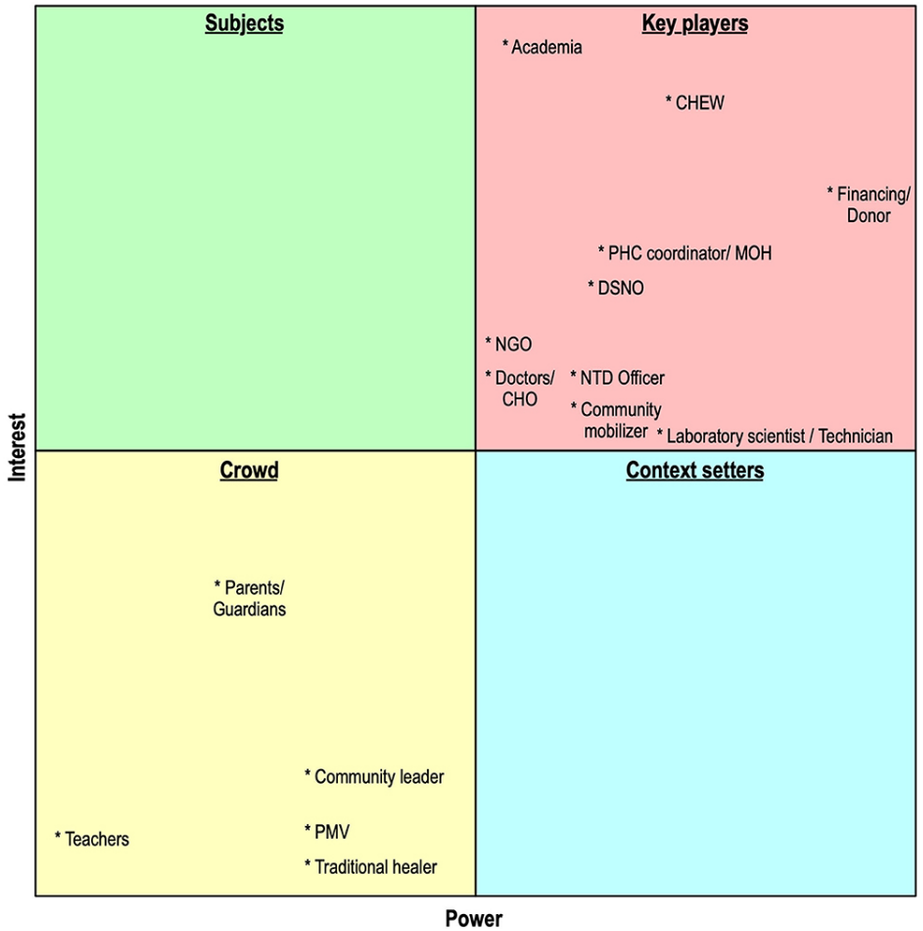

Figure 4. Stakeholder mapping using a power/interest matrix.

Key Findings

Evidence from the analysis indicates two main uses of stakeholders: co-creation and adoption. It is also clear that some stakeholders fall into both the co-creation category and the implementation category. This is similar to what was found by van Limburg (50).

Among stakeholders for co-creation, most of the identified stakeholders within a formally organized system showed greater interest in the development of the device to either improve their work or increase efficiency. This suggests that the non-availability of point of care devices can impact on disease management of schistosomiasis. Although stakeholders at the community level had a low interest, this is likely due to low awareness of the

disease, especially in its early stages or in cases of light infections (12, 42). Besides, the consequences of non-treatment are not probably clear to them due to the long time-to-complication seen in the disease (1, 2, 7).

The community-level stakeholders appear to demonstrate a low level of influence when analyzed individually. However, since the social power type was more common among these stakeholders, the stakeholders acting together can demonstrate a high level of power (26, 51, 52). For instance, they can decide not to allow the use of devices for testing within the community during large scale implementation. They can also refuse to go for testing based on their beliefs about the disease. As such, regardless of their low level of interests and power, it is important to keep them informed on device development processes such as prototypes for testing and as well as awareness campaigns that may precede device testing and adoption (29). Regular updates to the community will increase mobilization and buy-in, as well as the willingness to pay for schistosomiasis testing.

The most important type of stakeholders for our co-creation plan are the key players. These stakeholders demonstrated high levels of power by acting as key players within the health system (medical and organizational) and policy environment. These stakeholders are important for device co-creation and validation. The key players are important for strategizing and guiding product development. For instance, laboratory personnel can give insight to the peculiar challenges of equipment used within this context which may be different from the environmental context of the device developers. As expected, the financing/donor stakeholder has the highest level of power within stakeholders for co- creation because of the problems of financing healthcare and programs within the developing country context. It is well-known that donors strongly determine the direction of health policy within the context of Lower Middle-Income Countries (LMICs) (26). Engaging and working closely with these stakeholders will improve device design as well as increase acceptability by stakeholders who are important to adoption and implementation.

Limitations

One limitation of our study was that we did not interview some stakeholders, for instance, political actors and media, who may be important for implementation, as well as the Federal Ministry of Health (FMOH) staff who may be important for co-creation in our interviews. However, these do not strongly influence the results of our work. It is known that the FMOH as a stakeholder is primarily involved in giving policy direction for schistosomiasis control and elimination (9). State governments are by law able to domesticate the policy and adopt what works for them by actively engaging with other non-state actors directly. Results of what works and

progress on the schistosomiasis control program are usually reported to the FMOH. As such, we believe, we can leverage existing communication channels between the state and federal ministry to engage with stakeholders within the federal ministry during co-creation.

In respect of stakeholders for implementation, political actors especially were not interviewed because of the rapidly changing political landscape (52) in the state at the time of data collection and the long-life cycle of device development which creates problems with reengaging every new political actor throughout the device development lifecycle. Since co-creation is a major step in the life cycle of device development before the implementation phase, we believed that interacting with these co-creating stakeholders can increase our visibility within the healthcare context. Moreover, since some stakeholders are important for co-creation and implementation, our continuous engagement with these co-creating stakeholders would help to further identify other important stakeholders for implementation and adoption, as well as influence these implementing stakeholders (52). Finally, it is important to have a working prototype of the device first before involving other important implementers such as political actors and the media.

Another limitation is that some of our findings may not be generalizable to other parts of the country. Nigeria is a multi-ethnic society with ethnic groups concentrated in different regions. As such, the culture of the predominant ethnic group can affect how stakeholders interact with each other, how stakeholder roles are assigned, and the power dynamics within the schistosomiasis diagnostics landscape. For instance, in some parts of Nigeria, religious leaders may be a stakeholder within some communities. However, we believe this may not affect the result and the interpretation of the power-interest matrix for co-creation.

Future Directions

In the future, we plan to further identify the value proposition of stakeholders for device development, as well as explore relationships between the stakeholders using social network analysis for both co-creation and implementing stakeholders. Identifying how stakeholders collaborate and communicate can aid in stakeholder engagement leveraging on the relationship ties to achieve mass acceptance and application of the diagnostic device.

DATA AVAILABILITY STATEMENT

The raw data supporting the conclusions of this article will be made available by the authors, without undue reservation.

ETHICS STATEMENT

Ethical approval for the study was obtained from the Ethical Review Committee of the College of Medicine, University of Ibadan, Nigeria (NHREC/05/01/2008a). The patients/participants provided their written informed consent to participate in this study.

AUTHOR CONTRIBUTIONS

AO determined the overall structure of the study and the protocol and aligned it with the inputs from MK, OO, JD, and JV. AO analyzed the data with input from MK and OO.

All authors reviewed the analyses, interpretation, reporting for critical content, and read and approved the final manuscript.

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4.2. IMPROVING ACCESS TO DIAGNOSTICS FOR SCHISTOSOMIASIS CASE MANAGEMENT IN OYO STATE, NIGERIA: BARRIERS AND OPPORTUNITIES

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Abstract

Schistosomiasis is one of the Neglected Tropical Diseases that affects over 200 million people worldwide, of which 29 million people in Nigeria. The principal strategy for schistosomiasis in Nigeria is a control and elimination program which comprises a school-based Mass Drug Administration (MDA) with limitations of high re-infection rates and the exclusion of high-risk populations. The World Health Organization (WHO) recommends guided case management of schistosomiasis (diagnostic tests or symptom-based detection plus treatment) at the Primary Health Care (PHC) level to ensure more comprehensive morbidity control. However, these require experienced personnel with sufficient knowledge of symptoms and functioning laboratory equipment. Little is known about where, by whom and how diagnosis is performed at health facilities within the case management of schistosomiasis in Nigeria. Furthermore, there is a paucity of information on patients' health-seeking behaviour from the onset of disease symptoms until a cure is obtained. In this study, we describe both perspectives in Oyo state, Nigeria and address the barriers using adapted health-seeking stages and access framework. The opportunities for improving case management were identified, such as a prevalence study of high-risk groups, community education and screening, enhancing diagnostic capacity at the PHC through point-of-care diagnostics and strengthening the capability of health workers.

Keywords: schistosomiasis; barriers to diagnostics; access to healthcare; end-user perspectives; neglected tropical diseases; Nigeria; case management

1. INTRODUCTION

Schistosomiasis is a parasitic disease that affects over 200 million people around the world, and 90% of the infected population are in African countries. These countries have the highest burden of morbidity and mortality [1]. Nigeria is the most endemic country in Sub-Saharan Africa with 101.3 million people at risk, and 29 million infected [2]. The infection can cause anaemia, growth stunting, cognitive impairment, decreased

productivity and long-term health consequences such as bladder cancer and infertility [3]. Despite its high socio-economic burden [4], it has received limited attention from governments and stakeholders in healthcare settings, similarly to other Neglected Tropical Disease [2]. Although a prevalence study for schistosomiasis in Nigeria was conducted in 2015 [5], the selection of the sample collection was limited to children and did not address other high-risk groups such as adults [6,7].

Currently, vertical and horizontal programs are used for schistosomiasis control in Nigeria [8]. The control and elimination program is a vertical approach and a principal strategy for control of schistosomiasis (and other NTDs). The horizontal approach is the case management of individual cases at the primary health care level [9]. The control and elimination program provides annual mass treatment of praziquantel for school-age children aged 5 to 14, who are known as the most heavily infected part of the population [10]. Praziquantel has been reported to be a safe and effective treatment, and this approach is said to significantly reduce the prevalence of schistosomiasis and the intensity of infection in high endemic areas [11]. However, three major limitations characterised this approach including high re-infection rates [12], unsustainable mapping and delivery with its high dependency on donations of praziquantel [13,14], and exclusion of other high-risk groups such as people who frequently have contact with water for domestic and professional purposes [2,11].

In light of these limitations, there is a need to pay more attention to the horizontal approach (case management) because it can provide more sustainable, efficient and more localized interventions [9]. The case management approach, which is strongly recommended by the WHO, focuses on diagnosis and treatment [15,16]. In the event that the health facility does not have the diagnostic capability, symptom-based case detection is recommended. This approach has strong potentials in reducing disease transmission by shortening the infectious period of patients through early diagnosis and immediate treatment which will result in improved treatment outcomes [16].

The standard method for schistosomiasis diagnosis is microscopic examination in a lab-setting. The samples for Schistosoma haematobium (S. haematobium) are prepared either by urine filtration (using polycarbonate filters) or centrifugation. The samples for Schistosoma mansoni (S. mansoni) are prepared by Kato Katz faecal smear [17,18]. The challenges for sample preparation within sub-Saharan African context include the shortage of lab technicians and equipment at primary health care level [19] as well as the high labour-intensiveness and initial and maintenance costs [18]. There are alternative diagnostics methods, however, they have limitations [17].

Methods such as questionnaires, visible haematuria and urine reagent strips are available but have low sensitivity and specificity. Antibody or antigen detection-based tests are not yet commercially available. Point-of-care circulating cathodic antigen (CCA) test is on the market with high sensitivity and specificity, yet it is more specific to S. mansoni and has a disadvantage in affordability. For the health facilities without diagnostic capability, the WHO suggests the symptom-based case detection and treatment [15,16]. This is, for example currently being used in Ghana where the healthcare workers relate blood in urine (hematuria, dysuria) to S. haematobium and blood in stool and abdominal discomfort to S. mansoni [20]. Although the symptom-based case detection seems to be an effective method for morbidity control in high endemic areas with low resources, the detection depends on the knowledge of the health workers and prior-experience with schistosomiasis patients. There is a high possibility of failing to suspect cases with non-distinct symptoms [20,21]. It is also not clear if praziquantel is available at all levels of the healthcare system to treat the confirmed cases.

Overall, having an adequate diagnostic capability is essential to proper case management, but this requires skilled personnel with sufficient knowledge and functioning equipment. There have been reports indicating poor availability of basic equipment at the primary health care facilities in Nigeria and questions have also been raised about the quality of service delivery [22,23]. This can affect the diagnostic capability within the context of case management of schistosomiasis control. Nonetheless, to our knowledge, there is no specific study that has explored this aspect critically.

Apart from the diagnostic capabilities within the healthcare system, the disease awareness and knowledge of patients can affect health-seeking behaviour. Case management works with passive case detection, which is usually triggered by patients taking action to seek care based on a number of factors. A study in Kano state in Nigeria [24] indicates that the majority of the study participants did not have knowledge on cause, signs, and symptoms of schistosomiasis, even though the majority of them indicated that they are aware of the disease. In addition, only 35% indicated that they would seek treatment from clinics and hospitals. Another study in Adamawa state in Nigeria [25] showed that around 40% of its study participants did not seek any care, 30% visited the patent medicine vendor, while only 17% went to the hospitals. It is of note that patients, when seeking care, have a high preference toward self-medication or use of traditional healers, which may be due to the poverty and physical inaccessibility [24,25]. Nevertheless, there are information gaps on whether and how the patients become aware of the early signs after getting infected, and what barriers prevent them from taking action to seek care.

Therefore, the objective of this research is to explore how the case management currently takes place in Nigeria and to identify the barriers to access from patients and healthcare workers perspective by using empirical data. This would assist us in making appropriate recommendations for future improvement on the case management.

2. MATERIALS AND METHODS

This study was conducted as part of the interdisciplinary research project "INSPiRED"—Inclusive diagnoStics For Poverty RElated parasitic Diseases in Nigeria and Gabon funded by NWO—WOTRO Science for Global Development programme. The INSPiRED project aims to design and deliver new technical interventions for diagnostics of malaria, schistosomiasis and hookworm infection in close co-creation with local stakeholders.

2.1. Ethics

The study protocol was approved by the UI/UCH Joint Ethical Review Committee of University of Ibadan (10 Dec 2019) and with registration number NHREC/05/01/2008a. Study participants were provided with an information sheet explaining the objectives of the study, and all participants signed or verbally agreed to informed consent forms prior to participation.

2.2. Study Setting

This study took place in Oyo State, one of the 36 states in Nigeria, with an estimated population of 7.8 million people [26]. Data for this study were collected in December 2019 from two Local Government Areas (LGAs) of Oyo State; Ibadan North and Akinyele which are based in urban and rural areas respectively. The selection was based on their moderate-to-high prevalence of schistosomiasis and accessibility to the interviewees.

2.3. Study Sample

The study sample consisted of five categories of stakeholder based on a literature review and expert suggestions (See Table 1). All 29 respondents were purposively selected. They were contacted and informed about the research by the local research coordinator prior to the study.

Table 1. Stakeholder categories and respondents

	Stakeholder category	Respondents	LGA
1.	Community members who have experience with schistosomiasis	6 Parents / Guardians of people who were treated for schistosomiasis	Ibadan North, Akinyele
2.	Stakeholders within community that can impact on the patientde-cision to access care	1 Traditional healer 1 Community leader 1 Patent Medicine Vendor (PMV)	[1]Ibadan North
3.	Stakeholders in the formal health care	2 Community Health worker 2 Community mobilizers 1 Doctor 5 Lab personnel	Ibdadan North, Akinyele
4.	Stakeholders within Local and State Government	1 Medical Officer of Health/PHC Coordinator 2 DIsease Surveillance Notification Officers (DSNO) 1 PHC Coordinator 2 LGA NTD Officer 1 State NTD Officer	Ibdadan North, Akinyele

[1] The community in Akinyele did not have residential traditional healer or PMV.

2.4. Data Collection

We used a qualitative approach to data collection. Semi-structured interview guides with open-ended questions were developed based on the case management steps of schistosomiasis [15] and the health-seeking pathway in low-resource contexts [27] (See Figure 1). Van der Werf [15] describes the steps in passive case detection of schistosomiasis from a health care system perspective. She distinguishes five steps in the passive case detection as a liner process of infection, pathology, disease, health care visiting, and treatment. From practice and the literature, we are aware that the trajectory is more complex and can have multiple pathways within and outside the formal healthcare system. For example, informal health care providers such as Patent Medicine Vendors (PMVs) and traditional healers are known to be frequently the first choice of health-seeking by communities in Nigeria [28,29]. For this reason, we searched for a complementary model that would represent the complexity and alternative routes of healthcare-seeking behaviour of patients in Sub-Saharan Africa. This led to the work of R. E. Kohler et al. [27] who developed a six-stage health-seeking pathway based on interviews with women from Malawi. Even though their research was related to the early detection of breast cancer, it describes the complex trajectories of patients within the African context. We constructed a health-seeking pathway with six stages that was used to derive the main themes to be addressed. The questions were formulated to cover all the themes and to guide the semi-structured interviews (See Figure 1).

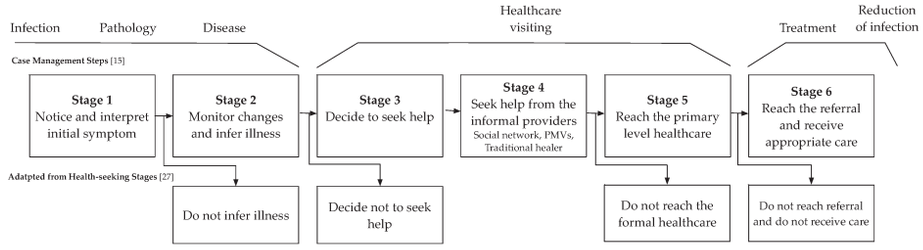

Figure 1. Adapted health-seeking pathway with six stages based on [15,27].

The study adopted a descriptive exploratory design using qualitative methods [Key informant Interview (KII) and In-depth Interview (IDI)]. The KIIs were conducted to explore the perspectives of the patients and health workers in accessing and performing the diagnosis and the case management, and IDIs to gain a broader understanding of challenges and collect insights for opportunities. The interviews were conducted in English or Yoruba (local language) for 45 min.

2.5. Data Entry and Analysis

All interviews were recorded and transcribed verbatim. Interviews conducted in Yoruba were translated into English by an external translator and reviewed by a language knowledge expert to ensure that the original meaning was not lost. Transcripts were analysed using the software Atlas ti version 8.4.4.

The framework of theory of access to healthcare was used to structure the data analysis and identify the barriers to access the case management of schistosomiasis. The 5A framework by Penchansky and Thomas's [30], which includes affordability, availability, accessibility, adequacy (or accommodation) and acceptability, is commonly used. However, we adopted Saurman's 6A Framework in our analysis because of an additional dimension on awareness considering its importance in remote and rural areas [31].

The lead researcher used pre-defined themes based on the 6A Framework on access to healthcare [31] to assign the codes using a deductive approach. The six analysed dimensions, described by their definitions and components adopted from another study [32] are shown in Table 2. Additionally, new themes were identified by inductive coding. The initial coding was done by the lead researcher and later reviewed by two other researchers of the team. This resulted in a list of barriers to access to schistosomiasis case management. Next, the themes and barriers were discussed and grouped into the six health seeking stages. Finally, the barriers were described based on (a) the six stages of the health seeking pathway and (b) in Figure 2; by

the 6As of the health access framework using the health seeker or provider perspectives.

Table 2. 6A Framework of access to helathcare

Dimensions	Component	Theme
Awareness	Communication and information	General health literacy Knowledge about symptoms, care and prevention
Accessibility	Location	Distribution of, and distance to, health care providers
Availability	Supply and demand	Incomplete medical infrastructure Lack of equipment Lack of health care professionals Lack of training for health care professionals
Acceptability	Consumer perception	Cultural belief and influence from the community
Affordability	Financial and incidental costs	Cost of treatment Cost of transport to health care provider
Adequacy (Accomodation)	Organisation	Mismatch between available information and awareness, knowledge and education needs Lack of relevant and complete diagnostic information

3. RESULTS

3.1. Health-Seeking Stages Identified in the Case Management

Based on the interviews, the six stages of the patient health-seeking pathway within the case management (See Figure 1) are described by common health-seeking behaviours. Next, identified themes within each stage which act as barriers are mentioned. The overview of the themes within 6A framework can be found in the table in Appendix A.

3.1.1. Stage 1: Notice and Interpret the Initial Symptoms

All the six 'category 1J interviewees mention the notification of blood in urine as an initial symptom for recognition of illness. Discomfort when urinating and fever were mentioned as well.

> *"I told her mum to keep her eyes on him, and she later saw him urinate and sighted blood in his urine, . . .".*—Parent of a child who had schistosomiasis from Rural LGA

In most cases described, identification of symptoms drew the immediate attention of the community members. However, lack of knowledge and other associations connected to the symptoms became barriers for community members to seek for health support (for schistosomiasis).

Theme 1: Lack of general knowledge on health and schistosomiasis among community.

It was often mentioned that the general understanding within the community related to healthcare is low, which leads to less active attitudes in seeking care. More specifically, the community's knowledge of schistosomiasis related to the cause, signs, and symptoms of the disease were limited. This lack of knowledge makes it difficult for the community to interpret the symptoms, even though they noticed the initial signs.

Theme 2: Cultural association and belief related to the symptoms

The symptoms are associated with cultural identity or beliefs within the community. This affects people not to seek for help and choose for traditional medicines in stage 4.

> *"I said it's like a cultural thing, once you have haematuria, that normalises you as a true son of the soil . . . "* —Public Health Researcher

> *"You know that dogs have blood in their urine. In the Southwest of Nigeria, it is called Atosi Aja. This is why they believe that it is not a medical condition and they prefer treating it traditionally"*—PHC Coordinator (Rural LGA)

> *"Some people are aware of schistosomiasis, but most people believe that the spiritual forces have cursed the victim"* —Community mobilizer (Urban LGA)

3.1.2. Stage 2: Monitor Changes and Infer Illness

After people become aware of the symptoms, they have the tendency to wait for several days before they take action. They monitor the symptoms and wait for the conditions to improve. It was mentioned by the guardians and parents of the patients that the symptoms are frequently associated with other diseases, for example, Sexually Transmitted Diseases (STDs). This makes people reluctant to seek care.

> *"after five days . . . , okay you want to see if his condition will be better before deciding to take him to the hospital."* —Parent of a child who had schistosomiasis (Rural LGA)

Theme 3: Trying out self-medication without prescription

While monitoring the symptoms, it is common to make use of over-the-

counter medications such as paracetamol or make traditional medicine at home. If the symptoms seem to disappear, people do not further seek for help. This reduces the chance of receiving appropriate care.

> *"We gave him paracetamol and yet there was no difference, he was sweating, and we took him outside to take fresh air . . . "* —Parent of a child who had schistosomiasis (Rural LGA)

3.1.3. Stage 3: Decide to Seek Help

Only after the symptom persists or becomes more severe do people decide to seek help. The patients consulted with their close ones in the community about their symptoms and where to seek help.

> *"Where I (people community) will go next is dependent on that. For instance, if I speak to a friend who is a pastor and he asks me to come to his church for healing prayers, then I would go to the church. If someone says that they had once experienced such and they saw a Community Health Extension Workers (CHEW), I would follow suit."* —Doctor PHC (Urban LGA)

According to the level of knowledge in healthcare and socioeconomic status, the patients choose where to seek help in the next stage. In the community, people also preferred seeking help from the informal healthcare providers such as traditional healers and PMVs considering the accessibility and affordability (Stage 4). Depending on the relationship with health workers, sometimes they reach out the formal healthcare directly (Stage 5).

Theme 4: The symptoms are associated with STD, which causes hesitation in sharing with others.

Due to the stigma around the STD, this type of misinterpretation causes unnecessary fear and confusion.

> *" . . . it is possible that it is a sexually transmitted disease . . . So it is possible that people may contract the disease but may be too shy or lack the courage to tell someone because of losing their dignity and privacy."* —Guardian of child who had schistosomiasis (Urban LGA)

3.1.4. Stage 4: Seek Help from the Social Network and Informal Healthcare Providers Stage

Stage 4.1. Seeking Help from Social Network

It is common to start seeking help by consulting other community members and ask for advice from someone who had similar experiences. Patients

discuss with a trusted person such as family, friends, or other community members.

> *"He said it just found out he urinated blood so when he mentioned it was where his apprentice told him there is someone that treated him when he contracted the same disease"*—Traditional healer (Urban LGA)

> *" he confided in someone that he had contracted the disease and I got to know through that person though I was warned not to ask him or pretend as if I am not aware"* —Guardian of a child who had schistosomiasis (Urban LGA)

Theme 5: Limited access to the proper information within the community due to low awareness on schistosomiasis

Since there is generally little knowledge on Schistosomiasis, it is difficult for patients to get access to the right information via their social network.

> *"he has never heard of it (schistosomiasis), he only knows about reddish urine"* —Guardian of a child who had schistosomiasis 2 (Urban LGA)

Stage 4.2. Seeking Help through Traditional Medicine

Traditional medicine was believed as an effective solution, especially when other people had positive experiences to relieve the similar symptoms. Moreover, traditional healers are more accessible and affordable as they are easily approached from the community, and the cost of treatment is relatively low. The belief that the disease is related to spiritual power (Theme 2) also influences patients to choose the traditional healers, who are respected among the community.

> *"they probably just tell them "oh it is spiritual problem" "Oh, it's not normal, it's something spiritual. "* —Public Health Researcher

> *"It depends on customs and traditions. It also depends on the condition because they may think that the disease is as a result of witchcraft and wizardry "* —PHC Coordinator (Rural LGA)

Stage 4.3. Seeking Over-the-Counter Medications from PMVs or Drug Vendors

Purchasing medicines from the PMVs or drug vendors were mentioned as a typical behaviour for health-seeking. Especially in rural communities, people prefer to buy over-the-counter medicines such as paracetamol and try self-medication as described in Theme 3. The patients or the guardians visit the PMVs and consult symptoms or ask for a specific medicine. For previous

cases of schistosomiasis, they purchased antibiotics and paracetamol without prescription. The health workers referred to this process as trial-and-error where patients trying out the given medicines for one to three days and come back if not effective. If the conditions of the patients are too serious for the PMVs to handle, the PMVs provide a referral for the patients to visit the health centre.

> *"I usually bought drugs from drug vendors that hawks"* —Mother with a treated child with schistosomiasis (Rural LGA)

> *"They want immediate solutions, so they first buy herbs or patronize the PMVs."* —Community Mobilizer/CHO (Rural LGA)

> *"Because of ignorance, the people go to them because they are at every nook and cranny"* —MOH/PHC Coordinator (Urban LGA)

Theme 6: Going through the process of trial-and-error medications without prescriptions at the PMVs.

Taking medicines without a prescription is not only causing a delay in receiving the proper care but also develops resistance to drugs such as antibiotics.

> *"They mostly do trial and error just in a bid to make money regardless of lacking knowledge . . . "*—NTD Officer (Urban LGA)

3.1.5. Stage 5: Reach the Primary Level Healthcare

The CHEWs or health workers at primary health centre provide health-related education on common diseases and build a close relationship with the community. This relationship increases the chance of community members contacting them or health centre when they become ill. The four community health workers we interviewed reportedly had a strong relationship with community members which positively influenced the patients' health-seeking pathway.

> *"The PHC is a bit far away from their places but they still come around because of the relationship we have with them."* —CHEW (Rural LGA)

Considering the misinterpretation of the symptoms (Theme 4), the trust between the patients and a health worker is important to open up about the symptoms.

> *"Based on the relationship we have with them; they can easily tell us without feeling embarrassed or shy. They know me, and I have been with them for a long time."* —Community mobilizer (Rural LGA)

Theme 7: Negative attitudes of the health workers may prevent people from accessing formal health care.

The negative attitudes of some of the health workers may become potential barriers to access formal health care.

> *"The attitude needs to be improved so that we can be more receptive to these people"* —MOH/PHC Coordinator (Urban LGA)

> *"We make sure things are friendly and simplified in order to make sure they are not scared"*—NTD Officer (Urban LGA)

Stage 5.1. Consultation

The consultation with health workers starts from asking about the symptoms and the patient history. If schistosomiasis is suspected, possible contact with water is also asked. The time to get attended was not considered as a challenge in both LGAs.

> *"When the patients are brought to the clinic, we ask about the complaints, we find out if the child bathes near wells and rivers and they say yes."* —Community mobilizer (Rural LGA)

Once the health care workers recognize the symptoms and suspect schistosomiasis, there are two actions they should take. First, provide the appropriate case management or refer the patients to another health centre or hospital where the patients can receive the care.

Secondly, report to the Local Government as schistosomiasis to be included in the Integrated Disease Surveillance Response program. This will call the attention of the Disease Surveillance Notification Officer (DSNO), and the DSNO who will initiate the surveillance protocol to collect a sample and confirm the case. For the surveillance protocol, the DSNO collects the sample and brings it to a qualified laboratory for diagnosis. However, this does not take place for unreported cases.

Theme 8: Knowledge gap of high-risk groups of schistosomiasis among the community

The stakeholders at the community level (Categories 2, 3) often mentioned that the prevalence is low in the LGAs where the interviews took place. However, the higher-level stakeholders (Categories 4, 5) mentioned specific communities are at higher risk of schistosomiasis, for example, around the riverine areas, which is not recognized by the health workers and cause low awareness. This is a clear gap in knowledge that can lead to the cases being

missed and underreported.

> *"In Ibadan (city), for instance, there is a location called Dandaaru. It is around University College Hospital. People live around that community and their children go there to bath. In the process, they get infected with schistosomiasis."* —Public health researcher

Theme 9: Failure in suspecting the case based on symptoms

Most health workers are familiar with blood in urine, but they may not associate the symptoms with schistosomiasis case. In addition, there may be non-specific symptoms which makes it difficult for the health workers to identify the case. This prevents the patients from receiving the appropriate care for schistosomiasis, and the surveillance program will miss the case.

> *"if a patient comes with a case of blood in their urine and if the health worker does not have adequate knowledge to say that it is similar to schistosomiasis, there is no way the patient can take a step further to investigate . . . There may be misdiagnosis and some cases may be entirely missed. Some may have the disease and assume that it is a sexually transmitted infections . . . Training of the health workers to build their skills to detect schistosomiasis is very important."* —MOH/PHC Coordinator (Urban LGA)

> *"I'm not sure maybe 5 or 9 of them had a microscopic (haematuria) and not the haematuria . .it wasn't like they came with symptoms."* —Public health researcher

Stage 5.2. Diagnosis

Once a schistosomiasis case is suspected, a diagnosis should take place to confirm the case and provide treatment. Preventing wastage of free medication from the health centres is another factor mentioned.

> *"You must carry out urinalysis with at least simple microscopy. It is very important to know what you are dealing with and to rule out certain thing . . . "* —MOH/PHC (Urban LGA)

> *"Diagnosis is very important because, without it, no treatment can be made."* —PHC Coordinator (Rural LGA)

The diagnosis will be performed within the facility if a laboratory is available and functioning. We inquired the lab scientists about the standard method for schistosomiasis which was confirmed as urine analysis. It involves the collection of a urine sample, sample preparation, urine strip tests, and

microscopic analysis. Urine filtration was not mentioned by any of the four labs we visited. The sample preparation was done by centrifuge as a standard procedure.

> *"Now a patient comes to the laboratory and the physician has requested a urinalysis, for a urine analysis and a urine microscopy"* —Lab scientist (Urban LGA)

However, none of the four health centres we visited had a functioning laboratory in place. The barriers include incomplete infrastructure and lack of equipment, unstable electricity and power supply, and lack of qualified health care professionals.

Theme 10: Incomplete medical infrastructure to perform diagnosis

In the primary health centre, there was a lack of adequate equipment to perform the microscopy such as centrifuge, microscope, clean and controlled environment, and a stable supply of electricity. The size of the space and the environment (excessive heat, exposure to sunlight) were also mentioned as reasons why the facility was not functioning.

> *"There is no machine (microscope). We do have labs, but we are limited to some tests to be carried out at the LGA level."* —NTD Officer (Rural LGA)

> *"But at times, when we don't have equipment, we call our boss and ask to either to refer the patient or if he is on his way down, if he is, he would bring the equipment needed from Moniya by his bike . . . "*— CHEW (Rural LGA)

Unstable power supply was another factor due to which microscopy cannot function properly. As an alternative solution, the generator was mentioned, but only two of the visited labs were equipped with it. The generators were functioning at the moment, but it was also mentioned that the generators frequently break down and do not function. Maintenance of the broken devices was an additional challenge especially when they do not have a back-up device.

> *"there is currently no power supply. We have an old generator and there is no money . . . "* —Lab scientist (Urban LGA)

Theme 11: Lack of lab scientists and technicians to perform diagnosis

The absence of lab scientists was a recurring issue at the primary level health centres. Among the four labs we visited, we interviewed at least one lab scientists or technician. In two labs attached to the primary health centre, only lab technicians were present. Even if they are available, potential insufficient training of the professionals was considered as a barrier.

> *" . . . Then manpower should be on ground. Scientists, more scientists should be on ground so that the work won't be too much on individuals . . . "* —Lab scientist at PHC (Urban LGA)

> *"She is a laboratory technician, not a full scientist. She is just a technician . . . "* When asked about the lab personnel at the PHC– Head of PHC (Urban LGA)

Theme 12: Incapability to perform the diagnosis with sufficient quality

One academic stakeholder mentioned that the lack of skills of lab scientists and technicians is one of the challenging factors to deliver diagnostic results with sufficient quality.

> *"the skill of their laboratory technician is not good enough to pick that, then you might miss even if there are 100 cases in that community . . . "* —Public Health Researcher

Theme 13: Extra steps of movements are required for diagnosis and treatment.

Theme 14: The costs incurred for extra steps are patient's responsibilities.

At the health centre without diagnostic capacity, diagnosis may be requested from other facilities. In this case, it is the responsibility of the patient to reach there and bring the results back for treatment. Some patients may not continue the health-seeking pathways due to the extra costs of transportation and time incurred. It was mentioned that the costs of diagnosis and treatment are free at the health centre. However, if these are not available at the health centre, it is under patients' own expenses to go to a private lab for diagnosis or pharmacy for treatment.

> *"our people are still poor, if test is expensive they will say they will come back. She told me she didn't have enough money on her for the test that she had only five hundred naira"* —Guardian of child who had schistosomiasis II (Urban LGA)

Stage 5.3. Symptom-Based Diagnosis and Treatment
In prior cases of schistosomiasis, health workers have provided treatment based on symptoms without diagnosis. The lack of knowledge of the health workers not only caused schistosomiasis case to be missed, but also questioned the reliability of the symptom-based treatment.

> *"We combine the signs and symptoms with the patient history of the patient . . . We treated them clinically as we did not have any laboratory to confirm it."* —Community Mobilizer (Rural LGA)

Theme 15: The symptom-based treatments are not always reliable.

The stakeholders from category 4 and 6 mentioned that the symptom-based treatment is not always reliable. As mentioned in theme 8 and 9, the case may not be suspected at all or fall under misdiagnosis or mistreatment.

> *"Even on clinical level, such a diagnosis can be missed . . . So, when you have this patient and you do not use your initiative to conclude that you have to conduct urinalysis with microscopy on this patient, it is possible to miss the diagnosis . . . "* —MOH/PHC Coordinator (Urban LGA)

Stage 5.4. Treatment and Follow-Up
Generally, the treatment will be provided according to the results of the diagnosis. In the previous cases, the treatment was given before receiving the diagnostic results. Even when DSNO requested the diagnosis, the treatment was given without waiting for confirmation due to the delay in receiving the results.

Theme 16: Treatment is given before the test results are available.

This happened when there was a delay in receiving the results. For the convenience of the patients, the treatment was given immediately, so they do not have to come back for the results and treatment—This relates back to the barriers in accessibility and affordability.

> *"After everything, my boss told me they got drugs and that it was schistosomiasis. However, I did not see the laboratory results."* —CHEW (Rural LGA)

> *"If you ask the patient to go home without giving them anything, they will not come back to you. This is why you have to reassure and give them something without the case being confirmed"* —PHC Coordinator (Rural LGA)

The follow-up takes place by the health workers to check on recovery via personal contact or phone call.

> *"after that they will tell them to take their drugs properly, they will also tell them to do check-up either the following or after two days . . . "* —Guardian of a child who had schistosomiasis II (Urban LGA)

3.1.6. Stage 6: Reach the Referral and Receive Appropriate Care
From the primary health care, the patients are referred to visit an advanced level of health care facility. In the areas we conducted our study, the Hospital affiliated to the University of Ibadan was often mentioned as a referral and, in most cases, patients followed the advice for schistosomiasis and other diseases. Once they reach the referral hospital, the patients received the appropriate care with diagnosis and treatment. However, there were still barriers such as the long-distance to the healthcare provider, the transportation costs and the general fear of health care.

Theme 17: Distance to the health care provider is far.

Theme 18: Transportation costs are unaffordable.

In the communities located in urban areas, access to the referred healthcare facility such as hospital was not described as a challenge. However, in the rural communities, the distance to the healthcare facility was major challenge in access as well as costs of transportation. Moreover, it was described that the patients might have to depend on other family members or neighbours to arrange transportation which cause additional delay in seeking care. One health worker mentioned that she offers to provide the transportation costs when she gives a referral. The time to travel to the health care provider was also seen as a challenge.

> *"Even transportation is a cause for concern. They want immediate attention and asking them to go to another hospital is like adding salt to their journey . . . "* —Community mobilizer/CHO (Rural LGA)

> *"Even if free drugs are available at the hospital, they have to think of the transport fare from their house to the hospital."* —PHC Coordinator (Rural LGA)

Theme 19: Fear of healthcare facility and uncertainty make people hesitant to reach referral. Another barrier identified

was the general fear for healthcare facility as the hospital was usually associated with a place "with stress" due to their prior experiences. The fear comes from the uncertainty of the further process in which they might have to spend excessive time and costs.

"We have heard of cases of people with phobias for health center that close their eyes when they walk pass by the facility" —NTD officer (Urban LGA)

"I said fear and shyness, fear that they will be admitted (to hospital) and may not be allowed to come go back home . . . " —Guardian of child who had schistosomiasis (Urban LGA)

3.2. Barriers to the Case Management and Diagnosis

In the final stage, the identified barriers were grouped according to the six stages of the healthcare seeking pathway and the 6A dimensions of access to healthcare (See Figure 2). It is also indicated if the barriers were from the perspectives of healthcare seeker or a provider.

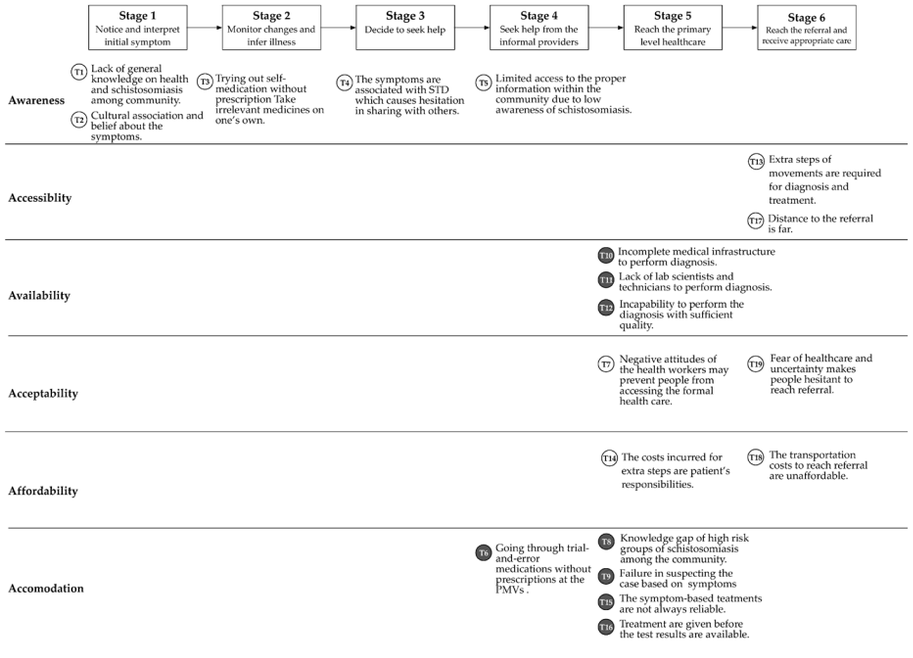

Figure 2. Identified barriers in the case management and diagnosis in 6A Framework. ◯ = Barriers from the healthcare seeker perspectives, ● = Barriers from the healthcare provider perspectives.

4. DISCUSSION

4.1. Main Findings

This study explored the health-seeking behaviours of patients and the diagnostic capability of the primary healthcare level in schistosomiasis case management in Oyo State, Nigeria. Based on the results, we identified barriers to access to adequate health care and diagnosis. The overall health-seeking pathway was found to be in line with the pathway as identified in the literature [15,27]. We elaborated on the health-seeking behaviours and barriers within each stage specifically related to schistosomiasis. Overall, the barriers from the healthcare seeker perspectives were spread over all six stages (See Appendix A). The disease awareness was major barrier for the patients at the beginning of the health-seeking pathway, followed by accessibility and affordability. The barriers from the provider perspectives were more present in the later stage of pathway (Stage 5 and 6) where the availability of diagnostics and disease detection rates by the health worker were challenging factors. During the interview, no other categories of health-seeking stages and barriers to access were mentioned which indicates the validity of the framework we used.

As mentioned in previous studies [24,25], awareness was one of the main barriers. Within our empirical study, a lack of awareness was spread over several stages of the health-seeking pathway. The barriers to awareness are more present in the early stages of health-seeking before visiting the health facilities and from the patients' perspectives. The low awareness of the disease and other associations connected to the symptoms in the community resulted in delay in seeking healthcare and self-medication. The patients often choose alternative routes (PMVs and traditional medicine) before they reach formal healthcare. This is similar to the health-seeking behaviour of other common diseases [28,29] using trial and errors of medication without prescription which causes delay in accessing care.

When patients seek out formal health care, schistosomiasis is often underestimated by the health workers. The barriers to the acceptability strongly influenced the decision-making where the health care workers attitudes and perception of formal health care were the major issues. The health care providers have multiple barriers related to accommodation including the knowledge gap and non-specific symptoms of the disease. Even when the case is suspected, the health care providers face challenges in providing laboratory confirmation of the case due to unavailability of the diagnostic equipment and personnel. The unavailability issues were directly related to the incomplete infrastructure, lack of training of personnel, and environmental challenges such as power supply. This leads to failure in following the recommended procedure of the case management and raises

additional barriers to accommodation. The symptom-based treatment, which is alternative to diagnosis, was found to be frequently not reliable due to the limited knowledge of the healthcare providers. Referral to another diagnostic facility is possible but the delay in receiving the result led to treating the patients without confirmation for the sake of convenience. Lastly, the referral to other facilities brings more burden of time and costs for the patients, which relates to the issues of accessibility and affordability.

4.2. Opportunities

Based on the identified barriers and comparing our findings with existing knowledge, we suggest following opportunities to improve access to the proper case management and diagnosis.

4.2.1. Community Sensitization Program for Awareness Creation

Active involvement of the community members for sensitization and health education will improve the general awareness on schistosomiasis by overcoming mis-associations around the symptoms and the passive attitudes in health-seeking behaviours. There is a need for focusing on the information on the disease causation, risk practices, key symptoms, consequences of the disease and delayed treatment. This will influence the community members to take desirable actions for prevention and seeking care once they notice early signs of the schistosomiasis. Multiple methods of dissemination should be used including informal healthcare providers such as traditional healers and PMVs.

4.2.2. A Study to Identify Prevalence of Schistosomiasis Among other High-Risk Groups

There is a need for a prevalence study focusing on other high-risk groups including the adults who frequently interact with water. Since children are already covered by the control and elimination program, this will help the health workers to realize the hidden burden of schistosomiasis in their local context. As the prevalence of schistosomiasis is perceived as low without evidence, schistosomiasis is “neglected” among the community and health workers. Presenting data specific to their local context will provide the health workers with awareness of the severity and urgency and consequently improve accommodation by providing the appropriate care for schistosomiasis. The prevalence study will generate needed evidence and guide the development of appropriate strategies for effective implementation of case management.

4.2.3. Enhancing the Existing Diagnostics Capacity

Stimulating adequate case management of schistosomiasis infection requires minimizing the number of steps by patients to reach the health centres where they can receive appropriate care. In this study, poor accessibility is evident

with a concomitant effect on PHC utilisation. The issue of transportation costs due to referrals cannot be resolved without improving the accessibility and availability of the health workers and equipment. Enhancing the existing diagnostic capacity at the primary level will reduce the additional movements to reach other health facility and laboratories. Complementing the existing laboratory infrastructure, provided with more equipment and skilled personnel, will be necessary as well as providing solutions for other environmental factors such as unstable power supply.

4.2.4. Implementation of Point-of-Care Diagnostics Solution

Implementing an affordable and simple point-of-care diagnostics solution will reduce the financial burden of equipment and personnel at each health facility. Point-of-diagnostics can confirm the detected cases immediately and will reduce the risk of missed or misdiagnosed cases. It will be a favourable solution to allow the task distribution with minimal training, for example, by enabling community-based diagnosis by the community health workers. If the sensitivity is sufficient enough, the point-of-care diagnostics solution can be utilized for other opportunities such as prevalence study or community-based screening with higher affordability and accessibility. From the patient perspectives, additional travel and costs to the diagnostic facility are no longer necessary and there will be no delay in the results.

4.2.5. Community-Based Screening for Treatment and Monitoring

It would be a feasible approach to improve the availability of diagnostics at the primary healthcare level by adding schistosomiasis screening to other health care interventions already in place. This will likely have an immediate impact in reducing the number of infections and help in the collection of data for prevalence monitoring. A new diagnostic method available at the point-of-care with smart, high sensitivity and immediate output generation will add immense value to carry out such screening and would stimulate demand for services. This will be an advantage for the health centre in rural areas by preventing additional travel to the diagnostic facility.

4.2.6. Capability Strengthening of the Health Workers

Increasing the capability of the health workers will be a key to improve detection rate at the community level. More suitable approaches for different endemic levels should be determined based on the prevalence study and guide the health workers. The training of the health workers should include suspecting schistosomiasis cases from the symptoms and the contextual factors and emphasize the importance of the diagnostics. The availability of smart diagnostics will be beneficial to detect light infections or asymptomatic cases and avoid misdiagnosis. The willingness of people to seek help in formal health care was strongly influenced by the close relationship between the health workers and the community. Accordingly,

the positive attitudes of the health workers towards the community should be emphasized in the training. New interventions should consider training the health care providers at the community level and the informal sector (PMVs and traditional medicine) to enhance collaboration between them. This will improve the awareness in the community.

4.3. Limitations of the Study

The limitations of this study should be noted. First, the patient's experience of schistosomiasis (stakeholder category 1) have taken place in the last 3 years. However, we were able to validate the findings and gain a more comprehensive understanding of other contextual and organizational factors through interviewing the multiple levels of stakeholders. The stories of the cases in the past were validated by confirming the facts with the health workers who put us in contact with the respondents as they were involved in the case as well. Second, the number of stakeholders were limited and they were selected from two LGAs, which can limit the generalizability of the results. Even though there was still limited access to health care and diagnostics, the LGAs were still considered to be close to the urban area (capital of the state). More studies can be conducted in more rural areas to deepen the understanding of barriers more specific to that context. Nevertheless, we believe the key findings and the identified barriers from this study are generalizable to similar settings and can be used to improve the case management of schistosomiasis.

AUTHOR CONTRIBUTIONS

Conceptualization, methodology, first analysis and validation; G.-Y.V., A.O. and J.C.D.; software, G.-Y.V.; original draft preparation, G.-Y.V.; writing—review and editing, G.-Y.V., A.O., J.C.D., J.v.E. and O.O.; visualization, G.-Y.V.; supervision, J.C.D., J.v.E. and O.O.; project administration in the field study, O.O.; All authors have read and agreed to the published version of the manuscript.

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CONFLICTS OF INTEREST

The funders had no role in the design of the study; in the collection, analyses, or interpretation of data; in the writing of the manuscript, or in the decision to publish the results.

APPENDIX A

Table A1. Barriers categorized in 6A dimensions and the perspectives

6A Dimension	Barriers Identified	HC Seeker	HC Provider
Awareness	T1: Lack of general knowledge on health and schistosomiasis among community (Stage 1)	√	
	T2: Cultural association and belief about the symptoms (Stage 1)	√	
	T3: Trying out self-medication without prescription take irrelevant medicine on one's own (Stage 2)	√	
	T4: The symptoms are associated with STD which causes hesitations in sharing with others (Stage 3)	√	
	T5: Limited access to the right information within the community due to low awareness of schistosomiasis (Stage 4)	√	
Accessibility	T13: Extra step of movements are required for diagnosis and treatment	√	
	T17: Distance to the referral is far (Stage 6)	√	
Availability	T10: Incomplete medical infrastructure to perform diagnosis (Stage 5)		√
	T11: Lack of lab scientists and technicians to perform diagnosis (Stage 5)		√
	T12: Incapability to perform the diagnosis with sufficient quality (Stage 5)		√
Acceptability	T7: Negative attitudes of the health workers may prevent people from accessing the formal health care (Stage 4)	√	
	T19: Fear of healthcare and uncertainty makes people hesitant to reach referral (Stage 5)	√	
Affordability	T14: The costs incurred for extra steps are patient's responsabilities	√	
	T18: The trasnportation costs to reach referral are unaffordable (Stage 6)	√	
Adequacy / Accomodation	T6: Going through trial-and-error medications without prescriptions at the PMVs (Stage 4)		√
	T8: Knowledge gap of high risk groups of schistosomiasi-samong the community (Stage 5)		√

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Chapter

5

STAKEHOLDER ASSESSMENT

In this chapter, two papers will highlight the results of stakeholder assessments. The first paper discusses the result of the social network analysis of the schistosomiasis control program in Oyo state, Nigeria. The second paper explores stakeholders' perspectives on new diagnostics and potential use scenarios.

5.1. SOCIAL NETWORK ANALYSIS OF THE SCHISTOSOMIASIS CONTROL PROGRAM IN TWO LOCAL GOVERNMENT AREAS IN OYO STATE, NIGERIA: INSIGHTS FOR NTD ELIMINATION PLANS

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Abstract

Background: Schistosomiasis is one of the neglected tropical diseases targeted for elimination by 2030. Achieving disease elimination requires collaboration between stakeholders, country ownership and the involvement of community-level stakeholders. The state of stakeholder relationship determines the ease and timeliness of meeting disease elimination targets.

Mapping stakeholder relationships is critical for assessing gaps in the schistosomiasis control program implementation, and providing a roadmap for improved stakeholder cohesion. The study aimed to measure the cohesiveness of the contact, collaboration and resource sharing networks, across 2 local government areas in Oyo state, Nigeria.

Materials and methods: This study used a Network Representative design for Social Network Analysis (SNA). The study was conducted within Oyo state, Nigeria using 2 Local Government Areas (LGAs):

Ibadan North (urban) and Akinyele (rural). Stakeholders were identified using a link-tracing approach. Data was collected using Qualtrics software from stakeholders across the state, local government, healthcare, academia, and non-governmental organizations. Data was analysed using Gephi software for network cohesion across the three networks.

Results: The social network analysis revealed high clustering and low density across the three networks implying low cohesion across multiple stakeholder categories. The contact and collaborative networks were the most active with the lowest level of cohesion seen in the resource-sharing network. Stakeholders were more active in the rural LGA than the urban, and stakeholders within the organized governance and public health system were the dominant actors in the schistosomiasis control program.

Conclusion: The low cohesion, high clustering and low network density among stakeholders within the schistosomiasis control program should be

addressed in other to drive innovation and meet the WHO schistosomiasis elimination target.

INTRODUCTION

Schistosomiasis is a Neglected Tropical Disease (NTD) endemic in 78 countries, with more than 90% of people infected with the disease living in Africa [1]. Within several national health systems, there is a focus on disease control and elimination through schistosomiasis control programs [2]. The focus of the schistosomiasis control program is country-specific, however, strategies for control are focused on a mix of policies including Water, Sanitation and Health education (WASH) activities, preventative chemotherapy in form of Mass Drug Administration (MDA), environmental control and disease surveillance [3,4]. These measures alone appear insufficient for schistosomiasis elimination since many countries are yet to eliminate the disease.

The WHO has set new targets for NTD control and elimination for 2021–2030 with schistosomiasis being planned for elimination by 2030. The pillars for meeting these targets include accelerating programmatic action, intensifying cross-cutting approaches, and changing operating models and culture by increasing country ownership [1]. These pillars can only be operationalized by stakeholders at the global, regional, national and subnational levels; and sustainable progress will largely depend on these stakeholders' abilities to collaborate to achieve these aims. Collaboration between stakeholders can take different forms and include elements of contact or communication, resource support and collaborative activities [5–7] all leading to stakeholder cohesion. Collaboration is usually preceded by stakeholder identification and engagement.

To achieve the WHO endgame, there is a need to engage all stakeholders within the schistosomiasis control stakeholder network for several reasons. First, stakeholder engagement is required for an effective definition of gaps and challenges within varying contexts. Second, proffering and operationalizing solutions to the gaps can only be effective if stakeholder buy- in is guaranteed. Finally, the development and diffusion of innovative practices and products such as new diagnostics to drive change and ensure disease elimination is possible if stakeholders collaborate. It is known that stakeholder engagement is shaped by various factors which include cultural, social and political context, and resource limitations [6]. Stakeholder engagement requires equitable contribution from all relevant stakeholders supported by a mutual understanding of roles and support as stakeholders have varying levels of time, resources, and skills [5] available to achieve the control and elimination of schistosomiasis.

The WHO has also emphasized the need for the integration and streamlining of various aspects of the control program into the healthcare system and the need for sectoral collaboration. However, it is unclear how the collaboration will be led as the roles of stakeholders have to be clearly defined to achieve the NTD elimination targets. Therefore, it is important to identify current gaps in the stakeholder collaborative network within the schistosomiasis control program. This is a prerequisite to proffering solutions which will lead to enhanced coordination, communication and collaboration for meeting disease elimination targets.

Research on stakeholders within the schistosomiasis control program in Nigeria has identified different stakeholder categories [8]. However, it is unclear how these stakeholders interact and if there are differences and similarities between interactions in both rural and urban contexts. It is known that strong coordination among stakeholders promotes role clarity and fosters inclusiveness, which strengthens collaboration leading to the timely meeting of targets [7]. Pillars 1 and 3 of the WHO endgame focus on collaboration and alignment among stakeholders not only at national or global levels, but more importantly at sub-national levels and the local government/municipal levels [1]. Furthermore, the involvement of community structures particularly community leaders and civic leaders including patient groups and people living with NTDs, all have a role to play in community buy-in and cooperation with the local NTD structures [9] leading to more disease awareness and sustained behavioural change.

As such, studying stakeholder relationships can give insights into the dynamics of collaboration among stakeholder groups to reveal gaps and opportunities for stronger collaborative actions to meet the WHO target. One of the ways stakeholder relationships can be studied is through Social Network Analysis (SNA). SNA, a type of systems research, is a method of investigating stakeholder influence, connectedness and cohesion within a network [10]. The analysis of social network structures is an offshoot of graph theory and promotes a way to understand stakeholders' influence based on their position within a network. Studying network dynamics can help build an understanding of specific relationship dynamics that can affect the operations of stakeholders, alongside the strength and importance of different stakeholders within these networks. These insights can provide opportunities to build trust, improve communication and information flow, increase collaboration, and maximize the potential of stakeholders thereby improving the whole system [10,11].

Social networks are known to be both multi-layered and multi-relational based on the social characteristics of the individual stakeholders, the relationship characteristics between stakeholders and the system or organization

wherein they function. [12]. This means that the relationship between the same stakeholders can vary based on the relational characteristic being explored leading to multiplicity of relational data.

One way to address the issues of the multiplicity of stakeholder relationships without using a reductionist, combinatorial approach to multiplex data on relationships [13,14] is to use the Network Representative method (NetRep method) [10]. The NetRep method is a newly developed methodology that enables efficient data collection by performing intensive sessions with representative actors/stakeholders and using non-parametric analysis in form of graphical interpretation to explore the patterns among multiple kinds of stakeholder relationships [10]. This simplifies explaining stakeholders' relationships and avoids extensive mathematical modelling interpretation. The NetRep method ensures the compactness of the dataset without sacrificing the quality and depth of the results [10]. This method was developed and used to visualize how the multiple relationships impact each other and explore the specific characteristics of different networks essential to the analysis of a regional governance system [10]. This system is analogous to the healthcare system in Nigeria in terms of role multiplicity and inter- actions between people, processes, products/services, and organizations all enmeshed within the sociocultural paradigm of strong informal relationships within the society. We will be exploring collaborative processes including contact patterns, resource support and linkages among the stakeholders within the schistosomiasis control program in Oyo state.

There are several studies including systematic reviews on social network analysis among healthcare organizations in developed countries [15–21], and a few studies on organizational SNA from a developing country setting [22–25]. Within the African context, there are no known studies exploring the relationships between the stakeholders within the local NTD network generally, the stakeholder network of the schistosomiasis control program specifically, and how the state of these relationships can affect disease control and elimination. As such, this study will contribute to the literature on the use of SNA in the healthcare context within the sub-Saharan African context, as well as an understanding of relational factors that impact schistosomiasis disease control policies.

METHODS

Ethics statement

Ethical approval was given by the University College Hospital, Ibadan/ University of Ibadan UCH/UI Joint Ethical Review Committee (UI/ EC/21/0100). Written Informed consent was given by all interviewed participants.

Study design

We used a comparative quantitative research design to assess the stakeholder relationship pat- terns within the schistosomiasis control program in 2 Local Government Areas (LGAs) in Oyo state, South-West Nigeria.

Study setting

Oyo state was selected based on previous research [8] carried out outlining the stakeholders' roles within the schistosomiasis control landscape, and the state's moderate prevalence of schistosomiasis. The study data was collected at 2 levels: state and local government levels. 2 Local Government Areas (LGAs): Ibadan North (urban) and Akinyele (rural) local government areas were purposively selected based on previous work [8] and previously established relationships with stakeholders in these LGAs. Choosing an urban and rural LGA was to aid comparison and document differences between stakeholder behaviour in different contexts within the same state.

Participant selection

Participant selection was based on a link-tracing approach. Four categories of stakeholders were sampled based on work done by [8]. These include stakeholders within both the formal health system (public and private) and the 3 levels of healthcare (primary, secondary and tertiary), stakeholders within the organized health governance who are in charge of local programs, stakeholders within the policy and financing space which includes Non-Governmental Organizations (NGOs) and developmental agencies that support the schistosomiasis control program within the state and stakeholders in academia who are working in the neglected tropical disease field. The roster of stakeholders generated from work done by Onasanya et al. (2020) was used to compile the network roster. A snowball approach was incorporated during data collection to validate as well as identify other stakeholders who may be important in the schistosomiasis control program. In total, 33 stakeholders were identified and 32 stakeholders were interviewed (Table 1). One stakeholder did not respond to interview requests.

Data collection

The number of respondents was largely similar across the 2 LGAs. 10 stakeholders were interviewed for Akinyele LGA and 9 stakeholders were interviewed in Ibadan North LGA. These stakeholders include primary healthcare workers in both public and private facilities and those within the LGA NTD governance structure. Other stakeholders were those within the state NTD governance structure, healthcare workers at the secondary and tertiary level of care and stakeholders within policy, financing and academia.

Procedure

Identified stakeholders were approached after the informed consent.

The Qualtrics software listed all previously identified stakeholders for the schistosomiasis control program. Participants were asked to list additional stakeholders and validate the stakeholder roaster. Thereafter, participants were asked to select the top 10 stakeholders that were important for the schistosomiasis control program. Questions relating to contact, linkage/ collaboration, and resource support were elicited about each participant's top list of stakeholders within a one year period (Table 2).

Table 1. Stakeholder distribution

Stakeholder category	Stakeholder level			
	State level	Local Governmen	Public health facility	Private health facility
Healthcare	Head of Laboratory services [1]	*Medical Officer of Health (MOH) [2]	Primary care: CHEW [2], CHO [1], Nurse [4], Doctor [3], Laboratory Technician [2] Secondary care: Laboratory scientist [1] Tertiary care: Doctor [1]	Private laboratory: Laboratory Scientists [3] Private hospitals: Doctors [1]
Governance	State Disease Surveillance and Notification Officer (DSNO) [1], Neglected Tropical Disease officer (NTD) [1], Researcher [1], Primary Health Care Director [1]	LG Disease Surveillance and Notification Officers [2], LG NTD officer [1]+	++	N/A
**Policy/ financing	WHO [1], CDC [1], Federal Monitoring and Evaluation Officer [1]	-	N/A	N/A
Academia	Researcher [1]	-	N/A	N/A
*MOH carries out policy, healthcare and governance functions + one DSNO has a dual role (DSNO + NTD officer) **policy/ financing stakeholders work within the state and not for the state ++ Doctors and CHO were both heads of facilities and healthcare workers				

Table 2. Network relationship terms

Network	Meaning	Constituent/types
Contact	Refers to any form of contact/ communication activity between stakeholders.	Response: YES/NO Frequency: Never Annual Biannual Quarterly Monthly Weekly Daily Type: Phone calls, Meetings, Emails, Others
Linkage/ collaboration	Refers to the degree of collaboration between stakeholders	Response: Not linked, Communication, Cooperation, Coordination, Collaboration, Partnership, Fully linked
Resource support	Refers to a stakeholder providing resource support to another stakeholder	Response: Yes/NO Type: Financial, Technical, Political, Training, Professional, IT, Ideas, Material-

Tools

The quantitative survey (Table 2) was designed by the investigators after a literature review and going through previously collected data [8]. A face and content validity review was conducted in consultation with public health experts to ensure that respondents fully comprehend the research questions and questions that address research objectives. Data was collected using the Qualtrics survey software 2021.

Data analysis

Data was coded and cleaned using Microsoft Excel software. Stakeholders were coded numerically as nodes while relationships were coded as edges. Analysis of the relationships between stakeholders was mapped using Gephi software version 0.9.6 202206221744. Data was analyzed by the local government area for contact, linkage, and resource support patterns at the network and stakeholder/actor levels (Table 3). Network levels indices calculated include network diameter, density and clustering. Actor-level indices calculated include degree and betweenness centrality. Data was visualized using the Fruchterman-Reingold layout which emphasizes complementarities.

After data analysis, 2 central stakeholders within the network were shown the network graphs to comment on network structure, relationship patterns and stakeholder list completeness as a means of data validation. The stakeholders agreed on the completeness of the network, relationship patterns and stakeholder list.

RESULT

NTD Network Cohesion

Table 4 shows the number of ties between stakeholders, network diameter, density and average clustering coefficient of the contact, collaboration and resource support networks of the 2 LGAs. Akinyele LGA has a higher number of ties across the three networks. The network diameter for the 2 LGAs across the network relationships was similar. The density of the three network relationships was low in both LGAs. However, the highest density was seen in the collaboration network in Akinyele (0.117) while the lowest density was seen in the resource support network in Ibadan North (0.021). The clustering coefficient was highest within the collaboration network in Akinyele LGA (0.648) and lowest within the resource support network (0.05) in Ibadan North. All multiplex relationships show the formation of strong connections between the local government, state, federal government and primary healthcare centres (Fig 1).

Table 3. Definition of social network terms

Network level indices	
Network diameter	Network diameter is the average space or separation between actors. It is the shortest distance between the two most distant stakeholders. Networks with low diameter are cohesive networks with little clustering. It measures the efficiency of information flow within the network
Average degree	This is a measure of the overall connectivity of the network
Density	This is the number of current connections within the network divided by the maximum number of connections possible. Measurement ranges from between 0 and 1. Destiny can be computed as low (<0.3), moderate (0.3-0.5), or High (>0.5) (18)
Average clustering coefficient/transitivity	This measures the degree of intra-group cohesion within a network. Networks with high clustering indicate that stakeholders are connected in dense pockets of interconnectivity. Clustering can accelerate intra-group behaviour change.
Actor level indices	
Degree centrality	This is the number of links incident to a certain node/actor. It is a measure of the involvement of the stakeholder in the network It can be used to find highly connected stakeholders who are more likely to have access to information and influence others' decisions
Betweenness centrality	This measures the actors/ stakeholders who act as 'bridges' between other stakeholders in the network. It is used for finding the individuals who are gatekeepers and can influence the flow of information and resources around a system. Since they connect different groups of stakeholders, they usually have multidisciplinary knowledge

Contact

Figs 1 and 2 shows the contact patterns in the 2 LGAs from the lowest to the highest organizational level. Most of the contact activities were between stakeholders within the governance (local and state) and healthcare sector in both LGAs. There was no contact activity with community-level stakeholders and developmental partners.

Linkage/collaboration

Within the linkage/collaboration networks, collaboration was strong between the state and local government governance structure. Other collaborating stakeholders were public health- care stakeholders, especially the primary healthcare centres (PHC). There were no collaboration links between developmental partners and other stakeholders at the state and local government levels.

Resource support

The resources support network showed similar patterns to the contact and collaboration net- works. There was strong resource support between local and state governance structures, with some resource support between the Primary health care (PHC) centres and the federal government.

Table 4. NTD network cohesion

	Contact		Linkage/collaboration		Resource support	
	IBN	Akinyele	IBN	Akinyele	IBN	Akinyele
Number of relational ties	41	58	50	72	24	43
Average degree	2.118	2.938	2.471	3.625	0.706	1.344
Network diameter	4	4	4	3	3	3
Network density	0.064	0.095	0.075	0.117	0.021	0.043
Average clustering coefficient	0.353	0.487	0.591	0.648	0.05	0.119

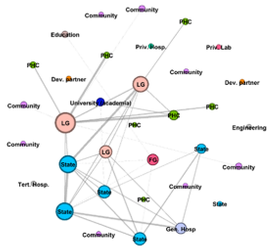
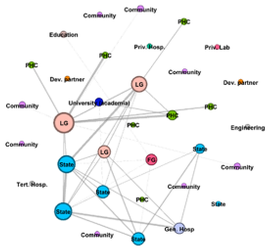
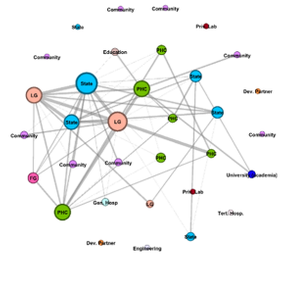
	Ibadan North (Urban)	Akinyele (Rural)
Contact		
Linkage/ collaboration		
Resource support		

Figure 1. Degree centrality across three networks

Ibadan North (Urban) Akinyele (Rural)

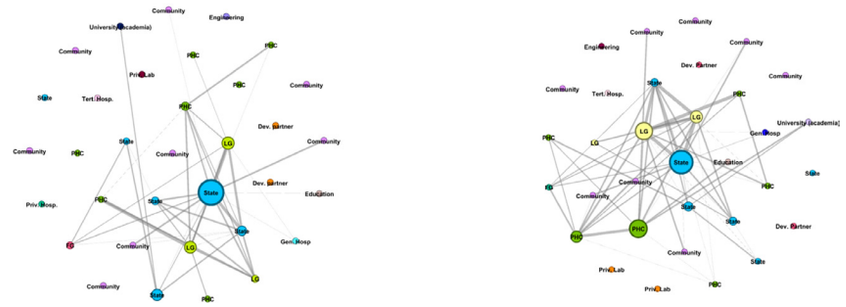


Figure 2. Betweenness centrality output (collaboration network).

DISCUSSION

We applied social network analysis to the schistosomiasis control program stakeholder networks in Oyo state using 2 local governments as examples. The social network analysis measured the strength of contact/ communication, collaboration and resource support networks over a 1-year period. Similar network structures were observed in both rural and urban LGAs. However, the rural local government appeared more active. The network structures displayed properties such as high clustering and low density. We will be analysing the three networks from three perspectives; whole network, stakeholder position and contextual.

From the whole network point of view, the three networks appear sparse (low density) with low levels of connections between all important stakeholders (Fig 1). Low network density can affect the effectiveness and efficiency of the stakeholders in meeting their goals, in this case, schistosomiasis elimination because of the sparsity of connections between stakeholders. Some studies have highlighted the importance of network density on network efficiency and effectiveness [24,26]. However, other studies argue that low density does not necessarily mean low efficiency since a network of strong and highly active stakeholders is not very effective [27– 30]. This argument does not apply in this case as the network is skewed towards some categories of stakeholders who are driving the activities seen within the schistosomiasis control stakeholder network with an absence of weak or strong ties to other clusters of stakeholders. Weak ties are important because they serve as bridges between different clusters of stakeholders and are important for the rapid spread of information and innovation [30]. Due to the absence of weak and or strong ties, innovative practices, products and plans geared towards eliminating schistosomiasis may not spread through the networks leading

to a lack of ownership by the community and other important stakeholders.

An in-depth look at the three networks shows differences between the contact, collaboration and resource support networks. The linkage/ collaboration network highlights the strength of the relationship between the stakeholders and appears to be the strongest network (Fig 1 and Table 4). The contact network highlights the contact/communication activities between the stakeholders and appears to be the second most active network with the resource support network being the least active. The contact network confirms the that there is truly some collaboration between the stakeholders because collaboration activities do require contact between stakeholders.

The resource support network is small indicating that resources (table 2) are not readily available and or shared between the stakeholders. This implies that collaboration between the active stakeholders is mainly a formality due to their expected roles from set policies. For instance, it is expected that the LG NTD officer submits monthly reports to the state NTD officer as part of the responsibilities of the officer. It is known that active networks with shared resources are more collaborative and innovative [31]. Lack of important shared resources such as ideas, training and materials means that the network may not be open to new ideas and innovative practices which may impact reaching the schistosomiasis elimination goal of 2030.

From the stakeholder level perspective across all three networks (Figs 1 and 2), it is clear that stakeholder relationships are strongest between the organized governance and health sector with actors at the state, local government, federal government and primary care actors being the dominant stakeholders. This shows that the government at all levels (local government, state and federal) are the strongest players in the schistosomiasis control program and are the main drivers of change. In other to meet the WHO schistosomiasis elimination goals of 2030, other stakeholders such as community-level stakeholders and patient groups must be involved to increase community cooperation and accelerate disease elimination [1]. For schistosomiasis to be eliminated within this context, other stakeholders outside of the organized governance system must be active either within their clusters or in connection with other strong stakeholders within other clusters.

Another interesting finding from the stakeholder perspective is the gap between the development partners and organized governance system both at the state and local government levels (Figs 1 and 2). It is well known that developmental partners such as the WHO and other Non-Governmental Organizations provide technical support to countries both at the national and sub-national levels [1,32]. However, this support appears absent in this instance. Although support is mainly given to states which have a very

high prevalence of schistosomiasis, Oyo state has a moderate incidence and it is expected that some forms of support in terms of resources, collaboration and contact activities should be seen in this context. Lack of collaboration between these important stakeholders means that meeting the schistosomiasis control goals, and the creation and diffusion of innovative practices and products may be limited or non-existent.

Another gap identified is the absence of relationships between stakeholders in public healthcare and the private healthcare sector. In addition, there is also no relationship between the organized health governance system (local, state and federal) and the private healthcare sector. There appears to be a parallelity in the organization of the healthcare system. This gap implies that stakeholders in the private healthcare system especially private laboratories do not necessarily have to report cases of schistosomiasis and are not involved in the data collection, reporting and training on schistosomiasis control. Consequently, cases of schistosomiasis may be largely underreported and this issue requires urgent policy action. It is known that the private sector is innovative [33], and involvement of this sector in schistosomiasis control may drive the development of innovative practices and may be one of the missing links in achieving schistosomiasis elimination.

The contextual perspective focuses on the network and actor positional differences between the urban and rural contexts in this research. The stakeholders within the rural LGA (Akinyele) are more active across the three networks compared with stakeholders in the Urban LGA (Ibadan North). There are several reasons for this pattern. First, schistosomiasis appears more dominant in rural communities where there is a lack of access to potable water and reliance on natural bodies of water which can be easily contaminated [3,34]. As such, these stakeholders are more likely to anticipate schistosomiasis infections thereby making more contact, collaborative actions and sharing more resources. Second, due to the sparse clustering of communities within rural areas, stakeholders within this context may rely more on communication, collaboration for information sharing and resource support such as training and ideas to reach their goals invariably leading to a more active network. Finally, due to the challenging topography of many rural areas, strong collaboration is critical in meeting policy-stipulated activities, and stakeholders within rural networks may rely strongly on community-level stakeholders for information. Evidence of this is seen in Figs 1 and 2.

It is important to emphasise that the peculiarities of the context such as cultural, political, physical and historical factors can affect stakeholder relationships and these should be strongly taken into account when working towards schistosomiasis control, and driving the adoption of innovative

practices and products for schistosomiasis elimination.

Limitations

This study is the only study to use SNA to measure the schistosomiasis control program network cohesion. Several limitations are noted that may impact the quality of the data. First, this study was cross-sectional and the data was collected in 2021 during the Covid-19 pandemic. It is possible that relationships between stakeholders dwindled during this period due to the focus of the health system on the pandemic. However, the effect of the pandemic on NTD activities was limited within the country and the streamlining of Covid-19 prevention activities into the NTD control activities ensured that NTD stakeholders were active during the research period [35]. Second, stakeholders interviewed gave a self-report of relationships which may be subject to over or under-reporting. Since trust has been built by prior relationships and interactions with the stakeholders [8,36], a true picture of current relationships was likely given. In addition, the use of a network roster which listed all stakeholders in combination with a snowball approach minimised under and over-reporting. Finally, this study was conducted in one state using the examples of 2 LGAs and cannot be generalised to other states and LGAs dues to differing stakeholder relationships. However, it can give insight into the picture of stakeholder relationships in similar settings in Nigeria, other developing country settings and across similar NTDs. This study can provide a baseline for other studies to measure collaboration within the schistosomiasis control program before implementing innovation or adopting the WHO NTD elimination plan.

Conclusion

This study has highlighted gaps in the stakeholder relationships within the schistosomiasis control program in a state in Southwestern Nigeria and its implication for meeting the WHO schistosomiasis elimination goals of 2030. The limited cohesion in stakeholder relationships across the contact, collaboration and resource-sharing networks can limit the progress recorded in schistosomiasis control and may be the missing link in reaching the schistosomiasis elimination goals promptly. Improved contact, collaboration and resource sharing across all layers of stakeholders can provide benefits such as improved capacity, responsiveness, innovation and openness to new ways of achieving set goals. This study also provides baseline data for interventions targeting improved collaboration among stakeholders in the schistosomiasis control network in Nigeria.

Further research is needed to map and understand stakeholder relations within the NTD context in Nigeria and Africa. Identifying weak links within NTD relational network can give insights into challenges and gaps with disease elimination and offers an opportunity to strengthen relational ties

and cohesion among NTD stakeholders.

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5.2. STAKEHOLDERS' PERSPECTIVES ON THE APPLICATION OF NEW DIAGNOSTIC DEVICES FOR URINARY SCHISTOSOMIASIS IN OYO STATE, NIGERIA: A Q-METHODOLOGY APPROACH

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Abstract

Urinary schistosomiasis is a waterborne parasitic infection caused by Schistosoma haematobium that affects approximately 30 million people annually in Nigeria. Treatment and eradication of this infection require effective diagnostics. However, current diagnostic tests have critical shortcomings and consequently are of limited value to stakeholders throughout the health care system who are involved in targeting the diagnosis and subsequent control of schistosomiasis. New diagnostic devices that fit the local health care infrastructure and support the different stakeholder diagnostic strategies remain a critical need. This study focuses on under- standing, by means of Q-methodology, the context of use and application of a new diagnostic device that is needed to effectively diagnose urinary schistosomiasis in Oyo State, Nigeria. Q-methodology is a technique that investigates subjectivity by exploring how stakeholders rank-order opinion statements about a phenomenon. In this study, 40 statements were administered to evaluate stakeholder perspectives on the context of use and application of potential new diagnostic devices and how these perspectives or viewpoints are shared with other stakeholders. Potential new diagnostic devices will need to be deployable to remote or distant communities, be affordable, identify and confirm infection status before treatment in patients whose diagnosis of urinary schistosomiasis is based on self-reporting, and equip health care facilities with diagnostic devices optimized for the local setting while requiring local minimal infrastructural settings. Similarly, the context of use and application of a potential new diagnostic device for urinary schistosomiasis is primarily associated with the tasks stakeholders throughout the health care system perform or procedures employed. These findings will guide the development of new diagnostic devices for schistosomiasis that match the contextual landscape and diagnostic strategies in Oyo.

INTRODUCTION

Urinary schistosomiasis is a water-borne parasitic infection caused by

Schistosoma haematobium. This disease is prevalent in Nigeria, especially in rural areas, and affects approximately 30 million people annually.[1–7] In specific regions, such as Oyo State, urinary schistosomiasis has an estimated prevalence of more than 50%.[2,8,9] Many studies on S. haematobium are predominately school based and report a disease prevalence of 17%–21% in urban areas and 32.7% in rural areas.[10–12] Efforts to control and eliminate schistosomiasis involve diagnosing individuals and gathering prevalence data that can be used for strategy development, program planning, and monitoring.[13] In Oyo, schistosomiasis is addressed through 2 approaches: (1) individual case management and (2) control and elimination.[2,5,14] In the individual case management approach, diagnosis by conventional microscopy followed by treatment is performed at a primary health care (PHC) facility.[15–17] In the control and elimination approach, the procedure involves the surveillance of high-risk groups and areas, followed by treatment to the entire group.[18,19] Onasanya et al. identified different stakeholders within 4 levels of the health care system in Oyo that are involved in diagnosing, controlling, and eliminating schistosomiasis:[5] (1) policy and economic, (2) organizational, (3) health care, and (4) community (Figure 1). Stakeholders at the policy and economic level include financing organizations, nongovernmental organizations (NGOs), and researchers. Organization-level stakeholders are health system managers that are interested in diagnostic devices that streamline the workflow and diagnostic efficiency. These stakeholders include medical officers of health, PHC coordinators, neglected tropical disease (NTD) officers, disease surveillance and notification officers (DSNOs), and teachers. Health care-level stakeholders include doctors, community health officers (CHOs), community health extension workers (CHEWS), and laboratory technicians who are interested in devices, particularly for use within remote areas. Lastly, community-level stakeholders, such as patients and other community members, are interested in diagnosis and treatment but lack expertise in using diagnostic devices for that purpose. Consequently, they rely on health care professionals for diagnoses and treatment.

Even though case management and control and elimination efforts are widely used simultaneously, the different stakeholders follow various procedures in implementing them. For example, at the health care level (level 3 in Figure 1) CHEWs and CHOs prioritize control and elimination at the community level, especially in remote communities that have limited or no health care facilities.[15,17,20,21] However, doctors and laboratory personnel within the same level prioritize individual case management.

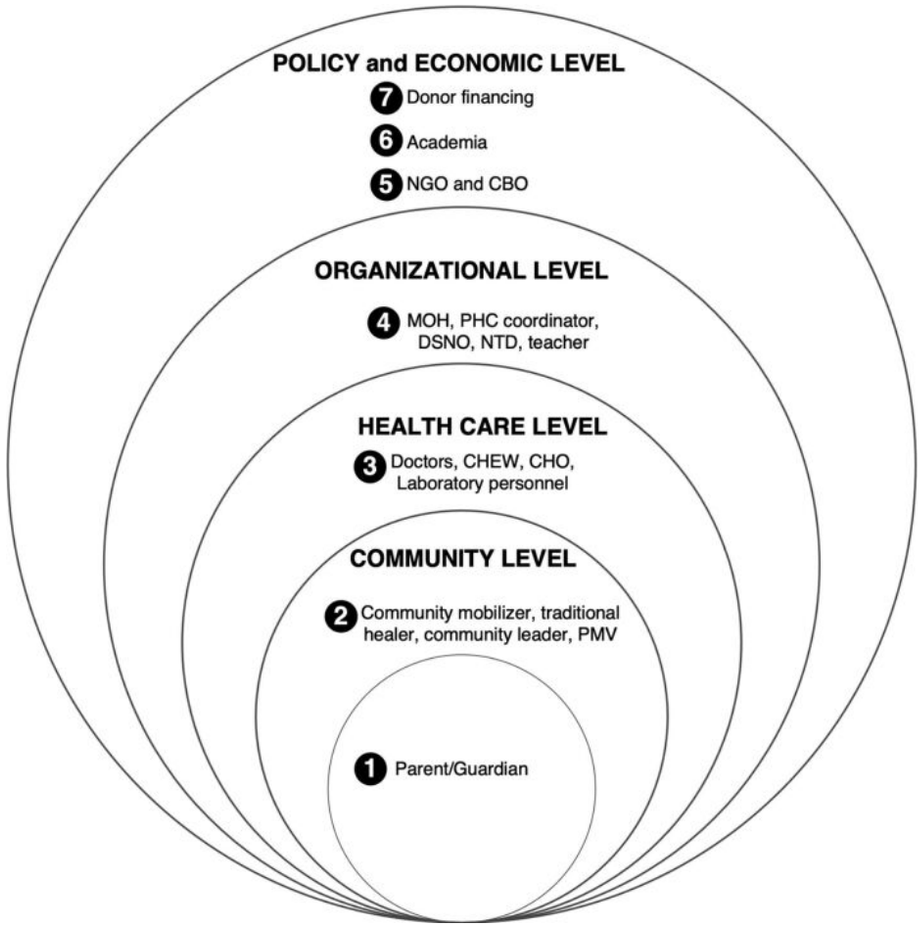
Similarly, the control and elimination approach is complex because it is addressed through a combination of different stakeholder procedures. For example, organizational-level stakeholders (level 4, Figure 1) prioritize

screening schools and doing mass drug administration (MDA) to school-aged children in the community or at a cluster of schools, while policy makers (level 5, Figure 1) prioritize MDA on a national level including adults and children.[18,19]

Even though all these procedures are important in actualizing individual case management and control and elimination, they may require different diagnostic devices that can be applied in different contexts. And these stakeholder groups are interested in different aspects of diagnostic devices. This necessitates new diagnostic devices that can support the various stakeholders in performing tasks targeting schistosomiasis. Therefore, it is important to understand stakeholder preferences and perspectives to reach a consensus on the best strategies for schistosomiasis control.

The main diagnostic tool for urinary schistosomiasis is conventional microscopy, which has critical shortcomings. Conventional microscopy is expensive, laborious to use, depends on well-trained personnel that rural communities often lack, cannot be deployed outside of the lab, and is most appropriate in well-equipped centralized laboratories not found in rural regions where schistosomiasis is prevalent.[1,3,9,22–24] As such, potential new diagnostic devices that can support stakeholders in targeting the diagnosis and subsequent control and elimination of urinary schistosomiasis are crucial.

Improved stakeholder capacity to perform such tasks is key to increasing diagnostic coverage, improving control, and eventually eliminating this infection.[25] However, these goals cannot be achieved if the design of current and new diagnostic devices does not consider the stakeholders' needs. Therefore, it is crucial to ensure that new diagnostic devices are developed to meet stakeholder needs as a means of supporting them in performing their respective tasks.



Abbreviations: CBO, community-based organization; CHEW, community health extension worker; CHO, community health officer; DSNO, disease surveillance and notification officer; MOH, medical officer of health; NGO, nongovernmental organization; NTD, neglected tropical disease; PHC, primary health care; PMV, patient medicine vendor.

Figure 1. Stakeholders Within the 4 Levels of the Health Care System in Oyo State, Nigeria[5]

Many new diagnostic devices for parasitic infections are under development, ranging from digital optical devices to sophisticated DNA-based analytic devices.[26–35] However, these devices are currently not deployable or commercially available and are therefore not available at the point of need.5,30 The World Health Organization estimates that 70% of medical devices in health care facilities in low-resource settings do not function well given that they were designed for the health care context in high-resource countries and were therefore not optimized for other settings.[20] According

to the United to Combat NTDs report on Delivering on Promises and Driving Progress, effective devices for urinary schistosomiasis remain an unmet need.[7] To be effective, new diagnostic devices for urinary schistosomiasis will need to (1) be designed for specific contexts of use, (2) fit the specific local (health care) infrastructure, (3) incorporate product requirements and performances suited for specific communities, and (4) be commercialized and implemented.[7,36.]

Health care systems are complex and include a diverse number of stakeholder groups, which of- ten bring distinct perspectives on issues related to care delivery and what constitutes appropriate treatment or quality of care.[37–42] Taking stakeholder perspectives and specific needs into account will enable them to fulfill tasks and implement strategies targeting the diagnosis and control of urinary schistosomiasis, which will ensure the uptake and use of new diagnostic devices to support the fight against this disease.[35] Therefore, we aimed to explore and understand the stakeholder perspectives on the context of use and application of potential new diagnostic devices for urinary schistosomiasis in Oyo. Context of use describes the interaction that occurs between the stakeholders (actors), diagnostic device (object), and location, while application describes the action of putting the diagnostic device into operation or use.[36] In this article, we present the different stakeholder perspectives that were studied.

METHOD

We applied Q-methodology to elucidate stakeholder perspectives on the context of use and application of new diagnostic devices for urinary schistosomiasis in Oyo. Q-methodology is a technique used in research to investigate subjectivity and people's viewpoints, perspectives, and beliefs, among other factors, regarding a particular phenomenon.[43–45] Q-methodology was suitable for gaining an understanding of the different perspectives on a potential new diagnostic device among the multiplicity of stakeholders who follow different procedures regarding the diagnosis of urinary schistosomiasis. In addition, as mentioned above, the health care system is recognized for its complexities and diverse stakeholder groups with distinct perspectives on issues of care delivery.[37–42] Therefore, the use of Q-methodology was suitable in this research to elucidate these different stake- holder perspectives. Q-methodology is used to reveal how and why people think the way they do and to uncover different patterns of thought while relying on a small number of respondents.[46,47] Unlike conventional surveys in which participants rate items in a questionnaire, Q-methodology com- pares perspectives between participants, and through factor analysis, identifies participants who share similar perspectives.[48,49]

In this study, the Q-methodology process was guided by the following steps: (1) collection of statements (also known as concourse development); (2) selection, development, and validation of statements deducted from the concourse (also known as Q-set); (3) participant selection (P-set), (4) selecting sorting distribution, (5) conducting the Q-sorting, (6) analysis, and (7) interpretation (Figure 2).[50] The steps outlined in this study facilitated a step-by-step implementation of Q-methodology as a research tool and did not aim to provide foundational material on how to conduct Q-methodology. Previous publications can be used to gain an in-depth understanding of Q-methodology.[39,50,51]

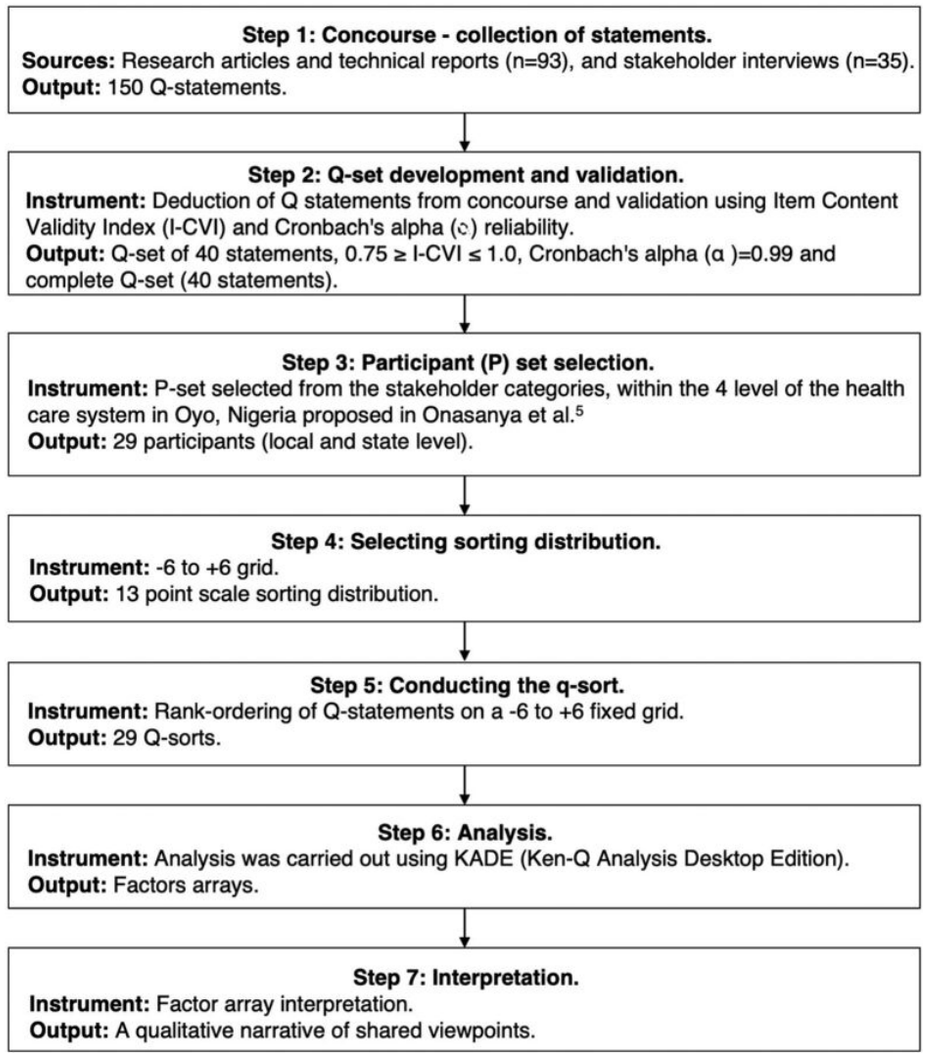
Step 1. Collection of Statements (Concourse)

A collection of 150 statements (Supplement 1) were gathered from literature (n=93) and stakeholder interviews (n=35) to build the concourse. Statements from literature were sourced from journal articles, conference proceedings, and NGO and government reports that contained insights on diagnosing urinary schistosomiasis in Nigeria and sub-Saharan Africa.[52] A variety of terms and combinations were searched in aca- demic databases such as PubMed, Science Direct, and Google Scholar. The following search terms were combined using the logical operators “and” or “or”: schistosomiasis diagnostic, tools, schistosomiasis stakeholder involvement, Nigeria, application, context of use, diagnostic tools for S. haematobium, approaches, and strategies. Statements pertaining to diagnosis, treatment, and patient-related diagnostic needs were identified by interviewing stakeholders from the 4 levels of the health care system (Table 1). These interviews provided additional opinion statements, which were combined with the findings from the literature.

Step 2. Q-Set Development and Validation

A Q-set is a selection of statements deducted from a concourse (step 1).[44,51,53] Forty statements were selected from the concourse in step 1 to make up the Q-set[53] (Supplement 2 Table 1). A Q-set of 40 opinion statements provided good coverage of the study, was sufficient to elicit existing viewpoints, and fell within the sample range (i.e., 30–50) that is generally accepted in Q-methodology.[43,51,54] The statements were selected based on 4 considerations as proposed by Uniting to Combat NTDs target product profiles, which provided a theoretical framework and ensured that the Q-set covered the essential diagnostic product requirements for diagnosing urinary schistosomiasis. Specifically, these requirements included (1) context use case, (2) infrastructure, (3) product requirements (design and performance), and (4) rollout strategy.[7,36,55] Infrastructure describes the facility, location, or setting, and product requirement describes the specifications for device design and performance. Rollout strategy describes strategies to introduce, integrate, and commercialize a new product to users. Four

domain experts validated the 40 selected statements. Three experts in the domain of parasitology and schistosomiasis diagnostics provided validation regarding urinary schistosomiasis diagnosis within the Nigerian context, and 1 Q-methodology expert provided validation on the construction of the Q-set. The domain expert validations were aimed at measuring the internal consistency and content validity of the Q-set. The internal consistency of the Q-set was measured using Cronbach’s alpha (a) reliability coefficient and the content validity was measured using the Item Content Validity Index (I-CVI).[56]



Perspectives on New Diagnostic Devices for Urinary Schistosomiasis[50]

Figure 2. Q-Methodology Study Process Used to Understand Stakeholders’

In measuring the content reliability and validity, the experts rated each of the Q-statements for readability, clarity of statement, and heterogeneity (breadth and depth)[53] (Supplement 2: Table 2.) Every statement was clear and made its own original contribution to the Q-set, without over- laps.[51] The domain expert rating (Supplement 3) was used to compute a statistical analysis of Cronbach's alpha reliability coefficient using Windows SPSS 26. The resulting Cronbach's alpha reliability coefficient was 0.99, which is acceptable and higher than the Nunnally norm of 0.7057 (Supplement 4). Similarly, the expert ratings were used to compute an I-CVI value for each of the 40 statements (Supplement 3): 32 statements scored an I-CVI value of 1.00, 8 statements had an I-CVI value of 0.88, and 1 statement had an I- CVI score of less than 0.80. Experts suggested was used to compute a statistical analysis of Cronbach's alpha reliability coefficient using Windows SPSS 26. The resulting Cronbach's alpha reliability coefficient was 0.99, which is acceptable and higher than the Nunnally norm of 0.7057 (Supplement 4). Similarly, the expert ratings were used to compute an I-CVI value for each of the 40 statements (Supplement 3): 32 statements scored an I-CVI value of 1.00, 8 statements had an I-CVI value of 0.88, and 1 statement had an I-CVI score of less than 0.80. Experts suggested minor changes in statement wording to improve clarity and readability, especially for the Q-statements with I-CVI values of less than 0.80.56 As a result of ex- pert feedback, minor edits were made to 2 statements (including statements with I-CVI values greater than 0.80) and 38 statements remained unchanged (Supplement 2 Table 1).

Table 1. Stakeholders Interviewed for Perspectives on the Context of Use and Application of Potential New Devices to Diagnose Urinary Schistosomiasis, Oyo, Nigeria[5]

Health Care Level	Stakeholder	Interview Count
Policy	Nongovernmental organization	1
	Academia/researcher	2
Organizational	Primary health care coordinator	1
	Medical officer of health	1
	Disease surveillance notification officer	2
	Neglected tropical disease officer	3
	Teacher	6
Health care	Doctors	1
	Community health extension worker	4
	Laboratory technician	4
	Community health worker	2
Community	Patient/guardian	5
	Community mobilizer	1
	Traditional healer	1
	Community leader	1

Table 2. Participant-Set Composition for Perspectives on the Context of Use and Application of Potential New Devices to Diagnose Urinary Schistosomiasis, Oyo, Nigeria

Stakeholder Level	Stakeholder	No. of Participants	
		Local Level	State Level
Policy and economy	Nongovernmental organization	1	1
	Financing	-	2
	Academia/researcher	1	1
Organizational	Medical officer of health/primary health care coordinator	1	1
	Disease surveillance notification officer	1	1
	Neglected tropical disease officer	2	1
Health care	Medical doctor	1	2
	Community health extension worker	1	1
	Laboratory technician	4	2
	Community health officer	4	1

Step 3. P-Set Selection

A total of 29 participants were purposively select- ed from 3 of the 4 health care system levels in Oyo (Table 2). We selected individuals based on their medical and scientific expertise in urinary schistosomiasis diagnosis and treatment in Oyo,[5] as well as their willingness to participate. Participants, which included individuals from the policy and economic, organization, and health care levels, represented high power and interest in the adoption of new diagnostic devices for schistosomiasis in Nigeria. We did not include community-level participants because they lacked the expertise in diagnosing urinary schistosomiasis using diagnostic devices and relied on health care professionals for diagnoses and treatment. The selected participants (n=29) were sufficient to establish and compare the different perspectives expressed in the Q-set. Likewise, a Q-set larger than the participant number was sufficient for this study because of the relevant background of the participants.[51]

Step 4. Selecting a Sorting Distribution

Data collection involved participants' rank-ordering statements on a fixed distribution. Compared with a free distribution, a fixed sorting distribution created an opportunity to standardize the process of ranking the statements.[51] Within this study, a Flatten- Gaussian 13-point scale (6 to 6) sorting fixed distribution with the poles labelled "most agree" to "most disagree" (Figure 3) was selected. This shape was selected to maximize the participant's proficient knowledge of the topic in achieving a granular rank order,[51] regarding the most relevant context and application of use for a new urinary schistosomiasis diagnostic device in Oyo.

Step 5. Conducting the Q-sort

Q-sort involved rank-ordering the 40 statements on the Flatten-Gaussian 13-point scale sorting distribution grid. A total of 29 Q-sorts were conducted within this research. Q-sorts were conducted using Easy-HtmlQ 2.0; a web-based platform for online Q-administration.[58] Easy-HtmlQ 2.0 was used to administer Q-sort remotely while providing live support via secure online calls within the boundaries of the COVID-19 pandemic. Conducting this study remotely or virtually, while not ideal, is an acceptable approach in Q-methodology.[59–61] The Easy-HtmlQ user-friendly interface allowed participants to familiarize themselves with the Q-set on digital cards. To reduce cognitive load, participants were first allowed to organize the statements into 3 piles: "strongly agree," "strongly disagree," and "neutral." Secondly, the 3 piles were ranked on the sorting grid from "most agree" (-6) to "most disagree" (+ 6). Each Q-sort exercise was completed with post-sorting questions within the Easy HtmlQ 2.0 to elucidate the reasons why statement rankings fell in extreme corners of the sorting grid and to understand the reasoning underlying rankings and trade-offs. The steps of

sorting and post- sorting questions are in line with recommended practices in Q-methodology.[44,62] Each Q-sorting lasted approximately 35–45 minutes per participant. The study was conducted with ethical approval from the Research Ethics Committees at the University of Ibadan-Nigeria (REF UI/EC/21/ 0100) and Delft University of Technology, the Netherlands. Participants were assured that participating in the study was voluntary and that information collected was anonymized and treated with confidentiality. All participants signed and provided informed consent before participating in the study and were allowed to withdraw from the study at any time. No participants expressed any hesitation to participate in the study.

Step 6. Analysis

Analysis was carried out using KADE (Ken-Q Analysis Desktop Edition) version 1.2.1 program.[63,64] The KADE program provided a simple and interactive visualization to analyze and interpret the data gathered. Q-sorts were entered into the KADE program for intercorrelation, and factors, also known as common perspectives, were identified using centroid factor analysis and varimax rotation. Fundamentally, factor analysis identifies the patterns of relationships within the data, or in this case participants' perspectives, and thereafter summarizes them into distinct patterns of occurrence.[50,65] Centroid factor analysis was preferred in this study because of its permissiveness for data exploration as opposed to principal component analysis, which resolves the data into a single mathematically best solution.[51] Varimax was preferred because it provides the most mathematically preferred solution in generating factors that when put together account for the maximum amount of study variance.[51] Varimax procedure in the KADE program provided factor loadings sorted from highest to lowest.[63]

Factor loadings sorted from highest to lowest provided a solution towards working our way down from the strongest factor load accounting for the maximum amount of study variance and produced clear and consistent factor interpretation and clustering.[51] Similarly, factors were retained for extraction if they had an eigenvalue (EV) $\geq$ 1.00 and 2 or more significant loadings (0.05 significant) following extraction.[51,54] EV is an indication of a factor's statistical strength. Factors with an EV less than 1.00 are often taken as a cut-off point, and factors with an EV above 1.00 are important and retained for extraction.[51] Iteration of the factor retention and extraction process continued until clear and consistent factor explanations and clustering emerged. At the end of this iterative process, the retained factors were documented in factor array scores and crib sheets (Supplements 5 and 6). A factor array table is a configuration of a Q-sort showing the viewpoint of a particular factor, grouping of statements, and their specific ranking value.[51] Crib sheet is a tool designed by Simon Watts of Nottingham Trent University, and it is used to examine factor array in detail through a

systematic and methodical approach that is consistent and delivers a holistic factor interpretation.[51,66]

Step 7. Interpretation

The factor array scores and crib sheets were interpreted to produce factor themes. Factor arrays provided the best possible estimates of relevant and holistic viewpoints and crib sheets were used to enforce holism by forcing engagement with every item in a factor array.[51] Statements with a statistical significance (P≤.05) were considered distinguishing statements.[43,54] The results and interpretation of the analysis were summarized in a qualitatively rich narrative with a coherent over- view of different perspectives (factors), its element, and the line of reasoning. For factor interpretation, it should be noted that the statement number and its corresponding rank in the factor array are represented as [statement; score]. For example, [24; -1] means statement 24 is ranked at -1 along the sorting grid (-6 to +6). This system of interpretation produces a succinct and holistic narrative because it shows how statements are linked within a factor.[67] The summarized narratives of the factors were further validated by experts that were representative of participants in each factor narrative. All experts had either medical or scientific expertise in diagnosing urinary schistosomiasis in Oyo, Nigeria. Each expert was assigned to read the factor they represented and engaged in qualitative discussions on whether the narrative was representative of the perspective shared within the diagnostic landscape in Oyo or not.

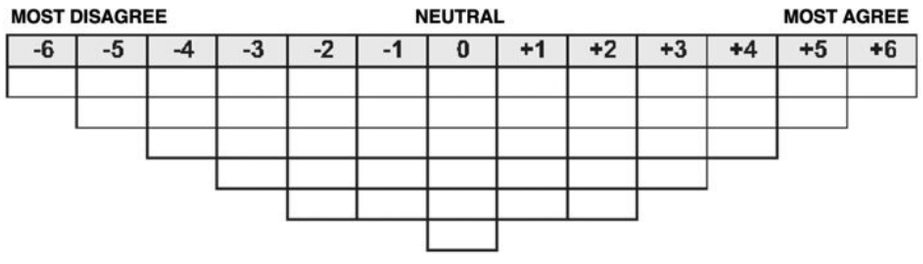


Figure 3. Flatten-Gaussian 13-Point Scale Sorting Fixed Distribution

RESULTS

To understand the stakeholder perspectives on the context of use and application of new diagnostic devices for urinary schistosomiasis in Oyo, Nigeria, a by-person factor analysis of 29 Q-sorts was performed. A factor array score of 4 distinct factors emerged (Table 3). These 4 factors collectively explained 33% of the study variance. A total explained variance of 33% is less than the widely used minimum range of 35%–40%.[68] However, a low explained variance is not necessarily problematic and may be meaningless,

especially when great care has been taken in selecting the Q-set and participant set.[51,54,69] Having only mathematical solutions such as total explained variance limits the opportunity to engage with the ranked statement.[51] Notably, a 5-factor solution would have offered a higher explained variance; however, it produced unclear and inconsistent factor explanation and clustering generated in the crib sheet (Supplement 5). A concise and consistent interpretation and explanation of factors or viewpoints were best achieved with a 4-factor solution (Supplement 6).

The interpretation of the factors revealed that the context of use and the application of new diagnostic devices for urinary schistosomiasis are both strongly influenced by 4 distinct factor themes. That is, new diagnostic devices will need to (1) be deployable to remote or distant communities, (2) be affordable, (3) identify and confirm infection status before treatment in patients with a diagnosis of urinary schistosomiasis based on self- reporting and be optimized for the local setting, and (4) fit within local minimal infrastructural settings (Table 4).

Factor 1: Deployable Diagnostics Devices to Remote or Distant Communities

Factor 1 (F1) had an EV of 4.77 and explained 16% of the total variance. A total of 10 respondents loaded significantly in this factor, and all in the positive pole. All 10 respondents were decision makers and performed supervisory, financing, and technical roles targeting the diagnosis of urinary schistosomiasis in Oyo. Four of the 10 respondents in F1 represented the policy and economic level of the health care system, including 2 individuals in the donor financing sector, 1 schistosomiasis control coordinator within the NGO sector, and 1 state university researcher. F1 also involved a DSNO and a medical officer of health at the state level (federal government). They represented the organizational level of the health care system that focuses on the pragmatic parts of schistosomiasis control, such as gathering information about urinary schistosomiasis that is then used for program planning. Similarly, F1 included 2 laboratory technologists, 1 medical doctor, and 1 CHEW at a state-run PHC facility. These participants represented the health care level that is interested in devices that improve the speed and accuracy of diagnosing urinary schistosomiasis.

Table 3. The 40 Statements and the Factor Array Scores of the 4 Factors

No. Statement		Factors				
		F1	F2	F3+	F3-	F4
	Context (Use Case)					
1	Microscopy using a concentration technique is the recommended method to prove active schistosomiasis, despite its low sensitivity and need for expert users.	0	-1	-1	-2	-3
2	Diagnosis should include the identification of schistosomia parasites in both humans and water sources that may be contaminated.	+2	0	+4	+2	0
3	Mass screening and diagnosis should be carried out alongside mass drug administration with praziquantel.	-2	-3	+4	-2	5
4	Schistosomiasis surveillance enables program managers to monitor the effectiveness of intervention strategies and identify which populations require continuing interventions.	-1	+5	+2	-1	+3
5	The availability of RDTs, which requires only minimal infrastructure, would improve diagnosis and survaillance simultaneously.	+3	-2[b]	+3	+2	+5
6	Implementing an affordable and simple POC diagnostics solution will reduce the financial burden of equipment and personal at each health facility.	0[b]	-2	-2	4[b]	-1
7	POC diagnostics that can be detected and confirm cases immediately will reduce the risk of missed or misdiagnosed cases.	+2	0	-3[b]	0	1
8	The quantification of egg excretion helps to assess the transmission potential of population living in endemic areas.	-1	-2	1	-1	-2
	Context (Use Case)					
9	Schistosomiasis control programs should target school-aged children only.	-6	-6	-1[b]	-5	-6
10	Due to low level of education and lack of training amont community health workers, incorrect treatment is often prescribed.	-3[a]	-1	0	0	3[b]
11	Presenting data on the severity of schistosomiasis infection of specific locations will guide the development of strategies for effective case management and control elimination.	+1	+2	-6[b]	+3	+1
12	Passive case detection, based on people's self-reporting has been considered a less expensive strategy for the control of schistosomiasis	-3	-2	6[b]	0	0
13	Prevalence and intensity of infection is often higher among children than among adults.	0	-1	-3	+1	0
	Infrastructure and location					
14	Schistosomiasis diagnosis should be done closest to the community as it reduces the time to carry samples back to the laboratory.	0	+1	2	0	+4
15	Diagnostic and treatment campaigns should target school-age children, adolescents and those whose occupations involve contact with infectious water (e.g. fishing, farming, irrigation, and domestic tasks in water).	-2	+3	+1	+1	-1

No. Statement		Factors				
		F1	F2	F3+	F3-	F4
16	Simple, rapid POC tests should be used in primary health care settings where patients often travel long distances to access health care facilities.	-1	-1	-2	+2	+2
17	Diagnostic devices should be deployed in primary health care centers, clinics, and health posts since they are the most lacking in equipment.	-4[a]	+4	-1[a]	+5	1[a]
18	Testing of urine samples for schistosomiasis with school-based surveys should be done at the school location.	-1	+1	0	-2	-5
19	It is convinient to treat patients for schistosomiasis infection without a confirmed diagnosis due to the delay in receiving test results from referral hospitals.	-5	-5	-5	-4	-4
	Product requirement					
20	Schistosomiasis elimination calls for developing novel diagnostic tools with higher sensitivity and specificity than microscopes.	+1	3[b]	-4	-1	-3
21	Diagnostic device for schistosomiasis with minimal to no sample preparation is ideal.	-2	-3	-2	-3	-5[a]
22	The diagnostic device should quantify eggs to provide an estimation of the number of people that have been exposed to schistosomiasis in a population.	5[a]	-5[b]	+1	-1[a]	+2
23	Devices should be easy to use by medical personnel and health workers such as CHEWs, CHOs, laboratory scientists to detect and diagnose schistosomiasis-infected patienets.	+1	+2	0	-5	-2
	Product requirement					
24	Patient samples should be processed in batches to get a faster turnaround time and increase the efficiency sample processing during mass campaigns or sensitization meetings.	0	0	+1	-4[b]	+3
25	Ideal diagnostic approaches should allow the concurrent detection of several pathogens in different biological samples such as urine, blood, and stool.	+3	0	+3	-3[a]	+1
26	Diagnostic devices should be sensitive enough for detecting very light schistosomiasis infections.	+4	-3	+5	-1	-1
27	Diagnostic devices should have their own reliable power sources due to the unstable power connectivity in rural and distant communities.	+6	-1	-1	+6	+6
28	The best diagnostic devices should be easy to trasport safely by car, motorbike, and bicycle to remote locations.	4[a]	+1	-4	+2	-1
29	Diagnostic devices should be compact and portable so that they can be easily deployed in the community.	+2	0[a]	+3	+3	-3[b]
30	Diagnostic devices/tests should identify and map out areas with large spread of schistosomiasis and be able to trace the source of the disease.	3[a]	0	0	0	-1
31	Devices should be locally repaired and maintained by local technicians in case of breakdown.	0	+2	-5[b]	+4	0
32	The device should be locally repaired and maintained by loca technicians in case of breakdown.	0	+2	-5[b]	+4	0

No. Statement		Factors				
		F1	F2	F3+	F3-	F4
	Rollout strategy					
33	Cost per diagnostic test should be free (covered by the government).	-1	4[a]	0	+1	-2
34	Cost per diagnostic test should be less than 1,000 Naira (US$2).	-5[b]	6[a]	-3	+3[a]	-2
35	Mass drug administration campaigns should be accompanied by mass diagnostic and disease awareness campaigns.	-2	+2	+2	1	0
37	New interventions should consider training the health care workers and the community level and the informal sector (PMVs and traditional medicine) to increase coverage to diagnostics.	-3	+1	-1	-6[b]	0
38	Diagnostic tools for schistosomiasis should be deployed and used at the community level by PMVs and community mobilizers as they already serve as trusted stakeholders in the community.	-4	-4	1[b]	-3	-4
39	The role of the village/community head is important in the acceptance of the new diagnostic device.	+5	-4[a]	-2[a]	+5	1[b]
40	Patients with schistosomiasis should be tested before being treated.	+2	+3	+5	-2[b]	+4

Abbreviations: CHEW, community health extension worker; CHO, community health officer; DSNO, disease surveillance notification officer; MOH, medical officer of health; NGO, nongovernmental organization; PMV, patent medicine vendor; POC, point-of-care; RDT, rapid diagnostic test.
[a]Distinguishing statement significant at *P<.05*
[b]Distinguishing statement significant at *P<.01*

F1 respondents emphasized the need for new diagnostic devices for urinary schistosomiasis that are deployable to remote communities and health care facilities [29; +2, 17; -4] (P≤.05) (Figure 4). New diagnostic devices that are deployable to re- mote communities will require their own reliable power sources owing to limited power connectivity in such areas [27; +6]. Similarly, deploying these new diagnostic devices to remote communities and health care facilities should be possible using bicycles, motorbikes, and cars [28; + 4] (P≤ .05). This will increase the ability to reach remote communities to detect S. haematobium cases and map areas with a large spread of the infection [30; +3*] (P≤.05). Deployable diagnostic devices will need to be sensitive and able to quantify eggs to estimate the intensity of infection [22; +5] (P≤.05). Estimating the population exposed to urinary schistosomiasis should not be limited to school-age children but should also include adults [9; -6]. The ability to identify populations exposed to this infection could be enhanced by leveraging the social power of community leaders [39; +5]. However, F1 respondents raised concerns about including nonclinical professionals in diagnostic processes [37;-3, 38; -4].

Factor 2: Affordable Diagnostic Tests and Devices

Factor 2 (F2) had an EV of 1.88 and accounted for 6% of the total variance. Five participants loaded significantly in the positive pole: 2 PHC laboratory technicians, 1 CHEW, 1 researcher, and 1 DSNO. All 5 participants operated in local government areas (LGAs) in Oyo. The PHC laboratory technician and CHO were interested in new devices that improve the speed and accuracy of diagnostics. They were proactive in the community and demonstrated high social relationships with the community members. The researcher represented the policy and economy level and provided technical expertise targeting the control and elimination of schistosomiasis at LGAs. The DSNO was interested in gathering and using prevalence data for planning.

F2 respondents emphasized that the cost per diagnostic test in the community should be less than 1,000 naira (N), approximately US$2, to be considered affordable or be covered by the government [33; +4, 34; +6] (P≤.05) (Figure 5). Affordable or free diagnostic tests will help increase diagnostic coverage in the communities and improve the ability to identify infected areas in need of treatment, MDA, or disease awareness campaigns [35; +2, 19; -5, 3; - 3]. Diagnostic tests and treatment campaigns should not only target school-age children [9,- 6] but should include other high-risk groups such as adolescents and people whose occupations involve contact with infectious water [15; +3].

Respondents in F2 further emphasized developing novel diagnostic devices that are affordable and deployable, have high sensitivity and specificity, and present (real-time) data on the severity of urinary schistosomiasis [20; +3, 11; +2] (P≤.01). Having data on infection severity will enable stakeholders to plan various tasks targeting the diagnosis and subsequent control of urinary schistosomiasis [36; +5, 4; +5]. These new diagnostic devices should be deployed in communities and PHC facilities that are most lacking in general laboratory equipment [17; +4, 23; +2, 38; -4].

Factor 3: Identify and Confirm Infection Status Before Treatment

Factor 3 (F3) has an EV of 1.65 and accounts for 6% of the total variance. Four participants loaded significantly in this bipolar factor. Two in the positive pole (F3+) and 2 in the negative pole (F3-). The F3+ respondents were both CHOs interested in a new diagnostic device increasing the speed and accuracy in identifying urinary schistosomiasis cases in the LGAs. Respondents in F3- included a laboratory technician at a private laboratory and a medical doctor at a tertiary health facility that offers specialized health care in the form of community-based outreach. F3+ respondents confirmed that passive case identification based on people's self-reporting is an affordable strategy to identify urinary schistosomiasis [12; + 6] (P≤ .01). (Figure 6). However, case

identification based on people's self-reporting should be supported with a diagnostic device that can identify and/or confirm infection status [3; +4] to support treatment with praziquantel [40; +5, 19; -5]. Diagnostic devices that can quickly identify infection status before treatment should be sensitive to detect a low-level infection [26; +5, 25; + 3].

Similar to F3+ respondents, F3- respondents did not emphasize the need to identify infection status before treatment [40;-2] (P≤.01). F3 respondents emphasized the need to detect and obtain data on the severity of infections in multiple biological samples [25; -3, 11; 3] to increase the capacity to identify infected groups and areas.

Similarly, such identification will guide the development of strategies to manage and control schistoso- miasis within such groups and areas. Community leaders who have high social power can support strategies to manage and control schistosomiasis in infected areas [39; 5]. However, F3- respondents raised concerns about training community members with no formal clinical expertise to detect and diagnose schistosomiasis [23; -5] [37; -6] (P≤.01). F3- respondents also emphasized equipping PHC facilities that currently have limited or no diagnostic devices to detect S. haematobium [17; +5, 16; +2] (Figure 7). New diagnostic devices that equip PHC facilities to detect S. haematobium will need to be maintained and repaired locally and to have their own reliable power sources owing to limited power access in some remote communities [27; +6, 31; +4, 29; +3].

Table 4. The 4 Distinct Factor Themes That Emerged From the Stakeholder Perspective on the Context of Use and Application of a Potential New Diagnostic Device for Urinary Schistosomiasis in Oyo, Nigeria

Factors	No. of Sorts	Loaders	Factor Theme
Factor 1	10	2 laboratory technicians, 2 donor financing, an NGO representative, a researcher, DSNO, MOH, medical doctor, and a CHEW	Deployable diagnostic devices to remote/ distant communities
Factor 2	5	2 lab technicians, a CHEW, researcher, and a DSNO	Affordable diagnostic tests/ devices
Factor 3þ	2	2 CHOs	Identify and confirm infection status before treatment in patients with a diagnosis of urinary schistosomiasis based on self-reporting
Factor 3–	2	A medical doctor and a laboratory technician	Equip health care facilities with diagnostic devices optimized for the local setting
Factor 4	5	An NTD officer at state level, a medical doctor, a CHEW, a CHO, and an NTD officer in an LGA	Simple POC devices/tests requiring mini mal local infrastructure
Confounded	3		
Nonsignificant	2		
Total	29		

Abbreviations: CHEW, community health extension worker; CHO, community health officer; DSNO, disease surveillance notification officer; LGA, local govern ment area; MOH, medical officer of health; NGO, nongovernmental organization; NTD, neglected tropical disease; POC, point-of-care.

Factor 4: Simple Point-of-Care Devices/Tests Requiring Minimal Local Infrastructure

Factor 4 (F4) has an EV of 1.35 and accounts for 5% of the total variance. Five participants loaded significantly in the positive pole. That is, NTD officers and medical doctors providing supervisory activities targeting urinary schistosomiasis in multiple LGAs. A CHEW and a CHO stationed at a community PHC facility were also included. F4 respondents were interested in new diagnostic devices that can improve the speed and accuracy of detecting S. haematobium cases in PHC facilities. F4 respondents emphasized the need for simple point-of-care (POC) diagnostic devices or tests that require minimal infrastructure [5; +5, 16; +2] (Figure 8) where patients often travel long distances to access health care facilities [16;+2]. Meeting this need will improve diagnostic coverage and surveillance beyond school-age children [3;+5, 16; +2, 9; -6, 18; -5, 5; +5]. Similarly, implementing simple POC diagnostic devices will ensure that the diagnosis is performed closest to the community [14; +4]. In the community, patient samples can

be collected and analyzed in batches (sample pooling strategy) to increase sample processing efficiency during campaigns or sensitization meetings [24; 3, 40; 4]. This approach will reduce the time needed to analyze individual patient samples in centralized laboratories, which are often far away [14; +4]. Simple POC diagnostic devices or tests that require minimal infrastructure would require their own reliable power sources, especially in remote communities with limited power access [27; +6].

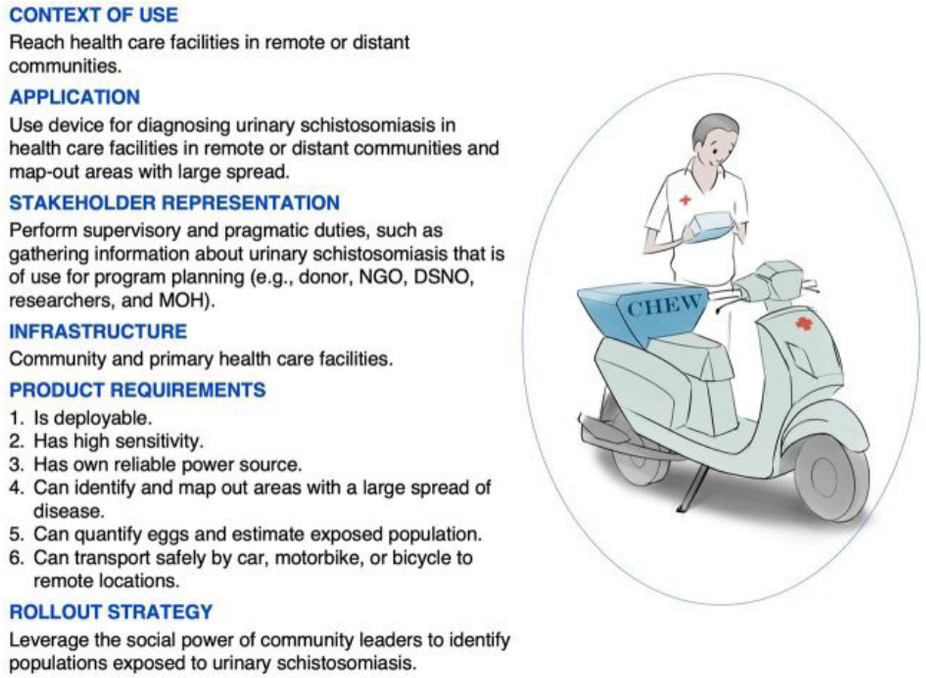


Figure 4. Factor 1: Context of Use and Application of a Deployable Diagnostic Device for Diagnosing Urinary Schistosomiasis in Ibadan, Nigeria

Validation of Results

To validate the results of this study, qualitative discussions were carried out with 5 experts about the 4 factors that emerged on the context of use and application of new diagnostic devices in Oyo, Nigeria. The experts included a laboratory technician, a researcher, a CHO, a medical doctor, and an NTD officer. Each expert was representative of loaders in each of the 4-factor themes (Table 4). The experts mentioned that all 4 factors were representative of viewpoints shared within the diagnostic landscape in Oyo. Interestingly, the viewpoints expressed in each factor were closely directed towards improving the ability of stakeholders to perform various tasks targeting the diagnosis and subsequent control of schistosomiasis.

Such tasks included identifying and gathering information on cases or areas that are affected by urinary schistosomiasis in Oyo. This finding suggests that the stakeholder perspectives on the context of use and application of new diagnostic devices are closely associated with the different stakeholder tasks and strategies targeting urinary schistosomiasis in Oyo.

DISCUSSION

This study explored stakeholder perspectives on the context of use and application of potential new diagnostic devices for urinary schistosomiasis in Oyo. The diagnosis and subsequent control of this infection currently rely on expensive diagnostic tools that are laborious to use in the local endemic context, depend on well-trained personnel often lacking in rural communities, and are not field deployable. These factors limit the capacity for stakeholders within the health system in Oyo (Figure 1) to perform tasks targeting the diagnosis and subsequent control of schistosomiasis.

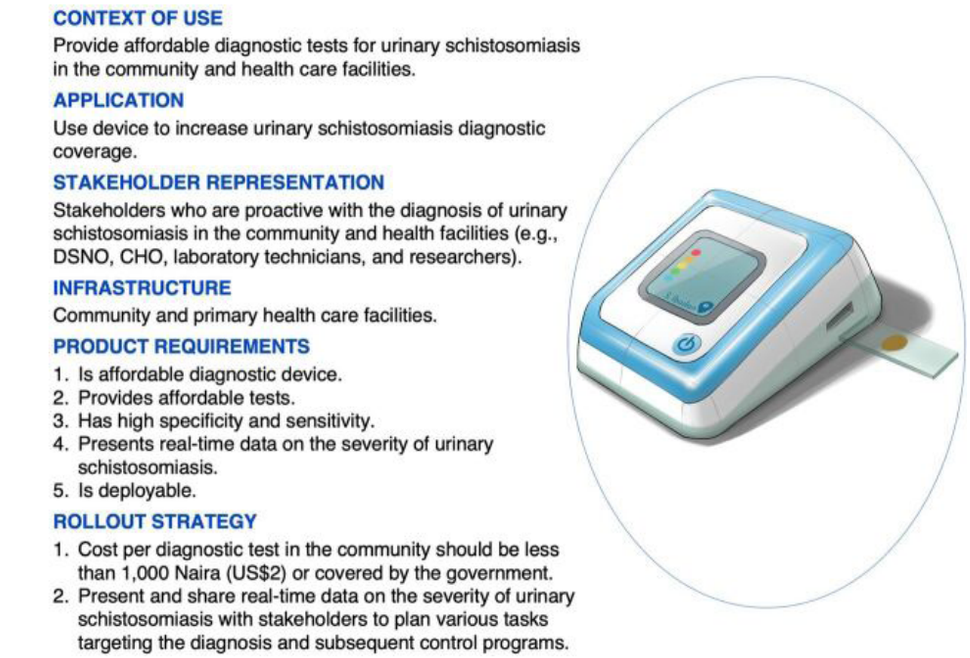


Figure 5. Factor 2: Context of Use and Application of Affordable Diagnostic Tests/Devices for Diagnosing Urinary Schistosomiasis in Oyo State, Nigeria

In investigating this issue, our findings revealed that new diagnostic devices that fit within the con- text of use will need to (1) be deployable to remote or distant communities, (2) be affordable, (3) identify and confirm infection status before treatment in patients with a diagnosis based on self-reporting,

and (4) be optimized for the local setting and fit within local minimal infrastructural settings. Similarly, the study revealed that the context of use and application of potential new diagnostic devices is largely associated with the stakeholder tasks or diagnostic strategies employed. These findings will contribute to driving progress in developing new diagnostic devices for urinary schistosomiasis in Oyo and globally in several ways.[7]

First, new diagnostic devices that are deployable will increase the capacity to diagnose and provide surveillance, especially in rural regions.[70] Deployable diagnostic devices will support stakeholders such as DSNOs, NGOs, and researchers to perform pragmatic and supervisory tasks in schistosomiasis control and elimination. Such pragmatic and supervisory parts include gathering data, mapping, monitoring, and using information about schistosomiasis for program surveillance and planning, especially in various communities. Communities can receive schistosomiasis diagnostic health services irrespective of their location.[1] However, deployable diagnostic devices will need to be sensitive for detecting low-level infections quickly; be safely transportable in cars, motorbikes, or bicycles; and have their own reliable power source because of the unstable power connectivity in rural regions.

CONTEXT OF USE

Support the identification/confirmation of urinary schistosomiasis in patients who were diagnosed with urinary schistosomiasis based on self-reporting.

APPLICATION

Use device to identify, verify, or confirm the present of urinary schistosomiasis.

STAKEHOLDER REPRESENTATION

CHOs

INFRASTRUCTURE

Mass drug administration campaigns.

PRODUCT REQUIREMENTS

1. Is sensitive to detect light urinary schistosomiasis cases.
2. Can diagnose urinary schistosomiasis in urine, blood, stool, and water bodies.

ROLLOUT STRATEGY

Use diagnostic device to support programs that identify urinary schistosomiasis cases based on people's self-reporting before MDA with praziquantel.

Figure 6. Factor 3+: Context of Use and Application of a New Diagnostic Device for Diagnosing Urinary Schistosomiasis in Oyo State to Identify Disease Status Before Treatment

CONTEXT OF USE

Equipping PHC facilities to effectively diagnose urinary schistosomiasis cases.

APPLICATION

Use device to equip PHC facilities.

STAKEHOLDER REPRESENTATION

Laboratory technicians and medical doctors.

INFRASTRUCTURE

PHC facilities.

PRODUCT REQUIREMENTS

1. Can be repaired/maintained locally.
2. Has own reliable power source.
3. Presents data on the severity of urinary schistosomiasis in specific locations.

ROLLOUT STRATEGY

Make available diagnostic devices with support maintenance/repair systems in distant/remote health care facilities.

Figure 7. Factor 3: Context of Use and Application of a New Diagnostic Device for Diagnosing Urinary Schistosomiasis in Oyo State to Equip Primary Health Care Facilities

CONTEXT OF USE

Diagnostic device/test requiring minimum infrastructure.

APPLICATION

Use device to improve diagnostic capabilities in PHC and remote communities.

STAKEHOLDER REPRESENTATION

Health care workers (e.g., NTD officers, CHEWs, CHOs, and medical doctors).

INFRASTRUCTURE

Health care facilities closest to/in remote communities.

PRODUCT REQUIREMENTS

1. Requires minimum infrastructure.
2. Has own reliable power source.
3. Can process patient samples in batches to increase diagnostics efficiency.

ROLLOUT STRATEGY

Patients with schistosomiasis should be tested before being treated during mass urinary schistosomiasis campaigns or sensitization meetings. In the community, patient samples can be collected and analyzed in batches (sample pooling strategy) to increase sample processing efficiency during mass campaigns or sensitization meetings.

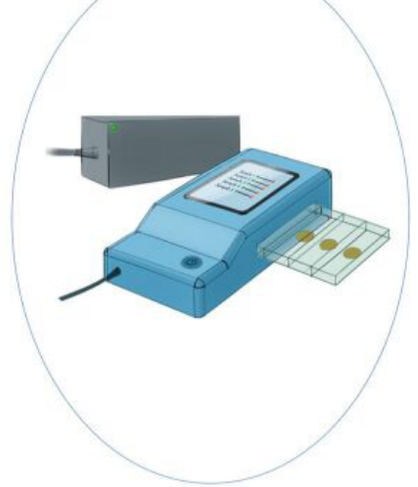


Figure 8. Factor 4: Context of Use and Application of a Simple POC Diagnostic Device for Diagnosing Urinary Schistosomiasis in Oyo State, Requiring Minimal Infrastructure

Second, affordable diagnostic tests or devices that are supported by policies that reduce the overall cost of diagnosis will make diagnostic testing more affordable in Nigeria, where urinary schistosomiasis diagnostic tests costing between US$1 and US$2 (approximately ₦400 to ₦1000) are either lacking or not commercially available.[1,71–73]

Third, new diagnostic devices that can identify infection status before treatment will support the identification and prioritization of patients or areas in need of treatment. However, MDA programs have not led to morbidity reduction since estimates that prioritize the number of people eligible for treatment from the number of people treated has often been problematic.[74–77] Overall, new diagnostic devices that can accurately identify infection status before treatment will support stakeholders at the health care, organizational, policy, and economic levels to prioritize MDAs in LGAs.

New diagnostic devices that can equip health facilities while requiring minimal infrastructure will increase diagnostic coverage especially in rural regions. In addition, equipping health facilities in rural regions will reduce the burden on patients who often travel long distances to access treatment and are unable to return for test results.[23] Lastly, new diagnostic devices will need to support stakeholders in performing various tasks and strategies targeting urinary schistosomiasis within the context of Nigeria, as shown in this Q-methodological study. This support will ensure that new diagnostic devices are accepted and used by many end users in Oyo.[5] Q-methodology served as a rigorous tool in this study because it is scientifically valid and reproducible in the domain of human-centered design. Human-centered design, or participatory design, seeks to understand user needs and insights to inform the design process.[78] Design researchers can benefit from using Q-methodology as a participatory design tool to identify stakeholder needs and product-service design requirements, especially at the formative stage of the design-innovation process as in this study.

Limitations

Although a small size of diverse respondents is not a limitation within this study, as large sample sizes are not required for a Q-methodology study, the findings are not generalizable beyond the small participant pool (Table 1). Furthermore, this study was conducted remotely using virtual digital platforms owing to COVID-19-related restrictions, which limited the ability to have in-person qualitative discussions. To ensure stakeholder viewpoints were extensively explored, written instructions and discussions within this study had to be clear and precise and solicited immediate feedback for clarifications. Considerable time was needed to prepare such concise instructions, which produced the key findings and their implications within this research. In-person conversations could have captured richer qualitative

information and insights, which might have added additional explanatory value to this study.

CONCLUSION

This study provides 2 key implications related to the development of potential new diagnostic devices and the stakeholders who perform tasks targeting urinary schistosomiasis control and elimination. First, medical device designers and technology companies should ensure the development of new diagnostic devices that can equip health care facilities with minimal infrastructure, be affordable, be deployable, and identify infection status before treatment. Second, the health care system and community stakeholders in Nigeria (Figure 1) should continuously participate and collaborate with the design industry in the human-centered design process of new diagnostic devices, thus ensuring stakeholder needs and viewpoints are considered in the design process. It is crucial to ensure that diagnostic devices are available at the point of need, are designed to function best within the local endemic health care context, and support stakeholders in performing tasks targeting control and eventual elimination of schistosomiasis.[5,20,25,30] In conclusion, the findings from this study will guide the development of new diagnostic devices for schistosomiasis that match the contextual landscape and stakeholder diagnostic strategies in Oyo.

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Chapter

6

CO-CREATING PRODUCT SPECIFICATIONS WITH STAKEHOLDERS

In this chapter, the development process and gaps with current TPPs for schistosomiasis elimination are discussed. The first study discusses the current limitations of TPPs for digital and non-digital diagnostics for schistosomiasis and highlights solutions to explore to improve the TPP development process and content. The second study highlights the process of developing a target product profile in a developing country context from a design perspective.

6.1. DEVELOPING INCLUSIVE DIGITAL HEALTH DIAGNOSTIC FOR SCHISTOSOMIASIS: A NEED FOR GUIDANCE VIA TARGET PRODUCT PROFILES

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Abstract

Introduction: The INSPIRED project aims to develop inclusive Digital Optical Diagnostic Devices (DODDs) for schistosomiasis, to support disease management by enabling rapid diagnostic results, to improve efficient data management to guide decision-making and to provide healthcare workers with critical health information to facilitate follow-up action. Due to the non-availability of Target Product Profiles (TPPs) for guiding the development of digital diagnostics for schistosomiasis, we explored existing diagnostic TPPs.

Method: Using a curated open access database (Notion database), we studied a selection of TPPs for diagnosing infectious diseases, focusing on specifications related to digital health products for Neglected Tropical Diseases (NTDs).

Result: Eighteen TPPs originating from 12 documents, covering 13 specific diseases, were selected and their characteristics were labeled and entered into the database. Further exploration of the database revealed several gaps, including a lack of stakeholder input, sustainability, and TPP availability. Other significant gaps related to digital health platform interconnectivity and data stewardship specifically in relation to digital diagnostics, including DODDs.

Discussion: These findings reflect two possible scenarios: (1) there is currently no need for digital diagnostic devices for schistosomiasis and, by extension for other NTDs; or (2) those needs are not yet covered by TPPs. Therefore, we recommend that digital health diagnostics are included in the use cases for schistosomiasis control and elimination, at least in the ideal/desirable scenario, as this will guide research and incentivize investment in digital health diagnostics for schistosomiasis.

INTRODUCTION

Schistosomiasis is a Neglected Tropical Disease (NTD) dominant in rural communities in tropical regions and affecting more than 250 million people worldwide (World Health Organization, 2023c). The WHO's NTD 2021-2030 roadmap sets global targets and milestones to prevent, control, and eliminate diseases and one of the actional points is the development of new tools and diagnostics (World Health Organization, 2020a).

There are several categories of diagnostics for schistosomiasis for which two use cases are possible: individual (test and treat) and population-level (monitoring and evaluation) (Samenjo et al., 2022; Sluiter et al., 2020). Considering the individual level, diagnostics are needed to detect diseases at the lowest levels of care. Population-level-based diagnostic strategies include methods such as systematic population screening or sample pooling strategies. In both situations, Point-of-Care (POC) diagnostic approaches play an essential role (Cavalcanti et al., 2019; Hoekstra et al., 2021).

Current and widely available tests for schistosomiasis includes microscopy, antibody detecting tests such as Enzyme-Linked Immunosorbent Assay (ELISA), Rapid Diagnostic Tests (RDTs) such as the POC-CCA urine-based lateral flow test and Nucleic Acid Amplification Tests (NAAT) (Ajibola et al., 2018; Hoekstra et al., 2021). Newer diagnostic tests are currently undergoing development focusing on the use of digital technology.

The INSPiRED consortium (http://inspired-diagnostics.info/) is developing digital optical diagnostic devices for schistosomiasis, which includes automated digital microscopes and optical readers (Meulah et al., 2022; Oyibo et al., 2022). Other groups are also developing optical digital devices for the detection of helminths eggs in either urine or stool samples (Armstrong et al., 2022; Bogoch et al., 2014; Holmström et al., 2017; Ward et al., 2022). In parallel, there are initiatives for digital technology based on NAAT which could potentially be applied to NTDs (Cunnington & The Digital Diagnostics for Africa Network, 2022). These digital diagnostic devices are part of a wide range of Digital Health Products (DHPs) that are being explored to support traditional methods of diagnosis, treatment, monitoring and evaluation of diseases (Table 1).

Table 1. Definition of key terms

Terms	Definition
Digital Health Products (DHP)	ICT-based health technologies including software (databases, platforms, web applications) and/or hardware (devices) with/without interconnectivity.
Digital Health Diagnostics (DHD)	Digital health products that use digital data to make or support disease diagnosis.
Digital Optical Diagnostic Devices (DODD)	Hardware (devices) using optical systems (automated/semi-automated) and digital data to make or support disease diagnosis.

The case for digital health diagnostics for schistosomiasis control

Digital Health Diagnostics (DHDs) are DHPs using digital data to make or support disease diagnosis and can be used by clinicians, patients, health workers and health policymakers to diagnose, and manage diseases and health risks, promote wellness, and support health-related decision-making processes (Ronquillo et al., 2022). They include a range of applications such as software and hardware (devices) with or without integrated software, with increasing interconnectivity among these components. They have the potential to reduce inefficiencies and costs related to manual procedures, thus improving access and quality of care, and increasing ownership of health by patients through personalized care (Center for Devices and Radiological Health, 2020).

As developers of Digital Optical Diagnostic Devices (DODDs), we envision that DODDs, a subset of DHDs could play an important role in controlling and eliminating schistosomiasis in low and middle-income countries for several reasons. First, conventional microscopy is the current standard, even though its' sensitivity is user dependent which will be a critical limitation in elimination settings (Ajibola et al., 2018; Hoekstra et al., 2021; Tabios et al., 2022). Furthermore, access to available diagnostics such as conventional microscopy is limited by costs and availability of skilled microscopists at the lowest level of care (Onasanya et al., 2020; Worrell et al., 2015). Second, POC diagnostics such as the PoC-CCA test is observer-dependent and lacks digital connectivity of the test outcomes (Casacuberta-Partal et al., 2019; Mewamba et al., 2021). This could potentially be addressed through the use of a digital reader to standardize the readout and directly provide digital data, thus supporting diagnostic decision-making (Casacuberta-Partal et al., 2019). Third, and perhaps most critical, data generated from the use of current diagnostic methods need to be manually collected and collated at several sub-national levels before it is available at the policy level for decision-making. This process is time-consuming and coupled with the possibility of data loss or data validity concerns, it can lead to a

slower decision-making process leading to failure to meet schistosomiasis control and elimination targets. DHDs can bridge these gaps by providing opportunities for interconnectivity with digital health platforms such as the District Health Information System (DHIS).

Interestingly, our recent literature review demonstrated that most DODDs for schistosomiasis are limited to the proof of concept stage, and very few devices are implemented and/or commercially available (Meulah et al., 2022). Guidance on the design and implementation of DODDs and by extension DHDs for schistosomiasis is urgently needed to facilitate and direct new digital developments.

Target product profiles for digital health diagnostics

Developing diagnostic tests requires guidance to highlight needs and minimally acceptable test specifications. This guidance has largely been in the form of Target Product Profiles (TPPs), a commonly used tool to describe the needs for new products to fulfil existing gaps and the requirements related to specific use cases. TPPs aim to guide researchers, policymakers, commercial parties, and funders towards the development of health products that fit the particular needs of a given context. This description is documented with a distinction between the minimum and ideal characteristics of the product.

The Diagnostic Technical Advisory Group (DTAG), commissioned by WHO, is the working group with a coordinating role in the development of TPPs (Figure 1) for NTDs to reach the goals described in the 2020-2030 roadmap (World Health Organization, 2020b). The diagnostic TPPs for schistosomiasis, developed by DTAG, are for (1) monitoring and evaluation of control programmes and (2) determining if the transmission has been interrupted and when to conduct post-mass drug administration (MDA) surveillance (World Health Organization, 2020b).

Source: WHO (World Health Organization, 2023b)

Figure 1. The WHO TPP drafting process

Although developing DHDs for schistosomiasis, and by extension, other NTDs, is the right step to meeting WHO targets, there are currently no guidelines to support developers in this process. A broad search for TPPs of DHDs for schistosomiasis and other NTDs yielded no information. The WHO Health Product Profile Directory (HPPD), which is a database of currently available health products targeting low-resource settings, includes 'digital health' as a product type. However, a search of the directory on June 15, 2022, revealed that DHPs are only available for TB, sexually transmitted infections and neonatal sepsis which are mainly focused on disease management and awareness. Furthermore, while many TPPs exist in the database, only a few TPPs can be found that are dedicated to digital products in the context of global health.

For schistosomiasis specifically and other NTDs broadly, there are no existing TPPs published by health organizations including the WHO that describe the needs for and characteristics of DHPs to facilitate schistosomiasis diagnostics. This could either indicate there is no need for DHPs in this context, or it could mean those needs are not specified and described yet. According to the road map for neglected tropical diseases 2021-2030 (World Health Organization, 2020a), digital health platforms for collecting and monitoring data are needed. However, this need is not further specified. This example appears to be the norm in the conversation about digital health: there is consensus about the need for digital health in general, but it lacks the understanding of what this digital health could and should entail.

This paper discusses the need for DHDs for schistosomiasis elimination and highlights the gaps in the current TPPs for schistosomiasis particularly the absence of guides for the development of digital diagnostics that can support the elimination of schistosomiasis. We analyzed available TPPs from the WHO and other sources focusing on schistosomiasis and digital health products for specific diseases, and offer potential resolutions which can support the development of TPPs for DHDs for schistosomiasis and alongside improving the TPP development process broadly. Studying a variety of TPPs that are related to NTDs and digital health products for global health diseases could contribute to an understanding of the actual need for TPPs for digital diagnostics for schistosomiasis.

METHODOLOGY

To explore what we can learn from existing TPPs concerning the need for DHDs for schistosomiasis, a publicly accessible database consisting of a selection of TPPs was curated (Notion database). Documents for the database were obtained from the results of a general web search using the Google search engine. The Google search was limited to the first six pages of the database. Other websites and databases of NGOs searched include PATH, FIND and MSF. The search was performed in June 2022.

While several organizations develop TPPs, only WHO and other non-profit health organizations were included in this study. TPPs from the private-for-profit sector were not included due to the risk of conflict of interest.

The inclusion criteria for a TPP to be entered into the database were based on the year of publication (≥ 2016) and three domains: (1) diagnostic tests using human samples to support mass drug administration programs (MDA) for NTDs; (2) diagnostic tools and digital devices to aid the detection of NTDs, HIV/AIDS, TB and malaria; (3) diagnostic systems such as digital health applications for NTDs, HIV/AIDS, TB and malaria. While there are 21 NTDs, only NTDs that include MDA as a treatment approach were included in the database (World Health Organization, 2020a). Based on this selection criteria, the TPPs for the following NTDs were then included in the database: foodborne trematodiases; lymphatic filariasis; onchocerciasis; scabies and other ectoparasites; schistosomiasis; soil-transmitted helminthiases; taeniasis/cysticercosis; and yaws and other endemic trepanemotoses.

The following search terms were used to find relevant TPPs:
Target Product Profile + Lymphatic filariasis, onchocerciasis, river blindness, schistosomiasis, ascariasis, trichuriasis, hookworm, soil-transmitted helminthiases, trachoma, foodborne trematodiases, taeniasis, cysticercosis, yaws, scabies.

Target Product Profile + Digital device, electronic device, digital health, e-health, smart device.

Target Product profiles + WHO, FIND, GHIT, PATH, Bill & Melinda Gates Foundation, UNICEF.

The contents of each TPP were categorized in the database according to predefined characteristics that are standardized in formal TPPs (i.e., all minimum and ideal characteristics were labelled in the database within a category). In this way, the contents of different TPPs can be easily searched and compared, and metadata can be analyzed. For easy handling, sharing and the functionality of adding and filtering multiple labels, the web-based application Notion was used to create and analyze the database.

Metadata was added to single characteristics and requirements as stated in the TPP, in the form of labels (e.g. context and user; functionality; performance; market and business). This database allows the user to categorize TPPs based on the specified use case (i.e., individual case management; mapping; monitoring and evaluation; stopping decisions; surveillance).

RESULTS

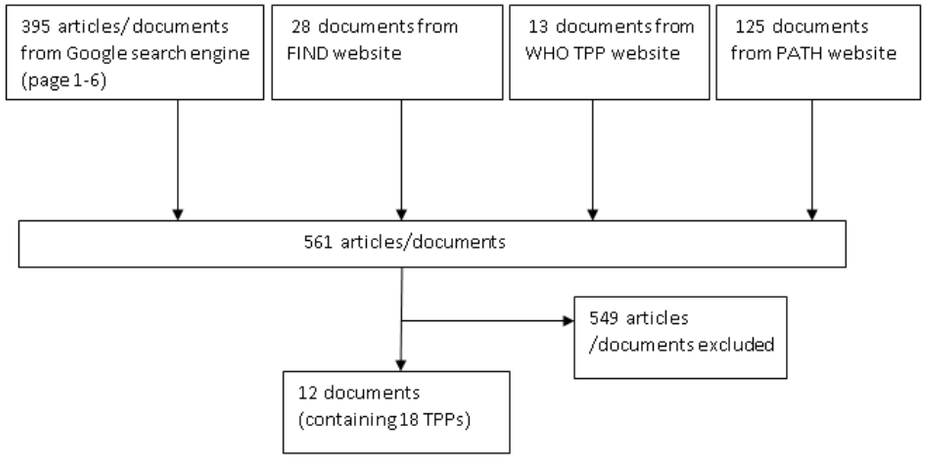

Figure 2. Flow chart of search method

Figure 2 demonstrates the process of data collection for the Notion database which is publicly available and can be explored by users. 18 TPPs that matched the criteria were found. The 18 TPPs originated from 12 documents. Some documents contained more than one TPP, for example, different TPPs for different use scenarios. The WHO was the (co)initiator

of 15 of the 18 TPPs and 12 TPPs were published between 2020 to 2022. 14 TPPs were related to the first search terms while the other 4 TPPs were related to digital devices and digital health (search terms 2 & 3), as found in Table 2 and the appendix. Two of those four TPPs target mobile phone use, while the other two describe dedicated digital devices. 12 TPPs mentioned stakeholders involved in the drafting process with a minimum of 6 to a maximum of 52 stakeholders. Only 2 TPP documents had TPP meeting notes available. 8 TPP development processes were sponsored by a funding agency, foundation or fund.

Table 2. Overview of database information

Initiator	Year	Target Product Profile	Targeted disease(s)	Disease control stage
WHO	2021	Diagnostic test for surveillance of lymphatic filariasis: Target product profile	Lymphatic filariasis	Surveillance
WHO	2021	Diagnostic test for lymphatic filariasis to support decisions for stopping triple therapy mass drug administration: target product profile	Lymphatic filariasis	Stopping decision
WHO	2021	Onchocerciasis: diagnostic target product profile to support preventive chemotherapy -mapping	Onchocerciasis	Mapping
WHO	2021	Onchocerciasis: diagnostic target product profile to support preventive chemotherapy - stopping decision	Onchocerciasis	Stopping decision
WHO	2021	Diagnostic target product profile for monitoring and evaluation of soil-transmitted helminth control programs	Soil-transmitted helminthiases	Monitoring and evaluation
Bill & Melinda Gates Foundation	2018	Target product profile for STH use-case #3 diagnostic (confirming decision to stop population-level intervention). STH, soil-transmitted helminth	Soil-transmitted helminthiases	Monitoring and evaluation, stopping decision
Bill & Melinda Gates Foundation	2018	Target product profile for STH use-case #1 and #2A diagnostic (mapping, monitoring population-level intervention). STH, soil-transmitted helminth	Soil-transmitted helminthiases	Mapping, monitoring and evaluation
WHO	2017	TPP for a specific test for the detection of T. solium taeniasis in humans (various platforms)	Taeniasis	Monitoring and evaluation, surveillance
WHO	2017	TPP for a point-of-care test for the detection of Taenia solium taeniasis in humans	Taeniasis	Individual case management, monitoring and evaluation, surveillance

Initiator	Year	Target Product Profile	Targeted disease(s)	Disease control stage
WHO	2022	2 Target product profile for the detection of a case of yaws and the detection of azithromycin resistance	Yaws	Mapping
WHO	2022	Scabies Diagnosis TPP – Mass Drug Administration Start	Scabies	Mapping
WHO	2022	Scabies Diagnosis TPP – Mass Drug Administration Start	Scabies	Stopping decision
FIND, WHO	2020	Electronic clinical decision support algorithms incorporating point-of-care diagnostic tests in low-resource settings: a target product profile	Diseases in low resource settings that require point-of-care diagnosis	Individual case management
WHO	2016	Target Product Profiles for digital health products for the End TB Strategy; Chapter 3: Diagnostic device connectivity for TB	Tuberculosis	Mapping, monitoring and evaluation, stopping decisions, surveillance
FIND	2020	Target Product Profile for a mobile app to read rapid diagnostic tests to strengthen infectious disease surveillance	Infectious diseases	Surveillance
WHO, FIND, MSF	2018	A Multiplex Multi-Analyte Diagnostic Platform	Severe febrile illness, HIV, Malaria, TB	Individual case management

DISCUSSION

Based on the content of the database, two broad themes emerged on the gaps and opportunities to improve current TPPs for applicability to DHDs. Theme 1 focuses on inclusivity and addresses gaps like TPP availability, stakeholder inclusion, and sustainability. Theme 2 applies mainly to DHP-specific considerations such as ethical and interconnectivity concerns.

Theme 1: Inclusivity

TPP availability

The availability and accessibility of TPPs are barriers to DHD device development. In this instance, there are no TPPs for developing DHPs for schistosomiasis within the WHO health product directory. This absence can impact the product development process and lead to a waste of time and financial resources in developing products which may not fit into the context of use or duplicity of healthcare products. Conversely, this absence causes a lack of incentive for developers to invest in digital health products as they

often rely on the TPPs before product development is initiated.

Although regular reviews of TPPs and the HPPD are necessary, TPPs are living documents and therefore previous versions should be maintained online for easy access and consultation. During the development of the database (2021-2022), the HPPD was not available online due to upgrades to the platform (personal communication with WHO representatives). Solving problems associated with TPP availability will include several strategies such as maintaining version history on TPPs online, reviewing TPPs alongside the review of disease control and elimination targets, and ensuring updated TPPs are made available with every review of NTD targets.

Stakeholder inclusion

The TPP drafting process involves consultation with stakeholders. 12 TPPs mentioned the types of stakeholders involved in the drafting process (Table 3). While it is sensible to determine relevant stakeholders per use-case (as TPPs are developed per use-case); there is a lack of transparency in the process and degree of involvement of stakeholders. For instance, there is no published list of stakeholders consulted in the TPP drafting process in the documents reviewed. Only 2TPPs had meeting notes available (these were both from the NGO database). Although the inclusion of end-user involvement in the TPP drafting process is documented in the DTAG process, the roles of these end-users are not clear (WHO, 2021). Considering and giving preference to stakeholders from schistosomiasis dominant areas is critical to improving contextual fit and uptake.

Table 3. TPP stakeholder information

Initiator	Year	Disease(s)	Stakeholder type	Group size	Meeting notes available
WHO	2021	Schistosomiasis	No information	22	No
WHO	2021	Schistosomiasis	No information	22	No
WHO	2021	Lymphatic filariasis	Lymphatic filariasis technical experts, end users and other stakeholders	14	No
WHO	2021	Lymphatic filariasis	Lymphatic filariasis technical experts, end users and other stakeholders	14	No
WHO	2021	Onchocerciasis	No information	-	No
WHO	2021	Onchocerciasis	No information	-	No
WHO	2021	Soil-transmitted helminthiases	No information	14	No
Bill & Melinda Gates Foundation	2018	Soil-transmitted helminthiases	"Diverse group of key opinion leaders"	48	No

Initiator	Year	Disease(s)	Stakeholder type	Group size	Meeting notes available
Bill & Melinda Gates Foundation	2018	Soil-transmitted helminthiases	Experts from academic institutions, industry, and private and public sectors	48	No
WHO	2017	Taeniasis	Experts from academic institutions, industry, and private and public sectors	47	No
WHO	2017	Taeniasis	Experts from academic institutions, industry, and private and public sectors	47	No
WHO	2022	Yaws	Experts from academic institutions	7	No
WHO	2022	Scabies	Experts from academic institutions and public health organizations	6	No
WHO	2022	Scabies	Experts from academic institutions	6	No
FIND, WHO	2022	Diseases in low-resource settings that require point-of-care diagnosis	Experts from academic institutions, industry, and private and public sectors	39	Yes
WHO	2016	Tuberculosis	Experts from academic institutions, industry, and private and public sectors	17	No
FIND	2020	Infectious diseases	Experts from academic institutions, industry, and private and public sectors	51	Yes
WHO, FIND, MSF	2018	Severe febrile illness, HIV, Malaria, TB	No information	52	No

The TPP drafting process could be more transparent in terms of which stakeholders are included in the process. One way to address this perceived lack of transparency is to include a list of all consulted stakeholders at the end of the TPP document including their roles and organizations represented. It is also important to identify and include stakeholders who are not usually included in these processes, such as design engineers, and field-based health workers including Community Health Extension Workers (CHEWs) which are the last link to communities in sub-Saharan Africa (Banda et al., 2021; Onasanya et al., 2020).

For end-user inclusion, it is essential to avoid proxy end-users such as researchers and healthcare managers and include actual end-users such

as CHEWs and other lower cadre healthcare staff. This recommendation is important when developing TPPs for DHDs that will potentially be used by CHEWs and can support the improvement of the current TPP drafting process.

Sustainability

Exploring the TPPs in the database also showed that sustainability does not play a role in any of the TPPs reviewed, not even in ideal scenarios. In alignment with the SDGs, environmental sustainability in diagnostic device design is an important aspect to consider in the development of TPPs for digital diagnostic devices and should ideally be part of the TPP. Sustainability covers a broad range of parameters including materials used, product lifecycle, and energy requirements and is not limited to only product disposal (Hinrichs-Krapels et al., 2022). Including sustainability in the TPP parameters will have the biggest impact on both device sustainability and environmental sustainability by bringing the sustainability discussion to the forefront of the product design process.

Our database revealed that components of several reviewed TPPs vary. Likewise, there are gaps in the level of detail regarding contextual factors that can affect the operationalization of the diagnostic product which can affect device sustainability. Focusing on all TPPs, by WHO and other NGOs, reveals variation in the level of detail, with more details on the performance and functionality characteristics and less detail on human operational factors such as ease of use and field applicability in low resource settings including ergonomic design which can affect the contextual fit and sustainability.

There is also a lack of inclusion of market perspectives which can impact sustainability. Although market perspectives and commercialization may be purposely omitted from the TPP, and there is no market in the NTD space for DHDs, we believe that funding NTDs and improving country ownership of eliminating schistosomiasis and other NTDs will require finding country-based financing mechanisms for digital diagnostics and other diagnostic tools. This can contribute to sustainable disease control and elimination strategies. We believe there is a need for DHDs and the absence of this perspective in the TPP eliminates its market potential. Including a commercial perspective will require input from health planning officers, health economists and private sector representatives from disease-dominant regions in the TPP drafting process.

In addition to the classical diagnostic performance indexes (sensitivity, specificity, accuracy), theme 2 presents additional considerations specifically related to DHPs using the software.

Theme 2: DHP-specific considerations for TPPs

2.1 Ethical considerations

Ethics is a critical issue in the development of DHPs and DHDs and should be incorporated into TPPs. While it may appear that TPPs for non-digital diagnostic medical devices may also apply to digital diagnostic medical devices, other concerns are not addressed by current TPPs such as data privacy, data sharing policies with third parties such as developers, and the management of all important stakeholders involved in the development and use of such devices. Therefore, aspects of ethical consideration to be considered include data privacy and informed consent, data protection and governance, data ownership and data storage. Stakeholders' involvement, roles and responsibilities regarding data considerations should be broadly defined in the TPPs.

2.2 Platform interconnectivity

For interconnected DHDs, interconnectivity is an important aspect for consideration to be included in TPPs. In principle, digital diagnostics should ideally interconnect with other established digital health systems such as health management information systems, logistics management information systems and electronic medical records. These ensure interoperability and reusability across different health program areas, supporting a more robust digital health system. Addressing these early in TPPs aligns with the WHO digital health strategy (World Health Organization, 2023a) and enhances a systems approach to schistosomiasis control.

CONCLUSION

There is great potential for DHPs, DHDs and DODDs that can detect schistosomiasis, collate, and transfer data to digital platforms such as the District Health Information System. DHDs can transform data management systems thereby making healthcare delivery easier and providing decision support for health workers and policymakers. The need for DHDs for NTDs is in place but is mainly driven by the scientific research community, and is not made actionable by concrete strategies, perhaps because it is not embedded in TPPs. Some TPPs provide clues to product profiles for DHPs (TB, malaria, HIV), but their relevance to schistosomiasis diagnostics is yet to be determined. Addressing inclusiveness is important for developing digital diagnostics because of the importance and impact of stakeholders, processes and context on the digital health diagnostic design process, device uptake, use and sustainability. This study thus highlights the need for DHDs for schistosomiasis elimination and elucidates gaps in the current TPPs for schistosomiasis, particularly the absence of guidelines for the development of DHPs, surprisingly not even in the ideal scenario. This study also provides an open-access database that others can use to easily search and compare the contents of different TPPs for multiple use-cases.

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6.2.TARGET PRODUCT PROFILES FOR DEVICES TO DIAGNOSE URINARY SCHISTOSOMIASIS IN NIGERIA

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Abstract

Schistosomiasis is a treatable and preventable neglected tropical disease of Public Health importance affecting over 200 million people worldwide while Nigeria is one of the high burden countries. Currently, available diagnostic tests are cumbersome, low in sensitivity and not field-adaptable given the high skills required that are not available in the rural settings where the diseases are majorly prevalent. There is an urgent need for an easy to use automated diagnostic device to replace the current gold standard, the human-operated microscope. Many promising automated diagnostic technologies are under development. However, a good understanding of the real needs within the local healthcare context is crucial in order to develop and implement a new health diagnostic device. Too often, there is a mismatch between what is needed and what is developed. A target product profile can guide the R&D process in matching with the needs in the local healthcare context. The goal of this project is to combine gaps in the healthcare system and needs from stakeholders with technological possibilities in order to develop a target product profile for a diagnostic device for S. haematobium for specific healthcare scenarios in Nigeria.

Keywords: Schistosomiasis, Nigeria, Neglected Tropical Disease, Global Health, Diagnostics, Target Product Profile, Control and Elimination Program, Case Management

I. INTRODUCTION

The goal of this project is to combine the gaps in the healthcare system and the needs of stakeholders with technological possibilities into a target product profile for a diagnostic device for urinary schistosomiasis for the most promising use case scenarios in Nigeria. The following sections provide an introduction to the disease and automated diagnostic technologies under development.

A. Schistosomiasis

The neglected tropical diseases (NTDs) are a group of disabling, chronic

diseases that are prevalent in tropical and subtropical, resource-constrained areas with poor sanitation and weak health systems [1]. Schistosomiasis is one of the NTDs and is caused by the Schistosoma parasite. People can get infected when they make contact with contaminated water during routine domestic, swimming, household, agricultural activities and wadding across streams/rivers (See Fig. 1). Freshwater snails carry parasites which penetrate the human skin. Schistosomiasis causes more than 300,000 deaths a year globally. Currently, 779 million people are at risk, and 207 million people are infected [2].

Figure 1. People washing clothes in snail infested water bodies in Oyo State, Nigeria.

The parasitic infection can cause anaemia, growth stunting, cognitive impairment, school absenteeism, decreased productivity and long-term health consequences such as bladder cancer and infertility [3]. About 80% of the yearly infections are among the rural dwellers in tropical sub-Saharan African countries, where access to clinical diagnostic instruments is practically limited. Accurate and reliable diagnosis is not only crucial for patient treatment but also critical for effective and efficient implementation of control and elimination strategy [4].

The focus of our project is on Nigeria, which is the most endemic country in Sub-Saharan Africa, with 37 million people at risk, and 29 million infected [5]. The goal of the World Health Organization (WHO) is to eliminate schistosomiasis as a public health problem in 2030. However, in 2018 there were still 29 million infected cases of schistosomiasis in Nigeria. We focus on Schistosoma haematobium (S. haematobium) in our project since it is the most dominant Schistosoma specie in Nigeria, accounting for 82% of the schistosomiasis infections.

Despite its high socio-economic burden [6], it has received limited attention from governments and stakeholders in healthcare settings similar to other NTDs [5]. To eliminate this major disease, diagnosis should be enabled at primary health level for case-control. Furthermore, field deployable diagnostics are required to increase the impact of control programs.

B. Diagnostics

Safe and effective medication, praziquantel, is commonly available for treatment [7]. However, accurate diagnostic techniques for schistosomiasis is hugely underdeveloped and remains a critical challenge, though reliable diagnosis is key for (early) treatment. The WHO gold standard for diagnostics of S. haematobium relies on manual microscopy examination of urine samples prepared by filtration, sedimentation or centrifugation [1].

Figure 2. The current gold standard for diagnostics of S. haematobium: human-operated microscopy.

The availability of conventional microscopy in remote or rural communities is limited by high cost, bulkiness of equipment, shortage of required expertise, lack of required maintenance skills and required spare parts [8]. Also, the manual microscopic examination of the filtered urine sample is time-consuming and prone to human error [1, 8]. Urine filtration method requires membrane filters which are expensive and are not commonly available at point of needs. In rural areas, the existence of tremendously erratic power supplies precludes the deployment of centrifuges. Furthermore, microscopy is cumbersome and requires highly trained personnel, and therefore reduces the opportunities of deploying diagnosis for community surveillance as an aid of tracking the progress of control implementation and reporting [9]. As can be concluded, diagnosis of the disease is limited by multiple

physical and logistical factors, which necessitates an urgent need for the development of reliable, sensitive, low cost, field-deployable and easy to use diagnostic tests for the detection of S. haematobium infections in low resource settings.

Nigeria is a context in need of schistosomiasis diagnostics for immediate treatment as well as for control and elimination programs. Currently, vertical and horizontal programs are used for schistosomiasis control in Nigeria [10]. The control and elimination program is a vertical approach and a principal strategy for control of schistosomiasis (and other NTDs). The horizontal approach is the case management of individual cases at the primary health care level [11]. The control and elimination program provides annual mass treatment of praziquantel for school-age children aged 5 to 14, who are known as the most heavily infected part of the population [12].

C. Smart health diagnostics

Our so-called INSPiRED project – INclusive diagnoStics For Poverty RElated parasitic Diseases in Nigeria and Gabon aims to reduce mortality of schistosomiasis by developing, in close co-creation with local stakeholders, smart and easy to operate digital optical diagnostic methods and devices for use in endemic regions [13]. The driving force behind the development of these type of new medical technologies is the desire to automate the process of sample observation and schistosoma egg detection, so the device becomes field deployable. In this perspective, hand-held digital microscopes and cellphone-based microscopes are promising alternatives for diagnosis of Schistosomiasis. Rapid progress in optical and computational processing technologies has resulted in, sufficiently sensitive low-cost diagnostics for use in low-resource settings [14].

Within the INSPiRED project, there are two types of optical diagnostic methods under development (Schistoscope and SODOS) where an optical system is combined with an algorithm to automatically detect and count S. haematobium ova in a urine sample [9, 15-18]. Since the procedure rules out human error, the test can reach a higher level of sensitivity and is not dependent on scarce skilled healthcare staff.

The Schistoscope (See Fig. 3) uses a reversed lens attached to a smartphone or Raspberry Pi camera to magnify a urine sample. The SODOS uses a lens-less optical sensor to perform a holographic analysis of urine samples. The algorithm digitally reconstructs the image, from which ova are classified.

Figure 3. Mobile phone and Raspberry Pi based Schistoscopes.

Implementing the algorithms and the optical system in a device offers several potential benefits compared to conventional microscopes. The main advantages of the smart diagnostic technologies compared to traditional microscopy are (See Fig 4):

- Simple and user friendly: No skilled staff needed, can be used by community healthcare workers.
- Rapid: Patient can wait for outcome at point of care. No need to come back a day later for diagnostic result.
- Sensitive: Not prone to human error. High throughput, which makes it ideal for field use.
- Robust and portable: Can be taken to the field, not dependent on the electricity grid.
- Affordable: Low initial and maintenance costs.
- Data collection: Real-time location and diagnostics data sharing for mapping purposes.

Nevertheless, clarity in identification of the diagnostic setting and an understanding of the intended end-users is needed. Thus, a more contextual research is required to design a product that is suitable for the healthcare system in Nigeria and fills a gap where currently no diagnostics are available.

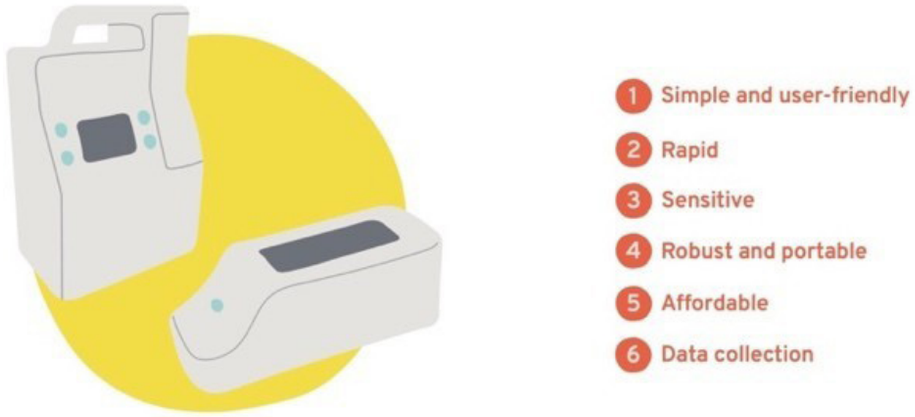

Figure 4. The main benefits of smart diagnostics.

II. METHOD

The goal of this project is to combine gaps in the healthcare system and needs from stakeholders with technological possibilities in order to develop a target product profile (TPP) for a diagnostic device for S. haematobium for specific health care scenarios in Nigeria. A TPP is a strategic document that lists desirable characteristics of a product, the minimal and optimal performance and operational features of diagnostic tests [19]. It is used as the first step toward product development. TPPs contain sufficient detail to allow developers and key stakeholders to understand the requirements for a product to be successful. This does not only include technical requirements, but also that allow use in a defined setting [20].

The approach of this project is based on a design thinking stepwise approach to develop a TPP for new diagnostic technology by Bengtson et al. [19]. This approach aims to match a diagnostic technology to a local healthcare context in an early stage of the Research and Development (R&D).

In order to collect data and insights from the local healthcare context, a three-week field research in Oyo State, Nigeria, was conducted in December, 2019 [13]. Oyo State was chosen as our study field; we consider the state to be a good representative of Nigeria as a whole, because of its' moderate prevalence of schistosomiasis (5.4%) in relation to the country's average prevalence of 8.5%. [21]. Furthermore, Oyo State is involved in the schistosomiasis control program. An ethical approval for the field study was obtained from the University of Ibadan prior to the study commencement.

An explorative, qualitative research with semi-structured interviews and observations was conducted in Oyo State, Nigeria. During the field research,

45 stakeholders were interviewed to identify gaps and stakeholders for case management on primary healthcare level and the control and elimination program [13]. By doing contextual research, the interests and needs of the stakeholders could be identified.

Furthermore, a better insight into the challenges and limitations of current diagnostics could be obtained. Stakeholders were identified from literature search, expert panel recommendation and snowballing. Using the state as a case study, we categorized stakeholders based on four levels: community level, healthcare level, health system organizational level and policy level. For the field research, a list of questions was prepared based on the framework of Aranda et al. [22] for holistic, contextual design for low resource setting, focusing on individual factors, physical environment, technical factors and systems and structures. For every type of stakeholder, a different interview guide was created. An overview of the diagnostic landscape for case management and the control and elimination program was visualized to help during interviews and to verify and adjust the scenarios to the real situation.

Figure 5. Semi-structured interviews with stakeholders in Oyo State.

The interviews from the field trip were transcribed, and the interviews conducted in Yoruba (local language) were translated. Observations in the health facilities were noted on the health facility observation sheet. Insights from the interviews and observations were translated and visualized into patient journeys, patient and health worker barriers. The context research was concluded with an overview of identified gaps in the healthcare system for case management and control and elimination program. By combining

gaps in the current healthcare contexts, specific needs of stakeholders and potential benefits of the new smart diagnostic technologies, 12 use scenarios were constructed (See Fig. 6). In consultation with stakeholders, three promising use scenarios were selected and translated into TPPs.

Figure 6. Approach toward the development of target product profiles.

III. GAPS IN CURRENT SCENARIOS IN NIGERIA

Two diagnostic contexts were explored; case management on primary healthcare level and the control & elimination program (See Fig. 7).

Figure 7. The two explored diagnostic contexts.

A. Case management

For exploration of case management, two communities, six healthcare facilities and three local government areas (LGA) were visited. The visited communities were an urban community in Ibadan North and a rural community Camp David in Akinyele. The health facilities visited included one primary healthcare clinic, three Primary Healthcare Centres (PHCs) and two private laboratories. Furthermore, local governments in Ibadan North, Ibadan North West and Akinyele were visited [13]. Based on the field

research, the diagnostic practices, challenges and stakeholders for case management were described.

When an individual is infected and seeks for a cure, she or he can be tested to determine the suitable treatment. Diagnosis on primary healthcare level is limited by poor infrastructure, lack of funding for better medical equipment, shortage of skilled technicians and microscopes, and superstitious beliefs of communities. The main problem in case management is that diagnosis is not conducted at primary level due to limited resources and awareness, which leads to a very few confirmed cases.

For case management, the stakeholders are divided into healthcare enablers, formal health providers, informal health providers and healthcare receivers. Their interests and potential roles in a new diagnostic scenario was identified. For each stakeholder, a persona was created to describe their strengths, weaknesses and potential role (See Fig. 8).

Figure 8. Example of a persona description of Case Management stakeholder.

In addition, the health-seeking pathways have been described by fourteen different patient journeys. Fig. 9 illustrates one of these patient journeys [13].

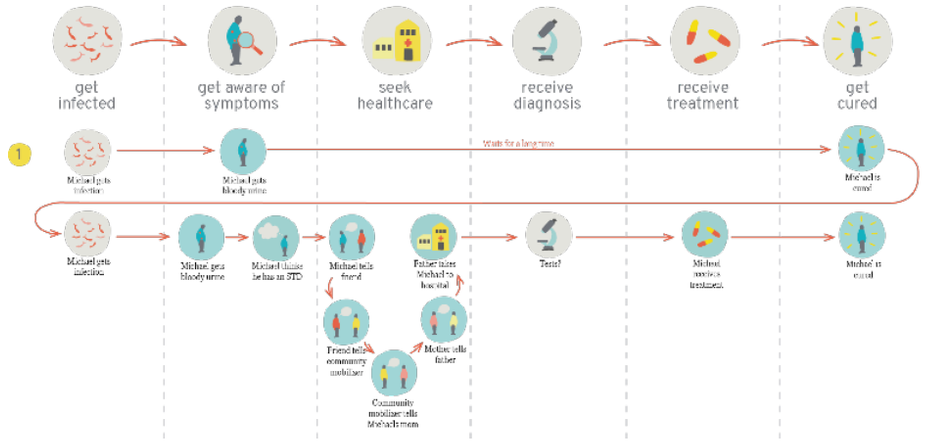

Figure 9. Example of patient journey in case management context.

Healthcare guidelines for treatment and reporting were combined with insights from the field research on diagnostic practices and stakeholder barriers, into gaps in the healthcare system. The main problem in case management is the limited amount of confirmed cases, which is due to limited resources and low level of awareness. The challenges for patients and health workers in each step of case management were listed, and the following gaps were formulated [13];

1. Limited care-seeking behaviour: Infected individuals do not visit a formal health facility when they have symptoms. Due to low awareness on schistosomiasis amongst community members, bloody urine is not perceived as symptom of a medical condition. Most people visit traditional healers, since they are close to the community, or patent medicine vendors, as they are affordable and accessible.
2. No tests in PHC laboratories: There are laboratories available in PHC centres, equipped with microscopes and centrifuges. However, urine analysis is not performed. Suspected schistosomiasis cases are referred to the hospital. Reasons being the proximity to a hospital, lack of skilled laboratory staff, lack of test materials or an unsuitable laboratory environment. In these laboratories, they only test for frequently occurring diseases.
3. Health workers miss cases: The education level of community health workers is low, and they assume a low prevalence of schistosomiasis. Schistosomiasis symptoms are often misinterpreted for other conditions, like STIs or malaria. Case definition of the WHO state that case of urinary schistosomiasis should only be suspected when an infected individual has bloody urine. As a result, wrong treatment is prescribed, and light and asymptomatic cases are never recognized.

4. DSNO guidelines are labour intensive: Once a case is suspected, it should be reported to the disease surveillance and notification officer (DSNO). The DSNO is responsible for getting a sample tested to confirm the case. This often results in extra work, since she or he has to pick up the sample at a PHC facility and bring it to an approved laboratory. In the meantime, the patient is already treated in the facility. Not all suspected cases are reported, and the DSNO does not always have time to get the case confirmed.
5. Few diagnoses in rural areas: Rural communities depend on streams in their daily living, which increases their risk of infection. It is difficult for infected individuals in rural communities to get diagnosed, since there is a limited number of PHC facilities. The health posts and clinics that are available are understaffed and lack resources, so they cannot carry out community-based services. Hospitals are inaccessible due to long distances, poor roads quality and expensive transport fares.
6. No check-up after referral or treatment: The community health worker does not see the patient back after referral to a hospital or administering treatment. There is no check-up or test to confirm cure afterwards. Community health workers do not know if the patient went to the hospital and if the patient has recovered.
7. No follow-up action after confirmed case: Since infected freshwater sources spread schistosomiasis, one confirmed case often means there are more infected individuals from the same community. There are no follow- up actions that take the focal geographical distribution of schistosomiasis into account.

B. Control and elimination

For exploration of the control and elimination program, four primary schools, one secondary school and the state government were visited. Semi-structured interviews were conducted with teachers, students and NTD coordinators on local- and state government level. Furthermore, phone interviews were conducted with the WHO and the NGO Evidence Action [13].

For the control and elimination program, the stakeholders are divided into stakeholders for the initiation, organization, mapping implementation, Deworming implementation and target populations. For each stakeholder, persona descriptions have been developed (see Fig. 10).

Figure 10. Example of a persona description of control and elimination program stakeholder.

The control and elimination program is divided into mapping of epidemiological data and mass drug administration during Deworming days. There are many challenges in the organization and execution of a control program to reduce the disease prevalence. Epidemiological surveys through which cases are confirmed, depend largely on data from children alone, so the current true disease prevalence is unknown. Consequently, the government gives it low priority and largely depend on donors for schistosomiasis control programs. Since, epidemiological surveys are donor-driven and not initiated by the government, this vicious circle continues.

Control program guidelines were combined with insights from the field research on diagnostic practices and stakeholder barriers, into gaps in the healthcare system [13]:

1. Limited availability of data on endemicity: The most recent data on schistosomiasis prevalence is the mapping of endemic data from school children between 2013-2015. There is no data available on the prevalence of schistosomiasis among the other risk groups, other than small scale screening results for research purposes.
2. No control program for risk groups: The Deworming initiative targets children from 5-14 years. Other populations at risk - small children and adults who have regular contact with freshwater are excluded from this control program. The Deworming initiative is dependent on support from NGOs and medicine donations. Since pharmaceutical company Merck donates praziquantel specifically for this age group, it cannot be administered to other risk groups. According to the strategy from Federal Ministry of Health (FMoH), in moderate or high-risk areas, adults at risk should receive treatment too.
3. No impact assessment plan for deworming day: According to WHO guidelines, the disease prevalence should be measured 5-6 years after the first mass drug administration round. Since the Deworming initiative started in 2016, the impact of the program should be assessed in 2021-2022. The Federal Ministry of Health is responsible for the initiation of this monitoring survey. Absence or unavailability of information and update on the impact of the program, leads to program fatigue in the target populations, health workers and community volunteers leading to loss of interest in the program, especially in low prevalence communities.
4. Target populations do not give consent: Proper sensitization is key to the control program, but limited due to time or resource constraints. There is low awareness of schistosomiasis in the community and high suspicion of free programs. If people do not understand why they have to give a sample, they will not participate. Some community members believe the rumours and conspiracy theories that are spread about sample collection and treatment.
5. No field-deployable diagnostics available: Microscopes are fragile and expensive, and filters for sample preparation may not be readily available in Nigeria. As a result, testing for the school-based survey was performed in hospital laboratories instead of at location of sample collection. It required sample transportation by car, which caused logistic problems. This makes epidemiological surveys time consuming and expensive. Dipsticks and questionnaires are available to field-deployable methods, but they lack sensitivity.
6. Control program is short-term focused: The control and elimination strategy in Nigeria appears to be short-term focused, with the roadmap ending at 2020. Plans should be developed on how to tackle future challenges in anticipation of a reduction in the prevalence and work towards elimination of the disease as a public health problem. A lower prevalence gives different requirements to the control strategy and the role of diagnostics [13].

IV. USE SCENARIOS

A. Twelve Use Scenarios

Next potential benefits of the smart diagnostic technology (See Fig. 4) and gaps in the healthcare system (see above) were combined into 12 most

promising use case scenarios for a new diagnostic device to improve case management on primary level and the control and elimination program in Nigeria (See Fig .11).

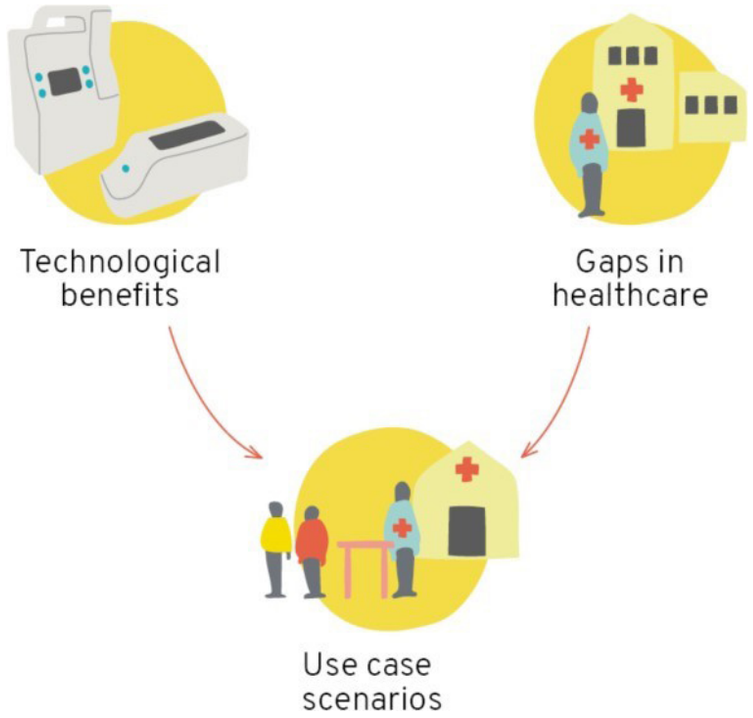

Figure 11. Development of use case scenarios.

Each scenario describes the use case and why there is a need for improved diagnostics. It states the envisioned target population, user of the test, and test location. Furthermore, the descriptions include the stage in case management or the control program to which the scenarios apply. Lastly, the complexity of the test is given on a scale from dipstick to microscopy to provide an idea of the envisioned test complexity. Figure 12 illustrates use scenario 2 – test at PHC consultation - which is based on the diagnostic gaps “Limited availability of data on endemicity” and “No impact assessment plan for Deworming day” in combination with the technical benefits “Rapid”, “Robust and portable”, “Affordable”, and “Data collection”.

B. Selection of three use scenarios

An online questionnaire was sent to 6 stakeholders in the field and seven members of the INSPiRED research team. The stakeholders from the field consisted of researchers and community health workers. These stakeholders were involved to obtain feedback and to select the most valuable scenarios

through which a diagnostic test can meet the needs of the end-users and stakeholders (See Fig 13).

The following three diagnostic scenarios were selected;

1. Test at PHC consult, where community health worker will perform the test. This enables case confirmation at PHC level.
2. Mapping of other risk groups, where adults are tested by a community health worker and/or lab assistant at occupational group meetings.
3. Test as sensitization tool, where diagnosis is done by a community resource person in communities to create awareness.

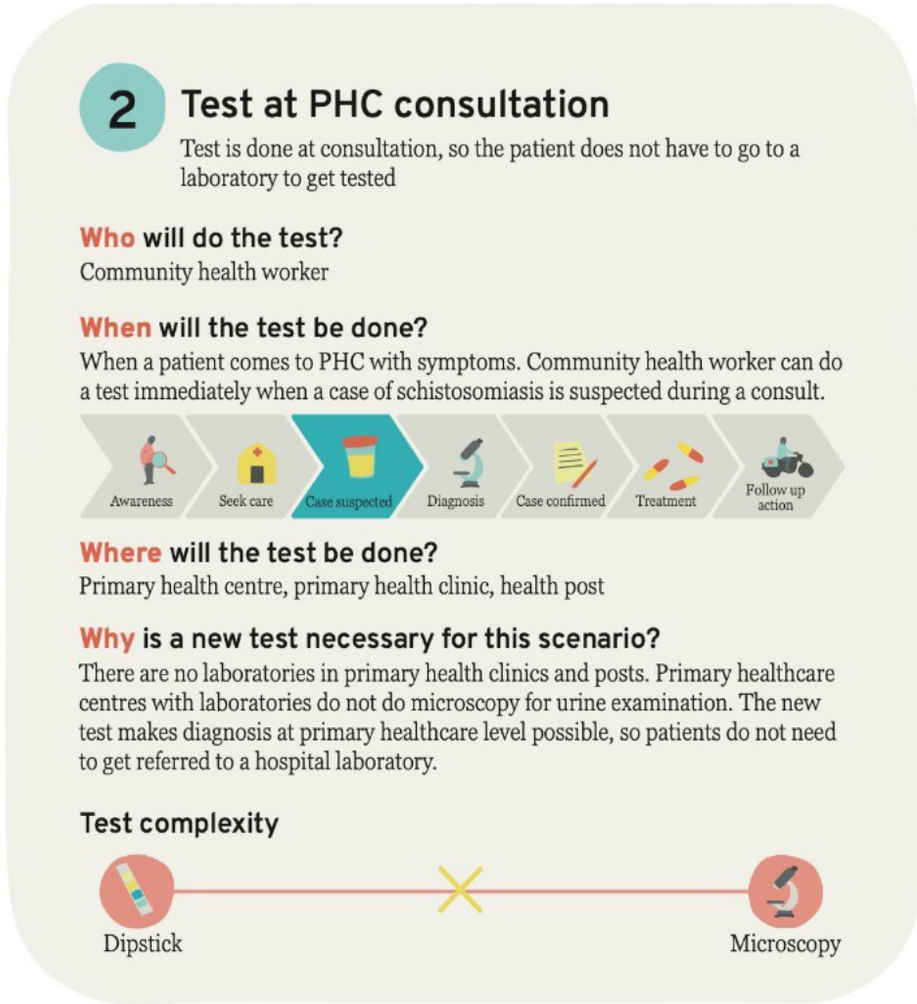

Figure 12. Example of description of use scenario.

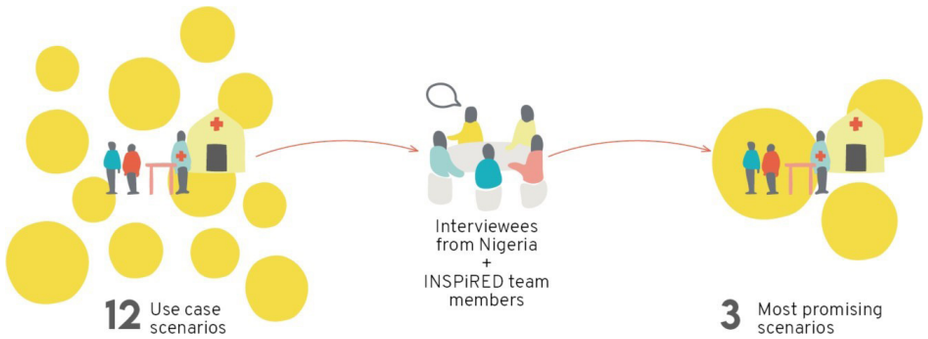

Figure 13. Selection of three most promising scenarios by stakeholders.

V. TPP AND EVALUATION

In the last step of our approach, the three selected use- scenarios were translated into target product profiles (TPP). A TPP describes the acceptable and ideal characteristics of a diagnostic test. These ideal values would make the device more attractive and match the needs of the local healthcare context. In addition to lists of acceptable and ideal attributes, TPPs should contain explanations to support the decision to include the attributes. A TPP is used to ensure that research and design activities are focused on relevant product and designed for the context and needs of the end-users [13].

Insights from the desk and field research were combined to create target product profiles for the selected use case scenarios. To determine the attributes on the target product profile, desired product qualities were retrieved during interviews in the field, a discussion session with 6 PhD students and a co-creation session with 14 Public Health master students. This resulted into six scoping attributes, 23 operational attributes, four performance attributes, and two price attributes (See Fig. 14).

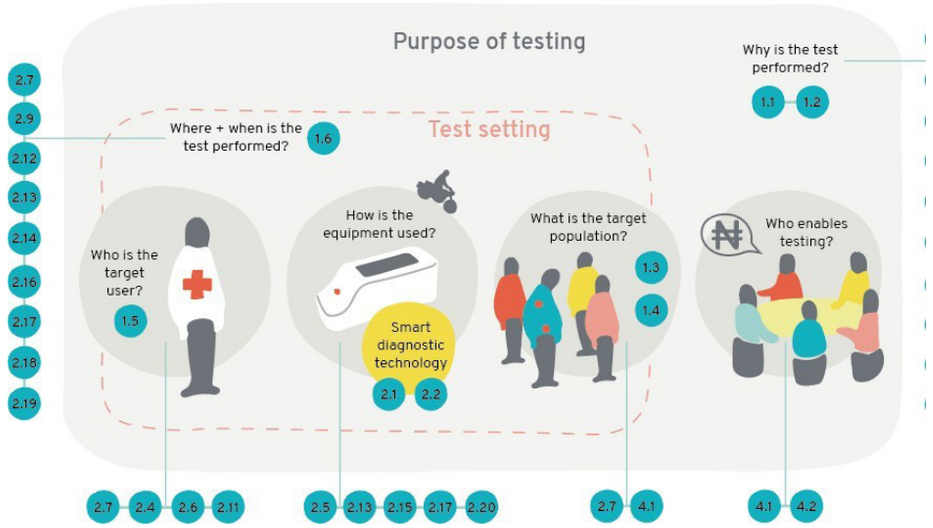

Figure 14. Characteristics of the product target profile.

The acceptable and ideal values for each of the 35 product attributes were merged into target product profiles for the three scenarios. Summary of each TPP is as following.

TPP for test at PHC consult – The diagnostic device will be used by a community health worker who requires the sample preparation and device interactions be as simple as possible. The device should include instructions on treatment and health education. The confirmed case should be shared with the DSNO in accordance to the guidelines. The sensitivity and specificity of the test should be sufficient enough to make a standard diagnosis comparable to the use of microscopy. Power requirements (minimal 8-hour operation between charges) and connectivity (via mobile network) are ideal.

TPP for mapping of other risk groups – Complying the WHO guidelines is necessary to allow the result of the mapping to be used for policy-making. It is important that the test results should be available on the same day, so that the infected individuals can get treatment(s) right after the confirmation. As the device will be transported from one location to another, the test kit should be able to tolerate transportation stress. Charging and calibration should be not required during the day to minimize the time. Participation in mapping has to be free for the community members and financial sponsor and the government involvement should be considered.

TPP for test as sensitization tool – The end users are the community resource people who are not formally trained as health workers. Considering that,

the device will not provide official diagnosis, but the test will be performed at the sensitization meetings. The device has a throughput of at least five samples per hour, and the results should be available before the end of the sensitzation meeting. Before the results are available, health education can take place to increase awareness. Ideally, the device can save the location data and number of infected samples to identify the location of infected water bodies. Figure 15 shows five of 35 attributes for the three selected use-scenarios.

	Test at PHC consult		Mapping of adults at risk		Test as sensitization tool	
	Acceptable	*Ideal*	*Acceptable*	*Ideal*	*Acceptable*	*Ideal*
Throughput	1 per day	>1 per day	>50 per day	>100 per day	>5 per day	>30 per day
Ease of use	Easy for someone with limited testing experience		Easy for someone with testing experience		Easy for someone with no testing experience	
Result	Presence and intensity of infection	Number of eggs	Number of eggs		Presence of infection	Number of eggs
GPS	No		Yes		Yes	
Withstand transport stress	No		Yes		Yes	

Figure 15. Five TPP attributes for the three selected use case scenarios.

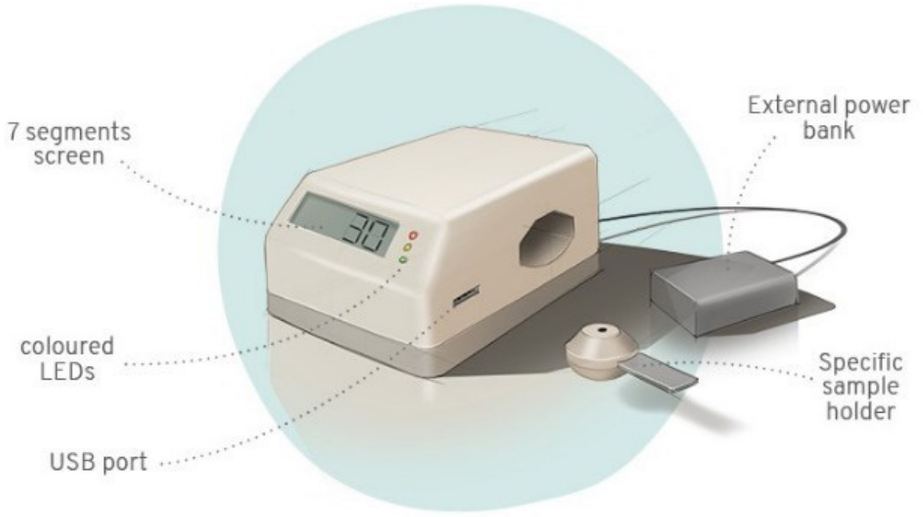

Figure 16. Design proposal based upon one of the developed target product profiles.

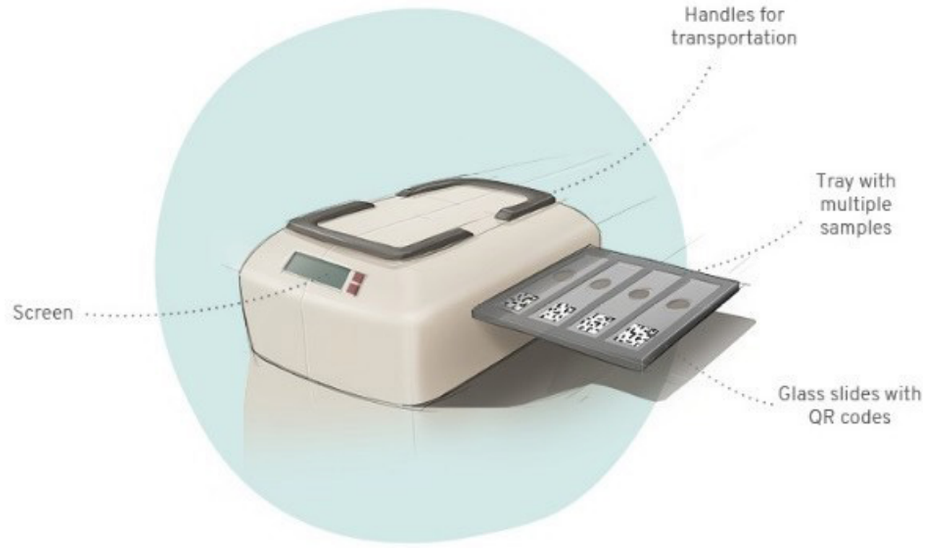

Figure 17. Design proposal based upon one of the developed target product profiles.

To validate the target product profiles as a design tool, a pressure cooker session was organized with Industrial Design Engineering Master students. Based on the TPPs, they developed several test proposals. Figure 16 shows a design proposal for a test at PHC consult, which is designed to be easy to use and affordable. Figure 17 shows a design proposal for a test for mapping of risk groups. This device is designed with a handle for portability and is designed to scan multiple samples at once to achieve a high throughput.

Furthermore, meetings were held with the INSPiRED team to explain the context of use and disease characteristics. The importance of this knowledge transfer process supports designers in their focus on useful TPP, thereby reducing design time and cost of redundant prototyping, as well as increasing the likelihood of adoption in the context-of-use.

VI. CONCLUSION AND RECOMMENDATION

The target product profiles proved to be useful in the design of a diagnostic device, provided that the designers have some knowledge about the disease and diagnosis. However, the target product profile should come with an explanation of the chosen values, so the designers understand the reasoning behind the acceptable and ideal values. The TPP should be supported by knowledge transfer on disease characteristics and context of use for designers. Since the development of target product profiles is an iterative process, it is essential to continue to interact with stakeholder research [23].

The developed TPPs successfully communicated the product requirements and context insights, which resulted in four test proposals. However, more time is required for the designers to develop these test proposals into design concepts.

The TPPs will be used to guide the further development of the diagnostic devices. They will function as a design brief for student design teams, who will develop functioning prototypes. These prototypes will be tested in the field on technical functionality, and acceptability and usability by stakeholders in the field.

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Chapter

7

USER RESEARCH

In the context of this research, two digital diagnostic devices for NTDs were evaluated in 2 studies using different methods. The first study highlights the user experience (including usability) and acceptability of the AiDx assist device by potential end-users. The second study explores the usability of the Schistoscope by different users.

7.1. TOWARDS INCLUSIVE DIAGNOSTICS FOR NEGLECTED TROPICAL DISEASES: USER EXPERIENCE OF A NEW DIGITAL DIAGNOSTIC DEVICE IN LOW-INCOME SETTINGS

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Abstract

Designing new and inclusive diagnostic tools to detect Neglected Tropical Diseases (NTDs) to achieve rational disease control requires a co-design process where end-users' input is important. Failure to involve all potential end-users in new diagnostics for NTDs can result in low use and adoption failure, leading to persistent infection hot spots and ineffective disease control. There are different categories of potential end-users of new diagnostic tools for NTD control, and it is unclear if there are differences between the user efficiency, effectiveness, perception, and acceptability across these end-user categories. This study evaluated the usability, user perception, contextual factors affecting the user's experience, and acceptability of a new digital optical diagnostic device for NTDs across three types of potential end users. A total of 21 participants were tested. Laboratory scientists, technicians, and Community Health Extension Workers (CHEWs) in training achieved similar scores on the usability and user perception questionnaires with no statistically significant difference between end-user categories. All participants also have high scores for the user perception domains which strongly correlate with the acceptability of the AiDx NTDx Assist device. This study indicates that, by providing digital diagnostic tools in combination with minimal training and support, CHEWs undergoing training and, by extension, CHEWs post-training, can be involved in the diagnoses of NTDs, potentially enhancing a community's capabilities to diagnose, treat, and control NTDs.

Keywords: NTDs; diagnostics; end-user; user experience; Nigeria

1. INTRODUCTION

Neglected Tropical Diseases (NTDs) are a group of diseases found in tropical and subtropical regions of the world, especially in Africa, Asia, and Latin America [1]. NTDs are common in regions where access to clean water and adequate human waste disposal are limited with significant effects on the physical, social, and economic well-being of more than one billion individuals

[2]. The limitations of current diagnostics for NTDs regarding performance and affordability have been highlighted in several studies [3–5], including ergonomic problems arising from the use of conventional microscopes [6].

To address these limitations, we designed a new diagnostic device to increase the screening of parasitic NTDs such as lymphatic filariasis, schistosomiasis, and onchocerciasis. This device, the AiDx NTDx Assist machine, is an automated digital microscope designed for the quick detection of parasites in blood and urine. It provides expert-independent analysis and could strengthen task-shifting programs such that non-experts, for instance, community healthcare workers, could be easily trained and empowered to perform quick sample screening for NTDs at the community and primary healthcare level. It has been validated for detection of lymphatic filariasis in Nigeria [7] in lab-based settings. Prepared slides are inserted into the device, patient data is input, and an automatic scan is started. The AiDx device has a processing speed of 10 min per sample, and the outputs of the scan are visually displayed and flagged when microfilaria is detected.

1.1. Designing for Neglected Tropical Diseases

Designing for the NTD space requires the involvement of stakeholders and end- users from the early stages of the design process in what is known as a human-centred approach to design [8]. Human factors play a critical role in the development and use of medical devices and diagnostics [9]. It is therefore important to co-create and improve devices by involving potential end-users in all stages of the design cycle, which include the specification, ideation, prototyping, and manufacturing process of diagnostic medical devices. One of the ways to improve the design, usability, and acceptability of a new NTD diagnostic device from a human-centred perspective is to evaluate the user experience by potential end-users.

User experience is defined as a user's perceptions and/or responses resulting from the use or anticipated use of a product [10]. User experience research focuses on the dynamics of experience, personal characteristics, context, and product interaction. Components of user experience research can include usability (i.e., functionality and system performance), user perception (i.e., interactive behaviour, assistive capabilities arising from the users' prior experiences, skills, attitudes, personalities, and abilities), and acceptability [11], all of which can be affected by contextual factors [12,13].

Usability is an important concept within user experience testing. It is the extent to which a product can be used by context-specific end-users to achieve specified goals [11]. Usability as an evaluation method is employed to redefine and improve a medical product during its development life-cycle, based on end-user requirements and needs. As such, usability testing can

be conducted at one point during the product development cycle or at multiple points during, for example, prototype validation. Usability testing can also be conducted at the end of the product development cycle using both simulated and real-life settings [14]. The Systems Usability Study (SUS) is a validated scale that is commonly employed for testing product usability [15]; however, SUS has limited use for medical devices due to the absence of important factors, such as human technical performance. Human technical performance-based testing parameters include efficiency, effectiveness, error rates, and satisfaction [11,16], and it is different from device performance-based testing that focuses on sensitivity and specificity.

The selection of end-users is important for the validity of a usability study. Therefore, it is critical to identify and recruit representative users. The number of recommended end-users for usability testing ranges from 15 [17] to 25 [18]. However, the number of testers needs to be carefully selected since a meticulously crafted criterion for selection will bring greater returns on problem detection during usability testing.

Apart from performance-based usability testing, user perception and acceptability have been employed to evaluate user health interventions in healthcare [19]. User perception testing deals with gathering cognitive information based on interactive behaviour with the product. Several concepts, such as perceived ease of use, perceived usefulness, intention to use, and perceived ease of learning, have been used to assess user perception [14,20–23]. For diagnostic devices, particularly, perceived ease of learning is an important concept to explore, as a tedious multi-step use process can impede both the perceived usability and potential acceptability of the device.

In addition to user perception, the acceptability of a product will determine willingness to adopt and use the product. Successful implementation and scale-up of diagnostic device usage depend on the usability, user perception, and subsequent acceptability of the intervention to both healthcare managers, who are the decision-makers for medical device procurement, and end-users [24]. The Technology Acceptance Model (TAM) has been used as a guiding framework to determine acceptability. There is a strong correlation between user perception concepts and the acceptability of new devices [20–23,25]. In this context, the user perception of the medical device by end-users is a strong determinant of acceptability by end-users, and we will be inferring the acceptability of this device from the user's perception of the device.

Although assessing acceptability is important for the subsequent use of diagnostic devices, it is also important to understand barriers to acceptability

beyond the user's perception of device usage. Other concepts, such as attitude to technology, trust, and contextual issues, can affect device acceptability [25] and should be elicited to give an all-encompassing assessment of acceptability.

In this study, we researched/explored the following three themes: (1) usability in terms of efficiency, effectiveness, error rate, and satisfaction; (2) user perception in terms of perceived ease of use, perceived ease of learning, perceived usefulness, and intention to use; and (3) contextual factors in terms of barriers to acceptability and proficiency with similar devices, all of which collectively contribute to the overall user experience (Figure 1).

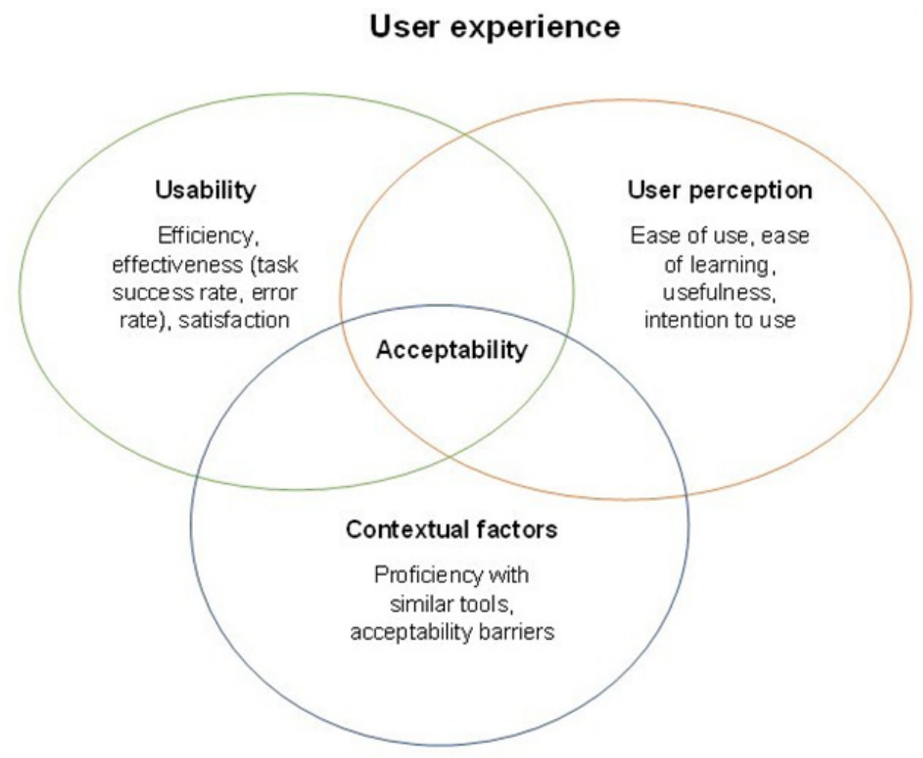

Figure 1. User experience conceptual diagram.

1.2. Problem Statement

Since NTDs are most common within Sub-Saharan Africa, it is imperative to carry out user experience testing of the AiDx NTDx Assist device within this context. It is known that contextual factors can affect the user experience and acceptability of medical devices [26], so the lack of

contextual understanding of the use context of devices is likely to lead to underperformance and abandonment of medical devices. Medical devices are usually created in a high-income context, and technology transfer is not usually considered, leading to acceptability failures in Africa [27]. One way to ensure technology is transferred appropriately is through the application of user experience studies to gauge end-user experience with device usage and fit within the user context. Nigeria was selected for the user experience testing for two reasons: it has a large population, and NTDs are endemic within the country [28]. This makes the country an important and relevant testing context for the device.

1.3. Aim and Objectives of the Study

This study aims to assess the user experience of a working model of the AiDx NTDx Assist device for diagnosing NTDs by evaluating usability, user perception, and contextual factors that can affect acceptability based on end-user personae. The objectives of this study were: (1) to assess usability by observing participants during the use of the device and a post-observation questionnaire; (2) to assess user perception by the use of a post-observation questionnaire; and (3) to assess contextual factors that can affect acceptability by interviewing end-users through a semi-structured questionnaire. Several prior studies have evaluated the user context [5,29], use-case, end-user personae [30], end-user perspective [31], and performance [7] of novel digital diagnostic optical devices in Nigeria. This study also aims to test laboratory-based use-case scenarios for the AiDx Assist device before deployment for field-based use-case scenarios. Therefore, the results of this study will complement previous research efforts to ensure the fit, uptake, and use of new digital diagnostic tools in endemic settings.

2. MATERIALS AND METHODS

2.1. Study Design

We used a moderated laboratory-based evaluative research approach focusing on the user experience aspects of the human-centred design methods.

2.2. Tools

Four tools were used in this study. These include (1) an instruction manual for use of the AiDx NTDx Assist device (Figure 2), (2) an observational checklist to be completed by a single investigator, (3) a semi-structured post-observational questionnaire, and (4) a user perception questionnaire to be completed by the participants.

Figure 2. The AiDx NTDx Assist device.

The instruction manual depicts four steps taken in using the device: (a) turning on the machine, (b) starting the application, (c) inputting slides, and (d) reading output results. The observational checklist measures timing and documents consistency in the use of the four steps when using the device. The post-observational, semi-structured questionnaire focuses on the overall experience with the task given, satisfaction, trust, and aesthetics.

The user perception questionnaire is a semi-structured questionnaire with three sections. Section 1 elicits proficiency with the devices. Section 2 focuses on user perception and contains 42 items within four distinct perception domains: (i) perceived ease of learning, (ii) perceived ease of use, (iii) perceived usefulness, and (iv) intention to use, on a five-point Likert scale (from 1—Strongly disagree to 5—Strongly agree). Section 2 is based on the work done by Parreira et al. (2020) which tests users' utilization of new technologies by focusing on interactions between functional and behavioural aspects. Parreira's scale was modified by reducing the questionnaire from a seven-point Likert scale to a five-point Likert scale to make the decision-making less confusing, increase the response rate, and provide a comparable scale to the SUS without data extrapolation. We also modified statements within selected domains to reflect our device's focus on NTDs and the healthcare context in Nigeria. Section 3 elucidates potential barriers to acceptability and suggestions to improve device acceptability. Data was captured using the Qualtrics software.

2.3. Study Participants and Ethics

Study participants' selection was based on data from user personae research [29,30] and included laboratory scientists, technicians, and Community Health Extension Workers (CHEWs) who are currently undergoing training (Table 1). We used second-year CHEWs in training as a proxy for CHEWs because invited CHEWs could not leave primary care centres to visit the testing laboratory due to health worker shortages. We infer that CHEWs in training perform worse or similarly to CHEWs in practice. All participants have prior knowledge and or experience with NTD diagnosis.

Table 1. Sociodemographic characteristics of the participants (n = 21).

Sex	Count
Female	13
Male	8
Education	
Postgraduate	5
University Graduate (B.Sc.)	3
Diploma (OND/HND)	1
Health Technology School	12
Years of Experience	
0-4	11
5-9	2
10-14	3
15-19	2
20-24	2
≥25	1
Level of training	
Community Health Extension Worker (CHEW) in-training	11
Laboratory Technologist/Technician	3
Laboratory Scientist	7

The study was approved by the UCH/UI Joint Ethical Review Committee, College of Medicine, University of Ibadan. (Reference: UI/EC/21/0641). All participants agreed to the data collection and signed informed consent forms.

2.4. Procedure

Participants were taken through a short demonstration and training (of about one hour) on the use of the AiDx NTDx Assist device using the instruction manual (Tool One). After training, participants were asked to use the device

based on what they learned from memory (i.e., without the aid of the user manual) under the observation of a single investigator (Tool two: observational checklist). The observational checklist captures four steps taken in using the device: (a) turning on the machine, (b) starting the application, (c) putting in slides, and (d) reading output results. The device scanning time was programmed for 8 min and not captured by the checklist since it is constant across all participants. Thereafter participants were asked to fill out the questionnaires (Tools three and four) to document their experience.

2.5. Data Analysis

Qualitative data were analysed by content analysis to identify end-users' opinions on acceptability barriers, trust, satisfaction, and aesthetics. For the quantitative data, descriptive statistics were generated and non-parametric tests such as the statistical test of percentages and Mann-Whitney U tests were carried out using Python software.

3. RESULTS

3.1. Usability Results

Using the observation checklist (Tool two); the following results were obtained.

3.1.1. Efficiency

Efficiency is the total time a user needs to complete the task successfully. Four tasks were assigned in this study: turning on the device, starting the application on the device, putting a slide into the device, and reading the device output. All participants had an average of 2.4 s, 2.8 s, 4.3 s, and 7.2 s across all tasks with variation across the different groups of participants (See Table 2). On average, the CHEWs in training spent less time per task than other groups.

Table 2. Descriptive statistics for assigned tasks.

Category	Turning on the device (secs)	Starting the application (secs)	Putting a slide (secs)	Reading result output (secs)	Average time (secs)	Average error rate (%)
CHEW in training	2.5±0.7	3.8±1.4	2.5±1.0	6.5±4.9	3.3±2.0	2.3%
Laboratory Technician	2.0±0.0	4.5±0.7	4.0±0.0	8.5±2.1	7.7±0.7	87.5%
Laboratory Scientist	2.5±1.0	4.8±3.2	2.8±1.4	8.0±3.9	4.5±4.6	9.3%
+All participants	2.4±0.8	2.8±1.2	4.3±2.2	7.2±4.3	4.2±2.1	33%

3.1.2. Effectiveness (Task Success Rate and Error Rate)

Effectiveness gives insight into the number of completed successful tasks without support from another human or the manual (task success rate), as well as the error rate. In this study, the task success rate was 100%. The error rate was calculated based on the number of deviations from manual instructions. For instance, pressing the wrong button for opening the device was considered an error. The average error rate was 33% across all participant groups with inter-group variations. Laboratory technicians had the largest error rate (87.5%) compared to CHEWs in training (2.3%) (See Table 2). The most common error noted was starting the application, followed by putting in a slide.

3.1.3. Satisfaction

Satisfaction data was collected using the semi-structured post-observational questionnaire (Tool three). Satisfaction is a broad category which includes domains such as overall experience, satisfaction with features, user trust, and others. In this study, all participants rated their experience as positive, and most were satisfied with the features, especially the visual output which made diagnosis easy. Most participants (20/21) rated the device as reliable for the diagnosis of NTDs. All participants (100%) commented positively about the device's appearance; however, three of 21 participants (14.3%) wanted the device to be smaller than the current size. Eighteen participants (85.7%) stated that the device could be used to support quality control checks of microscopy results.

3.2. Contextual Factors

Using Tools three and four, this part of the survey was used to assess contextual factors, such as proficiency with similar digital tools and acceptability barriers.

3.2.1. Proficiency with Similar Digital and Optical Devices

At baseline, all participants had used or had been previously taught how to use the listed devices in Figure 3, so we assessed the extent of proficiency with the devices. Results showed that most of the participants rated their proficiency with similar digital and optical devices as good. Less than 5% of participants had low levels of proficiency with the glucometer and microscope (Figure 3).

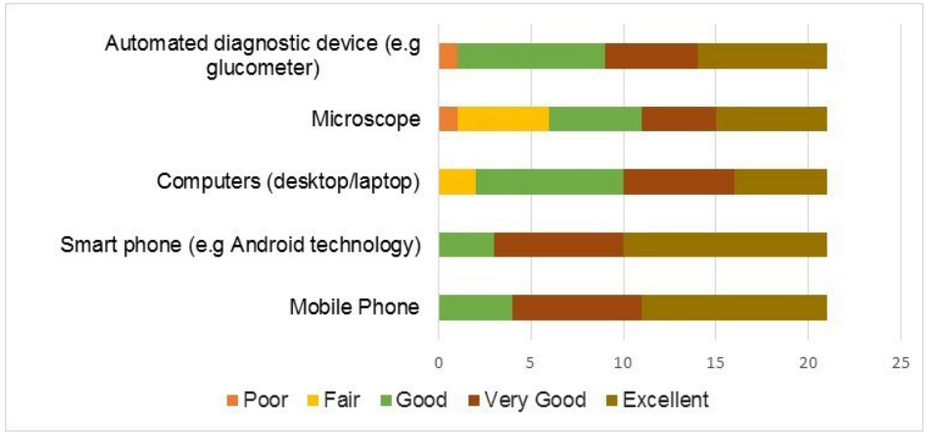

Figure 3. Proficiency rating with digital/optical devices by respondents.

Further analysis was done to assess the association between proficiency with the listed digital and optical tools and sociodemographic data. There was an association between the proficiency rating of optical/digital devices with years of experience as seen in Table 3. Participants whose level of training was higher or equal to laboratory technologists/technicians had a higher user proficiency with tools such as smartphones, optical devices, and automated diagnostic devices. Participants with greater than or equal to 10 years of work experience had a higher user proficiency with optical devices such as microscopes.

Table 3. Association between sociodemographic characteristics and proficiency with digital and optical tools.

Proficiency in digital/optical tools	Gender	Level of Education	Level of Training	Years of Experience
Mobile phone	0.83	0.69	0.07	0.58
Smartphone (Android technology)	0.95	0.64	0.01	0.52
Computer (desktop/laptop)	0.27	0.14	0.51	0.60
Optical devices (microscope)	0.11	0.14	0.00	0.01
Automated diagnostic device (e.g. glucometer)	0.52	0.08	0.01	0.22

3.2.2. Acceptability Barriers

We also studied potential barriers to acceptability and ways to improve device acceptability. Regarding potential barriers to acceptability, ten respondents (47.6%) mentioned problems with electricity supply hampering the use of the device and suggested the incorporation of alternate sources of

power, such as solar energy, if the device will be used in primary healthcare settings. Four respondents (19%) mentioned challenges with sourcing a separate computer monitor to view the results of the device output. They suggested that the device be interoperable by a mobile phone and/or android computing system which is readily available. One person (4.8%) mentioned the importance of acceptability by gate- keepers, such as the medical laboratory science associations, leading to better acceptability by laboratory scientists.

3.3. User Perception

Using Tool four, the user perception questionnaire tested four domains: perceived ease of learning, perceived ease of use, perceived usefulness, and intention to use. The mode of all the variables was five. The median was five for most of the variables, except for the ease of use which gave a value of four, indicating a good user experience scoring. The mean score was above four across the user perception domains. Cronbach's alpha was calculated to measure the questionnaire's internal consistency. The Cronbach's alpha of all items was 0.9248, showing a high level of reliability of the questionnaire as seen in Table 4.

Table 4. User perception domain summary statistics and reliability testing.

Perception domain	Mean ± S.D	Median	Mode	Cronbach's alpha (all items)
Ease of learning	4.1±1.2	5.0	5	0.9248
Ease of use	4.3±0.8	4.0	5	
Usefulness	4.6±0.5	5.0	5	
Intention to use	4.6±0.5	5.0	5	

Most of the respondents had a high level of scoring for each variable category. Ease of use and ease of learning had the highest variability. However, the variability noted is from a few outliers in the consensus scores for these two domains. The variability does not have a significant effect on the study outcomes. The usefulness and intention to use categories have the least variability in scoring.

We further carried out inter-group analysis using the Mann-Whitney U test to identify the differences between the dependent variables. These are the user perception domains and the independent variables which are the sociodemographic characteristics (Table 5). Results show no difference between the categorical groups highlighted in Table 3 and the user perception domains.

Table 5. Mann Whitney U test comparing inter-group characteristics.

Variables/Domains	Ease of learning	Ease of use	Usefulness	Intention to usee
Gender	W=54.5, p=0.85	W=50.5, p=0.90	W=63.0, p=0.34	W=47.0, p=0.66
Highest level of education	W=32.5, p=0.10	W=39.0, p=0.23	W=49.5, p=0.70	W=63.0, p=0.44
Level of training	W=48.5, p=0.67	W=43.5, p=0.41	W=74.0, p=0.085	W=74.0, p=0.08
Years of Experience	W=40.0, p=0.35	W=53.5, p=0.93	W=51.5, p=0.97	W=46.0, p=0.60
W= test statistic; p= p-value.				

4. DISCUSSION

This study aimed to evaluate the user experience of a new diagnostic device for NTDs within the sub-Saharan African context using identified potential end-users. To the best of our knowledge, a literature search for publications on the usability of medical devices within the Nigerian context did not yield any significant results. However, we found studies on digital health diagnostics for detecting NTDs [32–34] but only one study protocol [35] on user experience of a digital health diagnostic for skin NTDs within the African context.

Developing a medical diagnostic device requires the input of end-users. Involving end-users enables early identification of user needs and contextual requirements. A user experience study is important because it ensures that the prototypes and the final product meet end-user requirements. The user experience of a device can also determine its acceptability by end-users, which determines uptake and continual use. Many factors, such as user efficiency, effectiveness, and satisfaction, are important to consider for the usability aspects of the user experience study. In this study, the average user in CHEW training (4.2 s) was faster than laboratory scientists (4.5 s), with a similar pattern seen with the error rates, indicating that a faster time did not correlate with increased errors. The slightly faster speed of task completion by users in CHEW training may be due to faster reflexes due to the younger age group of the CHEWs in training. Laboratory technologists/technicians were slower and had a substantially higher error rate compared with laboratory scientists. Some studies point to limited experience with digital tools as a probable cause [36,37], although laboratory technicians indicated a high level of experience with digital tools in our study (Table 3). There were few laboratory technicians in the study sample (Table 1) which has likely amplified the error rates from one individual in the group. It is therefore likely that the efficiency rates and error rates may improve if more laboratory technologists/technicians were included in this study. However,

despite these factors, all categories of participants were able to complete the tasks within 4.2 s, which generally indicates that the design of the device allowed ease of use and consequent efficiency, thereby contributing to a positive user experience. In addition, most participants were satisfied with the device, contributing to a positive user experience and positively impacting the intention to use the device.

To use diagnostic devices such as the AiDx NTDx Assist device, it is important to consider other contextual factors, such as the proficiency of respondents with the use of devices that have similar characteristics. Considering contextual factors can be used to support the data and validate the results of the usability testing. In this study, the results of testing for proficiency with some medical and optical devices are similar to the output of the user perception questionnaire (Figure 2). This finding suggests that end-users who have interacted with medical devices or medical technology are likely to find other medical devices with similar characteristics that are easy to use. This familiarity may have a positive effect on the acceptability of similar new devices. In addition, the difference between experiential ratings for proficiency with similar digital tools (Table 3) did not have a direct relationship with the usability scores. This result indicates that prior exposure (training or experience-based) with similar tools with additional training is sufficient for high proficiency in the use of digital devices by the lowest end-user.

Other contextual factors explored in this study include barriers to acceptability. Technical infrastructure, such as availability of computer hardware, device interoperability with android technology, and electricity was highlighted as contributing to the barriers to the acceptability and use of the devices. This finding signifies that the actual use of the device use is also dependent on other non-human factors which may be a strong determinant of device abandonment, despite the positive user experience recorded.

We used a mix of end-users in this study to simulate the pattern of users of the device at the primary healthcare level. There were no significant differences between the user perception scores of the different end-users, signifying that the device is easy to use and can be used by the lowest cadre of healthcare workers. In addition, the data presented in this study indicate that the testing of similar devices may not necessarily require highly-skilled workers such as laboratory scientists. CHEWs-in-training and, by extension, CHEWs are a reliable testing group with scores similar to those of laboratory scientists.

The following user perception domains were assessed: perceived ease of learning, perceived ease of use, perceived usefulness, and intention to use.

These factors cover important aspects related to the acceptability of the device and can also be a strong determinant of the acceptance and use of a medical device [9,14,27]. The perceived ease of use, usefulness, and intention to use are strong determinants of acceptability [20–23,25], and the high scores for these domains suggest a high level of medical device acceptability by the end-users.

Devices that require minimal training are easy to learn and are a positive predictor of ease of use and acceptability, while the usefulness domain also strongly predicts acceptability [9,20]. The usefulness domain signifies the importance of the new device in the daily activities of the end-user. All the end-users agreed that the device was useful to their work, and they were willing to use and recommend the medical device for use to their colleagues. There are some limitations to the study. First, the inequality across tested groups may account for the variation in usability scores. For instance, a larger group of laboratory technicians may elicit a lower error rate and higher efficiency. Second, the study obtained results based on first-time use, and repeated use and testing will likely increase efficiency and effectiveness and reduce error rates across all groups.

5. CONCLUSIONS

Our findings have practical implications for NTD management. First, diagnostic devices must be accessible at the primary care level for early detection and treatment. Our study provides evidence that CHEWs can readily and effectively use digital diagnostic devices in the NTD context. Second, innovative medical devices suitable for the context of use are necessary to meet WHO targets for NTD control and elimination. Last, device suitability can be assessed through user experience studies in addition to performance metrics. Involving potential end-users in NTD diagnostic tool development reduces the risk of desertion, increases awareness, and aids early detection and treatment, particularly in low-resource settings.

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CONFLICTS OF INTEREST

Author Tope Agbana was employed by the company AiDx Medical. The remaining authors declare that the research was conducted in the absence of any commercial or financial relationships that could be construed as a potential conflict of interest.

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7.2. A USABILITY STUDY OF AN INNOVATIVE OPTICAL DEVICE FOR THE DIAGNOSIS OF SCHISTOSOMIASIS IN NIGERIA

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Abstract

Schistosomiasis is a neglected tropical disease that is predominantly diagnosed by conventional microscopy in Sub- Saharan Africa. However, effective diagnosis by conventional microscopy is limited by multiple technical and logistic barriers. Alternative diagnostic techniques are needed. The Schistoscope is a digital optical device that has been designed to support microscopists for the detection of schistosomiasis in endemic resource-limited settings. Aim: A user-centered design approach was used to assess the usability and user-acceptance of the Schistoscope compared to conventional microscopy in the Federal Capital Territory, Abuja, Nigeria. In this study, usability and acceptance are defined as being easy-to-use, efficient, and suitable in the daily workflow by end-users. Methods: Using a qualitative conventional context analysis approach, a mixed-methods questionnaire was used to elucidate themes related to the usability and user-acceptance of the device. Participants included trained microscopists and university students (n=17). Results: Participants answered both ranked and open questions. Overall the device's use was considered to be easy and acceptable in the routine workflow of a microscopist. The auto-scan feature was considered to have added value. Critical feedback regarding aesthetics of the device, particularly related to size, was noted by the participants. Conclusion: The usability approach used in this study elucidated valuable insights of end-users. The Schistoscope was very well perceived by both medical students and trained microscopists. Critical feedback will be used to further improve the next iterative design of the device.

Keywords:
Digital optical device, schistosomiasis, usability, mixed-model questionnaire, resource-limited settings.

I. INTRODUCTION

A. Epidemiology of Schistosomiasis

Schistosomiasis is a neglected tropical disease caused by infection with parasitic worms called schistosomes (trematode flatworms of the Schistosoma (S) genus), affecting more than 250 million people worldwide [1]. The majority of infected people live in Sub-Saharan Africa (SSA), especially in poor communities that lack access to clean water and adequate sanitation [2]. Populations in endemic regions are further affected by limited access to adequate diagnostics and general healthcare services. Schistosomiasis is spread through contact with larvae-infected fresh water [1]. The main human infective species in SSA are S. haematobium causing urinary schistosomiasis, and S. mansoni causing intestinal schistosomiasis. Symptoms of acute schistosomiasis are fever, diarrhea, fatigue, anemia and generally depleted nutritional status, myalgia, and malaise. Long term health consequences include organ failure, and for infected children growth stunting and cognitive impairment. The high socio-economic burden of this disease is exacerbated by indirect effects, including school absenteeism and reduced productivity in adults. Schistosomiasis can be treated with an anthelmintic drug called praziquantel which is safe and effective against all infective species [1], [2].

B. Current diagnostic approaches and challenges in resource-limited settings

Conventional microscopy is recommended by the World Health Organization as the reference standard technique for the diagnosis of schistosomiasis [2]. For urinary schistosomiasis, S. haematobium eggs are excreted in urine. To increase sensitivity, urine samples are concentrated by filtration, sedimentation, or centrifugation (provided a centrifuge and electricity are available). Eggs are then detected by examining either the filter- membrane or the urine sediment under a conventional microscope (manual examination) [3].

Although conventional microscopy is highly specific and quantitative, it has several limitations. Egg excretions are variable. Therefore, eggs are often missed in low-intensity infections or due to inter- and intra-variation in egg distribution, collectively resulting in reduced sensitivity [1]. Although the limitation of uneven egg distribution is not unique to microscopy, even highly trained microscopists can miss eggs and report inconsistent results. Microscopy is time-consuming and highly operator-dependent and therefore error-prone, particularly as user-fatigue develops after many hours of analyzing samples (field observations). It is also difficult to standardize microscopy as a readout. The use of conventional microscopy in (remote) endemic regions is further hindered by logistic constraints [4]. The availability of microscopes is limited by high costs, lack of both spare parts and required skills for repairs and maintenance, and erratic power supplies [4]. The use of alternative diagnostic tests, e.g. that detect adult worm- associated circulating antigens [3], is currently not feasible for routine use due to logistic and financial constraints.

C. Proposed diagnostic solution: digital optical devices

To address these diagnostic challenges, digital optical devices, some supported by artificial intelligence (AI), are being developed by various international research groups. They range from stand-alone devices to auxiliary components that are added to conventional microscopes [5], with or without the option of offline data analysis. All developments aim to achieve (semi-) automated detection and quantification of parasites in clinical samples. In line with these goals, the INSPiRED project aims to improve the diagnosis of parasitic diseases by developing and validating expert-independent, easy-to-use, and cost effective automated optical diagnostic devices for use in resource-limited settings. We have developed a digital optical device called the Schistoscope [6] (Figure 1 and 2). The development and validation processes involve multiple steps: (1) prototype development (i.e. system hardware design that includes optics; electrical components and embodiment, and currently costs approximately USD 700, and the interaction design); (2) data collection for the development of AI algorithms (i.e. training data set for system software) that are programmed to automatically identify specific pathogen features in a data set e.g. eggs (manuscript in preparation); (3) diagnostic performance evaluation, with and without AI, with respect to conventional microscopy as the reference standard (manuscript in preparation); and (4) usability and user-acceptance in the local context.

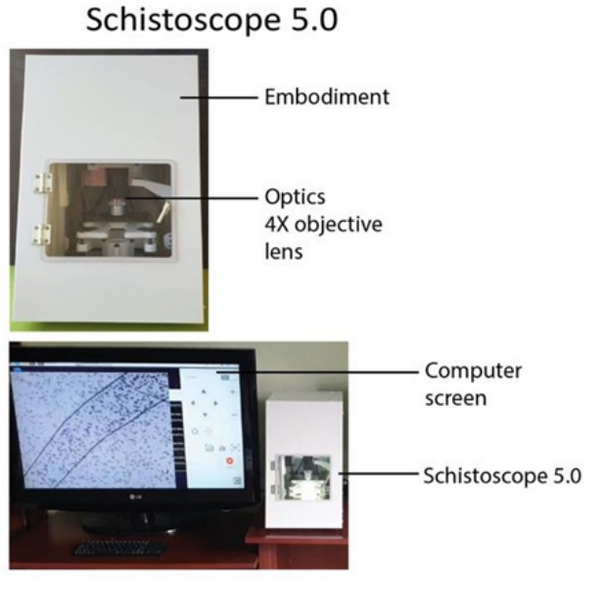


Figure 1. Schistoscope 5.0 (top) connected to a computer screen (bottom).

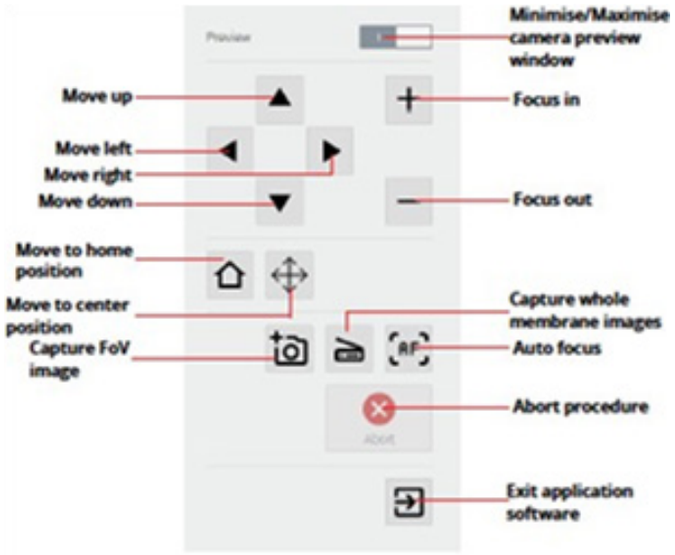


Figure 2. The graphical user interface of the Schistoscope 5.0

D. Beyond technical developments: usability and user acceptance in the local context

User-centered design (UCD) is an iterative design process in which designers focus on the users and their needs in each phase of the design process, from product conception to the final product [7]. A UCD approach involves four distinct phases: contextual inquiry, user specification, prototyping, and user experience [7]. Co-creation is the foundation of UCD during the research and development phase, and it facilitates researchers to elucidate product specifications [8]. While designing the Schistoscope, we understood the context of the users [8] and opportunities for this device [9]. We also identified and specified the user's requirements by developing a target product profile [10]. We are currently evaluating the diagnostic performance of the device, and assessing how the product fits into the end-user's work environment in SSA by conducting a usability and acceptability study. This close user involvement will enhance the probability of meeting their expectations, and

consequently increase uptake of the device in their daily practice [8]. The usability and user-acceptance study of the Schistoscope (version 5.0) was conducted in the Federal Capital Territory (FTC), Abuja, Nigeria, by health workers and medical students who are likely to use the device in their daily work activities. The aim of this paper is to describe the findings of the usability study.

II. METHODS

A. Study design and setting

Governed by a UCD approach, a mixed-model questionnaire was formulated by industrial designers of the INSPiRED project who also developed the prototype. The questionnaire consisted of several ranked questions using a 5-point Likert scale, and open questions to assess the usability of the device compared to conventional microscopy. This study was embedded within a larger epidemiology study that was conducted in the FTC (Abuja, Nigeria) in two area councils based on schistosomiasis prevalence and control with praziquantel treatment.

B. Ethical considerations

The study protocol to obtain urine samples was approved by the College of Medicine University of Lagos, Health Research Ethics Committee (CMUL/HREC/07/16/017) and the Federal Capital Territory's Health Research Ethics Committee (FHREC/2019/01/73/18-07-19). Community members who were asked to provide a urine sample for the epidemiology study, as well as participants of the usability study were informed that participation was voluntary and that they were free to withdraw from the study at any time.

C. Eligibility criteria and sample size

Participants that met the following criteria were considered to be eligible: aged 18 and older, able to speak, read, and write English, have experience with conventional microscopy, and live and work in an endemic region. A purposive sampling method was employed where maximum variation selection was used in an effort to produce a study sample that varied in terms of age, sex, and duration of microscopy experience (years). Thereafter, a snowballing sample method was employed which facilitated recruitment of 7 students at the College of Medicine, University of Lagos (Table 1). These participants represented the intended end-users as they had experience using conventional microscopy for the detection of schistosomiasis. The initial sample size was 18 end-users. Upon analyzing the data, one user was excluded from further analyses as the participant clearly did not understand the phrasing of the questions, as reflected in contradicting ranked responses. Data saturation can usually be reached with a sample size of 5-7 participants [11]. The final sample size included in this study was 17 end-users.

Table 1. CHARACTERISTICS OF STUDY PARTICIPANTS (N=NUMBER OF PARTICIPANTS THAT PROVIDED INFORMATION).

Characteristic	n	Average (range)
Age (years)	14	27.5 (20-41)
Sex (total)	15	
Female	10	67%*
Male	5	33%*
Time active as a microscopist (years)	8	5.6 (1-11)
*presented as a percentage		

D. Procedure

Five samples were prepared by the investigators by passing 10 mL urine through a filter membrane (13 mm diameter; 0.2 µm pore size), and placing the filter membrane onto a glass slide. The purpose of the prepared slides was only to facilitate the use of the device, and participants were not required to prepare or formally analyze the filter membrane on the slides (Figure 3).

Two investigators provided a brief introduction (study aim and their backgrounds) to the participants and remained present for the duration of the study. A printed user manual for the device of 5 pages (Figure 4) and accompanying questionnaire were given to each participant. Participants were not given a time-limit to complete the questionnaire, nor were they required to provide an answer for each question. Hardcopies of the questionnaires were collected at the end of the day.

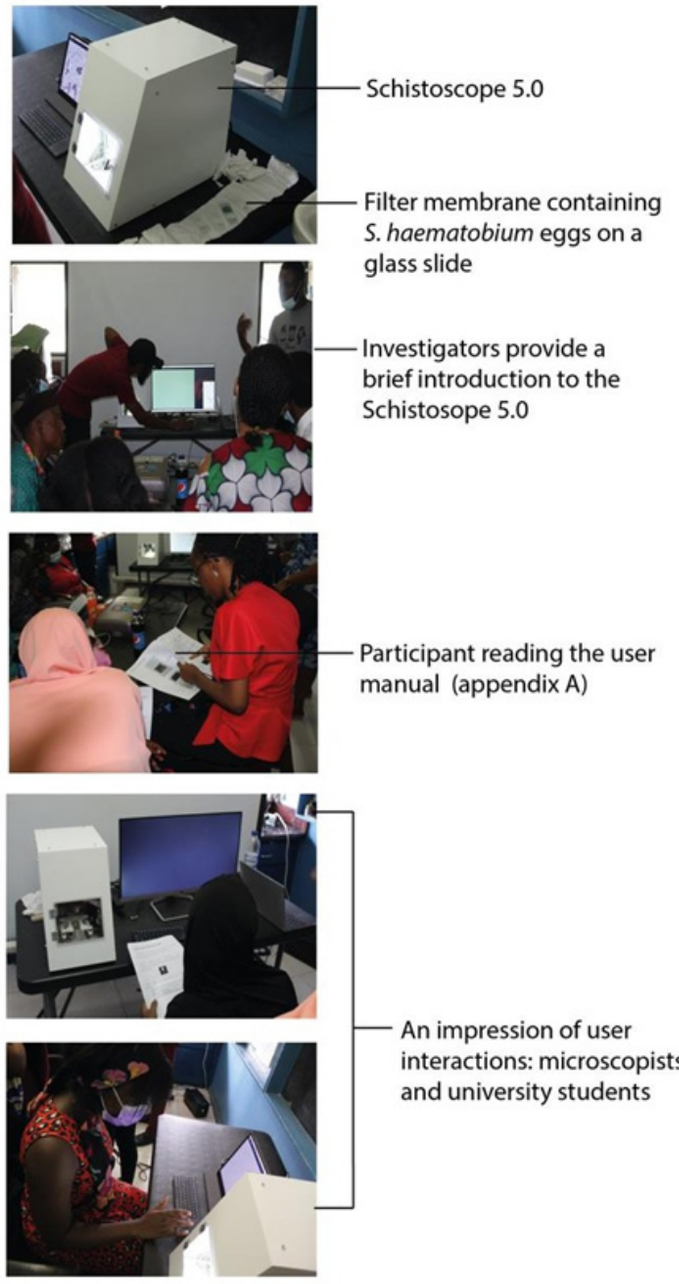
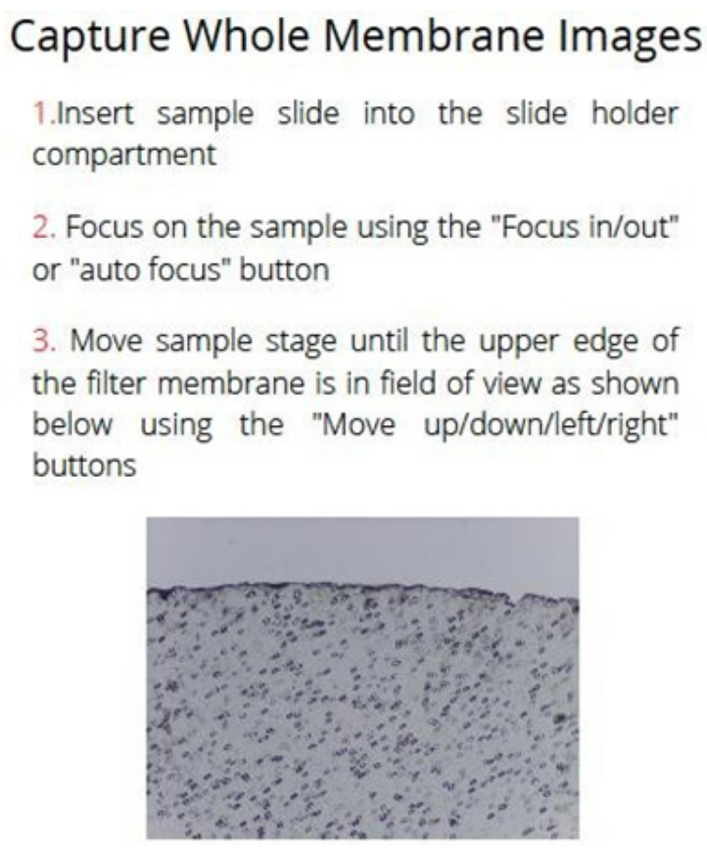


Figure 3. The study setting at the University of Lagos. From top to bottom: the investigators set-up the Schistoscope device and a computer screen. Slides containing a filter membrane were prepared by the investigators. After a brief introduction from the investigators, participants read the user manual. Thereafter, they began the user-interaction.

The device was placed in its OFF-state by the investigators. Participants were asked to turn on the device and start the desktop application (Figure 3). Next, a slide containing a filter membrane was given to the participant to perform the following tasks according to the user manual: (1) using the directional control buttons on the user-interface or a keyboard (Figure 2), move the stage to a position such that the microscope objective is directly above the filter membrane on the slide; (2) focus on the filter membrane by using the auto-focus feature; (3) capture an image of the filter membrane; (4) initialize the automatic slide scanning operation; (5) save the captured images to a USB and shut-down the device. On completion of the tasks the participants filled-in the questionnaire. The ranked statements in the questionnaire were formulated to understand the users' experience during different steps in the procedure. The 5-point Likert scale ranged from -2 to 2 in response to each statement. A "-2" score denotes that participants strongly disagreed with the statement, and a "2" score denotes strong agreement (Table 2).


Capture Whole Membrane Images

1.Insert sample slide into the slide holder compartment

2. Focus on the sample using the "Focus in/out" or "auto focus" button

3. Move sample stage until the upper edge of the filter membrane is in field of view as shown below using the "Move up/down/left/right" buttons

Figure 4. Sample page of the user manual.

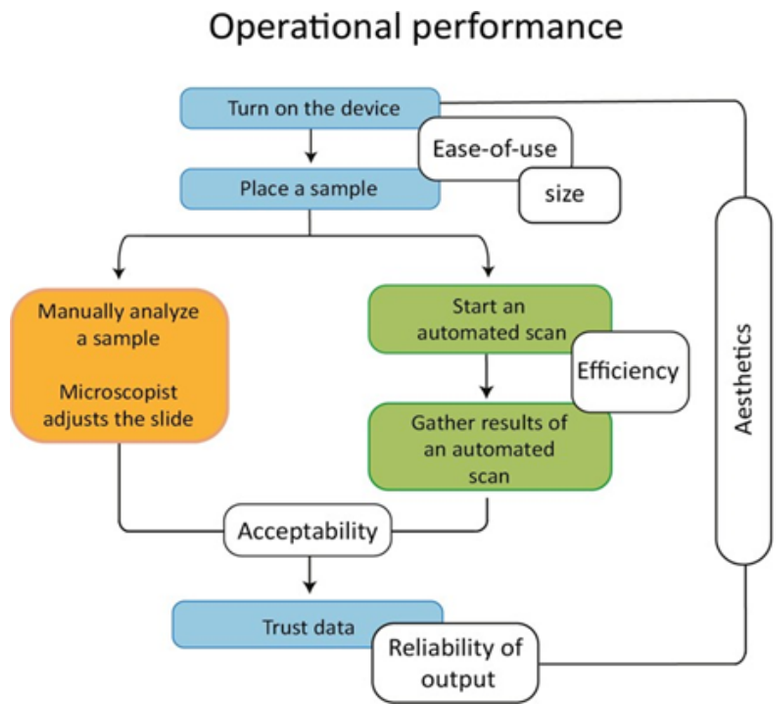


Figure 5. Graphical summary of the manual and automated procedure (orange and green blocks, respectively), and codes identified in this study (white blocks) that collectively relate to the operational performance of the device. The manual detection workflow is analogous to conventional microscopy (orange). The automated scan is unique to the Schistoscope 5.0 (green).

Table 2. PARTICIPANT RESPONSES RELATED TO USE OF THE SCHISTOSCOPE 5.0 IN COMPARISON TO CONVENTIONAL MICROSCOPY USING A 5-POINT LIKERT SCALE (N=17, UNLESS STATED OTHERWISE

Turn on the device	-2	-1	0	+1	+2	
Executing this task was difficult	14	3	-	-	-	-1.8 ± 0.4
The task is easier on the Schistoscope than on a standard microscope	14	3	-	-	-	-1.8 ± 0.4
I spend more time on this task than I expected	10	1	-	2	4	-0.6 ± 1.8
With standard microscopy, this task is different	2	2	3	3	7	0.6 ± 1.5
Place a sample						
Executing this task was difficult	12	5	-	-	-	-1.7 ± 0.5
The task is easier on the Schistoscope than on a standard microscope	12	3	1	-	1	-1.5 ± 1
I spend more time on this task than I expected	2	6	3	2	4	0 ± 1.5
With standard microscopy, this task is different	0	3	5	3	6	0.7 ± 1

Manually analyze a sample						
Executing this task was difficult	9	8	-	-	-	-1.5 ± 0.5
The task is easier on the Schistoscope than on a standard microscope	9	7	-	1	-	-1.4 ± 0.8
I spend more time on this task than I expected	2	3	4	2	6	0.4 ± 1.5
With standard microscopy, this task is different	-	1	1	6	9	1.4 ± 0.9
Start an automated scan						
Executing this task was difficult	10	6	1	-	-	-1.5 ± 0.6
The task is easier on the Schistoscope than on a standard microscope	2	3	2	1	8	0.6 ± 1.6
Gather results of the automated scan						
Executing this task was difficult	7	6	2	1	1	-1 ± 1.1
I spend more time on this task than I expected	2	2	2	3	8	0.8 ± 1.5
Trust (n=16)	-	-	-	6	10	1.6 ± 0.5

-2	Strongly disagree with the statement
-2	Disagree with the statement
0	Neutral
1	Agree with the statement
2	Strongly agree with the statement

E. Data Analysis

Confidentiality of information retrieved and anonymity of results was ensured by assigning unique codes to the questionnaires before data analysis. The data were digitized by two investigators. Thereafter all data were analyzed descriptively using Microsoft Excel software by one investigator. Ranked responses were analyzed quantitatively (Mann-Whitney statistics; Prism 9), and open-questions were used to support the ranked responses in a descriptive manner. A conventional qualitative content analysis approach was used to code the data [12]. User impressions were considered as 'codes', which were then grouped into meaningful categories based on the relationship between the codes. Categories were generated until all the data were considered, and then grouped into a central usability theme (operational performance). The co-authors discussed the codes that emerged from the descriptive analysis. No discrepancies occurred (Figure 5).

III. RESULTS AND DISCUSSION

The aim of this study was to elucidate the perceptions of end- users as they document their experiences with the device. The following codes were identified: ease of use; size; efficiency (time); acceptability compared to microscopy (workflow in daily routine); reliability of outcomes, and general

aesthetic impressions (Figure 5). Participants were also asked 8 open questions to document their overall experience when using the Schistoscope compared to conventional microscopy. Their responses were stratified into the codes, and the average score in response to each statement are discussed here:

A. Ease of Use

The participants agreed that it was easy to start the device (average score -1.8), and that this task was not time consuming (-0.6). They perceived this task as different compared to microscopy (0.6). The participants agreed that it was easy to place a sample into the Schistoscope (-1.7), however, placing a sample in a conventional microscope was considered to be easier (-1.5). Although participants reported a neutral response to the time taken to place a sample in the device (0), this task was perceived as different compared to microscopy (0.7). These responses to starting a new device and placing a sample in the device are inherently perceived as different. In the open questions, all the participants reported that the Schistoscope was easy to use from sample placement to capturing a digital image. The use of a computer screen (Figure 1) was well-perceived, and multiple participants stated that it was impressive to see the parasitic eggs projected clearly on the screen.

> *"I was impressed that I could see the eggs projected on the screen with ease"* –microscopist with 10 years' work experience

Other comments included the added value of the digital display on the screen which circumvented the need to look directly into the eyepiece for a magnified view of the slide, as would be required when using a conventional microscope. Interestingly, a student reported that the Schistoscope was easy to use without formal training, which is in line with the WHO recommendation of one-day training for diagnostic devices [4]. The use of the Schistoscope as both a manual and automated device was positively reported. In addition to one participant that stated that the manual operation of the device was easy, multiple participants noted that the automatic focus and scanning features of the Schistoscope were value added features.

> *"The simplicity of the device in focusing samples was amazing, the auto-focus button was one of the best features, it saves time and energy"* –microscopist with 3 years' work experience

Although the Schistoscope prototype tested in this study had an auto-focus feature, the analysis of the sample was performed manually, meaning that the end-user (microscopists and students) manually counted the number of S. haematobium eggs identified, analogous to conventional microscopy.

Numerous participants noted that automatic analysis would be an added value feature, where AI software could quantify the number of eggs. Such 'sample-in-answer-out' capabilities were noted as desirable features by the participants. Other display features that were suggested include a digital indication of which part of the slide is scanned during the auto-scan process as the field of view is changed in real-time, and the magnification status.

B. Suitability in the workflow and acceptability

The participants agreed that it was easy to manually analyze a sample (-1.5), however, this task was considered to be easier and less time consuming when using a conventional microscope (-1.4 and 0.4, respectively). Manually analyzing a sample on the Schistoscope was perceived as different compared to microscopy, as expected (1.4). To enhance the suitability and desirability of the device in the workflow in the field, an integrated sample storage unit was noted as an additional feature to store samples safely. Conventional microscopes contain 4 objective lenses (4X; 10X; 40X; and 100X). The Schistoscope 5.0 prototype had a single 4X objective lens which was sufficient to identify Schistosoma eggs, however, one participant noted that it would be advantageous to incorporate additional objective lenses. Another suggestion included the possibility to detect other pathogens, however, the scope of this particular prototype was focused on the detection of Schistosoma eggs. Finally, large data storage capabilities were noted by participants as desirable.

C. Efficiency

The participants agreed that it was easy to start an automated scan (-1.5), and to save the results of the scan (-1). They noted that it did not take more time than expected to start an automated scan or save results (0.6 and 0.8, respectively). Although participants were encouraged to provide their insights to each open question, this was not a requirement. Only two participants provided elaborate responses related to efficiency of use. In terms of the amount of time that it takes the end-user to scan a slide when using the auto-scan function, one participant reported that there should be a time limit on the device for this function. This participant noted that the use of the Schistoscope takes more time to perform a scan compared to a microscopist using a conventional microscope (~15 minutes for the Schistoscope, and less than 10 minutes for a conventional microscope; personal observations in the field). In agreement with this observation, another participant also noted that the auto-scan time should ideally take less than 10 minutes. It is well acknowledged that scan time and accuracy is a common trade-off i.e. a faster scan time could reduce accuracy, however, further improvements in scan-time can be explored in the next design iteration.

D. Reliability of data generated by the Schistoscope

Given that captured images are displayed on a screen, the majority of the participants noted that the data generated would be considered reliable. Interestingly, one participant noted that digital microscopy, like conventional microscopy, is only reliable provided that the microscopist can identify the eggs, and this relies on the expertise of the microscopist. However, a challenge remains when dealing with a negative sample.

> *"Yes, it is reliable if I can see a positive result, but not reliable if negative. Quality control is needed"* – microscopist with 10 years' experience

E. Aesthetics

Responses related to the size of the device demonstrate that it was generally perceived as too big. Suggestions were to reduce the size of the device to increase portability; and also reduce the amount of space that would be occupied on a laboratory bench or a table in the field. However, a device that is too small can also be easily misplaced. Other responses included the size of the door handle used to place a sample in the device was too small, undesirability of visible wires, and added value of a small screen fitted to the device to enhance portability by replacing the computer screen.

For each step in the process, no statistically significant differences in responses were identified between microscopists and students, indicating the ease-of-use for both groups.

IV. CONCLUSION

The aim of this study was to elucidate the perception(s) of end-users related to the use of the Schistoscope in a representative context. The mixed-model questionnaire consisted of several ranked and open questions to assess the usability of the device compared to conventional microscopy, and user-acceptance in terms of overall experience (interaction with the device), reliability of data generated, and aesthetics (size and general appearance). One user was excluded from the study due to contradicting responses. Therefore, negatively-worded questions are a limitation of the questionnaire design and can be rephrased as positively-worded (agreeable statements) in future usability studies.

The Schistoscope is a digital microscope, designed to support the daily work of a microscopist, that can be used manually, analogous to a conventional microscope except with a digital interface, or automated. Sample preparation is the same for both detection methods, so use of Schistoscope does not disrupt the workflow of the microscopist or other technicians in the laboratory or at field sites. It is therefore not surprising that the Schistoscope was perceived as easy to use by both students and

trained microscopists with very little training or explanation for operation. Summing up, it is expected that the use of this device can be implemented with minimal capacity building.

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Chapter

8

TOWARDS AN ADOPTION PLAN FOR NTD DIGITAL DIAGNOSTICS

This chapter discusses a better approach to schistosomiasis elimination using locally available resources. The first study highlights the current approach to schistosomiasis control and elimination and proffers a bottom-up approach to disease elimination through a contextual lens. The second study shows the result of contextualizing the end-user of an NTD digital diagnostic device within the healthcare system in Nigeria and the effect of adopting this approach on NTD elimination.

8.1. RETHINKING THE TOP-DOWN APPROACH TO SCHISTOSOMIASIS CONTROL AND ELIMINATION IN SUB-SAHARAN AFRICA

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Abstract

The control and elimination of schistosomiasis have over the last two decades involved several strategies, with the current strategy by the World Health Organization (WHO) focusing mainly on treatment with praziquantel during mass drug administration (MDA). However, the disease context is complex with an interplay of social, economic, political, and cultural factors that may affect achieving the goals of the Neglected Tropical Disease (NTD) 2021-2030 Roadmap. There is a need to revisit the current top-down and reactive approach to schistosomiasis control among sub-Saharan African countries and advocate for a dynamic and diversified approach. This paper highlights the challenges of praziquantel-focused policy for schistosomiasis control and new ways to move from schistosomiasis control to elimination in sub-Saharan Africa. We will also discuss an alternative and diversified approach that consists of a Systems Thinking Framework that embraces intersectoral collaboration fully and includes co-creating locally relevant strategies with affected communities. We propose that achieving the goals for control and elimination of schistosomiasis requires a bottom-up and pro-active approach involving multiple stakeholders. Such a pro-active integrated approach will pave the way for achieving the goals of the NTD 2021-2030 roadmap for schistosomiasis, and ultimately improve the wellbeing of those living in endemic areas.

Keywords:
Schistosomiasis, control, elimination, strategies, sub-Saharan Africa

INTRODUCTION

Schistosomiasis is a disease of poverty affecting over 250 million people worldwide (1). It is one of the most common waterborne parasitic diseases in the world (2). There are six known species that cause schistosomiasis in humans: Schistosoma (S) haematobium, S. mansoni, S. japonicum, S. mekongi, S. intercalatum, and S. guineensis. Of these six species, S. haematobium and S. mansoni are the most commonly found species in endemic-areas, with S. haematobium causing urogenital schistosomiasis

and S. mansoni causing intestinal schistosomiasis (3). S. haematobium has also been implicated in susceptibility to human immunodeficiency virus (HIV) (4), human papillomavirus (HPV) infections (5) and infertility (6).

Schistosomiasis is found mostly in low-income countries with the largest burden of disease in sub-Saharan Africa (1). Sub-Saharan Africa accounts for ~93% of the world's ~207 million schistosomiasis cases, with the highest prevalence found in Nigeria, Tanzania, Ghana, Mozambique, and the Democratic Republic of Congo. These 5 countries account for ~78 million cases (7, 8). Schistosomiasis commonly affects the poor living in rural, underprivileged urban or peri-urban settings with limited access to clean water, inadequate sanitation and hygiene services (9). It is also more common in fishing and agriculture dominant communities where direct interactions with water increase the risk of contracting the disease. Water-related domestic activities such as washing clothes and fetching water, as well as recreational water activities also increase the risk of infection for women and children (10).

Schistosomiasis does not only affect the health of infected persons by causing systematic and organ-specific inflammation, it also has social and economic implications for communities (7, 11). The disease is known to cause anemia, growth stunting and reduced productivity; and accounts for between 1.6 and 4.2 million disability-adjusted life years (DALYs) lost annually in sub-Saharan Africa (8, 12). Currently, the mainstay of treatment is with the use of praziquantel which is effective for the treatment of all species of schistosomiasis (7).

The World Health Organization (WHO) has developed several roadmaps for Neglected Tropical Diseases (NTDs), and many sub-Saharan African countries have made significant progress by rolling out national action plans and programmes targeting schistosomiasis control and elimination (13). Despite these efforts, schistosomiasis remains a huge problem in sub-Saharan Africa with an unmet need for treatment (14).

CHALLENGES WITH THE CURRENT STRATEGY FOR CONTROL AND ELIMINATION OF SCHISTOSOMIASIS

Attempts made toward schistosomiasis control and elimination have involved several strategies ranging from disease treatment to managing complications and controlling disease transmission (2, 13, 15, 16). Schistosomiasis is currently tackled with a combination of preventive chemotherapy dispersed through mass drug administrations (MDAs), and water, sanitation, and hygiene (WASH) programs (13, 15). However, it appears that the core focus of the WHO plan for schistosomiasis control and elimination is on preventive

chemotherapy, particularly MDAs in sub-Saharan Africa. Based on this stance, progress has been made on large scale treatments and partnerships with donor foundations, other international organizations and Merck, the producer of praziquantel (10, 13). Praziquantel is the drug of choice for the treatment of schistosomiasis as it has been considered cost-effective, relatively safe, inexpensive, and effective; with donor organizations willing to provide the drug at no cost (15). Despite these attributes, schistosomiasis is still highly endemic in several countries (13, 14).

This strategy of using praziquantel as the key bullet for schistosomiasis control and elimination in practice is reactive instead of proactive and is an unavoidable consequence of a one-size-fits-all approach. This reactive approach is limiting for several reasons.

First, despite efforts at making praziquantel available to those at-need and Merck KGaA's commitment to praziquantel donations, targets for MDA coverage have still not reached all people at risk who require treatment (14). This may indicate an under-representation or undercounting of cases based on low-level awareness (11, 17, 18), migratory patterns in which the disease is introduced to new or previously eliminated areas (19, 20), and an assumption of homogeneity of the disease transmission context across different regions and countries. For example, some countries such as Nigeria have prioritized praziquantel for school-aged children leaving adults and pre- school children uncovered during MDA (18). Therefore, in this context, it implies that schistosomiasis cannot be effectively eliminated in communities where MDA treatment is on-going.

Second, although there is a commitment to the donation of praziquantel, there is a high chance of recrudescence of disease to pre-MDA levels once donations reduce or cease, or even during MDA programmes (21, 22). Third, praziquantel itself has not demonstrated 100% curative ability in both single-dose and multidose regimens in various settings (23–25) implying that relying only on praziquantel treatment use during MDA is not an effective strategy for control and elimination of this disease. Fourth, given the neglected nature of the disease in most healthcare systems in sub-Saharan Africa, there is currently inadequate funding for the disease from the national governments which is likely to persist or worsen in the future once the current external funding and support reduce. There is also a potential for donor fatigue as current gains in treatment can be reversed when donation stops, because countries do not have sustainable strategies to own and incorporate programmes within their current healthcare systems (26). Lastly, the disease context is complex with an interplay of social, economic, political, and cultural factors (20, 27) that may affect achieving the goals of the NTD 2021-2030 Roadmap (28). In light of these challenges, there is a need to revisit the

current top-down approach to schistosomiasis control among sub-Saharan African countries irrespective of the level of endemicity.

There have been several resolutions over time by the WHO geared toward the control and elimination of schistosomiasis including renewing interest, addressing partnerships, and in 2012, the need to attach importance to both preventative and control strategies by developing applicable plans with progressive targets (2). In 2013, the "WHA66.12 resolution" on NTDs focused on advocating for continuous country ownership of programmes for NTD prevention, control, elimination, and eradication (2, 13). The current roadmap for 2021–2030 for NTDs also reiterates the importance of community-based and applied research for effective NTD programmes. It highlights the need to integrate mainstream approaches into national healthcare systems, coordinate action across sectors (which has been challenging to operationalize), and close coordination and multisectoral action across all sectors (beyond health) (16). However, it is unclear how sub-Saharan African countries can achieve their targets beyond the desire for easy wins through the use of praziquantel as a reactive way to achieve their aims. Clearly, attaining schistosomiasis control requires a dynamic approach that incorporates more proactive and holistic strategies beyond the current top-down approach to one that incorporates the socio-cultural, epidemiological, economic and geographical dynamics within each country to create a mix-set of feasible strategies for schistosomiasis control. The uptake and domestication of these strategies will require an in-depth look into the dynamics of each region and country.

DISCUSSION AND RECOMMENDATIONS

Achieving sustainable schistosomiasis control and elimination requires an innovative design that incorporates a wide range of factors and information influencing disease transmission and intervention successes, which are interdependent and interrelated, and which will benefit from a whole system context (29, 30). Therefore, we propose a proactive and dynamic approach with three broad strategies.

First, is the need to use a Systems Thinking Framework with a particular focus on medical products and technology, information and research, healthcare financing, and service delivery. This is hinged on the premise that the control and elimination of schistosomiasis, like all other NTDs, is affected by a multitude of social, cultural, economic, geographical and ecologic factors (28) which are interdependent, and for which the current use of praziquantel alone cannot solve. These interdependencies are best understood and addressed by looking at the system as a whole with a particular lens on weak points within the system (21, 26, 29).

Although the NTD 2021-2030 roadmap stresses the need for well-structured operational and implementation investigations, including community-based and applied research as the main fulcrum (16), it is still unclear how sub-Saharan countries can achieve this goal. As such, sub-Saharan countries need to identify key areas, wherein available resources can sustainably reduce schistosomiasis burden and also indirectly contribute to an improved healthcare system in the long-term. Improving access to medical products and technology includes drug procurement and supply chain for praziquantel by making it readily available for easy procurement and treatment of schistosomiasis in partnership with donors and the private sector, as well as investing in affordable, easy to use diagnostic tools which can reduce delays in accessing treatment. A number of these diagnostic tools, such as mobile phone-based technologies and rapid diagnostic tests, are either currently available or undergoing development (31–35).

There is also a need to manage information and promote research into drivers of regional and local hotspots of schistosomiasis (21, 22, 28). Service delivery has been one of the problems of schistosomiasis control in several sub-Saharan African countries with praziquantel mainly available during MDAs and the difficulty of identifying non-acute cases of urinary schistosomiasis (18). As such, we propose seeing schistosomiasis in the same light as malaria and adding regular screening at the primary care level for regions with a high prevalence to help capture those who are not covered by the MDA programmes. It is also important to capture NTDs diagnostics and treatment into current healthcare financing plans. Communities with a high incidence may benefit from specialized health insurance plans that can absorb the cost of treatment. Alternatively, it can be made mandatory through policies for coverage of NTDs by health management organizations to reduce out of pocket costs by persons with the disease. All these will require viable research with generated data used in designing effective communication interventions.

Second, strategies for schistosomiasis control and elimination should be multisectoral as the disease is not only a healthcare system problem but affects other areas of people's lives as well, such as livelihoods, recreation, and cultural practices. The physical environment is one of the key determinants of schistosomiasis infection and addressing issues related to this requires an in-depth look into sectors that relate directly to the physical environment, including socio-economic and cultural aspects (36). In this context, beyond the health ministry departments such as vector control, epidemiology, health education, medicine, nursing and pharmacology departments; other sectors/ministries/departments such as planning, statistics, community development, water resources, animal health, education, agriculture, environmental management, and finance are critical and should work

together as a team. Important elements to consider for involvement include how these sectors are affected or contribute to schistosomiasis, and how strategies can be drawn up synergistically to minimize infection and re-infection and help with control. Moreover, the multisectoral team equally needs to fashion out innovative activities. For example, the promotion of fish farming and raising of shrimps that are known to eat the cercariae of schistosomes in highly endemic areas can help reduce infection rates (37) and contribute to the local economy. The introduction of shrimps that feed on the Schistosoma cercariae may be more useful in riverine/swampy communities, and molluscicides in inland communities and localities that do not depend on rivers for economic activities. Introducing and promoting the planting and use of natural molluscicidal agents such as soapberry Endod (Phytolacca dodecandra), which is also toxic to miracidia and cercariae and doubles as a natural detergent for washing clothes (38, 39) is illustrative.

Furthermore, since schistosomiasis is more common along communities situated around dams (40), a percentage of profits made from dam-derived services should be allocated for the implementation of schistosomiasis control activities. Although schistosomiasis is common in more rural areas; rural-urban migration patterns, urban planning challenges and overcrowding, and problems of rampant open defecation due to poor sanitary facilities in sub-Saharan Africa have increased the risk of schistosomiasis in urban communities implying poor urban planning. The planning departments can also collaborate with communities and community-based organizations to push for clean water and improved hygiene and sanitary services. Clean water provision, sanitation and hygiene (WASH) is critical to schistosomiasis control and elimination by preventing contaminated faeces and urine from reaching open water sources such as rivers.

Third, there is a need to co-create locally relevant strategies with affected communities and regions since the burden of schistosomiasis is not equally distributed across most sub-Saharan African countries and even within countries (7, 17, 41). Therefore, affected regions and communities should be seen as collaborators in dealing with schistosomiasis control and elimination. For most control programmes, the government attempts MDA as a broad strategy without looking in-depth at the peculiarities of these communities and their challenges which can be drivers of schistosomiasis infection and burden (26, 28, 29). Thus, the current one-size-fits-all intervention using a top-down approach may be a contributor to the limited success of schistosomiasis control and elimination in sub- Saharan Africa. This is due to the complex interplay of factors and heterogeneity between individuals and their settings (28, 42, 43) making it difficult to understand drivers of schistosomiasis within high-risk communities and inability to create potentially useful and scalable solutions within these contexts.

Consequently, identifying contextual problems related to schistosomiasis and developing localized solutions can go a long way in achieving schistosomiasis control and elimination solutions. In this context, the control and elimination of schistosomiasis should not just be done for the people, but with the people as the NTD 2021-2030 Roadmap has clearly highlighted ownership as being critical for schistosomiasis control and elimination. Ownership should not only be seen at the government level through policies, but there is also the need for communities to own these strategies by viewing the people in these communities as collaborators in the fight against schistosomiasis and co-creating strategies with them (44). Co-creation takes into consideration the heterogeneity (45) within countries that are based on social, behavioral, and economic factors related to infection in the at-risk population. Schistosomiasis control and elimination requires a participatory approach involving both the at-risk population and the local governance structure charting a path together for the control and elimination for communities and regions (44). For example, communities can use locally available materials and techniques such as composting toilets for improved sanitation, thus reducing open defecation and consequently reducing schistosomiasis infection. Since materials can be locally sourced and are culturally acceptable, they are more likely to be easily maintained and thus contribute to local sustainability. This can also drive a sense of ownership by communities to push for the elimination of schistosomiasis within their localities.

Co-creation has also been documented to be effective in reducing NTDs (44). The development and use of locally relevant technologies and knowledge are critical to schistosomiasis control and elimination within communities and endemic regions. Put together, the strategies from all regions then become the input to develop broad and comprehensive national policies which are locally relevant for communities. Using this proactive approach will increase the likelihood of sustainable schistosomiasis control and elimination.

CONCLUSION

We propose that achieving the goals for control and elimination of schistosomiasis requires a proactive approach involving a range of stakeholders and a mixed-set of pluriform strategies that consider heterogeneity at the national and regional levels, as well as local transmission factors. These strategies should focus on locally relevant and acceptable ways to increase awareness, reduce transmission and infection, and equitable ways of treating the disease.

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8.2. DIAGNOSTIC TASK SHIFTING FOR NTDS: OUTCOME OF A PRELIMINARY QUASI-EXPERIMENTAL STUDY FOR MICROFILARIA DETECTION USING A NOVEL DIAGNOSTIC DEVICE IN NIGERIA

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Abstract

Background: Lymphatic filariasis (LF) is a Neglected Tropical Disease (NTD) with high morbidity. Tools for detecting LF are either not readily available or used by Community Health Extension Workers (CHEWs) at Primary Health Centers. A newly developed diagnostic device, the AiDx Assist, is targeted for use by CHEWs.

Objective: The study aims to determine the efficiency (speed) and effectiveness (diagnostic capacity) of CHEWs compared to laboratory scientists for detecting LF with the new device, using the World Health Organization's Target Product Profile (TPP) for LF diagnostics as a guide.

Methods: This study utilized a Quasi-experimental design. 7 students undergoing the CHEW program (intervention group) were randomly selected while 2 laboratory scientists (control group) were purposively recruited and were trained to use the device. Thereafter, both groups were tested based on 64 sample slides provided.

Results: The intervention group's efficiency (speed) was similar to the control group. Computed Effectiveness (diagnostic capacity) parameters for the intervention group demonstrated a sensitivity of 85.7% and a specificity of 82.5%.

Conclusion: Given this preliminary result, task shifting to CHEWs for the diagnosis of LF is highly likely to be successful, thereby reducing the prevalence of LF in low-resource settings.

INTRODUCTION

Lymphatic filariasis (LF), one of the Neglected Tropical Diseases (NTDs), is a parasitic infection caused by microscopic worms spread by bites from a range of mosquitoes. It is a cause of significant morbidity including lymphedema, elephantiasis, and hydrocele and is a leading cause of permanent disability and socio-economic loss worldwide.[1,2] In 2018, about 51 million people were infected globally[3] while 341 million Africans are at

risk and require intervention.[4] LF is prevalent in Nigeria and the country ranks third globally.[5] The prevalence varies between and within geopolitical zones and numerous studies[6–8] identified a prevalence ranging from 4% in the North-central to 33% in the North-West.[9]

Diagnostic tests for LF include microscopy, polymerase chain reaction (PCR) and antigen tests.[2] Microscopy using a thick film is the usual mode of diagnosis in Nigeria since PCR is expensive, and antigen tests are not always readily available at Primary Health Centers (PHCs).[9] In addition, the use of microscopy can be challenging in low-resource settings due to the high cost of procuring microscopes for every PHC, and the unavailability of trained personnel to use the microscope.[10]

Nigeria's healthcare structure allows non-physician, non-nurse cadres, such as Community Health Extension Workers (CHEWs) to work in PHCs due to health worker shortages. CHEWs have been a stop-gap to the health worker challenge using a task-shifting approach to healthcare delivery.[11] CHEWs undergo three-year training at Colleges of Health Technology and are the link between communities and the health system. CHEWs are predominant in PHCs serving communities with acute physician and nursing shortages.[11] They are also the first point of call in health posts and small PHCs serving hard-to-reach communities. CHEWs have been trained to make simple diagnoses, undertake simple bedside laboratory tests such as rapid diagnostic tests for malaria, offer treatment for diseases such as malaria, and provide some family planning services.[12] Since LF is predominant in hard-to-reach areas, adequate diagnosis and treatment may not be available due to a lack of skilled personnel for clinical and laboratory diagnosis, thus contributing to the high LF prevalence in Nigeria.

There is a need for task shifting of more complex laboratory processes to CHEWs in other to improve treatment rates, reduce disease burden and reduce the prevalence of LF and other NTDs in Nigeria. There are currently other diagnostic methods being designed for diagnosing NTDs in general and LF specifically, and the World Health Organization (WHO) has developed a Target Product Profile (TPP), which is a guide for diagnostics developers for LF.[13] The TPP guide was used as a guideline to test 3 parameters: the context of use (tool user), performance metrics (specificity and sensitivity) and tool design (throughput and training requirements). The WHO guideline specifies that the diagnostic tool for LF should be easily usable at the primary level of care wherein CHEWs work in Nigeria, require minimal training of less than 1hr, specificity of >78%, sensitivity of >82%, require ≤10 user step, and easily interpreted by untrained eyes. As such, we compared 2 end-users' efficiency and effectiveness using a new diagnostic device, the AiDx assist machine for these 3 components of the TPP.

The AiDx Assist is a duo-diagnostic system that is developed based on a novel methodology that combines technical optics and specialized data-driven algorithms to realize an integrated, portable, and reliable digital optical diagnostic system for the rapid screening of NTD.[14] The traditional microscopy-based diagnostic methods have been reported to have sufficiently high specificity necessary for successful elimination programs. However, the cost, need for trained personnel and access to standard microscopes, however, limits the deployment and application of microscopy-based methods for monitoring and surveillance programs. The AiDx has been developed as a fully automated point-of-care device for the specific detection of NTDs such as LF, Schistosomiasis, and Helminthiasis in urine, blood and stool samples accordingly as seen in figure 1.[14]

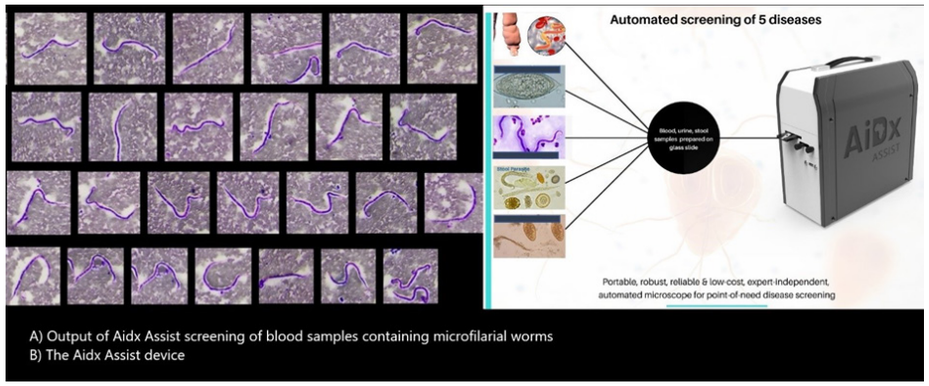

Figure 1. The AiDx Assist Output

The expert-independent device is currently optimized to be faster, cheaper, and perform with an accuracy comparable to expert human microscopists. The system output provides additional information on the estimated infection load making it suitable to measure the efficacy of the administered drugs on an infected patient. The generated diagnostic data can be analyzed offline and uploaded onto remote servers. This will accelerate prompt large-scale diagnoses in community mapping for instituting intervention and monitoring. Developed working prototypes have recently undergone low-scale assessments and testing in Nigeria.[14] Furthermore, the diagnostic tool has been optimized for minimal computational effort. As a result, the device, therefore, requires minimal power consumption and it also has an in-built power supply which makes it suitable for use in rural communities with no access to electricity. The robust and portable prototype is usable on the field with limited infrastructure. The usability of the AiDx device in communities where electricity is a challenge makes it a diagnostic tool of choice for the NTD Elimination program.

Prior test conducted in Nigeria with the device has demonstrated 94% sensitivity and a specificity of 99% in the detection of Schistosoma eggs in urine samples compared with microscopy[14] when used by laboratory scientists. These performance metrics were measured based on a completely automated scan of the prepared sample slides in the x and y direction and the integration of a data-driven autofocus algorithm with an average time for scanning of 8 minutes.

The purpose of the current study was to determine whether the same or similar, results would occur if students undergoing the CHEW program used the AiDx Assist device to make a diagnosis of LF compared to laboratory scientists. The purpose of the current study was to investigate the efficiency (speed) and effectiveness (diagnostic capacity) of students undergoing the CHEW program compared to laboratory scientists to make a diagnosis of LF when using the AiDx Assist device. As such, the study aims to:

1. Assess if a minimum of 1hr training is sufficient to train students undergoing the CHEW program to use a new diagnostic device
2. Assess if students undergoing the CHEW program can use a diagnostic device for diagnosing LF after training
3. Compare the efficiency (speed) of using the devices by students undergoing the CHEW program compared to those of medical laboratory scientists when using the AiDx Assist device
4. Compare the effectiveness (diagnostic capacity) of students undergoing the CHEW program compared to those of medical laboratory scientists when using the AiDx Assist device.

METHODS

Study design

This study utilized a Quasi-experimental design that used a control group but no pre-test because we are comparing the efficiency and effectiveness of students undergoing the CHEW program in using a newly created diagnostic device to which they have not been exposed a priori (Static Group Comparison).[15] A quantitative-structured observational approach was used.

Study participants

7 students who were undergoing the Community Health Extension Worker (CHEW) training (year 2) were randomly selected from a class of 30 students from the School of Hygiene, Ibadan, Oyo State, Nigeria. Year 2 were selected for the study because they had received training on NTDs and had some laboratory training sessions. Year 3 students (final year) were not available at the time of the study. Trained laboratory scientists/ parasitologists with more than 15 years of experience were purposively

selected. The students undergoing the CHEW program are the intervention group while the laboratory scientists are the control group.

Intervention activities

All Participants (students undergoing the CHEW program and laboratory scientists) were taken through a 1-hour training. During the training, knowledge of microfilaria and its detection was elicited and the participants were trained on the use of the AiDx Assist device. The training agenda includes device components, software interface, starting the diagnostic scan, reading the AiDx report visual output and writing out the result. Thereafter, they took a one-hour break After the break, all participants were presented with 64 prepared slides of suspected filariasis to scan using the AiDx device and make a diagnosis.

Procedure

The procedure for the use of the AiDx machine was broken into 3 steps. The CHEW students) were to 1) independently insert the slides into the machine, 2) start an automatic scan, and 3) read, and report AiDx's visual output for the presence/ absence of filarial worms from the AiDx Assist. Thereafter, the fully trained medical laboratory scientists with >15 years of experience followed the 3 steps highlighted above. Any discordant result was validated by comparing them to standard microscopy results. Figure 2 shows a CHEW student using the AiDx device.

Figure 2. CHEW students using the AiDx

Data
Observational data on AiDx Assist's user efficiency (speed) was collected using a quantitative observational tool. The observation tool involves using a timer to note the time taken to carry out each step of the process of use of the AiDx Assist device by an observer. After the use of the device, the presence /absence of parasites was noted. The effectiveness (diagnostic capacity) was derived by comparing the results written down by the CHEW to those derived by the laboratory scientists. Using a 4*4 table, we calculated the sensitivity, specificity, the negative predictive value. All data were entered into Microsoft Excel software version 2201.

Consent
Written informed consent was obtained from all participants before enrolment. This study was approved by the UCH/UI Joint Ethical Review Committee, College of Medicine, University of Ibadan. (Reference: UI/EC/21/0641).

RESULTS

Sample socio-demography
Seven (7) female students undergoing the CHEW program, age range 20-27 years were recruited. They all use smartphones and have been exposed to the use of microscopes during their training. Two (2) male medical laboratory scientists/ parasitologists with 15 years of experience were recruited who use smartphones and actively use microscopes in their line of work.

Assessment of training and use
All participants were able to use the AiDx device after a 1-hour training followed by a 1-hour break. CHEW students spent an average of 10.6 minutes using the device compared with laboratory scientists who used an average of 9.8 minutes.

User Efficiency: time spent per task
With the use of the AiDx machine, the control group (laboratory scientists) were faster than the intervention group (students undergoing the CHEW program) by an average of one minute in total. As regards reading and recording the output of the AiDx machine, the control group was 50% faster than the intervention group. However, the difference was an average of 1 minute. This means that the intervention group's efficiency (speed) of use of the AiDx Assist machine is similar to the user efficiency of the control group as shown in Table 1 and Table 2.

Table 1. AiDx Assist user efficiency (speed) of respondents

	Placing a sample (secs)	Starting an automated scan (secs)	Time for scanning (secs)	Reading Output (secs)	Total result (mins)
CHEW program students (no experience)	3.1	14.5	480	133.9	10.5
	3.2	16.6	480	136.8	10.6
	3.0	18.00	480	139.6	10.7
	3.1	17.7	480	148.4	10.8
	3.0	20.4	480	130.9	10.6
	3.1	17.63	480	134.1	10.6
	3.2	19.8	480	137.5	10.7
Mean	**3.1**	**17.8**	**480**	**137.3**	**10.6**
Laboratory scientists	2.7	13.8	480	82.4	9.7
(>15yrs experience)	3.2	14.3	480	99.4	9.9
Mean	**2.9**	**14.0**	**480**	**90.9**	**9.80**

Table 2. Level of significance of user efficiency

	Mean (minutes)	Standard deviation	T statistics	95%CI	Significance level
CHEW students (Intervention group)	10.6	0.2	17.75	0.711 to 0.889	P < 0.0001*
Laboratory scientist (control group)	9.8	0.3			

*Significant

Effectiveness (Diagnostic capacity)
Sensitivity is the ability of a diagnostic test to accurately identify patients with a disease while specificity is the ability of a diagnostic test to correctly identify patients without the disease. When compared with the control group, the intervention group had a sensitivity of about 86% and a specificity of 83% for samples assessed using the AiDx Assist machine. The sensitivity and specificity tests were used to determine the diagnostic accuracy of the intervention group. Students undergoing the CHEW program had an accuracy of 82.8% (71.32-91.10%) compared with laboratory scientists as shown in Table 3.

Table 3. Effectiveness (diagnostic capacity) of CHEW program students compared to laboratory scientists

Statistic	value	95%CI
Sensitivity	85.71%	42.13 - 99.64%
Specificity	82.46%	70.09 - 91.25%
Positive predictive value	37.50%	24.05 - 53.20%
Negative predictive value	97.92%	88.41 - 99.66%
Accuracy	82.81%	71.32 - 91.10%

DISCUSSION

This study highlights the result of a quasi-experimental study involving the use of an Artificial intelligence-enabled device for diagnosing LF at the primary care level. The AiDx Assist device offers a cost-effective solution for alleviating human resource limitations in primary healthcare settings, as it does not require a significant level of laboratory expertise for use. In addition, diagnostic data can be analyzed remotely, expediting community mapping and intervention.

The results derived from the study indicate that students undergoing the CHEW program were proficient in their capacity to use the AiDx assist device compared to laboratory scientists. The difference in timing for reading results was an average of 1 minute for reading the scanned results, and less than a minute for starting and placing samples and starting at automatic scan. This shows that with adequate training and more exposure to the AiDx Assist machine, CHEWs may replace laboratory scientists in making a diagnosis of lymphatic filariasis at the community level, especially in hard-to-reach areas. It is known that the time taken to make a diagnosis is a challenge with lymphatic filariasis and other NTDs[10] as personnel at the health centres and health posts do not have the requisite training for making a laboratory-based diagnosis. Other studies have also corroborated this data concerning the user efficiency (speed) of non-laboratory personnel for laboratory-based work. For instance, task shifting to nurses for HIV testing using a device[16] and task shifting to non-laboratory personnel using devices to test for clinical chemistry parameters.[17]

The diagnostic capacity (effectiveness) deals with the ability to make an accurate diagnosis using the AiDx device. As regards the diagnostic capacity of the students undergoing the CHEW program, they have a sensitivity of 85.71%, a specificity of 82.46% and an accuracy of 82.8% compared with Laboratory scientists. This indicates that students undergoing the CHEW program can make a laboratory-based diagnosis of lymphatic filariasis

and other NTDs at the community level even with minimal training. To the best of our knowledge, this is the first study of its kind to compare laboratory scientists to students undergoing the CHEW program as regards diagnostic performance with the AiDx machine. However, some studies have also compared the diagnostic capacity of laboratory personnel with non-laboratory personnel.[18,19] Data from some studies indicate that the competency and capacity for the use of equipment-based near-patient testing are independent of user laboratory qualifications.[16,17] Some studies on task shifting have shown that CHEWs can be trained for clinical duties such as treatment of diabetes, hypertension and tobacco cessation[20–22] and HIV with positive results.[19,23,24] The use of CHEWs is also demonstrated to be cost-effective for the treatment of hypertension in low-resource settings.[25] Other studies have also demonstrated the capability to task shift from laboratory scientists to nurses.[16]

Previous tests conducted in Nigeria using the AiDX assist device have demonstrated impressive results. When used by laboratory scientists, the device showed a sensitivity of 94% and a specificity of 99% in detecting Schistosoma eggs in urine samples compared to traditional microscopy methods.[14] In comparison, students undergoing the CHEW program achieved a sensitivity of 86% and a specificity of 83%. While there is some variation in the effectiveness of the machine's use between the two groups, the overall performance remains quite satisfactory. In addition, based on the WHO requirement of specificity and sensitivity of >78%, and >82% respectively for LF diagnostic devices, it is clear that students undergoing the CHEW program meet the minimum criteria expected for device use effectiveness. This suggests that CHEWs can effectively provide diagnostic laboratory services using artificial intelligence-enhanced tools, thereby contributing to improved healthcare outcomes.

Our results show that CHEW-led diagnostic testing for microfilaria and by extension, other NTDs will ensure decentralization of LF testing, timely return of test results and timely treatment without compromising the quality of testing. This also falls in line with the World Health Organization's (WHO) expectations for Target Product Profiles (TPP) for new diagnostics. It is expected that new diagnostics like the AiDx assist device should be usable by the lowest healthcare cadre, with minimal training that can be given within a day.[13] Given this preliminary result, task shifting for the diagnosis of LF is highly likely. However, achieving this aim will require strong, and consistent training, guidance, and support of CHEWs,[26] and the use of artificial intelligence-supported diagnostic devices is a strong base for task shifting for NTDs.

Some limitations are noted in this study. First, this study only compared

the diagnostic capacity of CHEW program students to laboratory scientists using already prepared slide specimens. It did not compare the technical capacity to collect and process samples for analysis. We did not test if sample processing skills may likely limit the capacity of CHEW to use the AiDx machine in low-resource settings. However, Vojnov et al. (2019) have demonstrated that specimen collection was easy to perform and acceptable for non-laboratory staff.[19] Other studies have also demonstrated that non-laboratory personnel can be trained to process samples for analysis.[16,24]

Second, the recorded speed of reading the diagnostic output of the AiDx machine by both laboratory scientists and CHEW undergoing training may not be as rapid as in non-observed settings compared with this study. The real speed of undertaking the task may likely be slower than observed in this study. Third, the sample size of the prepared slides was small and the diagnostic capacity of CHEW may be different to what was found in this study. Finally, this is a preliminary study and larger studies are currently being planned to validate the result of this study.

CONCLUSION

This study has demonstrated that students undergoing the CHEW program were comparable to lab scientists in efficiency (speed) and effectiveness (diagnostic capacity) in detecting blood microfilaria using the AiDx Assist device with good result outcomes after training for one hour. This shows that the technical and experiential requirements for new diagnostic device operations and result interpretation are minimal. Therefore, it is possible for diagnostic task shifting of laboratory process for diagnosing LF to CHEWs thereby supporting the achievement of the WHO 2030 goals for NTDs.

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SECTION 3

Pictural overview of the diagnostic devices

Chapter

9

The Schistoscope Device

Figure 9.1. A setup of the Schistoscope

Figure 9.2. Stakeholder observing the Schistoscope

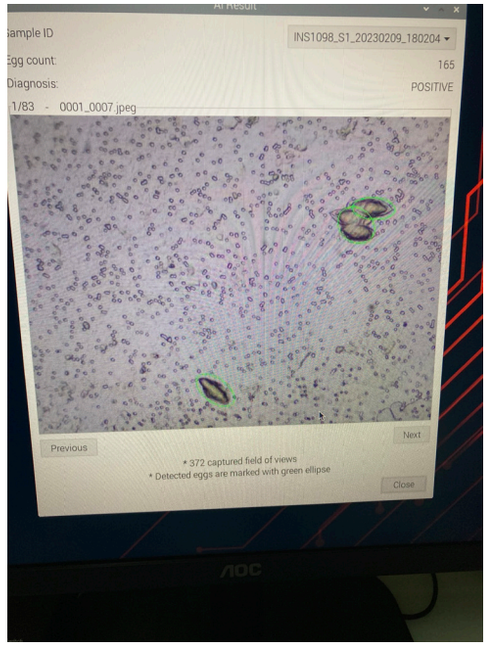

Figure 9.3. Output from scanned slides showing Schistosoma Haematobium eggs

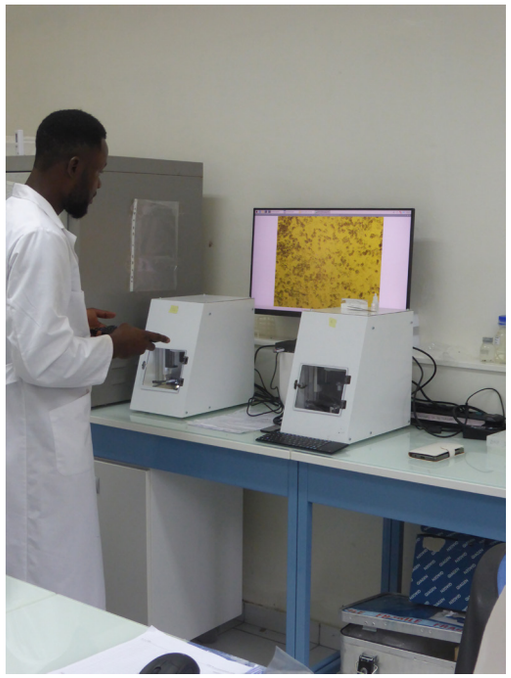

Figure 9.4. Laboratory scientist using the 2 Schistscopes

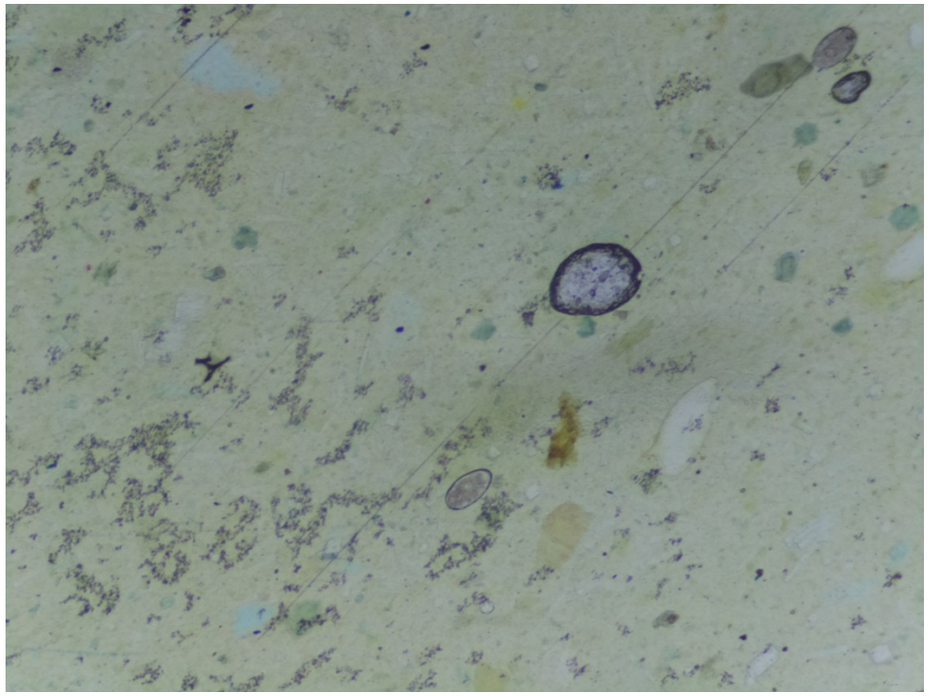

Figure 9.5. Output from Schistoscope scanning showing Helminthiasis infection

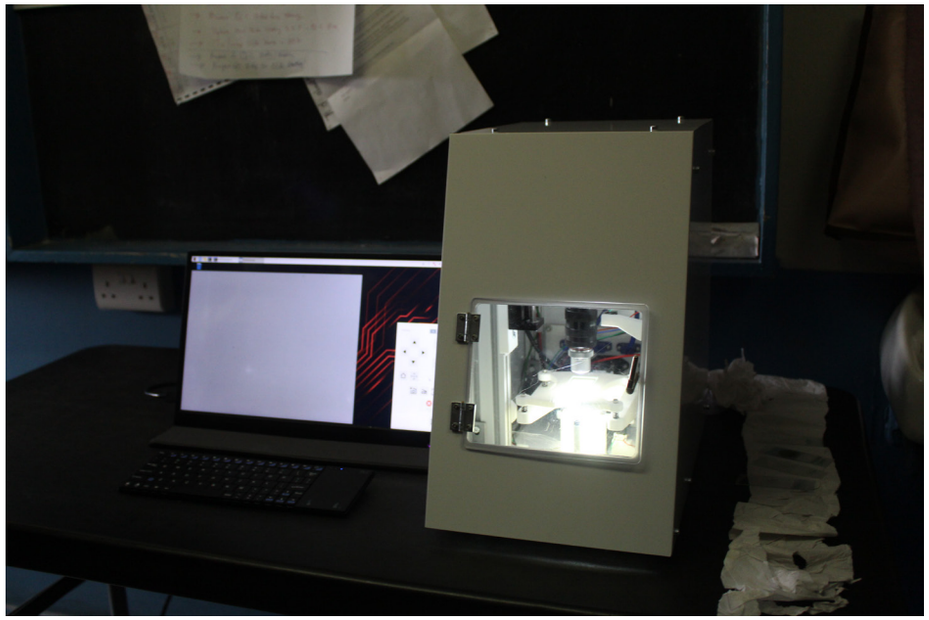

Figure 9.6. The Schisctoscope scanning inserted slides

Chapter

10

The AiDx Device

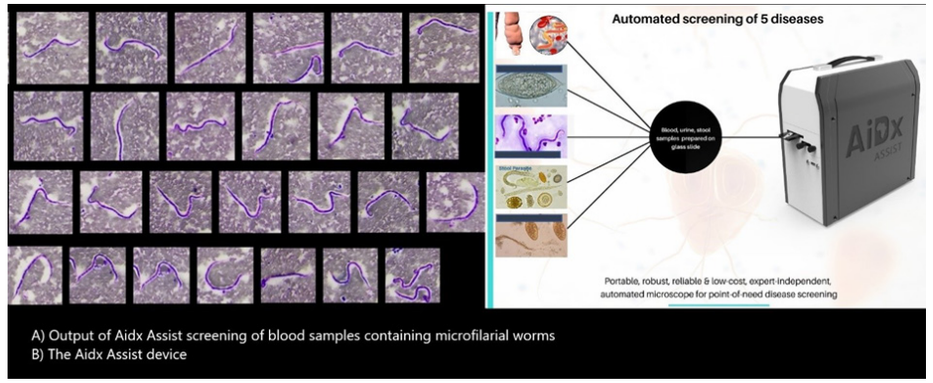

Figure 10.1. The AiDx device

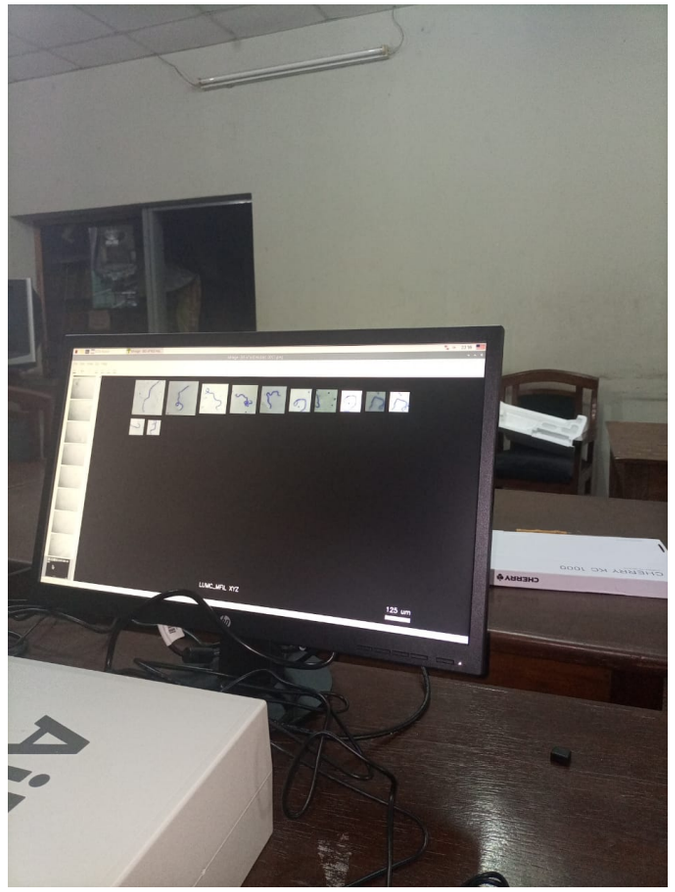

Figure 10.2. Output from the AiDx device showing filarial worm infection

Figure 10.3. Community Health Health Extension Workers(CHEW) Students using the AiDx Device

Figure 10.4. Laboratory scientist using the AiDx device

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English Summary

The need for new diagnostics for NTDs
Neglected Tropical Diseases (NTDs) are a group of infections affecting more than 2 billion and are a cause of significant morbidity and mortality. Despite their significant burden, NTDs are frequently disregarded in the research and development of new diagnostics, medications, and vaccines. New digital diagnostics for neglected tropical diseases (NTDs) are needed, as the current mainstay of diagnosis for most parasitic NTDs, the microscope, is often unavailable or requires expertise not readily available at the primary level of care. Digital optical diagnostics can fill this role for affordable and user-friendly NTD diagnostic devices that can facilitate NTD treatment and monitoring and evaluation thereby contributing to improved healthcare outcomes. Designing these products necessitates an understanding of the social and healthcare context in which they will be used, the design process and the diagnostic device design, which require collaborating with stakeholders in the relevant use setting. The main objective of this thesis is to investigate how smart optical diagnostics for NTDs can be created for endemic countries by integrating local experience and knowledge leading to local system uptake.

The use context of digital diagnostics for NTDs
From this thesis, it was shown that the use context is the environment in which a diagnostic device will be used and it is a complex system that involves interactions between the physical, social, cultural, and environmental setting, including healthcare organizational goals, policies, workflow tasks, resources, and users. The use context includes the social and healthcare context which is interconnected and involves individuals, communities, and institutions. The social context influences awareness, and interest in prevention, diagnosis, and treatment, as well as the availability, accessibility, affordability, accommodation, and acceptability of resources (human, infrastructural, and material) at the individual, community, and institutional levels. Collaboration and coordination among stakeholders in the use context is important for the outcome of the design process, the diagnostic device design, and the adoption of the diagnostic device. This is important for resource allocation, alignment with national and international strategies, and the development of new diagnostics.

The design process for developing an NTD diagnostic device
The design process for developing an NTD diagnostic device in this thesis is a 5-step iterative process that includes empathizing, defining, ideating, prototyping, and testing. It was shown that co-creation with stakeholders is crucial for the design process because it fosters collaboration between groups that may not typically be involved in product design, leading to a shared understanding of the disease process and raising awareness of challenges and opportunities in the diagnostic landscape. Several tools for

stakeholder mapping and analysis for co-creation include social network analysis, q-methodology, document reviews and interviews.

The diagnostic device design process for NTD diagnostics

The design of a diagnostic device is an iterative process that requires input from stakeholders in five key areas including the overall design and evaluation of the device, the software system, the hardware system, the structural composition, specification, and style of the device, and the product manual. The diagnostic device design process also required co-creation with a wide range of stakeholders crucial for developing product specifications.

The outcome of the thesis shows two main categories of product specifications: broad-based and context-based exist. Broad-based specifications include technical, regulatory, and business specifications. Technical specifications can be divided into two categories: manufacturing and performance-based. Manufacturing specifications relate to the materials, electrical and machinery needed to give the product form and function, while performance-based specifications are related to functionality with specific requirements such as sensitivity, specificity, and speed. Regulatory specifications relate to standards set by regulatory bodies such as the International Standards Organization (ISO) and the World Health Organization (WHO). Business-based specifications relate to financing and comparing new diagnostics to current models of diagnosis. Manufacturing specifications have a strong influence on the business case for new diagnostics, especially in countries where funding for NTDs is not a priority.

Context-based specifications are associated with contextual factors that may affect user experience, usability, and acceptability within the context of use. Context-based specifications can influence manufacturing and business specifications.

Based on the interrelatedness of the two categories of product specifications, different product use scenarios for NTD diagnostics were created. In the Nigerian context, three potential use scenarios for new NTD diagnostics include screening programs, monitoring and evaluation, and point-of-care testing.

Adopting new diagnostics for NTDs

The adoption of new diagnostic devices for Neglected Tropical Diseases (NTDs) is a complex process that involves various stakeholders and stages such as research and evaluation, training and education, implementation and integration, monitoring and evaluation, support and maintenance, device evaluation and improvement, and scale-up. Understanding the context and contextual factors at all stages is crucial in designing an adoption process

for digital diagnostics for NTDs in low-resource settings. Scarce resources, lack of infrastructural support, political instability, and cultural differences can affect adoption and scale-up. Therefore, conducting a thorough needs analysis and involving culturally-aware stakeholders can help identify unique difficulties within the developing context and undertake a cost and feasibility analysis.

The diagnostic device and its implementation process have a dynamic relationship with the context, and it is important to assess the perceived need for the innovation to be implemented, its potential compatibility with existing routines, and an assessment of user expectations during the design process and diagnostic device design. To positively affect the adoption of NTD diagnostics in low-resource settings, a multifaceted strategy involving cooperation between stakeholders at various levels can be employed. Engaging local stakeholders and communities, encouraging collaboration between national and sub-national governments, non-governmental organizations, research institutions, and the private sector, providing adequate training and support to healthcare workers, addressing regulatory and policy barriers, undertaking multiple proofs of concept studies, and monitoring and evaluating diagnostics used during implementation are some possible strategies to ensure device adoption.

Within the Sub-Saharan African context, helminthic NTD elimination requires a systemic design approach involving zooming in and out of the context of use, design process, and diagnostic device design while managing and co-creating with stakeholders to ensure the development and adoption of newly developed digital diagnostic devices for NTDs. By following these strategies, the development and adoption of NTD diagnostic tests that are contextually fit, useful, and acceptable can lead to an uptake in the local context.

Nederlandse Samenvatting

De behoefte aan nieuwe diagnostiek voor NTD's

Verwaarloosde tropische ziekten (neglected tropical diseases (NTD's)) zijn een groep infecties waaraan meer dan 2 miljard mensen lijden en die een oorzaak zijn van aanzienlijke morbiditeit en mortaliteit. Ondanks de ingrijpende gevolgen voor grote groepen mensen worden NTD's vaak buiten beschouwing gelaten bij het onderzoek naar en de ontwikkeling van nieuwe diagnostiek, medicijnen en vaccins. Nieuwe digitale diagnostiek voor verwaarloosde tropische ziekten (NTD's) is nodig, aangezien de huidige spil van de diagnose voor de meeste parasitaire NTD's, de microscoop, vaak niet beschikbaar is of de vereiste expertise niet direct beschikbaar is op het eerstelijnsniveau van de zorg. Digitale optische diagnostiek kan een deel van deze functie vervullen door middel van betaalbare en gebruiksvriendelijke NTD-diagnostische apparaten die NTD-behandeling en -monitoring en -evaluatie kunnen vereenvoudigen en zo bijdragen aan betere gezondheidszorg. Het ontwerpen van deze producten vereist inzicht in de sociale- en gezondheidszorgcontext waarin ze zullen worden gebruikt, het ontwerpproces als zodanig en het ontwerp van het diagnostische apparaat, waarvoor samenwerking met belanghebbenden in de relevante gebruiksomgeving vereist is. Het hoofddoel van dit proefschrift is om te onderzoeken hoe slimme optische diagnostiek voor NTD's kan worden ontwikkeld voor endemische landen door lokale ervaring en kennis te integreren, leidend tot verbeterde lokale systeemadoptie.

De gebruikscontext van digitale diagnostiek voor NTD's

Uit dit proefschrift is gebleken dat de gebruikscontext waarin een diagnostisch apparaat zal worden gebruikt een complex systeem is dat interacties omvat tussen de fysieke, sociale, culturele en natuurlijke factoren, inclusief de doelstellingen van de zorgorganisatie, beleid, werkstroomtaken, bronnen en gebruikers. De gebruikscontext omvat derhalve de sociale en zorgcontext die met elkaar verbonden zijn en waarbij individuen, gemeenschappen en instellingen betrokken zijn. De sociale context beïnvloedt het bewustzijn van en de belangstelling voor preventie, diagnose en behandeling, evenals de beschikbaarheid, toegankelijkheid, betaalbaarheid, adaptatie en acceptatie van middelen (menselijke, infrastructurele en materiële) op individueel, gemeenschaps- en institutioneel niveau. Samenwerking en coördinatie tussen belanghebbenden in de gebruikscontext is belangrijk voor de inrichting van het ontwerpproces, de kwaliteit van het ontwerp van het diagnostisch hulpmiddel en voor de acceptatie van het diagnostisch hulpmiddel. Dit is belangrijk voor de toewijzing van middelen, afstemming op nationale en internationale strategieën en de ontwikkeling van nieuwe diagnostiek.

Het ontwerpproces voor het ontwikkelen van een NTD diagnostisch apparaat

Het ontwerpproces in dit proefschrift voor het ontwikkelen van een NTD-

diagnostisch apparaat is een vijf-stappen en iteratief proces dat inleven, definiëren, ideevorming, prototyping en testen omvat. Er werd aangetoond dat co-creatie met belanghebbenden cruciaal is in het ontwerpproces, omdat het de samenwerking bevordert tussen groepen die doorgaans niet betrokken zijn bij het productontwerp, leidend tot een gedeeld begrip van het ziekteproces en bewustwording van uitdagingen en kansen in de diagnostiek. Verschillende tools voor het in kaart brengen en analyseren van belanghebbenden voor co-creatie omvatten onder andere analyse van sociale netwerken, q-methodologie, review van documenten en interviews.

Het ontwerpproces voor diagnostische apparaten voor NTD-diagnostiek

Het ontwerp van een diagnostisch apparaat is een iteratief proces dat input vereist van belanghebbenden op vijf belangrijke deelgebieden, waaronder het algemene ontwerp en de evaluatie van het apparaat, het software-systeem, het hardware-systeem, de constructie, specificatie en stijl van het apparaat, en de producthandleiding. Het ontwerpproces van het diagnostische apparaat vereiste ook co-creatie met een breed scala aan belanghebbenden, cruciaal voor het ontwikkelen van productspecificaties.

De uitkomst van het proefschrift laat zien dat er twee hoofdcategorieën van productspecificaties zijn te onderscheiden: breed en context gebaseerd. Brede specificaties omvatten technische, regelgeving gerelateerde en bedrijfsmatige specificaties. Technische specificaties kunnen worden onderverdeeld in twee categorieën: productie en prestatiegericht. Productie specificaties hebben betrekking op de materialen keuze, en op de product vorm en constructie, terwijl op prestaties gerichte specificaties betrekking hebben op functionaliteit met specifieke vereisten zoals diagnostische gevoeligheid, diagnostische specificiteit en snelheid. Voorts zijn er specificaties die hebben betrekking op normen die zijn vastgesteld door regelgevende instanties zoals de International Standards Organization (ISO) en de Wereldgezondheidsorganisatie (WHO). Bedrijfsmatige specificaties hebben betrekking op het financieren en vergelijken van nieuwe diagnostiek met huidige vormen van diagnose. Productie gerichte specificaties hebben een sterke invloed op de businesscase voor nieuwe diagnostiek, vooral in landen waar financiering voor NTD's geen prioriteit heeft.

Context gebaseerde specificaties worden geassocieerd met gebruikerservaring, bruikbaarheid en acceptatie binnen de gebruikscontext. Context gebaseerde specificaties beïnvloeden met name fabricageen operationele eigenschappen.

Gebaseerd op de onderlinge samenhang van de twee categorieën productspecificaties, zijn verschillende product-gebruiksscenario's voor NTD-diagnostiek gemaakt. In de Nigeriaanse context zijn er drie mogelijke

gebruiksscenario's voor nieuwe NTD-diagnostiek: screeningsprogramma's, monitoring en evaluatie, en point-of-care-testen.

Adoptie van nieuwe diagnostiek voor NTD's

De adoptie van nieuwe diagnostische apparaten voor verwaarloosde tropische ziektes (NTD's) is een complex proces waarbij diverse belanghebbenden in verschillende stadia betrokken zijn, zoals onderzoek en evaluatie, training en onderwijs, implementatie en integratie, monitoring en evaluatie, ondersteuning en onderhoud, evaluatie en verbetering van apparaten, en schaalvergroting. Het begrijpen van de context en contextuele factoren in alle stadia is cruciaal bij het ontwerpen van een adoptieproces voor digitale diagnostiek voor NTD's in omgevingen met beperkte middelen. Schaarse middelen, gebrek aan infrastructurele ondersteuning, politieke instabiliteit en culturele verschillen kunnen de adoptie en opschaling beïnvloeden. Daarom kan het uitvoeren van een grondige behoefteanalyse en het betrekken van cultureel bewuste belanghebbenden helpen bij het identificeren van unieke problemen binnen de ontwikkelingscontext en het uitvoeren van een kosten- en haalbaarheidsanalyse.

Het diagnostische apparaat en het implementatieproces ervan hebben een dynamische relatie met de context, en het is belangrijk om de daadwerkelijke behoefte aan de te implementeren innovatie te beoordelen, de mogelijke aansluiting met bestaande routines en een beoordeling van de verwachtingen van de gebruiker tijdens het ontwerpproces. Om de adoptie van NTD-diagnostiek in omgevingen met weinig middelen positief te beïnvloeden, kan een veelzijdige strategie worden gebruikt waarbij samenwerking tussen belanghebbenden op verschillende niveaus centraal staat. Het betrekken van lokale belanghebbenden en gemeenschappen, het stimuleren van samenwerking tussen nationale en sub-nationale overheden, niet-gouvernementele organisaties, onderzoeksinstellingen en de particuliere sector, het bieden van adequate training en ondersteuning aan gezondheidswerkers, het aanpakken van regelgevende en beleidsbelemmeringen, het uitvoeren van meerdere proof-of-concept-studies, en het bewaken en evalueren van diagnostische gegevens die tijdens de implementatie worden gebruikt, zijn mogelijke strategieën om een verbeterde adoptie van deze apparaten te bevorderen.

Binnen de context van Sub-Sahara Afrika vereist de eliminatie van NTD een systemische ontwerpbenadering waarbij wordt in- en uitgezoomd op de gebruikscontext, het ontwerpproces en het ontwerp van diagnostische apparaten, terwijl het beheer en co-creatie met belanghebbenden zorgt voor de ontwikkeling en adoptie van nieuwe ontwikkelde digitale diagnostische apparaten voor NTD's. Door deze strategieën te volgen, kan de ontwikkeling en adoptie van NTD-diagnostische tests die contextueel geschikt, nuttig en acceptabel zijn, leiden tot adoptie in de lokale context.

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About the author

Adeola Onasanya (1988, Ibadan) holds a Bachelor of Medicine and Bachelor of Surgery degree from the University of Ibadan in Nigeria, obtained in 2011. Adeola obtained a Master of Science degree in Health Economics and Health Policy from the University of Birmingham in the United Kingdom in 2015. Adeola Onasanya's PhD thesis from Delft University of Technology in the Netherlands focus on co-creating new digital diagnostics for Neglected Tropical Diseases with stakeholders.

Adeola's research experience spans across different organizations and countries. She is the Executive Director of GloEpid, a Non-governmental Organization focused on using Artificial Intelligence and IT to support surveillance of Epidemic-prone diseases. Prior to her PhD, she worked as a Research Fellow at the Nigeria Institute of Social and Economic Research, a Public Health Team Lead, where she supervised a field team for an HIV/AIDS survey. She also served as a Public Health Manager, where she provided insights into health IT adoption in Nigeria and implemented health finance interventions for remote communities.

Outside of her academic and professional pursuits, Adeola actively engages in community involvement and administrative activities. She serves as a board member and team member for several non-governmental organizations focused on teenagers and youths, drug abuse rehabilitation, and technology development.