SMART DIAGNOSTICS FOR LOW RESOURCE SETTINGS

Target product profiles for devices to diagnose urinary schistosomiasis in Nigeria

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Smart diagnostics for low resource settings

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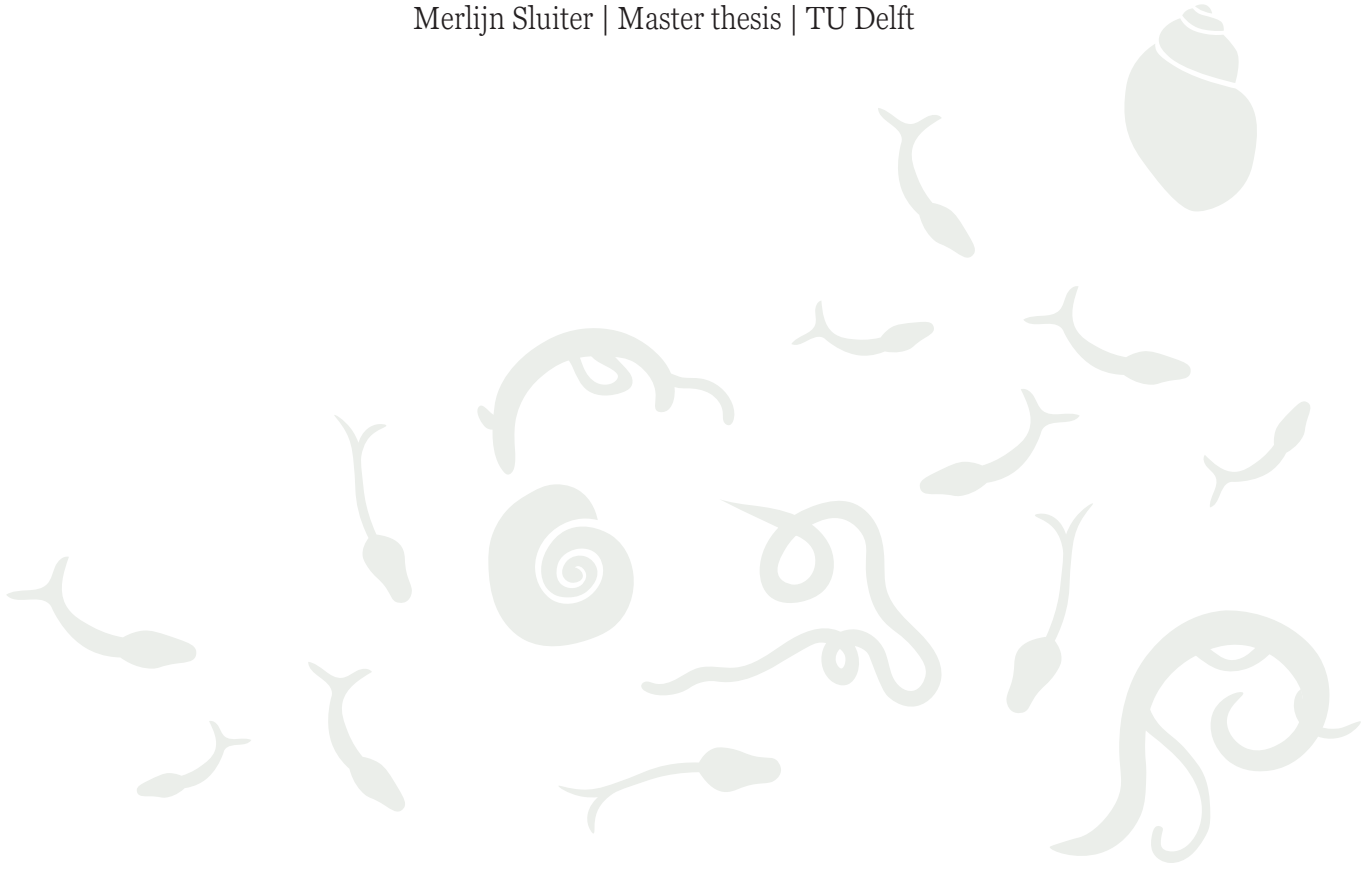


Image 1. Two boys in Akinyele, Nigeria

Preface

The report in front of you presents the final result of my graduation project for the master program Integrated Product Design at Delft University of Technology. The subject of this project is smart diagnostics for low resource settings. During this project I developed target product profiles for devices to diagnose urinary schistosomiasis in Nigeria.

I had the opportunity to work with a lot of interesting and inspiring people. I would like to thank you all for your help and feedback along the way.

First of all, I want to thank my supervisors. JC, thank you for providing me the opportunity for this project, linking me to so many people and for your boundless enthusiasm. Jo, thank you for your critical, but constructive feedback - it proved to be very helpful.

G-Young of course! Thank you for being a great travel companion. I am happy we went on this adventure together and thank you for all your input and feedback during the rest of the project.

Thanks Adeola, it was great to do the field research together with you. You were very helpful in your role as bridge between Nigeria and the INSPiRED project.

Thanks to professor Oladepo, for the warm welcome you gave us at the University of Ibadan. A big thanks to Ope, for arranging all the interviews and logistics. You gave us a great introduction to the Nigerian culture and its gastronomic delights.

I want to thank all the people in Nigeria that made time for us for an interview, and sharing all their stories and ideas. Thanks to the public health students and PhD students for participating in our sessions and providing feedback to our findings.

Furthermore, I would like to thank everyone involved in the INSPiRED project for the informative and inspiring meetings and for providing feedback to my scenarios.

Last but not least, I would like to thank the AED teams for joining the creative sessions; good luck with designing the new Schistoscope!

Enjoy reading!

Merlijn

Executive summary

Urinary schistosomiasis is a neglected tropical disease caused by the Schistosoma haematobium parasite. People can get infected when they get into contact with contaminated fresh water. The disease is most prevalent amongst children, farmers and rural communities in Sub-Saharan Africa. Currently, the disease is diagnosed by microscopic egg count in laboratories. However, there are limitations to use of this method in low resource settings.

At Delft University of Technology, smart diagnostics are under development that allow diagnosis of urinary schistosomiasis without microscope. However, the user and diagnostic setting for these tests has not been specified yet.

The goal of this project is to combine 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 specific use case scenarios. This project takes Nigeria as study field.

There are two optical diagnostic methods under development, which combine a simple optical system with an algorithm to automatically detect S. haematobium ova in urine samples. The Schistoscope uses a reversed lens attached to a smartphone or Raspberry Pi camera to magnify and take an image of an urine sample. An algorithm localizes and classifies potential ova. The SODOS uses an optical sensor and a lens to perform a holographic analysis of urine samples. The algorithm digitally reconstructs the image, from which ova are classified. These technologies can offer the following benefits compared to microscopy; 1) Simple and user friendly; 2) Rapid; 3) Sensitive; 4) Robust and portable; 5) Affordable; 6) Data collection.

An qualitative research with semi-structured interviews was conducted in Oyo State, Nigeria to explore the context and identify gaps and stakeholders for i) case management on primary healthcare level, and ii) the control & elimination program.

The main problem in case management is that diagnosis is not done at primary level due to limited resources and awareness, which leads very few confirmed cases. For case management, the stakeholders are divided into healthcare enablers, formal health providers, informal health providers and healthcare receivers.

The control & elimination program is divided into i) mapping of schistosomiasis prevalence and ii) mass drug administration during Deworming days. The problem in the control & elimination program is that lack of diagnosis leads to an unknown disease prevalence. As a result, there is limited government interest and funding. For the control & elimination program the stakeholders are divided into initiation, organization, mapping implementation, Deworming implementation and target populations.

The benefits from technology were combined with gaps in the healthcare context into twelve opportunities for diagnostic scenarios. Three diagnostic scenarios were selected; 1) Test at PHC consult by a community health worker, which allows testing at PHC level; 2) Mapping of adult populations at risk, where adults are tested at occupational group meetings by community health worker and/or lab assistant; 3) Test as sensitization tool, where diagnosis is done by a community resource person in communities to create awareness.

Insights from the research were combined into target product profiles with acceptable and ideal values for product attributes. A creative session was organized to determine the value of this specification list for product design.

Image 2. Poster for Deworming day at primary school in Ibadan North

Glossary

Abbreviations

CBO	Community Based Organizations
CHEW	Community Health Extension Worker
CHW	Community Health Worker
CORP	Community Resource Person
DSNO	Disease Surveillance and Notification Officer
FoV	Field of View
FMoH	Federal Ministry of Health
IDSR	Integrated Disease Surveillance Report
JCHEW	Junior Community Health Extension Worker
LGA	Local Government Area
LRS	Low Resource Settings
LUMC	Leiden University Medical Centre
MDA	Mass Drug Administration
NHMIS	National Health Management Information System
NPHCDA	National Primary Health Care Development Agency
NGO	Non Governmental Organization
NTD	Neglected Tropical Disease
PCT	Preventive Chemotherapy
PHC	Primary Healthcare
PMV	Patent Medical Vendor
POC	Point of Care
PZQ	Praziquantel
RDT	Rapid Diagnostic Test
SAC	School Aged children
SMoH	State Ministry of Health
SPHCDA	State Primary Health Care Development Agency
STH	Soil Transmitted Helminths
UCH	University College Hospital
UI	University of Ibadan
VDC	Village Development Committee
WASH	Water, Sanitation and Hygiene
WDC	Ward Development Committee
WHO	World Health Organization

Definitions

Schistosomiasis - Acute and chronic disease caused by parasitic worms [1]

Schistosoma Haematobium – Parasitic worm that causes urinary schistosomiasis [1]

Low resource setting - Resource constrained (human, economic and environmental) area, rural or urban, with limited infrastructure or basic services in a low- or middle income country.[2]

Control - Reduction of disease incidence, prevalence, morbidity, and/or mortality to a locally acceptable level as a result of deliberate efforts [3]

Elimination as a public health problem – Achievement of measurable targets set by WHO, for schistosomiasis it is defined as ≤1% proportion of heavy intensity infections among populations at risk [3] [4]

Elimination/interruption of transmission –Reduction to zero of incidence of schistosomiasis in a defined geographical area as a result of deliberate efforts [3]

Morbidity control - Reduction of the prevalence of heavy intensity infections to ≤5% among populations at risk [4]

Point of Care tests - Diagnostic test performed near the patient or clinic, which results are available in a short time [5][6]

Sensitivity – Test characteristic that describes the proportion of true positive results; the percentage of positive cases who are identified as having the condition

Specificity – Test characteristic that describes the proportion of true negative results; the percentage of healthy people who are identified as not having the condition

Accuracy – Proportion of true results, either true positive or true negative

Suspected case – In non-endemic/ low prevalence areas; a case of urinary schistosomiasis is suspected when a person either has visible haematuria or a positive reagent strip for haematuria [7]

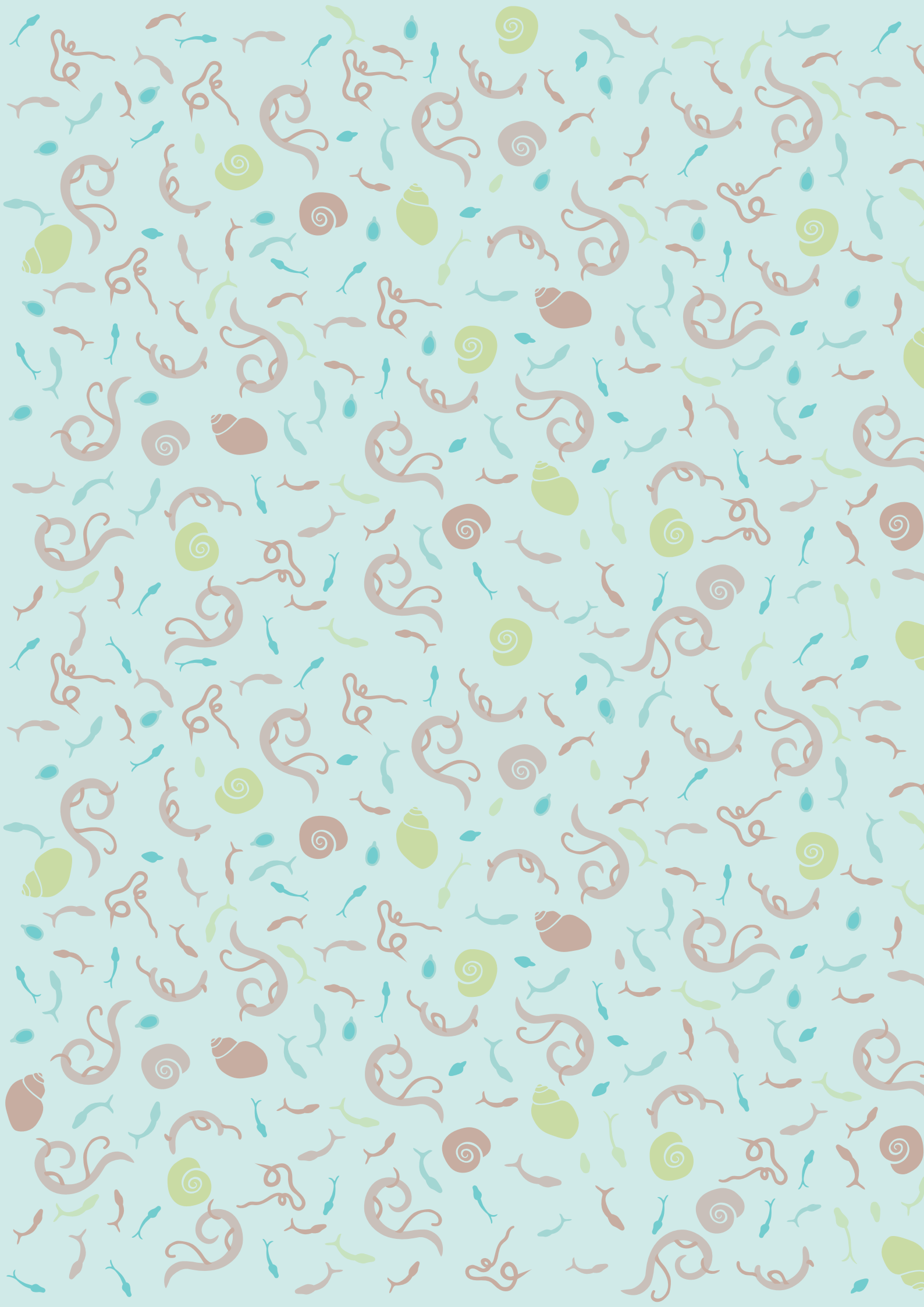
Confirmed case – Case is confirmed when a person has S. haematobium eggs in urine and/ or visible haematuria and/or a positive reagent strip, depending on endemicity in area [7]

I Introduction

II Disease & Diagnostics

III Technology

IV Context



1 INTRODUCTION

Chapter 1

PROJECT SCOPE

This chapter introduces the subject, the challenge and the goal of the project. The first section gives an introduction to the context. The second section states the design challenge, the scope and the research questions.

1.1 Introduction

Schistosomiasis

Schistosomiasis is a neglected tropical disease (NTD) caused by the Schistosoma parasite. People can get infected when they are in contact with contaminated water. Fresh water snails carry parasites which can penetrate the human skin.

The disease occurs in sub Saharan Africa and the Middle east. Schistosomiasis causes more than 300,000 deaths a year globally. Currently, 779 million people are at risk and 207 million people are infected. [8] Its prevalence is highest amongst people – especially children - in low resource settings, since they often depend on fresh water bodies for their daily living. A low resource setting refers to a resource constrained area, rural or urban, with limited infrastructure or basic services in a low- or middle income country. [2]

This project focusses on urinary schistosomiasis, which is caused by Schistosoma haematobium. Infected people excrete Schistosoma eggs in their urine. Several diagnostic methods exist, among which urine microscopy is the golden standard. A urine sample is filtrated or centrifuged, after which parasites' eggs can be identified under a microscope. The amount of eggs corresponds to the severity of the infection.

In low resource settings, diagnosis of schistosomiasis can be limited by poor infrastructure, lack of money for better medical equipment, shortage of skilled laboratory technicians and superstitious beliefs of communities.

In endemic countries, there are control programs with mass drug administration to prevent long term S. haematobium infections with chronic effects and further transmission. Diagnostics contribute to control programs during mapping surveys, where populations at risk are tested. However, testing urine samples with a microscope is a time-consuming process and requires highly skilled lab technicians.

Diagnosis of the disease is limited by multiple physical and logistical factors, so there is 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. There are many involved stakeholders; the local communities, health care facilities, the government and NGOs, with different needs concerning diagnostics that should be taken into account.

Developments in diagnostic technology

At the Faculty of Mechanical Engineering of Delft University of Technology, there are diagnostic methods under development that enable diagnosis of S. haematobium infections without the use of a microscope. The driving force behind the development of new medical technologies is the desire to automate the process of sample observation and egg detection, so the device becomes field deployable.

Several devices have been developed over the last few years which use an algorithm to recognize shapes in urine samples and classify them as Schistosoma ova to determine whether someone has an infection. This technology allows a lot of form freedom for the design of the device, since it does not require fragile and expensive objectives and lenses. Recognizing and counting of the eggs can be done automatically, so operating the device does not require a skilled lab technician. This gives an opportunity for the design of a device for low resource settings, which could enable diagnosis at community level and make testing cheaper, more time efficient and accurate.

Context

This project will take Nigeria as study field. This Sub-Saharan country has the highest prevalence of S. haematobium infections worldwide. The goal of the World Health Organization is to eliminate schistosomiasis as public health problem in 2030. However, in 2018 there were still 29 million infected cases of schistosomiasis in Nigeria.

Diagnostic tests for schistosomiasis are mainly performed in equipped laboratories in private facilities or hospitals. There is a control program for school aged children, who receive treatment during Deworming Days. To determine the control program strategy, prevalence data on the disease was required, for which diagnosis was done on large scale.

To eliminate this major disease, diagnosis should be enabled at primary health level as well. Furthermore, field deployable diagnostics are required to increase the impact of control programs.

Image 3. Streetview in Ibadan

1.2 Challenge

Most products are designed for the top of the pyramid. These products are often unsuitable for the majority of the world's population - those who belong to the bottom of the economic pyramid. Microscopes were not designed for use in Sub-Saharan Africa. To design products for low resource settings, designers must have a deep understanding of the context from an early stage in product development. [2] Contextual research is required to adapt products to the local possibilities and gain knowledge on socioeconomic context. [9]

The INSPiRED project (inclusive diagnostics for poverty related parasitic diseases) aims to reduce mortality of diseases such as malaria, schistosomiasis and hookworm by introducing smart and easy to operate optical diagnostic methods and devices in endemic regions. [10] The multidisciplinary INSPiRED team includes biomedical scientists, engineers, public health experts and product designers from universities in the Netherlands, Nigeria and Gabon.

Several functioning prototypes of diagnostic devices have been developed. Most of these devices were developed from a technical perspective with limited involvement of stakeholders in the field, instead of designed to fit a local need. The diagnostic setting and the intended end user have not been decided on yet.

The challenge in this project is to identify gaps in the current diagnostic context and find promising opportunities for the application of these new technologies. By doing contextual research, the interests and needs of the stakeholders can be identified. Furthermore, a better insight in the challenges and limitations of current diagnostics can be obtained. Not only the patients and healthcare workers should be involved, but also parties like the government and NGOs. The team members of the INSPiRED project will be involved in various stages of the process, to share and discuss insights and join in decision making. This allows the results of this research to be valuable for the progress of the project.

Project goal

The goal of this graduation 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 health care scenarios in Nigeria.

A target product profile (TPP) is a strategic document that lists desirable characteristics of a product. It is used as 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. [11]

Combine gaps in the healthcare system and needs from stakeholders with technological possibilities into a target product profile for a diagnostic device for urinary schistosomiasis for specific use case scenarios in Nigeria.

Image 4. Interview in the field, guided by a template of the patient journey

These TPPs can serve as a starting point for designers, researchers and engineers in further development of the diagnostic devices. To prove its quality and effectiveness as a design tool, some design proposals will be developed.

Project Scope

The research of this project will focus on the diagnostic practices of S. haematobium infections in Oyo State, Nigeria. Oyo State is a state in the southwest of Nigeria is endemic for urinary schistosomiasis.

The context research focusses on case management on primary healthcare level and the Control & Elimination program for schistosomiasis. Diagnostics in hospitals is explored, but will not be the target of the device, since equipment is already available in their laboratories. Since diagnosis for research purposes does not directly influence the control program nor immediately improve the health condition of the community it is out of scope for this project.

One of the goals of INSPiRED project is to design diagnostic devices that can be manufactured, maintained and repaired locally. However, this is not taken into account in this research.

Research questions

This project aims to answer the following research questions.

RQ1: What are the benefits of and opportunities for the new technologies for the diagnosis of S. haematobium infections?

RQ2: What are the current diagnostic practices and challenges concerning S. haematobium infections within the health care system in Nigeria?

RQ3: Who are the important stakeholders and what are their needs in diagnostics for S. haematobium infections and future implementation of a diagnostic device?

RQ4: What are the most promising use case scenarios of a new diagnostic device to improve i) case management on primary level, and ii) control & elimination program?

RQ5: What product specifications fit these health care scenarios and the needs of the stakeholders best?

RQ6: What is the value of a target product profile in communication of context insights and design requirements in a design project?

Chapter 2

PROJECT APPROACH

This chapter explains the approach of the project and provides an overview of the different parts of the report.

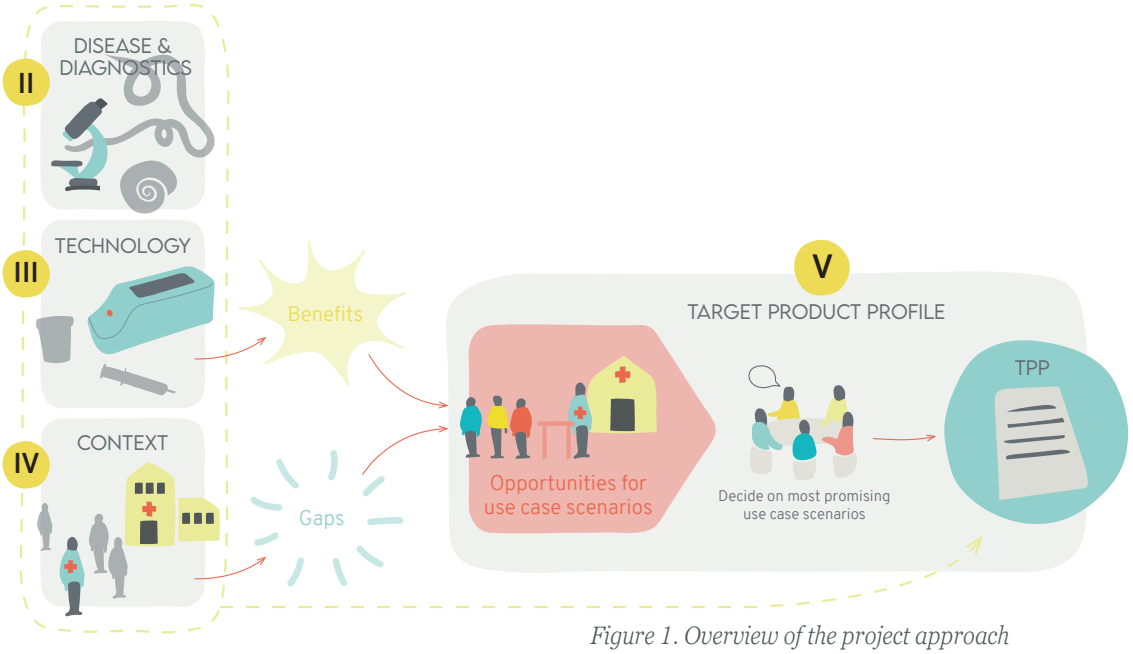


Figure 1. Overview of the project approach

2.1 Approach

When developing a target product profile for NTD diagnostics, the type of biomarker is usually decided based on research insights. [11] However, since the aim of this project is to find opportunities for the developed diagnostic technology, the biomarker – Schistosoma ova - has been determined from the beginning, instead of looking at other available technologies for diagnostic tooling. The approach of this thesis is based on the design thinking approach to develop a concept TPP by Bengtson et al. [12] This approach aims to match a diagnostic technology to a local healthcare context.

Report set up

This report consists of six parts. This chapter is part of part I - Introduction. Figure 1 provides an overview of the project approach.

II Disease and Diagnostics

In part II a short literature review was conducted to gain basic knowledge on the disease, explore available diagnostic methods and identify their limitations. Experts from Leiden University Medical Centre were consulted to fill some research gaps.

III Technology

The technology part focusses on the developed optical diagnostic technologies and devices. This part aims to answer RQ1: What are the benefits and opportunities for the new technologies for the diagnosis of S. haematobium infections?

To get a basic understanding of the technology, experts on technology and design were consulted as well as relevant reports and articles. Part III of this report gives a short overview of the developed prototypes and their benefits and limitations. One of the prototypes was taken to the field to receive some feedback on from a 'user' perspective.

IV Context

Part IV aims to answer RQ2: What are the current diagnostic practices and challenges concerning S. haematobium infections within the health care system in Nigeria? and RQ3: Who are the important stakeholders and what are their interests in diagnostics for S. haematobium infections and future implementation of a diagnostic device?

Desktop research

Prior to the field trip, desktop research was conducted to get basic insight in the healthcare system in Nigeria. This gives insight in how the system should theoretically work. After the field trip, more research was conducted to fill the knowledge gaps after the interviews.

Preparations

For the field research, a list of questions were prepared based on the framework for holistic contextual design for low resource setting, focussing on individual factors, physical environment, technical factors and systems and structures [2]. For every type of stakeholder, a different interview guide was created, which can be found in appendix B.

Furthermore, journeys were created for the patient, staff and equipment (see appendix C-2 - C-4). Cards corresponding to the steps in the journey in both English and Yoruba were made to serve as guidance during the interviews. An observation sheet was created to help collecting information about health facilities, see appendix C-1. An overview of the diagnostic landscape for case management and the control & elimination program was visualized to help during interviews and to verify and adjust the scenarios to the real situation. These images can be found in appendix C-5.

Prior to the field research, Dr. Keshinro from Leiden University Medical Centre (LUMC) was consulted to verify and enrich the visual overviews of the diagnostic landscape. She is involved in the INSPiRED project and is acquainted with the Nigerian healthcare system.

Field research

A three week field research to Oyo State, Nigeria was conducted. Oyo State was chosen as study field, since this state is considered to be representative of Nigeria as a whole. Oyo State is one of the states whose prevalence (5.4%) is closest to the country's average prevalence of schistosomiasis (8,5%) [13]. Furthermore, Oyo State is involved in the schistosomiasis control program. The goal of the field research was to get an in-depth understanding of the context and diagnostic practices, identify gaps in the healthcare system and understand the needs and challenges of the stakeholders. An ethical approval for the field study was obtained from the University of Ibadan.

For **exploration of case management**, two communities, six health facilities and three local government areas (LGA) were visited. The visited communities were an urban community in Ibadan North and the rural community Camp David in Akinyele. The visited health facilities included one primary healthcare clinic, three primary healthcare centres and two private laboratories. See appendix E for a description of the facilities, its staff, available resources and location details. Furthermore, local governments in Ibadan North, Ibadan North West and Akinyele were visited. Information was gathered by observations and semi-structured interviews with community members, local government employees and health care workers.

Figure 2. Map of Ibadan and surrounding LGAs with locations of visited communities, health facilities and schools

For **exploration of the control & elimination** program, four primary schools, one secondary school and the Oyo 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.

To obtain insights in gaps in the health care system and limitations in current diagnostic practices, three researchers from University College Hospital Ibadan were interviewed.

Table 1 gives an overview of all interviews. Some interviewees are mentioned twice, since they fulfilled a double function. See appendix D for the field trip itinerary with an extended list of all interviewees.

The field research was concluded by a co-creation session with public health students to validate and enrich findings and come up with preliminary requirements. A feedback session with six PhD students was organized to discuss the prototype of the Schistoscope and explore desired product qualities.

Results

The interviews from the field trip were transcribed and the interviews conducted in Yoruba were translated. Observations in the health facilities were noted on the health facility observation sheet. Insights from the interviews and observations were translated into patient and health worker barriers. The context research is concluded with an overview of identified gaps in the healthcare system for case management and control & elimination program.

V Target Product Profile

This part aims to answer RQ4: What are the most promising use case scenarios of a new diagnostic device to improve i) case management on primary level, and ii) control & elimination program?. Use case scenarios for the new diagnostic tests were developed, based on promising combinations of the benefits of new technologies and the identified gaps in the health care system. An online questionnaire was sent to stakeholders in the field and members of the INSPiRED team to select the most valuable scenarios through which a diagnostic test can meet the needs of the end users and stakeholders. Furthermore, four members of the INSPiRED team provided face to face feedback,

To get insights in which product attributes are important, an overview was made of the desired product qualities that were mentioned during the interviews with stakeholders, the PhD feedback session and the results from the co-creation session.

Insights from part II, III and IV were combined to create target product profiles for the selected use case scenarios. These TPPs give an overview of RQ5: What product specifications fit these health care scenarios and the needs of the stakeholders best?

A creative session was organized to answer RQ6: What is the value of a target product profile in communication of context insights and design requirements in a design project? Two sessions were organized to validate the content of the TPP and to research the usefulness of TPP as a tool. The the students created test proposals based on the TPPs to confirm the usability of the TPP as a design tool.

Occupation	Number of interviewees
Community health worker	4
Laboratory staff	4 scientists 1 technician 2 assistants
Medical doctor	2
PHC Coordinator	2
Disease Surveillance and Notification Officer	3 LGA DSNOs 1 assistant
Teachers	12
Students	2 primary school 6 high school
Community members	>5
Community mobilizer	3
Community chairman	1
LGA NTD officer	2
State NTD coordinator	1
Evidence Action coordinator	1
WHO TB coordinator	1
Patent medicine vendor	1
Traditional healer	1
Researcher	3

Table 1. Interviewees during the field trip

2.2 Planning

This graduation project started November 25th, 2019 and ended the May 11th, 2020. The field research to Nigeria was conducted from November 29th until December 21st, 2019. The planning of the project can be found in appendix A.

II

DISEASE & DIAGNOSTICS

Chapter 3

SCHISTOSOMIASIS

This chapter provides an introduction to the disease urinary schistosomiasis.

3.1 Urinary schistosomiasis

Schistosomiasis, also known as Bilharzia or snail fever, is a parasitic disease caused by Schistosoma worms. Infection takes place in fresh water when the larvae of the parasite penetrate the skin. [1] Species that can infect humans are S. haematobium, S. mansoni and S. japonicum. This research focusses on urinary schistosomiasis, caused by S. haematobium.

Infection and transmission

Figure 3 illustrates the lifecycle of the S. haematobium parasite. Schistosoma ova leave the human body in urine. The eggs hatch once they are released in fresh water and then turn into larvae – miracidia - that penetrate freshwater snail hosts. After 5 to 6 weeks, the miracidia have multiplied and transformed into cercariae. They emerge from their intermediate host into the water, where they can penetrate the human skin water within 1-2 minutes of exposure. [13][1]

Inside a human host, the cercariae transform into schistosomulae. They travel from the lungs to the liver where they mature into adult worms. The adult worms move to the veins of the urinary tract. Most of the eggs they produce are stuck in tissue, but a proportion escapes through the bladder. Egg excretion to the urine starts about 8-12 weeks after infection. [14] [15]

The number of excreted eggs in urine decreases with host age. After the age of 20 years, excretion of eggs declines as either a result of increasing immunity in case of an old infection or due to changes in behaviour resulting in reduced exposure to fresh water. [15] [16]

Epidemiology

Schistosomiasis occurs in (sub)tropical areas all over the world, but is most prevalent in Egypt and Sub Saharan Africa. According to the most recent estimations from WHO, globally 436 million people are at risk of urinary schistosomiasis and 112 million people are infected. [14][7]

There is a correlation between low income and prevalence of the disease. Schistosomiasis mostly affects poor and rural communities without access to adequate sanitation and safe drinking water. [1]

Schistosomiasis is characterised by a focal distribution, since it is spread via infected water bodies. [17] [18] Migration to urban areas and other population movements spread the disease to new areas. [1]

Risk groups

The prevalence of schistosomiasis is highest among children. Contact with infected water through swimming and inadequate hygiene make them vulnerable to infection. Other risk groups are agricultural and fishing populations, since their occupation requires contract with water. Women doing domestic chores in water also have an elevated chance of infection. [19]

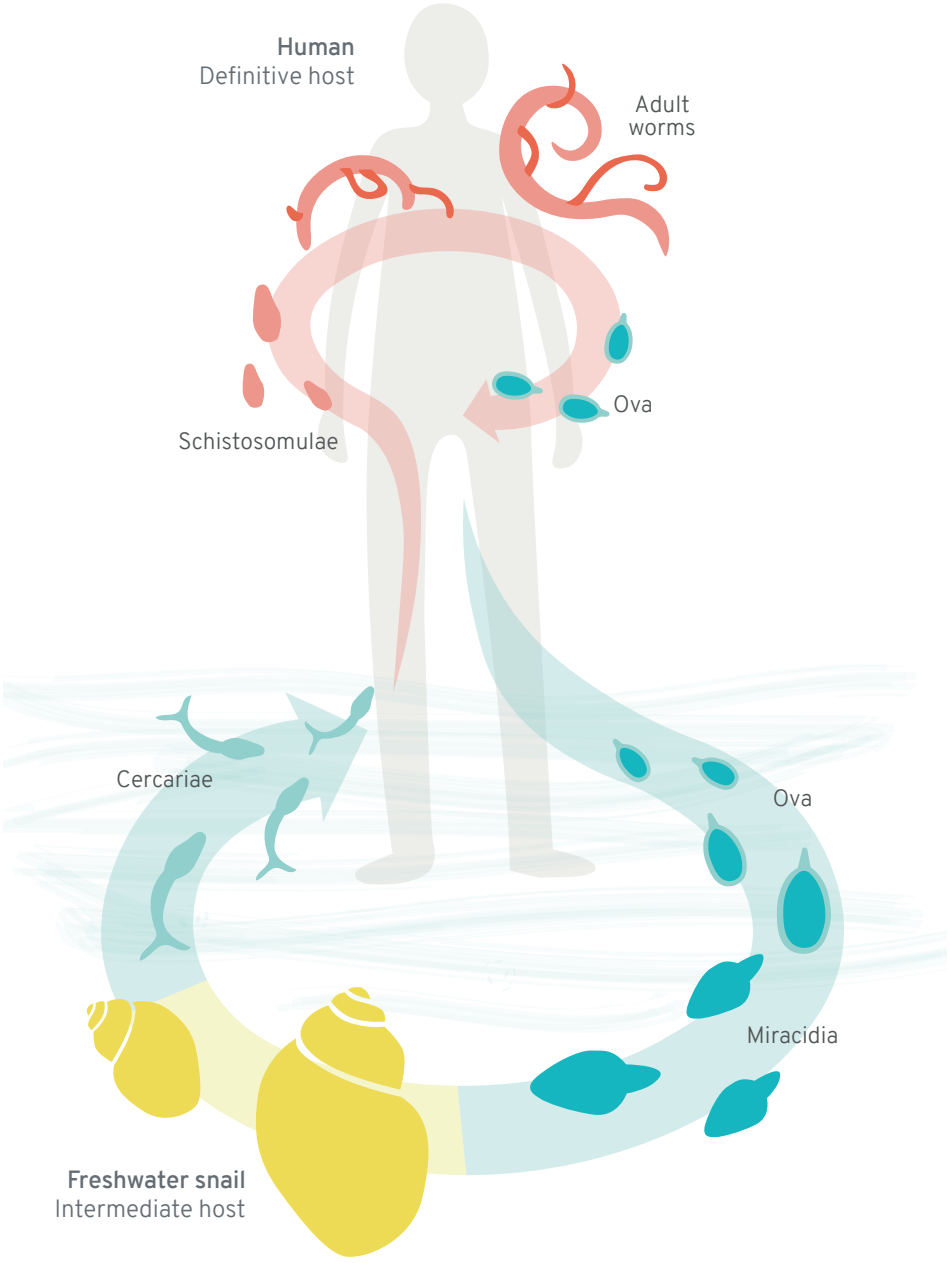


Figure 3. Lifecycle of S. haematobium

Symptoms

A first potential reaction is Swimmer's itch, a rash which can occur 1–2 days after infection. After a few days to weeks, acute schistosomiasis can occur – also known as Katayama fever. Infected individuals can get a fever with coughing and shortage of breath as a result of schistosomulae travelling through the lungs. [13]

The most visible symptom of a chronic S. haematobium infection is terminal haematuria: blood at the end of urination. Other frequent occurring symptoms are painful urination (dysuria), kidney dysfunction and uretral or bladder dysfunction. [13] Advanced cases of S. haematobium can result in fibrosis of the bladder and ureter, kidney damage or bladder cancer, and may eventually lead to death. [1]

Usually, the severity of the disease depends on the intensity of infection. Clinical symptoms occur in 80% of the infected individuals. Individuals with light infections with a few worms, especially in case of adults, remain asymptomatic. [15]

Impact

The S. haematobium infection disables more than it kills its victim. Chronic schistosomiasis effects the ability to work, resulting in not only health related, but also economic implications for the patient. For children, the disease causes anaemia, impaired growth and reduces the ability to learn and develop.

Death estimates caused by the disease vary between 24 072 and 200 000 a year. In 2000, WHO estimated a global annual death rate of 200 000 patients. By now, this number has probably decreased as a result of the control and elimination programs. [6]

Treatment

There is no vaccine available for schistosomiasis. The infection is treated with the chemotherapeutic drug **praziquantel** (PZQ). It provides a safe and effective oral treatment against all Schistosoma species in humans. However, the medicine is relatively ineffective against juvenile worms and does not prevent reinfection. [14] [12] There is no evidence that the Schistosoma parasite develops resistance to praziquantel. [14]

The recommended dosage of praziquantel is 40 mg/kg. The medicine usually comes in tablets of 600 mg, which cost around $0.13. The shelf life of the tablets is up to 4 years. [11] [15]

Safety of use of praziquantel by children under 4 year old has not been proven. The drug is safe to be used by pregnant women. [16]

The alternative medicine metriphonate is only effective against S. haematobium, not against other Schistosoma species. It is not produced anymore, but can still be found on the generic market in some countries. [11][9]

3.2 Key takeaways

- Urinary schistosomiasis is a parasitic disease caused by Schistosoma Haematobium
- The disease is most prevalent in Egypt and Sub-Saharan Africa
- People can get infected in contaminated fresh water
- Risk groups are children and people whose occupation involves water contact
- The most visible symptom is bloody urine
- Urinary schistosomiasis can eventually lead to bladder cancer
- Schistosomiasis can be cured by praziquantel

Chapter 4

DIAGNOSTIC METHODS

This chapter provides an overview of the available diagnostic methods to detect S. haematobium infections. Insights on the limitations of the existing methods are used in creation of opportunities for diagnostic scenarios in chapter 10 and in decision making on product specifications in chapter 11.

There are several methods to diagnose S. haematobium infections. These methods detect several indications of infections; haematuria, parasitic eggs, antibodies, antigens or DNA. [18] [23]

The World Health Organization (WHO) created case definitions for infected individuals.

In endemic areas with moderate or high prevalence of S. haematobium, a case is **confirmed** when a person has either visible haematuria, a positive reagent strip for haematuria or when eggs in urine are detected with a microscope.

In non-endemic areas and areas of low prevalence, a case is **suspected** when a person has either visible haematuria or a positive reagent strip for haematuria. A case is **confirmed** when a person has eggs in urine, which are detected with a microscope. [24][25]

In the following sections, the different diagnostic methods are discussed in more detail.

4.1 Detection of haematuria

There are two methods to detect haematuria in urine: direct observation and reagent strips.

Questionnaire

Visible haematuria can be detected by visual inspection for blood in urine samples. These **macrohaematuria** make the urine pink, red or brown and indicate a heavy infection. Questionnaires are a method used for rapid screening of S. haematobium infections. They are sent to primary schools, where teachers ask children whether they have blood in their urine.

Questionnaires are a useful tool to get an indication of the frequency of infection in a community. However, this method depends on honesty of children and whether teachers return all the forms. Besides that, questionnaires have limited accuracy, since not all infected children will have gross haematuria. [26]

Reagent strip

In the majority of cases, children with urinary schistosomiasis have microscopic blood in their urine. These **microhaematuria** are not visible by direct observation but can be detected with chemical reagent strips. [1] [27] For one minute, this stick is dipped in the urine sample, after which the colour on the strip is compared to the supplied colour scale.

In contrast to the excretion of eggs, haematuria are more consistently present in urine, so the strips can be used at any time of the day. [28] The method is relatively accurate.[29][30] Their low price, ease of use and fast results make the dipsticks useful for monitoring control programs. However, the results can be influenced by haematuria of a different origin. [31] [32]

4.2 Microscopic egg count

The golden standard to diagnose urinary schistosomiasis is microscopic egg count. This method is based on the detection of S. haematobium ova in urine. For this method, a urine sample is collected. The eggs are separated from the liquid by filtration or sedimentation, after which the eggs are counted with a microscope. [27]

According to WHO standards, the specimen should consist of a single terminal urine sample of at least 10 ml, collected in a 250 ml urine pot.[33] Preferably, the sample should be collected between 10 am and 2 pm, since the egg concentration is highest in midstream urine. [27][34]

After the collection of a sample, the urine must be examined as soon as possible, otherwise eggs will hatch, release miracidia and become invisible.[33] Keeping the samples out of the sun and in the dark and cold also prevents hatching. [27] The sample can be fixed by adding one ml 40% formaldehyde for preservation and it prevents odouring of the urine. [37]

Filtration

Filtration with membrane filters is the is the standard diagnostic technique when quantitative information is required. [1] The method requires a 10 ml plastic syringe, Lugol iodine, nylon, paper or polycarbonate filters and a filter holder.[27]

First, a filter is placed in a filterholder. 10 ml urine is drawn into a syringe and is attached to the filter holder. Then, the urine is pushed through the filter. Afterwards, the syringe is disconnected from the filterholder and the filter is removed and placed on a microscope slide. A drop of Lugol iodine solution can be added to improve the visibility of the eggs. [27]

Sedimentation

Sedimentation of the urine sample requires a centrifuge, tubes and Pasteur pipettes. [27]

According to WHO standards, the urine should be poured into a conical flask and sedimented for an hour. Afterwards, the supernatant is removed and the sediment is poured into a centrifuge tube. It is put into the machine and centrifuged at 2000g for 2 minutes. Exceeding 2000g or extending the centrifugation time might result in hatching of the ova. The deposit is examined under the microscope for the presence of ova. [27]

Sedimentation by gravity, where the urine sample sediments in 4.5 – 5 hours is a highly reliable method. [37]

The sedimentation method is cheaper and easier to perform than filtration. Some consider this method less sensitive than filtration, but there is no scientific evidence for this statement.

Microscopy

Microscopic examination requires a microscope, microscopic slides and coverslips. The glass slide is covered with a slip and placed under the microscope. Eggs are counted manually. Schistosoma ova are large - about 120 to 150 mm long - and have a terminal spine at one end (see image 5). [27]

The of microscopy results should be reported according to the egg count categories (table 2).

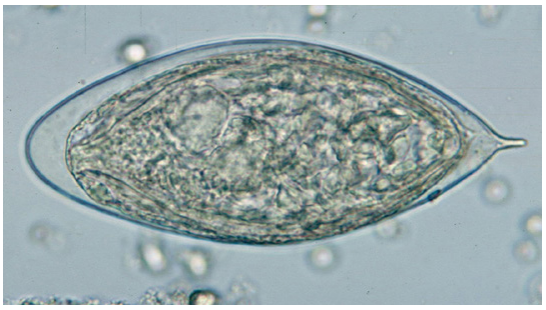


Image 5. Microscopic image of S. haematobium ovum

After the examination, the urine sample is discarded in a bucket. Bleach, methylated spirit, medicated soap and disinfectant wipes are used to wash all reusable equipment (tweezers, filter holders, syringes, urine containers, glass slides). [27] The used filters can either be discarded in a waste container containing disinfectant or cleaned and reused. Plastic filters can be reused when they are soaked in bleach, washed with a detergent and rinsed with water. To ensure the filter is free of parasites, it needs to be checked under the microscope before reusing. [21]

Category	Number of eggs
Light intensity infection	< 50 eggs per 10 ml urine
Heavy intensity infection	> 50 eggs per 10 ml urine or visible haematuria

Table 2. Classes of intensity of schistosome by questionnaire or microscopy [27] [17]

Limitations of methods

Microscopic egg count has some limitations.

Firstly, microscopy has relatively a low sensitivity: around 80%, depending on the context. The result of microscopic egg count is dependent on operators expertise, which makes manual microscopic examination prone to human error. [40] Furthermore, the method is sensitive to environmental influences. Light, temperature or dust levels influence microscopy and may lead to false results.

Secondly, single examinations may not adequately reflect the worm burden, since egg excretion varies per day and moment during the day.

After infection, it takes a few weeks before eggs are excreted in urine, so it takes time until the infection can be detected. Furthermore, ova are only produced when a person is infected by both male and female adult worms. Besides that, patients with very light infections might not excrete ova. Light infections with few eggs are easily misdiagnosed. [16] [38] [31] As a result, the prevalence of the disease may be underestimated. [39]

Heavy infected individuals can have a high concentration of blood in their urine, which complicates the identification and counting of the number of ova. When adults have been infected for a long time, they will not excrete eggs anymore, meaning that even severe infections cannot be recognizes with microscopy anymore.

There are several ways to increase the sensitivity of microscopic egg count, like repeated sampling or collection of larger urine samples. To detect light infections, the whole urine sample should be examined and repeated on at least 6 consecutive days. [35] However, this comes at the price of increased labour and diagnosis time.

Filtration and sedimentation both have disadvantages that result in lower sensitivity. In case of filtration, Schistosoma ova pass through the filter pores or get stuck in the syringe or the filter holder. The risk of sedimentation is that eggs are left in the supernatant or get stuck in the tube.

Lastly, sedimentation and manual microscopic examination of a urine sample are labour intensive and time-consuming, requiring between 10-30 minutes. [39]

4.3 Other diagnostic methods

Detection of antibodies

Serological tests can detect schistosome specific antibodies with high sensitivity. However, the result is not quantitative, it the method cannot distinguish between past and present infections and it is challenged by cross reactivity. Furthermore, this is a costly and difficult method, making it difficult to use in the field. [31][41]

Detection of antigens

There are methods based on the detection of circulating anodic antigens (CAA) and circulating cathodic antigens (CCA). [31] A sensitive laboratory based test for these antigens is available. The antigen levels correlate with the number of worms. [42]

POC-CCA is a point-of-care test used for the detection of S. mansoni infections. [29] However, the test is not applicable for the detection of S. haematobium infections, since there is hardly any CCA in urine. CAA is present in urine and blood from individuals with S. haematobium infections, but the rapid diagnostic test (RDT) is still under development. [23] [43][44]

Detection of DNA

There are polymerase chain reaction (PCR) based methods that detect parasite DNA. These methods are highly sensitive and specific, and can detect the disease in an earlier stage. However, they come at a high price and b require high skilled laboratory staff. [31]

A combination of PCR and CAA is the most accurate method at the moment, and is often taken as the reference method when determining the accuracy of other diagnostic methods.

Overview of diagnostic methods

Table 3 provides an overview of the existing diagnostic tests. It summarizes the accuracy and applicability for use on primary health care level and in basic laboratories.

Diagnostic method	Unit of diagnosis	Sensitivity	Specificity	Quantification	Throughput	PHC level	Basic lab	Cost
Questionnaire	Macrohaematuria	Low	Low	Low	High	Yes	Yes	Low
Reagent strip	Microhaematuria	Low	Low	Medium	High	Yes	Yes	Medium
Microscopy	Schistosoma ova	Medium	High	High	Medium	Yes	Yes	Medium
ELISA, IHA	Antibody	High	Low	Low	High	No	No	High
POC-CCA	CCA (Antigen)	Low	High	Medium	High	Yes	Yes	Medium
UCP-LF CAA	CAA (Antigen)	High	High	Medium	Medium	No	No	High
PCR	DNA	High	High	Medium	Medium	No	No	High

Table 3. Accuracy and applicability of diagnostic tests for urinary schistosomiasis [32] [17]

4.4 Applicability of diagnostic tests

Diagnostics in low resource settings

In response to the need for improved diagnostic tests in low resource settings, WHO has defined ASSURED criteria. These criteria describe the ideal characteristics for an diagnostic test and can be used to select the most appropriate test for deployment in low resource settings (LRS). ASSURED stands for **A**ffordable, **S**ensitive, **S**pecific, **U**ser-friendly, **R**apid and robust, **E**quipment-free and **D**eliverable to end-users. [45] [46] The criteria are very generic and have not been specified. [45] See table 4 for the criteria. [48][6]

Currently, none of the available diagnostic methods fit all of these attributes. Microscopy is does not fulfil the sensitivity, user friendly and equipment-free requirements. [49][6] POC-CCA fulfils the most criteria for schistosomiasis, but the current price ($1 - $1,66 per test) might be too high for use in LRS [47] [23] . In addition, its sensitivity is limited for detection of S. haematobium.

	Criteria	
A	Affordability	Affordable for those at risk of infection
S	Sensitivity	Few false negatives
S	Specificity	Few false positives
U	User friendly	Simple to perform with minimal training
R	Rapid & Robust	Rapid - results available in less than 30 minutes to enable treatment at first visit Robust - does not require refrigerated storage
E	Equipment free	Doest not require equipment
D	Deliverable to end users	Deliverable to those who need it

Table 4. ASSURED criteria [45][4]

4.5 Key takeaways

- There are diagnostic methods based on detection of haematuria, ova, antigens, antibodies or DNA
- Microscopy is the golden standard, but it lacks sensitivity and requires skilled users
- Urine is collected, centrifuged or filtrated and the eggs are counted with a microscope
- Eggs start hatching after 30 minutes, which makes the sample unusable
- None of the available methods fulfils the ASSURED criteria for diagnostics in low resource settings

Chapter 5

CONTROL & ELIMINATION

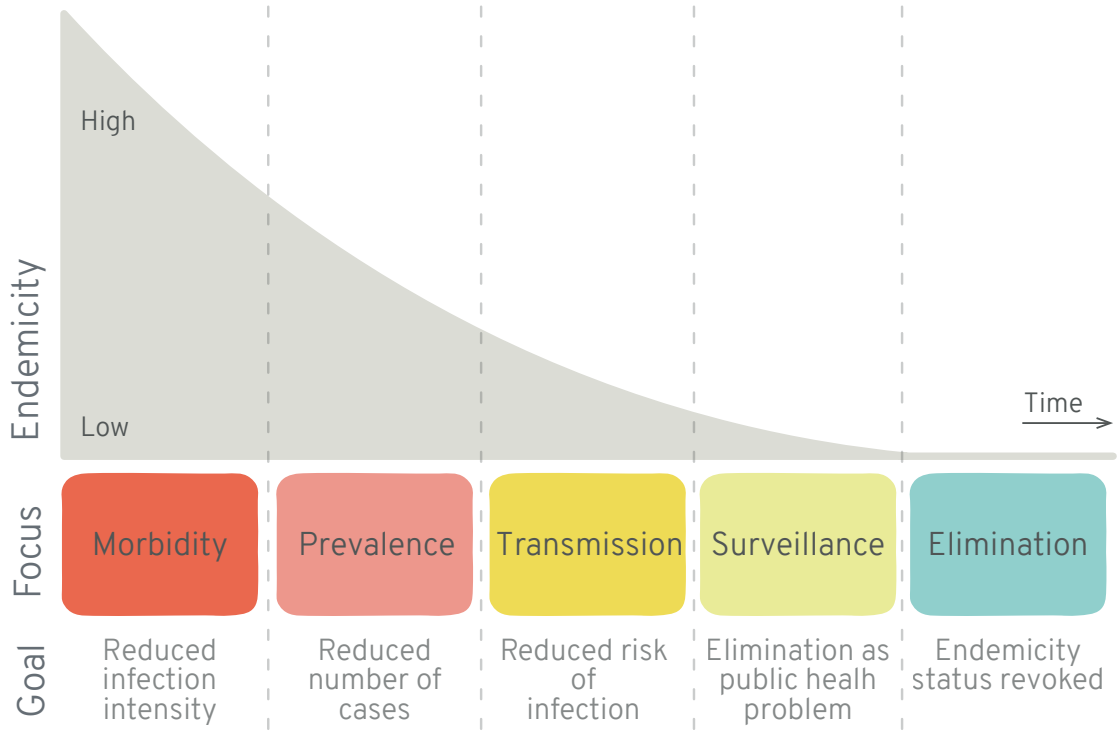


Figure 3. Stages in disease control

This chapter describes the goals of the World Health Organization and their strategy for schistosomiasis control, the limitations of this strategy and the role and requirements of diagnostics in the control and elimination.

Currently, the World Health Organization (WHO) is trying to control and eventually eliminate schistosomiasis. Control means putting effort in the reduction of disease incidence, prevalence, morbidity, and/or mortality to a locally acceptable level. The control of a disease consists out of the following stages: morbidity, prevalence, transmission, surveillance and elimination of the disease, as illustrated in figure 3. [3]

The WHO target for 2020 for schistosomiasis is **morbidity control**. This means reducing the prevalence of heavy intensity infections to ≤5% among populations at risk. The target for 2030 is the **elimination of schistosomiasis as a public health problem** in all countries. This is defined as a ≤1% proportion of heavy intensity infections among the populations at risk. [4]

5.1 Control program

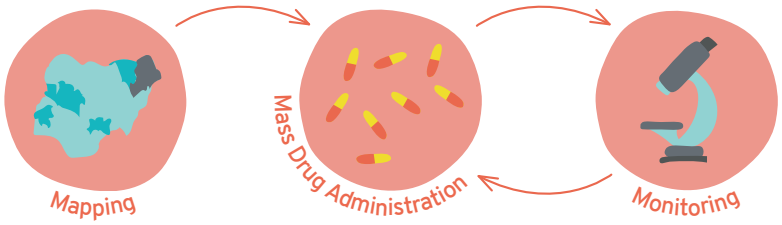


Figure 4. Main steps in the control program

WHO has developed a strategy for control and elimination of schistosomiasis. It focuses on controlling the disease though **preventive chemotherapy** (PCT). This means that populations at risk receive praziquantel without individual diagnosis. The groups that are targeted for treatment are school aged children (SAC) in endemic areas, adults who have occupations that involve contact with infected water and communities living in highly endemic areas. [1]

The WHO goal is to treat at least 75% of all SAC and others at risk by 2020. [51] So far a 71% PCT coverage rate has been reached for SAC [52]. The aim of the control program is, as mentioned before, morbidity control. Periodic treatment of populations at risk will cure subtle morbidity and prevent infected individuals from developing severe, late-stage morbidity due to schistosomiasis. [22] PCT interventions will decrease morbidity if a high coverage is sustained for 5–8 years. Maintaining a reduction in prevalence requires continuing the intervention. [3]

Pharmaceutical company Merck annually donates 250 million tablets of praziquantel (PZQ) to target school children. This donation is coordinated and distributed by WHO. [52]

Since medicines are available, the focus of WHO for control of schistosomiasis is on mass drug administration (MDA) rather than intensified case management. [53]

There are three main steps in the control program; **mapping of prevalence, mass drug administration** and **monitoring and evaluation** of the program, see figure 4.

Mapping of prevalence

The first step in the control and elimination program is mapping of the disease. Baseline information on disease prevalence is essential in planning control programs for schistosomiasis. [12] According to WHO guidelines, data should be collected from school aged children, for both STH and schistosomiasis at the same time. At schools, samples are collected for testing. The recommended method is the detection of eggs in urine with the filtration technique. [27] The second option is the detection of haematuria in the sample by questionnaires and dipsticks.

The prevalence of infection among the children determines the community category, see table 5. This data is used to determine the mass medication approach and for monitoring the impact of the control program in a later stage. [14]

Category	Number of eggs
I High prevalence	> 30% visible haematuria (by questionnaire) or > 50% infected (by microscopy)
II Moderate prevalence	< 30% visible haematuria (by questionnaire) or 10-50% infected (by microscopy)
III Low prevalence	< 10% infected (by microscopy)

Table 5. Community diagnosis through schools for urinary schistosomiasis by survey [11]

Mass drug administration

The treatment frequency is determined by the disease prevalence among school aged children. The recommended strategies by WHO can be found in table 6. During treatment days, teachers measure the height or weight of their children and treat them with Deworming drugs for both schistosomiasis and STH. The praziquantel dose depends on the height or weight of the child. Since MDA treats everyone rather than targeted chemotherapy, a lot of uninfected people are treated. [54]

Category	Intervention in schools	Health services and community based intervention
I High prevalence	Targeted treatment of SAC, once a year	• Access to PZQ for passive case treatment • Community directed treatment for high risk groups recommended
II Moderate prevalence	Targeted treatment of SAC, once every 2 years	• Access to PZQ for passive case treatment
III Low prevalence	Targeted treatment of SAC, twice during primary schooling	• Access to PZQ for passive case treatment

Table 6. Recommended treatment strategies by WHO (2002) [11]

Monitoring & Evaluation

Monitoring and evaluation is an essential part of the control program, to ensure efficient implementation and maximal benefit for targeted communities. Routine monitoring of Deworming involves recording the percentage of SAC treated and the quantity of drugs used.[55] Coverage is the minimum process indicator for assessing the performance of PCT interventions. [22]

Five to six years after the first round of treatment, the program impact should be assessed by an epidemiological survey. [55] A number of sentinel sites, representative of each treatment strategy, are selected in which the proportion of heavy infections and the prevalence of infections should be determined amongst the treated population [18]. The method for monitoring is similar to the epidemiological survey for mapping the baseline data. A new strategy is determined, depending on the measured disease prevalence.

After four more years, the prevalence should be evaluated again and will result in a new strategy. [22] Figure 5 gives An overview of the control program and the recommended strategies. According to WHO guidelines, morbidity control or elimination of the disease as public health problem are expected to be reached after two evaluations.

When PCT has expanded and the prevalence of schistosomiasis has decreased, the focus will change from monitoring the progress of the control program to deciding to scale down or stop interventions. Eventually, when transmission of the disease is minimal, the focus will be on surveillance.

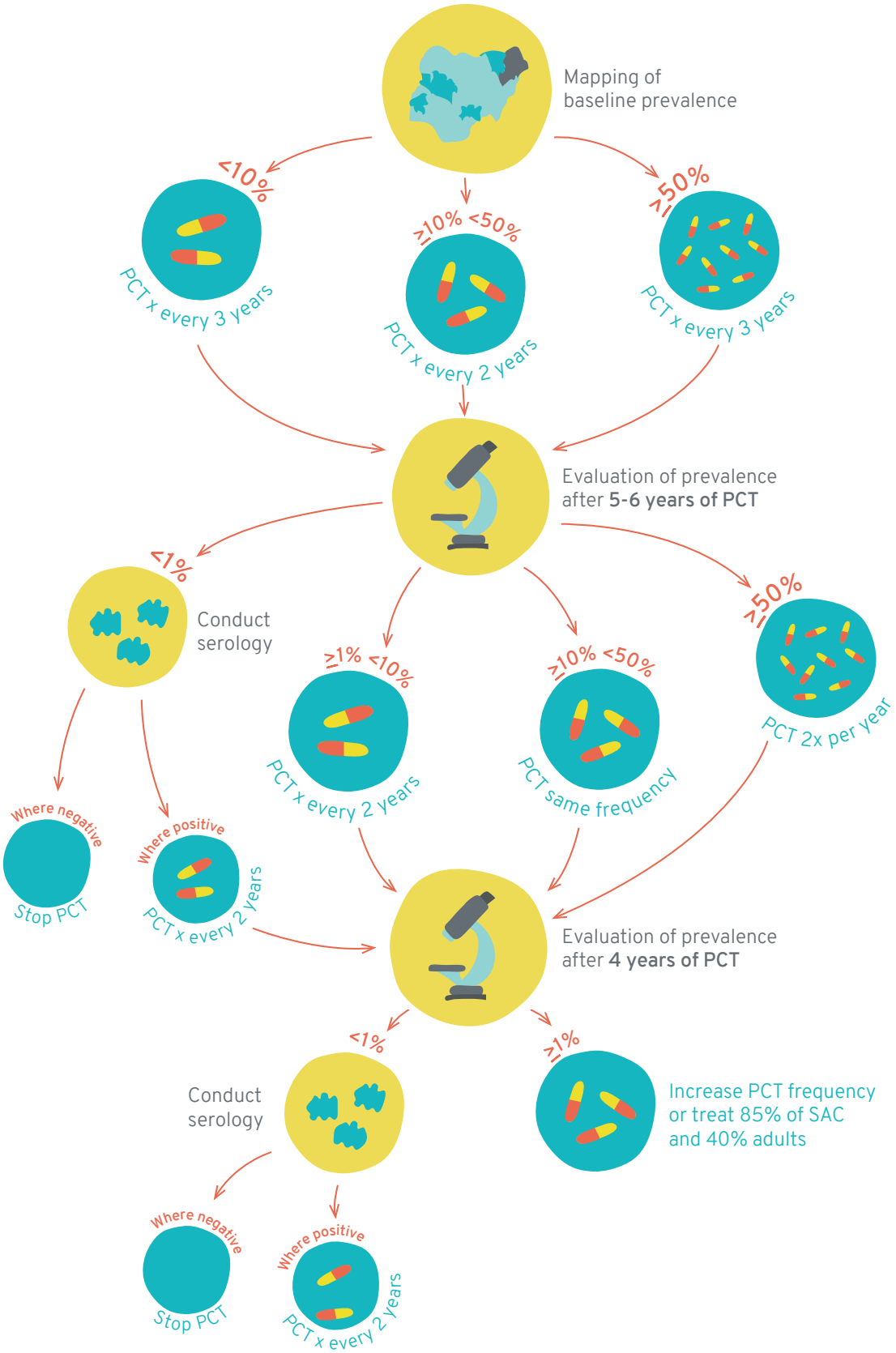


Figure 5. Overview control program and preventive chemotherapy strategies

5.2 Role of diagnostics

Limitations of MDA

Mass drug administration (MDA) is not sufficient to eliminate schistosomiasis transmission by itself. The risk of reinfection after treatment is high in endemic countries. [40] As a result, praziquantel based control programmes only have a temporary effect on transmission and are limited in their potential to interrupt disease transmission on the long term [21].

It is difficult to achieve full coverage and this becomes more difficult once the disease prevalence is lower. At a certain point, the MDA is no longer the most cost effective strategy or will not be accepted by the community anymore.

Furthermore, it is impossible to eliminate the disease as long as sanitation is poor and infected snails remain.[56] [53] In endemic areas, once mass treatment with praziquantel is stopped, disease prevalence can return to baseline levels within 18–24 months. [54] Treatments should always be accompanied by efforts to improve water supply and sanitation. In a next phase of the control program, intermediate hosts should be targeted as well. [40][24]

WHO defined three critical actions in their roadmap to reach the goal of elimination of schistosomiasis as public health problem in 2030;

1. Define an indicator for measuring morbidity
2. Implement effective interventions, including extending MDA to all populations at risk and ensuring access to the necessary drugs; implement targeted snail control; continue micro-mapping and targeting
3. Develop diagnostic tests, including standardized POC diagnostics, and develop new interventions, including alternatives to praziquantel and methods of snail control [52]

Role of diagnostics in control

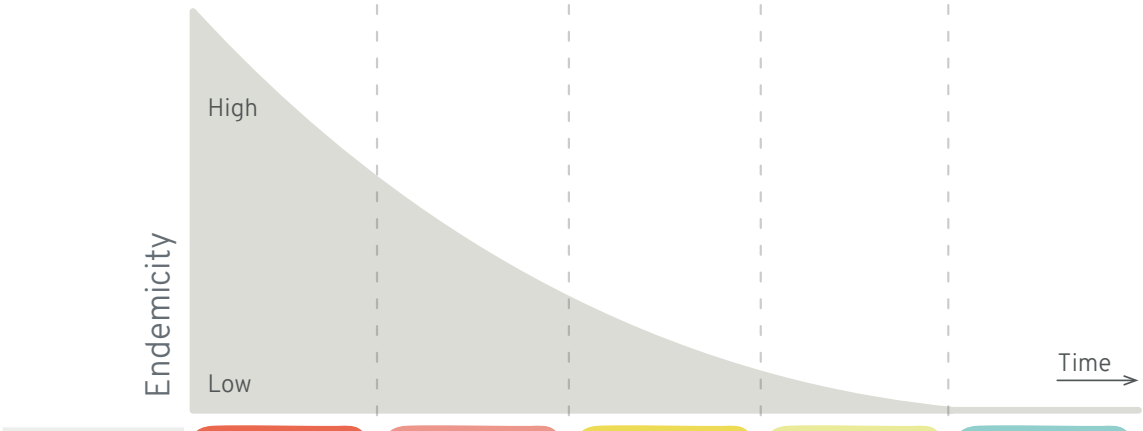
Strengthening diagnostics is critical to reach the WHO targets. To prepare for the future, the development of fitting diagnostic tools needs attention now. [53] There is a tendency to emphasize on drug treatment, therefore the importance of diagnostics is often neglected. When a control program becomes more successful and prevalence drops, the accurate assessment of the epidemiological situation becomes more essential. [41]

There are four moments at which the schistosomiasis control programs require diagnostics. [32][11]

1. **Mapping** to establish baseline disease prevalence
2. **Impact monitoring** after interventions have started to measure the prevalence
3. **The stopping decision**, which determines whether the morbidity target has been reached
4. **Post-elimination surveillance** after intervention has stopped to detect potential re-emerge of the disease

Falling endemicity levels influence the control focus and the diagnostic needs and tools. In every stage of the control program, the diagnostic requirements differ depending on the target. An overview of these requirements can be found in table 7.

Decisions on diagnostic methods are a compromise between quality and quantity. For large scale applications, decisions should be based on cost effectiveness, accuracy, simplicity and robustness. For mapping purposes, cost and simplicity are more important than sensitivity. [41] [57] A switch to more sensitive and specific methods is required once the control program progresses. [58][40] [32] There will be a need to use new diagnostic tools and/or technologies that can assist in identifying hot spots of transmission for intensified interventions. [4]



Stage of control	Morbidity	Prevalence	Transmission	Surveillance	Elimination
Goal	Reduced infection intensity	Reduced number of cases	Reduced risk for infection	Elimination as public health problem	Endemicity status withdrawn
Target	Human host	Human host	Human host, Intermediate host	Human host, Intermediate host	Human host, Intermediate host
Diagnostic preference	Simplicity, low cost, high throughput	Sensitivity, specificity	High sensitivity, specificity	High sensitivity, specificity	High sensitivity, high specificity
Tools	Questionnaires, reagent strips, microscopic egg count	Questionnaires, reagent strips, microscopic egg count	Antibody detection, antigen detection	Antibody detection	PCR, antibody detection
Strengths	Good indicator	Good indicator	-	High sensitivity	Certified testing
Limitations	Neglects light infections	Not sensitive enough	Antigen test not sensitive enough, intermediate host testing is complicated	Crossreactions, specificity problems	System not yet available

Table 7. Influence of falling endemicity levels on control focus and diagnostic needs and tools [40][24]

5.3 Key takeaways

- The target from the World Health Organization for 2030 is the elimination of schistosomiasis as public health problem
- Their strategy focusses on preventive chemotherapy for populations at risk
- There are three steps in the control program

1. Mapping, to collect data on baseline disease prevalence
2. Mass drug administration, where treatment is administered to risk groups. The frequency depends on community prevalence
3. Monitoring and evaluation, where impact of a control program is assessed

- Diagnostics play an important role in the control program and should be strengthened
- Diagnostic needs depend on the stage of the control program

III

TECHNOLOGY

Chapter 6

SMART DIAGNOSTIC TECHNOLOGY

In response to the need for improved diagnostic tests in low resource settings, new diagnostic technologies are being developed. At Delft University of Technology, engineers are developing optical and computer technologies that allow automated S. haematobium ova detection. This technology offers several benefits compared to the standard diagnostic method; manual microscopy.[59]

Prototypes are developed based on two different technologies. The Schistoscope is based on a reverse lens system. SODOS is based on holographic imaging. Both devices run an algorithm that detects the ova.

This chapter aims to answer the research question; What are the benefits of and opportunities for the new technologies for the diagnosis of S. haematobium infections? The next paragraphs dig deeper into these new technologies, the developed prototypes and their main limitations and benefits.

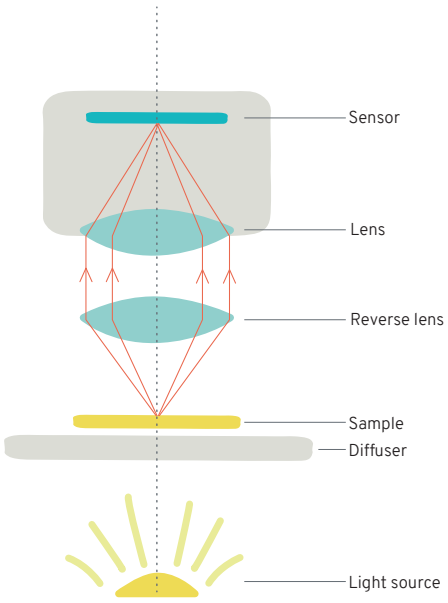


Figure 6. Set up of Schistoscope

6.1 Schistoscope

Technical principle

The technical principle of the Schistoscope consists out of an **optical system** and an **computational application**. It functions like an automated microscope, specifically for detection of S. haematobium infections.

Usually, the optical components are the most expensive parts of a microscope. The bigger the lens, the better the image quality. However, since S. haematobium ova are relatively big, they can be detected with low magnification. A small and straight forward optical system can already provide good images. [60]

There are two methods where the objective lens and eyepiece of the microscope are replaced by an simple optical attachment in front of a camera.

The first option is using a ball lens for magnification. This is a cheap option, but the field of view with acceptable image quality is limited. [60]

The second option is the placement of an identical reversed camera lens in front of a normal camera lens. When a sample is positioned at the focus point of the reverse lens, the set up (see figure 6) can give a x1 magnification of a field of view (FoV) equal to the camera sensor area. The distance between the camera lens and the reversed lens determined the focus point. The bigger this distance, the closer the focus point. Illumination of the sample should be provided by a light with diffuser. A reversed lens system can provide high resolution images over a wide field of view. [60]

The optical system can be used to take a picture of a urine sample, see image 10. An application on the computational unit uses an algorithm to identify the number of ova in the sample. Detecting the ova is done in two steps; (1) **localizing** the potential ova and (2) **classifying** the potential objects using a trained image classifier. [39]

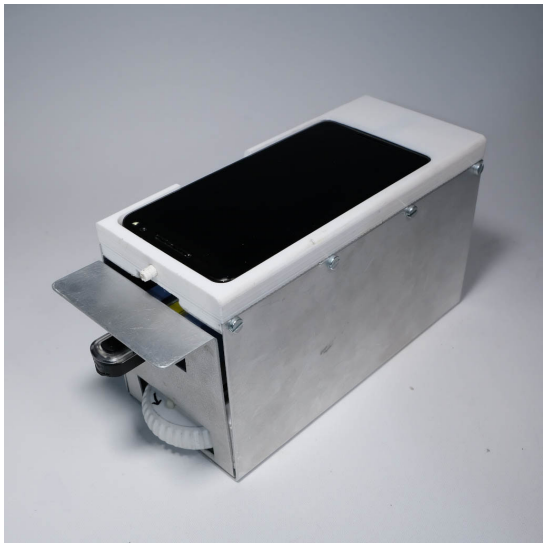


Image 6. Prototype of Schistoscope 1

Image 7. Prototype of Schistoscope 2A

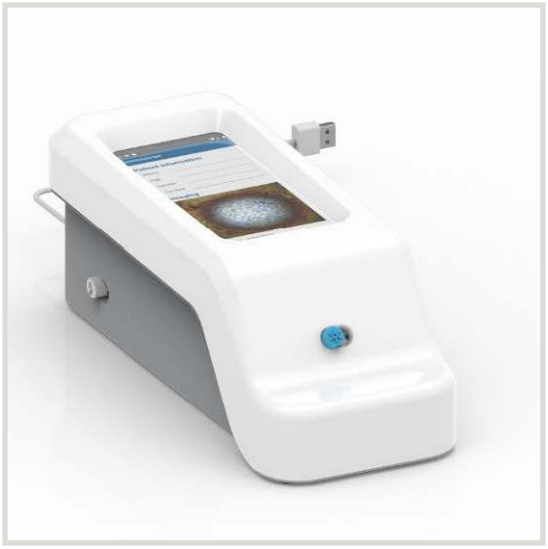


Image 8. Render of Schistoscope 2B

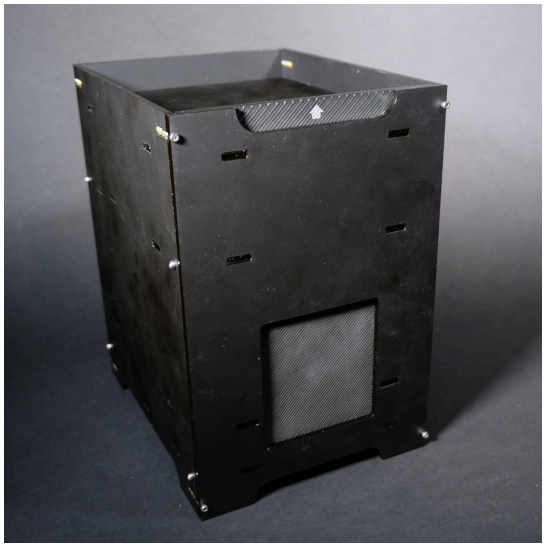


Image 9. Prototype of Schistoscope 3

Schistoscope prototypes

Over the last few years, four versions of the Schistoscope have been developed. The goal was to develop a digital microscope which offers an integrated diagnostics solution (sample preparation and diagnosis) with the support of a smart algorithm (for detection and quantification of the S. haematobium ova) which can be produced and maintained in Africa (use of locally available components and 3D-printing)[38].

The four prototypes are shown in image 6-9 and the specifications are listed in table 8. Schistoscope 1 and 2B use the ability of a **smartphone** to capture images and process data. The advantage of the use of a mobile phone is the integrated connectivity, intuitiveness of use, wide availability and local repairability.

The designs include a customized filter holder, to improve ease of use for the operator and avoid leaking of urine. The Schistoscope 1.0 was tested in the field in Nigeria. Research insights on robustness, shape, power supply and repairability were used during the design of Schistoscope 2B. [61][62]

Schistoscope 2A and 3 use a **Raspberry Pi** as computational unit. This is a cheap microcomputer which allows easy implementation of algorithms and an open source design. Since a raspberry pi is small and modular, the device can be more efficient in battery use and size.

Schistoscope 2A uses an 4x objective instead of a lens to achieve 1 FoV, but it is not recommended due to its high price. Schistoscope 3 was developed as proof of technical concept and for local manufacturability. Product functions for usability in the field are excluded in the prototype. [61] [38] [63] [39][59]

Prototype	Schistoscope 1	Schistoscope 2A	Schistoscope 2B	Schistoscope 3
Embodiment development	Team Zoom, 2018	Team Brandpunt, 2019	Team Elements, 2019	Satyajith Jujjavarpu, 2020
Optical system	Reverse lens attached to smartphone camera	Reversed 4x objective to Raspberry Pi camera	Reverse lens attached to smartphone camera	Reverse lens attached to Raspberry Pi camera
Computational unit	Smartphone Moto X Style 2015	Raspberry Pi 3+	Smartphone Redmi Note 7	Raspberry Pi 3+
Computation time	5 seconds	6.2 seconds	Unknown	6.2 seconds
Connectivity	Mobile network	WiFi	Mobile network	-
Power supply		External power bank	Internal power bank	-
Field of view	1 FoV	1 FoV of 15 mm	1 FoV of 3.5 mm	Multiple FoV
Sample preparation	Customized filterholder	-	Customized filterholder	WHO filtration procedure
Filter	Locally available filter cloth	14 mm filter	3.5	WHO filter 13 mm
Movement	Sample moves along Z axis	Sample moves along Z axis	Sample moves along Z axis	Sample moves along Z axis, camera moves along X and Y axis
Material	3D prints Sheet metal	3D prints Off-the-shelf parts	3D prints	3D prints Laser cuts
Estimated cost	-	€ 125 (batch size 10-100)	€ 480 (batch size 10)	€ 200 (for prototype)

Table 8. Characteristics of SChitoscope prototypes [61] [38] [63] [39][59]

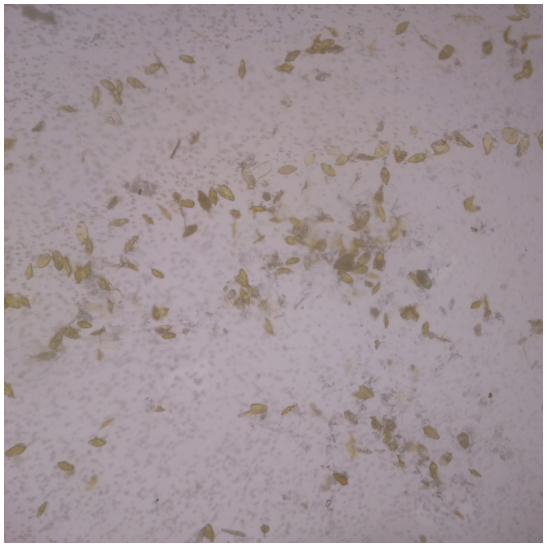


Image 10. Image of ova captured by Schistoscope 3

Image 11. Discussion about Schistoscope in Nigeria

Image 12. Discussion about customized filter holder in Nigeria

Field feedback

The prototype of the Schistoscope 2B was taken to Nigeria and presented during a session with six PhD students from the Public Health Faculty of the University of Ibadan, see image 11 and 12. The prototype was used as a tool to start a discussion about the required product qualities for the field, see appendix I-3 for the feedback. The results were used in chapter 11 for the target product profile.

Limitations

The diagnostic technology is **still under development** and does not work perfectly yet. Besides, there are some limitations to this technology.

Full automation of diagnosis is the ultimate goal, since it eliminates human intervention. Currently, the Schistoscope still requires manual focussing, so diagnosis still requires a skilled test operator.

The cheap camera lenses in the Schistoscope provide limited image quality, so multiple FoV are required to get a good result. To obtain multiple measurements extra product parts are added to move the camera or sample along the X and Y axis. To automate the process, the algorithm should be able to detect the boundaries of the urine filter. [60] This makes the device more complex and expensive.

Furthermore, the detection software has only been developed for the mobile phone, not yet for Raspberry Pi.[39] In the future, this software should be developed so the Raspberri Pi can be used as computational unit.

Even if the device is fully automated, the diagnostic procedure with the Schistoscope will still require **manual sample preparation**. The result of the test will depend on the skills of the person preparing the sample.

6.2 Smart Optical Diagnostic of Schistosomiasis

Image 13. Prototype of SODOS

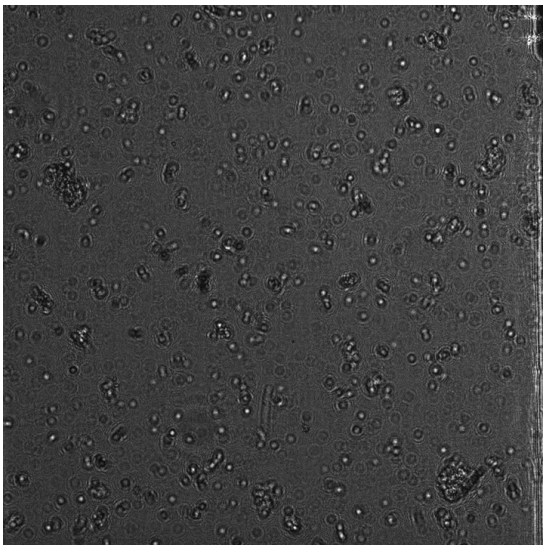


Image 14. Image of ova captured by SODOS

Technology

Besides the Schistoscope, there is a second technical principle. This is a lens free method, based on the **automated flow based holographic analysis** of urine samples.

An optical sensor is combined with a laser to make a holographic images of urine in a flow cell. A **digital reconstruction** of images for various depths can be made from one single recording. An algorithm detects S. haematobium ova in the pictures. Theoretically, it will take around 2-3 minutes to detect and calculate the amount of eggs in the sample with this smart diagnostic technology. [64] [65] This method can achieve a **high resolution over a large field of view**.

SODOS

Image 13 shows the prototype of the **Smart Optical Diagnostic of Schistosomiasis** (SODOS). This diagnostic test does not require sample preparation. A syringe with 12 ml urine is put into the machine and is automatically pushed through a flow cell. An image is reconstructed by the algorithm (see image 14) and amount of ova is counted. Internal sensors register the temperature, humidity and GPS location of the measurement. The system is controlled by a Rasperry Pi. An additional phone application was created to collect patient data and the location of collected samples. [65][64] The prototype has been tested in Ivory Coast. It needs to be further **optimized and simplified**.

Limitations

The diagnostic technology is **still under development** and does not work perfectly yet. Replacing the disposable flow cell is difficult and time-consuming, so it should be replaced by a reusable one. Currently, it takes 20-30 minutes to record the whole sample and the image files were very large. The reconstruction and classification algorithms were not yet tested in the field. They should be further developed and trained with more data. [64][65] Besides, there are some limitations to the technology itself.

This method eliminates expensive lenses, but it comes at the cost of the **high computational demand**. [64] [65]

Furthermore, this technology cannot be used for samples prepared on standard glass slides, since it requires the sample to be positioned close to the sensor. As a result, samples can not be stored compactly for quality control after testing.

6.3 Diagnostic benefits

The algorithms and optics for the Schistoscope and the SODOS have not been fully developed and optimized yet, but they are promising for future implementation in diagnostic devices designed for low resource settings. Implementing the algorithms and the optical system in a device offers several potential benefits compared to conventional microscopes.

1 Simple and user-friendly

Microscopic egg count is difficult to perform and labour intensive. The urine sample needs to be prepared and observed through an objective. If ova are visible, they should be counted manually. The new technology allows simple and user friendly testing. Manual observing and counting is not required. The holographic method does not require sample preparation which makes it user friendly for users without medical training.

2 Rapid

Microscopic egg count takes between 1-5 minutes, depending on the infection intensity, amount of blood in the sample and the experience of the observer. [65] Furthermore, sample preparation requires time. The total urine analysis takes 10-30 minutes.
Theoretically, the holographic analysis can be done in 2-3 minutes and does not require sample preparation. [65] The classification algorithm of the Schistoscope should be able to allow egg detection and counting in barely 4 seconds, excluding time for imaging and sample preparation. [38]

3 Sensitive

The sensitivity of microscopy is limited, partially because manual counting is prone to human error. Moreover, there are limitations to sedimentation and filtration that result in lower sensitivity.
Smart diagnostic technologies use an algorithm to detect and count the S. haematobium ova in the urine. Since the procedure rules out human error, the test can reach a higher level of sensitivity. Furthermore, SODOS does not require sample preparation.

4 Robust and portable

Microscopes are designed for laboratory environments. The lenses and objectives are fragile and the device requires constant electricity.
The smart diagnostic technologies allow a lot of form freedom so the for transportation do not requires lenses and can be powered by a battery
There are no fragile lenses or objectives required for obtaining an focussed image of the magnified sample, so the device can be more robust than a conventional microscope. Batteries or an independent power supply enables use outside a lab setting.

5 Affordable

Lenses and objectives are the most expensive parts of a microscope.
The smart diagnostic technologies do not require expensive parts for the optical system and the amount of parts is limited. Furthermore, the aim of INSPiRED, is to optimize the devices for local manufacturing and maintenance, which reduces cost of production and repair.

6 Data collection

Results of microscopy are written down on paper.
The algorithms of the SODOS and schistoscope run on a smartphone or a Raspberry Pi. Incorporating electronics, sensors and data storage allows storing of healthcare data. An incorporated GPS sensor can simplify data collection and mapping. [32] There is an option to share the collected data via the phone network or WiFi.

Limitations

There are some limitations to the technologies. These smart diagnostic methods can never fulfil all ASSURED criteria, since the test cannot be equipment free.

There are some limitations of these technologies that are similar to those for microscopy described in chapter 4.2, since these methods are all based on the detection of ova. The device might never reach a very high sensitivity since it only detects eggs in the urine instead of schistosomes inside the body. Furthermore, eggs might have hatched and the examination of one urine sample might not adequately reflect the infection intensity.

The urine of heavy infected individuals might contain too much blood for the algorithm to recognize ova. Some adults who have been infected might not excrete eggs anymore.

Lastly, at the moment, the algorithms are only trained to detect S. haematobium ova and can not detect other objects in the urine.

6.4 Key takeaways

- There are two optical diagnostic methods under development at Delft University of Technology that can automatically detect S. haematobium ova in urine samples
- Schistoscope uses a reversed lens attached to a camera and an algorithm to classify ova
- SODOS is lens less imaging method with holographic imaging and an algorithm that reconstructs an image and recognizes eggs
- These technologies offer the following benefits compared to microscopy:
  - **Simple and user friendly**, it does not required high skilled operator
  - **Rapid,** the algorithm is faster than lab staff
  - **Robust and portable,** since there it can be powered by an independent power source
  - **Sensitive**, since it rules out human error
  - **Affordable,** since it does not require expensive parts
  - **Data collection,** it can save and share healthcare and location data

Image 15. Lab assistant in ARFH private laboratory

IV CONTEXT

Chapter 7

NIGERIA

Figure 7. Map of Nigeria

This chapter aims to give an introduction to the context. It contains basic information about Nigeria, the organization of the healthcare system and an introduction to schistosomiasis in Nigeria.

7.1 Country profile

Nigeria is a country in sub-Saharan Africa with a population of almost 196 million people. It is the most densely populated country in Africa. [66] The Nigerian population is very young, with only 29,4% of the Nigerians is above 15 years old. [51] 85 percent of the school aged children go to primary school. [66]

Nigeria has a lower-middle income economy with a gross national income of $1960 per capita [66]. There is economic inequality; 48% of the population lives in extreme poverty. [67] 55% of the population lives in rural areas [69]. Access to electricity is limited in Nigeria, especially in rural areas where only 23% of the population has access to electricity. [70]

The country has a tropical climate. The southwest it is hot and humid most of the year, while the southeast is dry. Land inwards is a savannah climate with wet and dry seasons. [68]

Nigeria is made up of 36 states and the federal capital territory Abuja. These states are divided into 774 local government areas (LGA), which are divided into wards. [51]

Social organization

Nigeria is culturally diverse with 350 different ethnic groups. The most dominant three are Hausa in the north, Ibo in the southeast and Yoruba in the southwest. Nigeria's main language is English, but it is poorly understood in many rural areas. The other important languages are Hausa, Igbo and Yoruba.

Average communities consist out of 2500-12000 people. In the south, respected elders of the community run the villages. Most communities have Village Development Committees (VDC) or Ward Development Committees (WDC), that coordinate and link communities with health facilities. These committees are led by an elected chairperson and include members from religious groups, community based organizations (CBO), community health workers, NGOs and informal healthcare providers.[71] [51]

Major activities in the communities evolve around religion. Major religions are Christianity (53,6%) and Islam (44,4%). [69]

Town announcers are an important communication channel within communities. Furthermore, radio is a very wide-spread medium. About 85% of the population can be reached over the radio [51] Only 42% of the population has access to the internet. [72]

Urbanization results in overcrowding, urban congestion, poor housing, poor environmental sanitation and crimes. [51] Sufficient infrastructure is lacking in most places. In rural areas, there are dirt roads or holes in the tarmac. During the rainy season, roads are often impassable which makes some communities inaccessible by car. Most people in rural areas travel by motorbike. The infrastructure in urban areas is better, but traffic jams are a big problem.

Oyo State

The field study takes place in Oyo State in the south west of Nigeria with a population over 7 million. Capital of the state is Ibadan, where the state government is located. The state is divided into 33 LGAs. There are 8831 communities and 2618 primary schools in Oyo State. The majority of the people are Yoruba.

Image 16. Market in Ibadan

7.2 Healthcare system

The health system in Nigeria is in a deplorable state, it overall health performance ranking 187th out of 191 Member States by WHO. [51] The life expectancy in Nigeria is 52 years.

In 2019, healthcare spending made up 3.33% of the country's GDP. Around 90% of population lives without health insurance. There is a high reliance on out-of-pocket health payments to finance healthcare [75]. Expenditure on health per capita is $118 per year. [71]

Healthcare in Nigeria consists of formal and informal health care delivery systems. They operate side by side but with minimal collaboration. There are nearly 36000 registered health facilities in the country, of which 1562 facilities are located in Oyo State. [51]

There are more government-owned health facilities than private facilities in Nigeria (67% public, 33% private) However, the ratio of public to private is much higher in the north than in the south. [76]

An overview of the Nigerian healthcare system can be found in figure 8.

Formal healthcare system

The formal healthcare system is run by the Federal Ministry of Health (FMoH). The goal of the national health policy is to create a comprehensive health care system based on primary healthcare (PHC) that is promotive, protective, preventive, restorative and rehabilitative to all citizens. [51][74] Most services provided by formal health care providers are clinic based, with minimal outreach and community based services. [77] There are three tiers of healthcare; tertiary, secondary and primary healthcare.

Tertiary healthcare is the highest level of healthcare and consists of teaching and specialized hospitals. Tertiary health facilities make up 0.25% of the total amount of health facilities in Nigeria. [76] Usually, there is one tertiary hospital per state [78]

Secondary healthcare includes general hospitals that provide services to patients referred from PHC facilities. Secondary health facilities make up 12% of all facilities in Nigeria. Most of the secondary health facilities are privately owned. [76] Usually there is one general hospital per LGA [78]

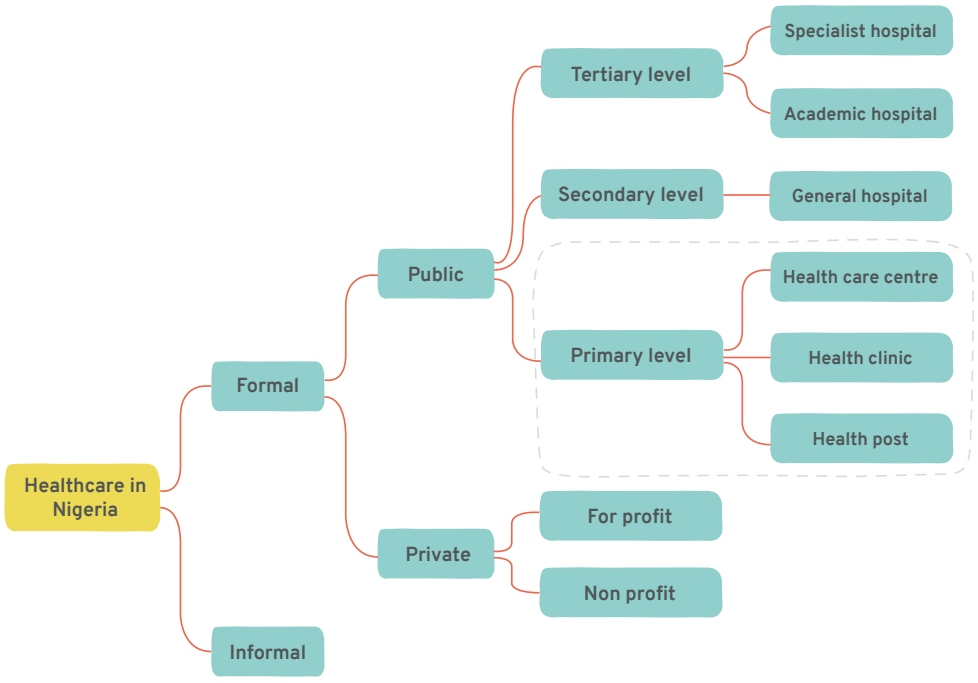


Figure 8. Overview of the healthcare system in Nigeria

Primary health care (PHC) is the lowest level of healthcare. PHC facilities make up 88% of health facilities in Nigeria. [75] There are three types of primary healthcare facilities; primary healthcare centres, primary health clinics and health posts, see table 9. [77] They differ in service provision, size and resources. PHC centres have a laboratory and a pharmacy.[78]

Every LGA has a **PHC coordinator** that connect PHC facilities to the state ministry of health (SMoH). She or he coordinates the staff that is posted from state level by the s**tate primary health care development agency** (SPHCDA).

Community health workers (CHW) are government employees that are connected to public PHC facilities. CHWs provide the ward minimum health care package (WMHCP), which are the PHC services that must be provided at ward level. [71]

CHWs are divided into three categories. **Community health officers** (CHO) receive the highest level of training and are based at PHC centres. They provide a range of health services and oversee health facility management. [71] **Community health extension workers** (CHEW) provide similar services, but focus more on preventive care and health education. They spend 40% of their time in the community and 60% at the health facility. CHEWs are supervised by CHOs. **Junior health extension workers** (JCHEWS) have received less training and provide a narrower scope of services. They spend 90% of their time in communities and 10% at the health facility. JCHEWs are supervised by CHEWs.[71]

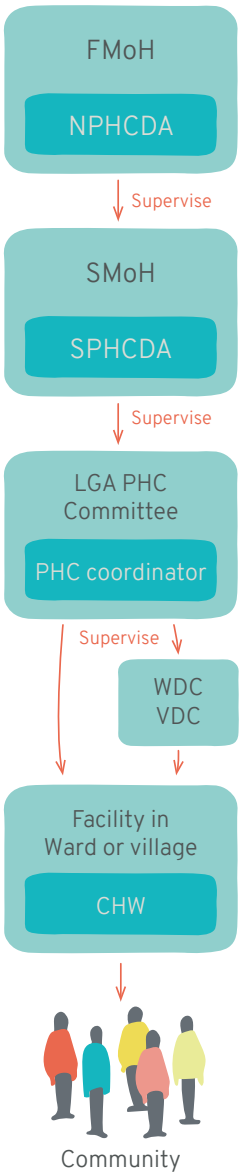


Figure 9. Overview structure of PHC [5]

Facility	Level of management	Number of facilities	Community health workers
Primary health centre	LGA	1 per ward (10,000 - 30,000 persons)	• 1 CHO • 3 CHEWs • 6 JCHEWs
Primary health clinic	LGA or WDC	1 per group of villages/neighbourhoods (2000 - 5000 persons)	• 2 CHEWs • 4 JCHEWs
Health post	VDC or CDC	1 per village or neighbourhood (500 persons)	• 1 JCHEW

Table 9. Types of health facilities; management, coverage and staff [5][10]

Data collection

The Federal Ministry of Health (FMoH) has selected 40 diseases and public health related conditions for the Integrated Disease Surveillance and Response (IDSR) system in Nigeria. Schistosomiasis is one of those diseases. [79]

When there is a case one of these priority diseases in a health facility, they have to report to the LGA national health management information system unit (NHMIS) using IDSR forms. These forms are send weekly and summarize the number of cases and deaths for each of the priority diseases and conditions. The LGA **disease surveillance and notification officer** (DSNO) collects and reviews the data form all health facilities in the area and sends the forms monthly to the state NHMIS unit. The state DSNO collects and reviews data from all LGAs in the state and sends it to national NHMIS unit, from where they send a yearly report to WHO [79] [71] [25] [7]

In case of a suspected outbreak, community health workers have to notify the LGA DSNO immediately. A sample needs to be collected for laboratory confirmation.

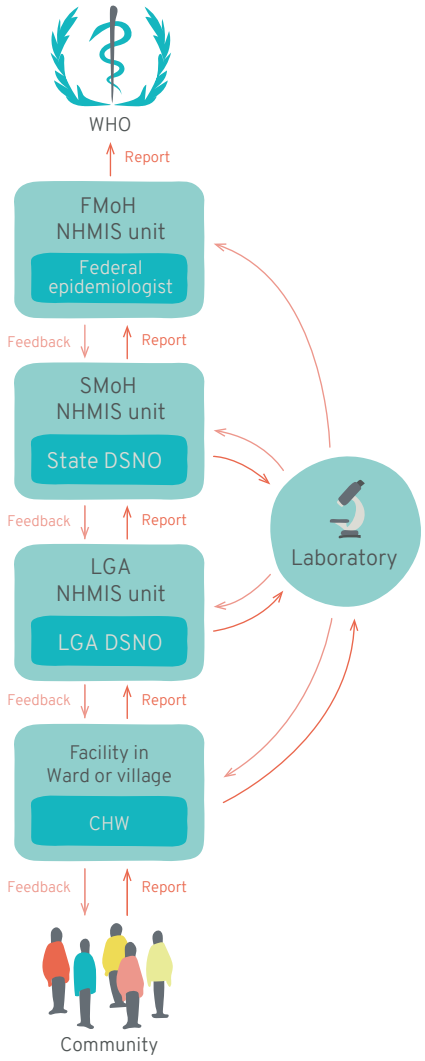


Figure 10. Information flow in IDSR system

Image 17. Map with disease outbreaks in Ibadan North West in LGA DSNO office

Informal healthcare system

The informal healthcare includes traditional healers, patent medicine vendors and community resource persons. The informal healthcare system plays an important role in health care provision since the providers are close to the community.

Traditional healers do traditional herbalism. Traditional healers help community members with physical and spiritual issues.

Patent medicine vendors sell medicine that do not require prescription, like paracetamol. They sell their goods in small shops. PMVs have basic health training, but do not perform any tests.

Community resource persons (CORP) are informal community health providers working in public and private sectors, often supported by NGOs. They provide services in the community and refer clients to health facilities.

7.3 Schistosomiasis in Nigeria

Nigeria has the greatest number of schistosomiasis cases worldwide [8][80]. An estimated 23.8 million school children are at risk of schistosomiasis. [55][81]. S. haematobium is the most dominant Schistosoma species in Nigeria, which causes 82% of all schistosomiasis infections [13]. In the last mapping exercise, 8.1% of the tested school aged children were tested positive for urinary schistosomiasis. There is no data available on the prevalence amongst adults.

Figure 11 shows the prevalence of S. haematobium infections in Oyo State amongst school children. Prevalence varies from 0 – 19,6%, with an average prevalence of infection of 5.4%. Of these cases, 76% were light infections, 14% were heavy infections. Out of the 33 LGAs in Oyo State, 31 were endemic and categorized as moderate or low prevalence. There were no positive cases tested in the LGAs Ido and Ibadan North West. [13]

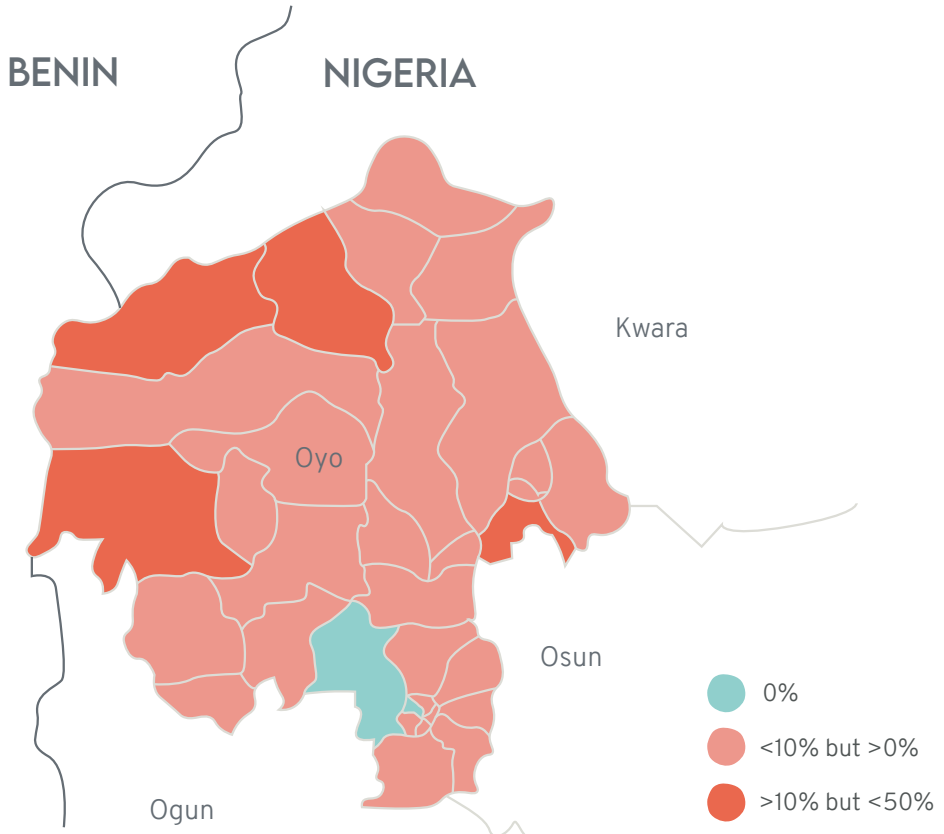


Figure 11. Prevalence of Schistosomiasis Haematobium per LGA in Oyo State amongst SAC in 2015

Government strategy

The national goal of Federal Ministry of Health is to **eliminate schistosomiasis as a public health problem by 2020**. The objectives are to establish control programs in all states and to achieve at least 75% PCT coverage in LGAs by 2020. [51]

Their strategies are mass drug administration for school aged children (SAC), health education and promotion of behavioural change, improvement of water supply and sanitation, and control of snails. [51] Table 10 presents the treatment guideline for schistosomiasis. [13]

Schistosomiasis is categorized as **preventive chemotherapy NTD**, since medicine for mass drug administration is available.

Furthermore, the FMoH uses active case detection and facility management as key strategies for case management, but so far it only covers 10% of the LGAs. [51]

Since not everyone is included in the control program and active case detection, **passive case detection** is very important. Passive case detection is when public health facilities wait for an individual to show symptoms and seek care.

Category	Prevalence	Action	
High risk	≥50%	Targeted treatment of SAC, once a year	Also treat adults considered to be at risk
Moderate risk	≥10% but <50%	Targeted treatment of SAC, once every 2 years	Also treat adults considered to be at risk
Low risk	<10%	Targeted treatment of SAC, twice during primary schooling	Praziquantel should be available in health posts and clinics

Table 10. Recommended actions by federal ministry of health based on prevalence by parasitological methods

7.4 Key takeaways

- Nigeria is divided into states, which are divided into local government areas
- Healthcare system is divided into formal and informal healthcare providers
- Formal healthcare is divided into primary, secondary and tertiary level, and into public and private facilities
- Community health workers provide healthcare at PHC facilities
- Disease Surveillance and Notification Officer collects data on priority diseases
- Informal healthcare providers include patent medicine vendors, traditional healers and community resource persons
- Nigeria has the greatest number of schistosomiasis cases worldwide
- The goal of the Federal Ministry of Health is to eliminate schistosomiasis as a public health problem by 2020
- Healthcare contexts for schistosomiasis in Nigeria are control & elimination program and case management.

Chapter 8

CASE MANAGEMENT

This chapter aims to answer RQ2: What are the current diagnostic practices and challenges concerning S. haematobium infections within the health care system in Nigeria? and RQ3: Who are the important stakeholders and what are their needs in diagnostics for S. haematobium infections and future implementation of a diagnostic device? A distinction has been made between case management and the control & elimination program. This chapter describes diagnostic practices, challenges and stakeholders for **case management.**

To explore case management in Oyo State, six health facilities, two communities and three local government areas in Oyo State were visited and different stakeholders were interviewed (see appendix D for an overview). This chapter will elaborate on the **journey of the infected individual** and the various healthcare options. Furthermore, an insight into the **diagnostic method and use of equipment** will be given. An overview of the stakeholders that are involved in case management is given and the chapter concludes by listing **barriers** that patients and health workers have to overcome in their journey towards diagnosis, cure and sharing the data.

Image 18. Activities in Dandaru river in Ibadan

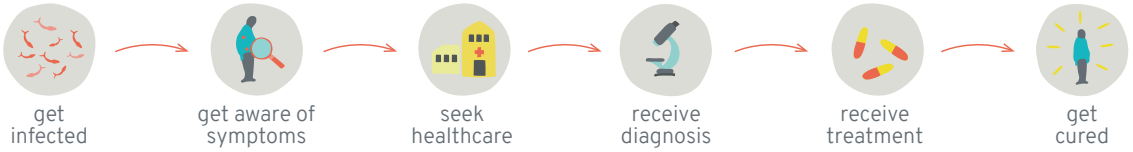


Figure 12. Steps in patient journey

Passive case detection is when public health facilities wait until an individual shows symptoms and seeks care. See figure 12 for the steps in the patient journey.

Infection

The first step of the patient journey is infection, which can take place in fresh water bodies. Lakes, rivers, ponds and streams are abundant in Nigeria. Moreover, there are man-made water bodies like dams and canals for the agricultural sector. [76] During the field trip several water related activities were observed. Community members were bathing, doing laundry and cleaning motorcycles in streams. Children were swimming in the water, see image 18.

In urban areas, the use of water from rivers and streams is most common among the poor population. In rural areas, streams provide drinking water for the community since they often lack wells or other sources of water. Farmers and fishermen come into contact with fresh water during their work. In some parts of Ibadan, there are Hausa communities that migrated from the North of Nigeria. According to a UCH researcher, they work as farmers and often bring infections back to the community after holidays to the North. Furthermore, a community mobilizer mentioned that some church members bathe in the streams as a traditional ritual.

In addition, there is a lack of adequate sanitation. In rural areas, community members sometimes do not have toilets at all. At the visited school grounds, the toilets were vandalized by criminals. As a result, the disease can spread fast.

> 'The farmers, fishermen and others in the rural areas are more exposed, because the same water they urinate into is what they drink and walk through'
> LGA NTD officer Akinyele

Awareness of symptoms

The symptom that is most well-known and alarming for people is bloody urine. Infected individuals take action once they – or their parents - discover that there are a few drops of blood in their terminal urine.

According to a physician from KDF and interviewed community mobilizers, people with symptoms often seek for advice from their surroundings first. They often consult **community mobilizers** for health related advice when they are feeling sick. When a case is serious, community mobilizers advise to visit PHC facilities or a hospital to get checked and diagnosed. The community mobilizers that were interviewed did perform RDTs, but did not administer drugs, even though they can provide Deworming medication. [71] Their education level is limited and knowledge is mainly based on experience.

There are informants in the community that play a role in active case finding, increasing awareness and health seeking behaviour. **Community mobilizers** go around the community, discuss issues and take action when they see someone showing symptoms. Furthermore, **teachers** have an advisory role in the community too. The interviewed teachers mentioned that if they observe that something is wrong with a child, they advise parents to take their child to the hospital.

LGA NTD officers are CORPs that create awareness on neglected tropical diseases (NTD) in the community. They focus on surveillance and executing NTD awareness programs. They sensitize community leaders to report suspected cases to them. LGA disease surveillance and notification officers (DSNO) have a few informants in each community. These informants communicate any health related issues in their community to the DSNO.

Seeking healthcare

Infected individuals can be divided into five groups;

1. People who go to an informal provider
2. People who go to a public PHC facility
3. People who go to a public hospital
4. People who go to a private facility
5. People who do nothing

The decision they make determines the paths in their patient journey. Variables that determine where sick people go are **health condition, levels of education, awareness of disease, geographical restrictions, relationship to health workers, history of infection** and **socioeconomic status**

8.1 Informal health providers

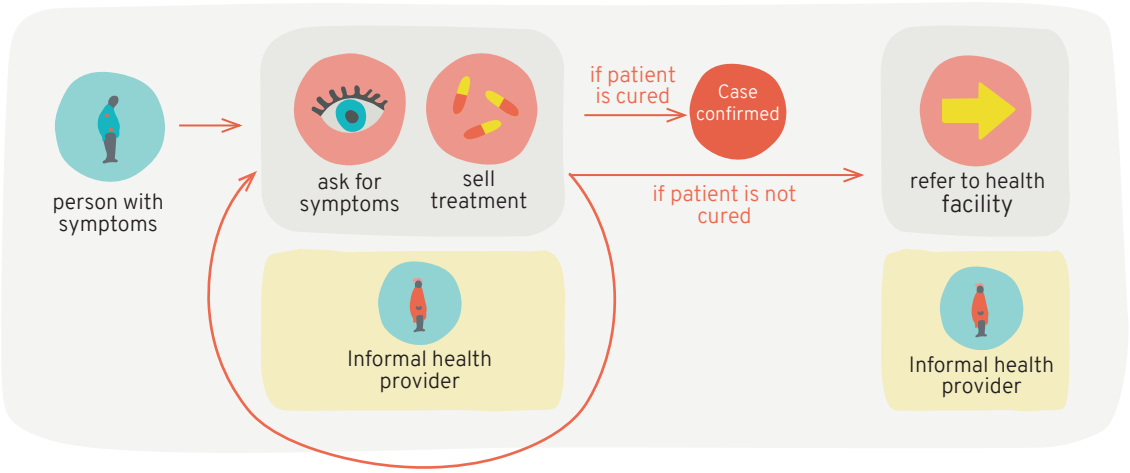


Figure 13. Process map for case management by PMV or traditional healer

Most infected individuals go to informal healthcare providers. **Patent medicine vendors** can be found on every corner and sell medicine without prescription for a low price. They have limited knowledge on healthcare, so they do trial and error based on symptoms. One PMV was interviewed during the field trip; she refers customers to a health facility if there are no improvements after a few days or when people come with severe illnesses beyond what her drugs can cure. In case of individuals with bloody urine, she sells antibiotics.

Traditional healers treat illnesses with a , in their eyes, spiritual cause. For other illnesses they instead provide a relieve in the form of herbal concoctions, since they do not have the means to test and identify the exact disease. During the field trip, one traditional healer was interviewed. He gives herbal concoctions when someone suffers from bloody urine. In case there is no improvement after a few days, the patient will be referred to a health facility. The healer mentioned that he also refers patients to health facilities to find out the effectiveness of his treatment.

8.2 PHC facilities

When an infected individual visits a primary healthcare facility, she or he will be examined by a community health worker (CHW). According to the national standing orders, CHW should asks for symptoms, patient history and whether the patient has a history of swimming in streams.

If the individual complains about blood in their last stream of urine, the guidelines for CHO and CHEW instruct that examination should include urine macroscopy. If available, microscopy should be included as well. When blood or ova are detected in urine, the clinical judgement and treatment depends on the age group. An overview of these is provided in table 11. [82][83] When adults complain about blood in urine, bladder cancer can be suspected as well, in case they will immediately will be referred. [82] JCHEWs always have to refer patients when they suspect schistosomiasis after complaints of bloody urine.[83] Community health workers can administer and/or provide Deworming medication. [71]

According to the NHMIS protocol, CHWs at health facilities should immediately notify the LGA disease surveillance and notification officer (DSNO) when a case of schistosomiasis is suspected. [79] (see chapter 7.2). The LGA DSNO should come to the facility collect a urine sample and take it to an approved laboratory for microscopic examination. After the case is confirmed, the DSNO gives the result back to the infected individual, so she or he can be treated at the PHC facility.

Observations in the field

In reality, the guidelines are not always followed. Most of the interviewed community health workers referred their cases immediately to the hospital.

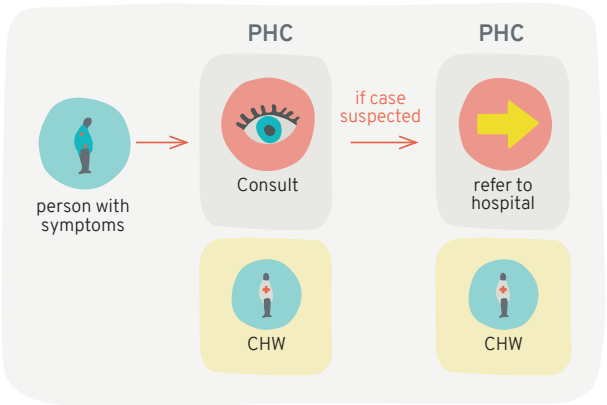


Figure 14. Process map for referral

One lab technician in Ibadan North PHC centre said that she once performed urine analysis in the PHC laboratory a long time ago, but that it is very uncommon. In the laboratories of the other PHC centres, they never perform urine analysis for urinary schistosomiasis.

Age category	Classified condition	If case is suspected	After treatment
Children 1-5 y/o	Severe condition	Treat with cotrimoxazole; encourage fluid intake	If condition did not improve after 3 days; check for eggs by microscope; if positive, treat with metriphonate
Children 6-12 y/o	Moderate condition	Treat with metriphonate for 6 weeks or 2 tablets of PZQ	If no improvement, refer to hospital
Adolescents > 12 y/o	Moderate condition	Check for eggs; if positive, administer metriphonate for 6 weeks or PZQ 60 mg/kg/day in 3 doses or 2400 mg/4 tablets	Review after 2 weeks, if no improvement, refer to hospital
Adults	Severe condition	Treat with PZQ 1200 mg directly and then 600 mg daily x 5 days	

Table 11. Guidelines according to national standing orders for CHEWs and CHOs; details can be found in appendix F [66]

Image 19. PHC centre in Ibadan North

In Ibadan North, there were some suspected cases reported to the LGA DSNO, who came to collect urine samples. These patients were kept in the PHC, where they received symptom based treatment before case confirmation. After confirmation, the health worker knew whether the right treatment was administered. Else, it will be changed. See figure 16 for an overview.

In Akinyele, the DSNO did not pick up any samples. According to a CHO in Akinyele, signs and symptoms were combined with the patient history and suspected cases are treated clinically without laboratory confirmation, see figure 15. The case was documented on the IDSR form and send to the DSNO.

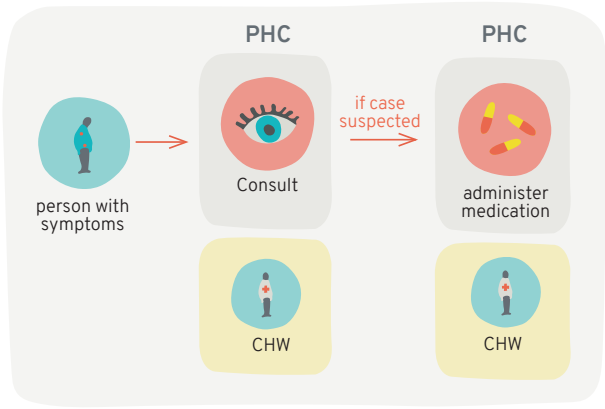


Figure 15. Process map for treatment administration

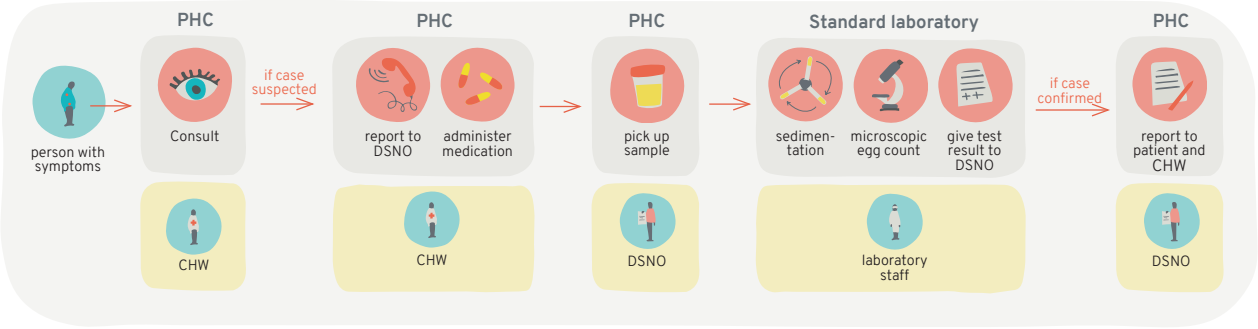


Figure 16. Process map for cases reported to DSNO

8.3 Private facility or hospital

The procedure for hospital is similar to private health facilities. When an infected individual visits the facility, she or he will be examined by a **physician** and asked about the persons history and symptoms. If a case of urinary schistosomiasis is suspected, a urine examination from the laboratory is requested. The patient is sent to the laboratory inside the hospital or the private facility, or referred to a private laboratory.

According to the lab director from Giftrolab, some hospitals call private laboratories to pick up samples. A messenger from the lab will go to the hospital to pick up the sample and delivers the results back to the hospital. Some patients go to a private laboratory immediately without referral.

The **laboratory staff** is divided into scientists, technicians and assistants. Their education levels, responsibilities and work differ. In general, lab scientists and technicians do the diagnosis and lab assistants collect samples and prepare slides. The laboratory staff performs the test that the physician requests and does not interpret the results.

After this, the patient brings the urine sample to the lab, after which she or he usually waits at the facility. When the test is finished, the lab assistant gives the result to the patient. The patient brings the results back to the physician, who interprets the results, makes a diagnosis and prescribes treatment. The patient pick up the treatment at a **pharmacy.** A simplified overview of the process is visualized in figure 17.

Laboratory procedure

The test procedure was identical in the two visited private laboratories. After urine collection, the urine is checked for **macrohaematuria** and **microhaematuria.** Thereafter, 10 ml of the sample is **centrifuged** and a glass slide is prepared. During the field research, One laboratory technician sedimented the sample by gravity for 30 minutes, since their centrifuge was not functioning at the time of visit. None of the lab staff used filtration as sample preparation method.

After sample preparation, the sample slide is examined under a **microscope**. Usually, the physician requests a broad urine examination, where the observer looks for any object in the urine. Sometimes, doctors ask to specifically look for schistosoma ova. In case the reagent strip for microhaematuria is positive, the observer will look for haematuria as well. The **quantitative results** are written down on paper. In the field research, one of the laboratory scientists mentioned that if someone else than a scientist does the test, a scientist might check the results before they are given back to the patient.

The required time to perform urine analysis varied per interviewee. One of the laboratory technicians mentioned that centrifugation takes 5 minutes and microscopy 3-5 minutes, while an other laboratory assistant said that microscopy takes 10-15 minutes and the whole process 45 minutes. They mentioned experience of the observer and availability of electricity as main influences on the time to result.

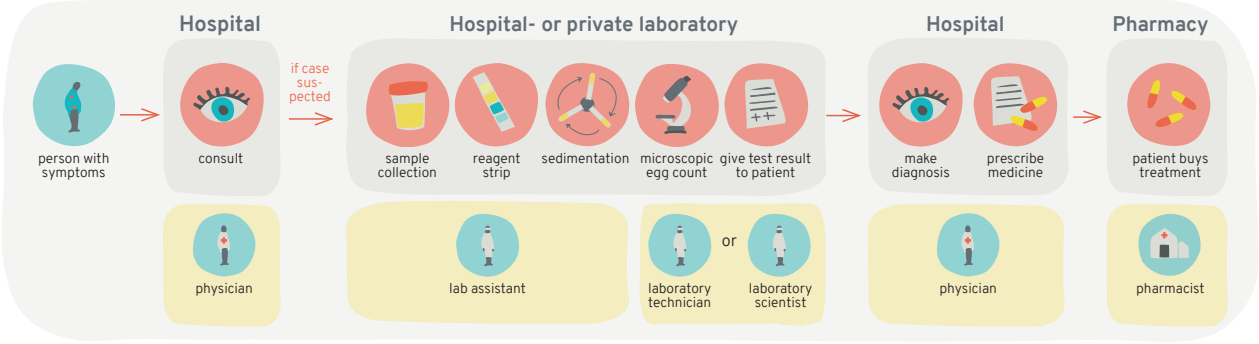


Figure 17. Process map for case management in hospital or private facility

8.4 Equipment journey

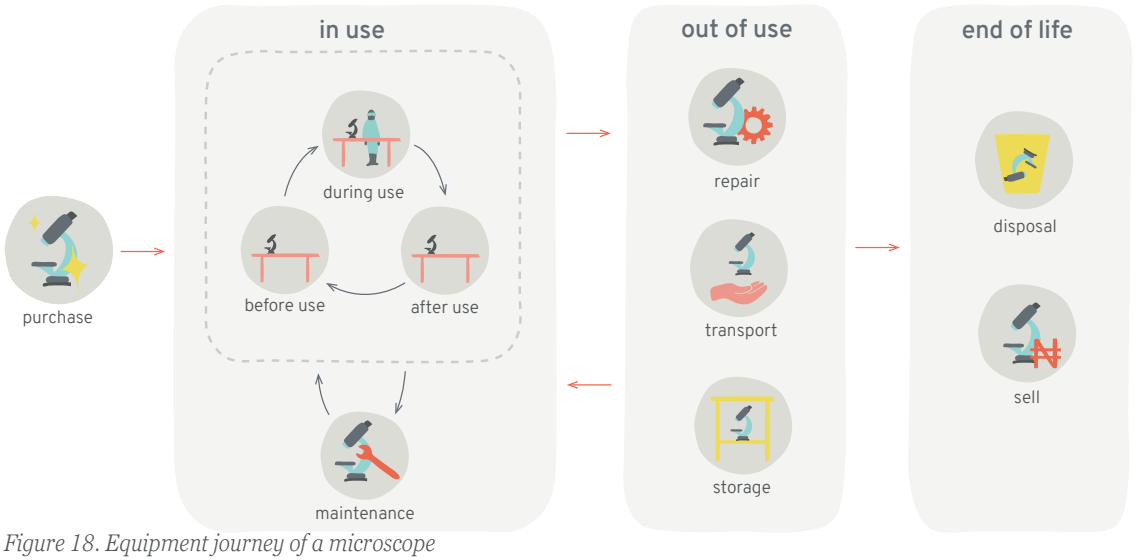


Figure 18. Equipment journey of a microscope

Research into stages of the life of laboratory equipment gives insights in the product use, use environment and decision making. The journey in figure 18, is based on the equipment from the PHC laboratories and the private laboratories. Insights from the equipment journey were used to list health worker barriers and find opportunities for improvement of equipment.

The equipment used for urine examination are **centrifuges** for sedimentation and **microscopes** for egg count. All the laboratories that were visited during the field trip had at least one functioning microscope and centrifuge, see appendix E. In the two private laboratories, they performed urine analysis with the equipment. In the laboratories of PHC centres, the equipment was only used for other tests, mostly malaria.

New equipment

An average microscope costs around 100,000 naira, equal to €250. Deployment of new equipment is usually demand driven. In public facilities, equipment is requested from the **LGA PHC coordinator**. She or he forwards the request to the state primary healthcare development agency (**SPHCDA**), who is responsible for the supply of resources. In private facilities, the head of the facility requests new equipment from the donor or purchases it her or himself. In one public PHC centre, there was a donated microscope.

According to the interviewed lab staff, new equipment is required when current equipment malfunctions or when there is a need for increased test capacity. In the private labs, they replaced some of the old microscopes with new and stronger models, since they made the examination for the lab staff easier and faster, even though the old microscopes were still functioning. In another private lab they received training from a biomedical engineer when new equipment arrived.

Equipment in use

The microscopes in the visited laboratories were placed in a permanent spot on the workbench, except for the PHC laboratory in Akinyele where the microscope was stored in a box to protect it from dust, see image 21. The environmental circumstances in the laboratory varied, depending on the cleanliness, the availability of air conditioning, windows and electricity.

Before use, the microscope is uncovered and cleaned from dust with lens paper. In one of the private labs they performed a daily routine quality check, where all machines were powered on and checked.

Image 20. Microscope in use in Gifrolab

Image 21. Microscope in box in PHC centre Akinyele

Image 22. Old microscopes out of use in Giftrolab

These microscopes are usually operated by the lab scientists or technicians. The interviewed lab assistants know how to use the device, but do not perform any tests. One of the lab assistants mentioned that potential problems are breaking of the coverslips or breaking the glass slide when the objective accidentally touches it.

In case of a power cut, KDF private PHC centre and Giftrolab private laboratory use generators to provide electricity. ARFH private laboratory used a battery for this, which could power the microscope for 2-3 hours. In case an external uninterruptible power supply is available, it will only be used for machines that perform tests consuming the reagent when the power goes off and is not restored immediately.

At the end of the day, the microscope is turned off and covered.

In ARFH private lab, general maintenance is done every few months. A biomedical engineer visits, checks the devices and does necessary calibration when needed.

Equipment out of use

A microscope is taken out of use when it is broken or replaced by a more modern device. Repair of broken equipment in ARFH private lab is done by a biomedical engineer from the supplier of the equipment.

A lab scientist in Giftrolab mentioned that microscopes do not break often. By the time they break, they are usually old and it is better to replace them with a better and newer microscope. Furthermore, for him it was easier to request a new microscope than to repair one. He stored the old microscopes in his lab, instead of disposing them, see image 22. At ARFH private laboratory, they dispose old equipment or sell parts as scrap.

Image 23. Children in rural community Camp David

8.5 Patient stories

During the field research, we spoke to five people who were the parent or guardian of someone who suffered from urinary schistosomiasis in the past. The stories in figure 19 illustrate the different paths that infected individuals go through in an attempt to get cured. Since these are perceptions of the storytellers instead of the words of the patient her- or himself and some background details are missing, these stories are merely used as inspiration for listing patient barriers. The extended version of each story can be found in appendix G.

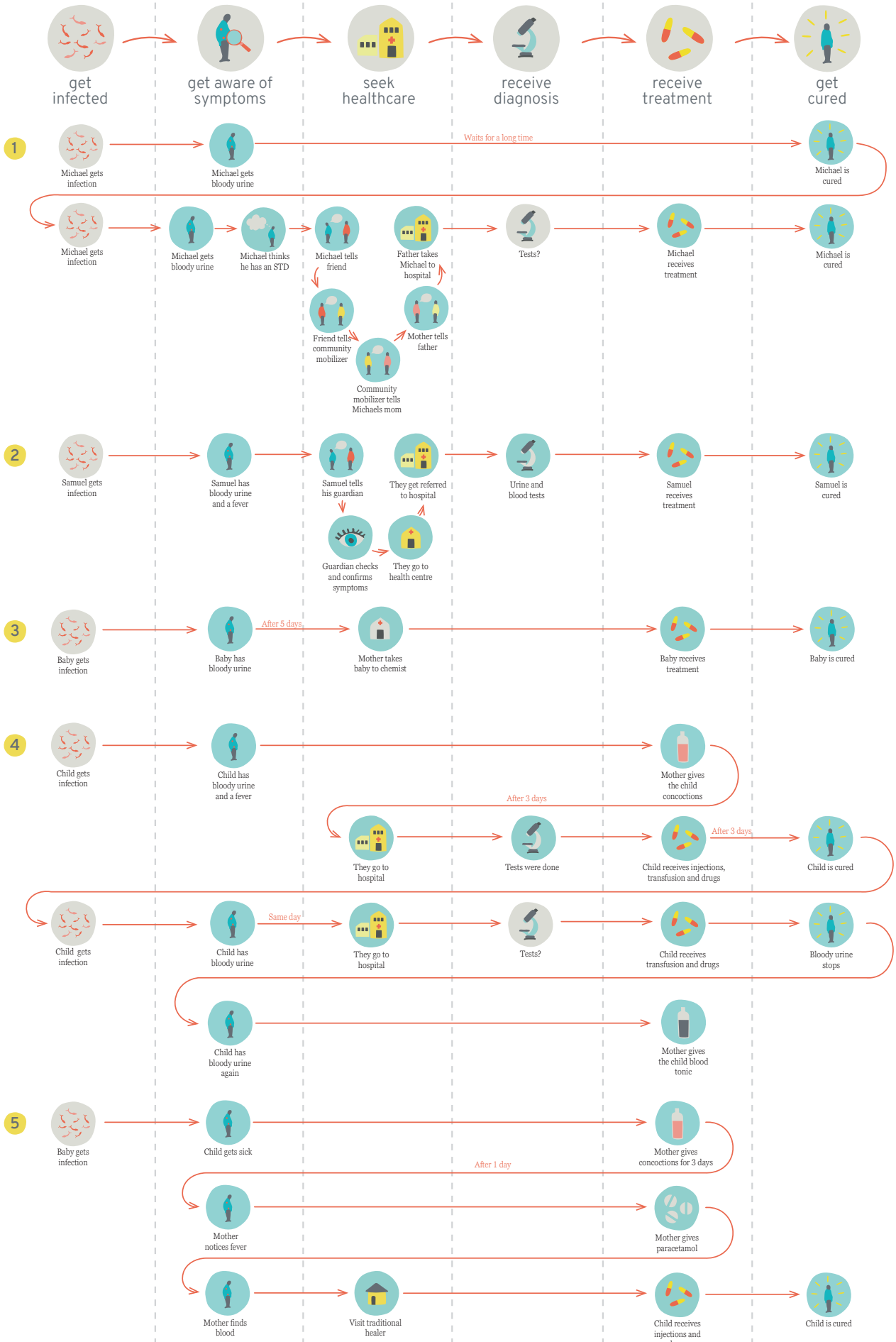


Figure 19. Patient stories from the field

8.6 Challenges for patients

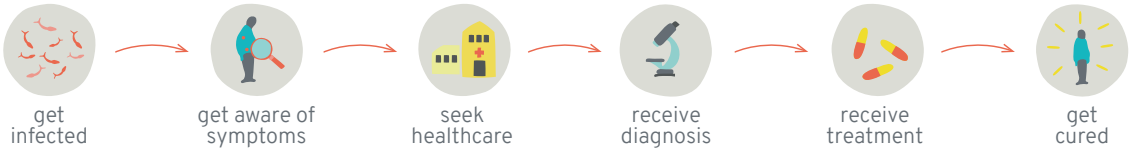


Figure 20. Patient journey

There were very few cases of urinary schistosomiasis in the visited health centres. The interviewed health workers saw a few cases a year, see appendix E for the exact numbers, while the disease is endemic in all visited LGAs except Ibadan North West. To understand why there are so few infected individuals that are diagnosed in health centres and reported to the DSNO, the barriers for patients in each step in the patient journey are listed. To understand the main challenges for patients in case management, the barriers are categorized into five categories; acceptability, accommodation, affordability, accessibility and availability. [91]

- Acceptability
- Accommodation
- Affordability
- Accessibility
- Availability

The barriers were gathered during interviews with community members, community health workers, laboratory staff, community resource persons, PHC coordinators and DSNOs. Some insights were gathered during interviews with the state WHO TB coordinator and researchers from UCH. Some barriers were extracted from the patient stories in chapter 8.5.

Barriers to become aware

Once people are infected, are not always aware of their condition. This can have several reasons.

Community members have **little knowledge on Schistosoma infection and transmission**, since there is no sufficient health education program. The six interviewed secondary school children all received health education, but did not know that they could get infected from contact with water. According to the LGA NTD officers, there is not enough material to create awareness, since there are no posters of leaflets for schistosomiasis. '*Due to the name attached to the program; neglected tropical diseases, the program itself is affected*' Furthermore, two CHWs agreed that increasing the awareness is the best way to improve diagnosis. One DSNO emphasized that to increase the number of reported cases, the sensitization should include the importance of reporting, so he will be notified when there is a case suspected in the community.

Infected individuals **do not immediately present symptoms after infection.** It takes weeks before schistosomes have matured and excrete the eggs that cause symptoms. Some infected people even remain asymptomatic. [16]

Furthermore, blood in urine is **not always perceived as a symptom of medical condition.** According to the state WHO coordinator and an UCH researcher, there are some areas and ethnic groups where bloody urine is seen as boy menstruation and a sign of adulthood for men. The researcher said; '*For some people, it is a cultural thing; they truly believe that you are from that community if you have it; if you do not they will begin to have*

doubts about your heritage' Two interviewees mentioned that in some communities, bloody urine is seen as a curse caused by spiritual forces or as a result of witchcraft. They will visit a traditional healer instead of a formal health facility.

Barriers to come to action

Not all symptomatic individuals seek help from formal healthcare providers. For this, the following reasons were identified.

Some symptomatic individuals are **ashamed to tell anyone** about their bloody urine. Painful urination or have coloured urine can be mistaken for a symptom of an STI, see patient story 1. Furthermore, according to a PHC coordinator, some people have negative ideas about bloody urine, since they associate it with dogs. Multiple interviewees mentioned that some symptomatic individuals have a **fear of being stigmatized** by other members of the community. It is very important that there is a good trust relationship between the community and the health workers to increase health seeking behaviour.

Community members often seek advice from their surroundings before they visit a health facility. When they ask someone with power in the community, the advice is usually followed. The physician from KDF said '*If I speak to a friend who is a pastor and he asks me to come to church for healing prayers, I will go to the church*.' Some people get **wrong advice** when they consult informal health workers with bloody urine, due to their low level of knowledge. The traditional healer assumed that bloody urine is caused by having sex with a woman on her period. One community mobilizer assumed the bloody urine was caused by a STI. Instead of referring them to a health facility, the informal health workers advised their patients to change their sexual behaviour.

Often, people prefer to go to **someone they know personally and also trust**. They go to a traditional healer, because he is close to the community members. According to a school principal, hospitals still seem scary for people in the community, they are especially afraid that they will receive injections. A PHC coordinator mentioned that this fear originates from superstitious beliefs or conspiracy theories about injections. One LGA NTD officer heard of cases of people with phobias for health centres who close their eyes when they walk past the facility. She tries to be approachable, by being friendly and simplifying information, so people are not scared to go to PHC facilities. The PHC coordinator argues that the attitude of hospital staff and community health workers needs to be improved. A better atmosphere will make them more receptive for people, resulting in more people that will come to them. A **good relationship between the health worker and community** is important. A community mobilizer and CHEW said '*The PHC is a bit far away from their places, but they still come around because of the relationship we have with them*.'

Furthermore, ignorance is a big problem. Some symptomatic individuals **assume that diagnosis and medical treatment is not required** to stop their bloody urine. One teacher said '*They believe more in the traditional health care and some feel that it is more superior than orthodox or modern medicine. They believe because it's how they've been doing thing it should continue as thus'* There are examples of patients where the symptoms stopped after drinking herbal concoctions instead of medical treatment and cases that were cured without taking any treatment, see the patient stories in chapter 8.5. In addition, people **wait a long time before they visit a hospital**. According to a JCHEW, as long as the disease is mild they will go to local drug sellers. Once the symptoms become severe, they come down to her clinic. The secondary school principal said '*only when there are complications they seek for help. This is why the death rate in the villages is higher*'. Since many Nigerians are very religious, some people think that whether symptoms stop is beyond control of any health worker; it is in the hands of god.

According to the interviewed health workers, community members first go for the most **affordable** healthcare option. Consults in

public health facilities are free, but people have to pay for the medicine and tests. Therefore, instead they visit informal health care providers. PMVs sell drugs for as low as 20-50 naira and the interviewed traditional healer provided free services to the people that could not afford to pay him money.

A community mobilizer mentioned that people look for **immediate solutions** to their problems, so they will buy herbs or visit PMVs. Informal healthcare providers are more widely spread and accessible. In urban areas, there are PMVs on every street corner.

Distance to health facilities is not a problem in the city, but is considered to be the main barrier in rural areas by Akinyele's community mobilizer. *'The road is really bad especially during the rainy season and transport is expensive'*. The dirt roads are often **inaccessible** for cars and travelling is **time consuming and costly.** According to a PHC coordinator, there is no sufficient amount of health facilities in rural areas due to **government ignorance.** The JCHEW in the health clinic mentioned that sometimes people in rural areas have to walk for hours to the nearest facility. A two hour bike journey costs around 1500 Naira. Not only the journey itself is costly, it also means that that person cannot work and earn money that day.

Barriers to get diagnosed

Once a patient seeks healthcare, there are several barriers to receiving a diagnosis.

There is a **shortage of community health workers** on primary healthcare level. According to the PHC coordinators, there is not enough staff posted from the SPHCDA, so there are a lot of volunteers working in the community. Due to limited availability of CHEWs and JCHEWs, there is barely time for community based services and home visits in Ibadan North and Akinyele. A PHC coordinator said that people prefer to go to a hospital immediately instead of PHC facilities, because they know that doctors are available there. Multiple interviewees mentioned that there are enough skilled people, but they are not recruited by the government.

Logistics is considered to be a big problem. Even when the patient has arrived at a formal healthcare facility, there are **logistical challenges** to get diagnosed for schistosomiasis. According to a PHC coordinator, people do not go to hospitals because they have to pay for the transport fare from their house to the hospital. The community mobilizer in Akinyele said *'They want immediate attention and asking them to go to another hospital is like adding salt to their injury. They will tell you that they want to go and look for money but they will not go, this is why primary healthcare is very important; it is at their doorstep'*. If people go to a PHC they do not want to be referred to a laboratory or hospital, it is too time consuming and the insecurity of what will happen is stressful.

In hospitals and private facilities, all steps of the **testing and treatment take place at a different location**. The patient has to get sample bottles at one location, then go to the lab, then walk another distance to submit the results. If the tests involve multiple samples, they will all be taken at different places in the hospital.

Furthermore, the **price of tests in the lab is too high**. Patients usually pay around 300 naira for urine examination. However, as can be seen in the patient stories in chapter 8.5, a lot of **unnecessary tests** are done which raises the costs. A physician mentioned that patients do not know the cost of a test when a doctor requests it. They have to go to the test location to find out how much it will cost.

Barriers to receive treatment

Financial constraints are mentioned as one of the main problems to receive treatment. *'Everybody wants to be cured but if they do not have a way to pay for treatments, then their hands are tied'*. In the pharmacy that was visited during the field trip, the price of 6 praziquantel tablets is 500 naira. However, in the patient stories we saw that often multiple treatments or unnecessary medicine are prescribed. In the health clinic, the patient does not have to pay if the drugs are available.

Praziquantel is **not available** at PMVs, since it needs to be prescribed. Praziquantel is on the primary health essential drug list for PHC centres and clinics. [77][62] However, the medicine was not available at the facilities. In KDF PHC centre, praziquantel is not available since it is so rarely used, that it will expire on the shelf. They refer people to a pharmacy instead. The NTD officer in Akinyele mentioned that the drugs were only available during the implementation of the control program implementation of the Deworming day. '*After the exercise, there will be no more praziquantel. It will not be available at the LGA level, talk less of the PHC facility*'.

Barriers to get cured

It is possible that patients do not get cured from treatment. This can happen when treatment is prescribed to treat symptoms or on presumptive grounds, when a suspected case is not confirmed. Due to low awareness, health workers might prescribe the **wrong treatment.** One CHEW mentioned that she would prescribe antibiotics in case of a patient with bloody urine. Furthermore, when praziquantel is not taken in the **right dosage** for the infection intensity or the patients weight, it might not cure the disease.

Often, there is **no check-up** after the health worker prescribed treatment. The physician in KDF mentioned that they only do check-ups when a patient comes back to the facility by itself. In the health clinic, they do check-ups because they know the people in the community. According a WHO coordinator, a confirmation of cure would improve case management for schistosomiasis.

Image 24. Domestic tasks in Camp David, Akinyele

8.7 Challenges for health workers

Figure 21. Health worker journey

Similar to the patient barriers in chapter 8.6, this chapter lists the challenges for the health workers to confirm and report cases of schistosomiasis, based on interviews in the field.

Barriers to suspect a case

Community health workers **do not have adequate knowledge** about urinary schistosomiasis; there is no emphasis on schistosomiasis during their training since it is not a common threat. One PHC coordinator said '*Now, when you challenge any of my staff and you ask them how many species of schistosomiasis they have, hardly will anyone tell you*' . Multiple interviewees agree that the staff needs to be educated and requires further training. According to dr Keshinro from LUMC, some community health workers in Nigeria have **ego issues**. They pretend to be doctors and work beyond their education level and limits and perform practices that they are not trained to do. Health workers do not want to admit that they do not know something. Instead of referring the patient, they administer the wrong treatment.

Health workers **assume low prevalence,** especially in urban areas. Since they do not see a lot of cases, they conclude schistosomiasis does to occur in their area. The mentioned reasons for the decreased number of cases are increased awareness, changed water related behaviour and the control program.

Furthermore, **light and asymptomatic cases of schistosomiasis are often missed**. According to the health worker guidelines, a case should only be suspected once someone has bloody urine. [82] The medical doctor from KDF mentioned that health workers will only start thinking about schistosomiasis when a patient had contact with water or has bloody urine. '*We have a lot of endemic diseases, so unless the patient has the signs and conditions, it would be tough*'. Since some people will never get terminal haematuria, a case might never be suspected. According to another medical doctor, urine microscopy should be requested when a patient comes with dysuria, otherwise diagnosis might be missed.

Health workers often **misinterpret schistosomiasis symptoms**. Katayama fever is interpreted as symptoms for malaria and not associated with schistosomiasis. According to Akinyele's PHC coordinator, coloured urine can be mistaken for a symptom of an STI, jaundice or malaria.

> 'We lack the man power and the skills to diagnose schistosomiasis, this might be due to the fact that we are not looking for it as we do not find what we are not looking for'
>
> WHO TB officer Oyo State

Barriers to test

According to the DSNO in Ibadan North, there is a **limited number of standard laboratories at PHC level**. As a result he has to bring a sample to UCH when a case is suspected. '*If we had labs we would be conducting these tests ourselves and we will be able to make diagnosis and be able to make laboratory confirmation* ' There were laboratories in the three visited PHCs, but they did not perform urine analysis for schistosomiasis. The lab staff in PHC laboratory in Ibadan North mentioned that the environment in their lab is unsuitable for urine examination. The place is either too small, dusty or the light is not good. Therefore, patients are referred to hospitals to get tested.

There is a **shortage of both manpower and skills in the laboratories**. The lab staff in PHC laboratories is trained to perform certain simple analyses; they mostly do malaria tests. Lab assistants are not allowed to perform tests themselves and have to refer patients or wait for a laboratory scientist. According to the head of Giftrolab, even in the private sector there are a lot of labs that do not employ qualified people to handle the samples. At UCH, the tertiary hospital in Ibadan, absence of trained staff was also considered a challenge. Two interviewees mentioned that the laboratory staff is skilled enough to perform schistosomiasis analyses, but they might require a refresher.

One of the main challenges in diagnosis is the **lack of equipment**. The NTD officer in Akinyele said '*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*' Microscopes, dipsticks and ancillary supplies for sample preparation should be available at PHC centres.[78] In rural areas, the availability of microscopes is limited due to **high cost** and **dependency on donations**. The JCHEW in the rural clinic said *'At times, when we don't have equipments, we call our boss and ask to either refer the patient or if he is on his way down, he would bring the equipments from Moniya with his bike*' Repair of broken equipment was only done in private facilities. Public facilities request equipment from the PHC coordinator, who forwards the request to the state. The state primary healthcare development agency (SPHCDA) decides whether new equipment is supplied to the facilities, which can be a long and bureaucratic process.

Availability of electricity is limited due to frequent and long lasting power cuts. In rural areas, there is no electricity at all. Since microscopes and centrifuges are electricity dependent, this negatively influences the test opportunities. All visited facilities owned a generator, but only used it for essential purposes. Multiple interviewees mentioned the absence of a power supply as the main reason why microscopes are not used.

Barrier to diagnose

During the interviews, there were no challenges mentioned in making the diagnosis. However, there are some **limitations to microscopy** as a method, listed in chapter 4.2. Microscopy has limited sensitivity and is prone to human error, which can result in a wrong diagnosis.

Barrier to administer treatment

Praziquantel is on the primary health essential drug list for primary health care centre and health clinics. [92][78] However, the medicine was **not available** at the visited facilities, so the patients have to be sent to a pharmacy.

Barrier to report data

The disease surveillance and notification officer in Ibadan North thinks there is **under reporting of cases.** According to the WHO coordinator, the surveillance for schistosomiasis in Oyo State is poor. Since there are 42 diseases selected in the national health management information system (NHMIS), they prioritize some. He thinks that **schistosomiasis is not prioritized** since it is not of direct public health importance, so cases are not reported.

According to the DSNOs, not all **facilities are precise with filling in their IDSR forms** and reporting them weekly to the LGA DSNO. Since this is a manual process and requires a lot of steps, the data that is collected at state DNSO and FMoH NHMIS unit does not represent the actual number of cases.

Private facilities are not obliged to report their cases to the DSNO. In Ibadan North, only the big hospitals with laboratories report cases. Many private laboratories are not associated with hospitals and do not report.

A case of schistosomiasis is **only reported when it is confirmed by microscopy** in an approved laboratory. In KDF PHC centre, not all suspected cases are communicated to the DSNO since the staff is too busy and the reporting of cases requires a whole protocol. It is easier to treat or refer the case instead of informing the

DSNO. According to the PHC coordinator in Akinyele, it takes a very long time to connect with the DSNO, go to UCH and receive results.

Instructions for community health workers do not correspond with the NHMIS guidelines. This results in different ways in which health workers handle their suspected cases. Some will treat the patient without reporting to the DSNO, others inform the DSNO when a case is suspected, so she or he can pick up the sample and bring it to a laboratory.

8.8 Stakeholder overview

This section gives an overview of the involved stakeholders in case management on primary healthcare level. Based on insights from the field research, this paragraph describes their current role and needs in case management and their potential role in a future scenario with new diagnostics.

The healthcare enablers from state and national level are not included, since they were not interviewed in the field. Most important stakeholders on higher levels are the **Federal Ministry of Health** (FMoH) that develop policies and strategies and the **State Primary Healthcare Development Agency** (SPHCDA) who provide resources to primary healthcare level.

Healthcare receivers

Community influencers

Healthcare providers

Community health worker

I want to help all sick community members to get healthy

Strengths + Weaknesses
+ Accessible for community
- Limited resources
- Limited test experience

Potential role
Performing test in PHC, active case detection

Physician

I want to cure all the sick people that come to me

Strengths + Weaknesses
+ Educated
- Limited test experience
- Only present in few PHC facilities

Potential role
Performing test in PHC, interpreting results

Laboratory staff

I want to have the resources to perform requested tests to the best of my ability

Strengths + Weaknesses
+ Experience with tests and sample preparation
- Follows orders

Potential role
Performing test in PHC laboratory

Informal healthcare providers

Traditional healer

I take care of my community

I try to cure people while making money

PMV

Strengths + Weaknesses
+ Trusted by community
- No formal health education

Potential role
Refer patients to PHC, increase awareness

Healthcare enablers

Disease surveillance and notification officer

I want to get all suspected schistosomiasis cases confirmed

Strengths + Weaknesses
+ Contact with facilities and communities
- Busy
- Not directly involved in providing care

Potential role
Enabling case confirmation at PHC facility

Primary healthcare coordinator

I want all the facilities in my LGA to have sufficient resources

Strengths + Weaknesses
+ Contact with facilities
- Not directly involved in providing care

Potential role
Providing equipment to PHC facilities

8.9 Gaps in case management

This paragraph summarizes the insights from the context research. Healthcare guidelines are combined with insights from the field research on diagnostic practices and stakeholder barriers, into **gaps in the healthcare system**.

Currently, there are a lot of challenges for health workers and patients in case management. This leads to a limited number of confirmed schistosomiasis cases. Because of this, prevalence is underestimated and the government interest is low. As a result, the government provides little funding for awareness programs and limited resources for health centres. Consequently, there are few suspected cases that are confirmed – it is a vicious circle (see figure 22).

The gaps were validated and enriched during a co-creation session with public health students in Nigeria, see appendix H. Filling (a few of) the gaps in the healthcare system might break the circle.

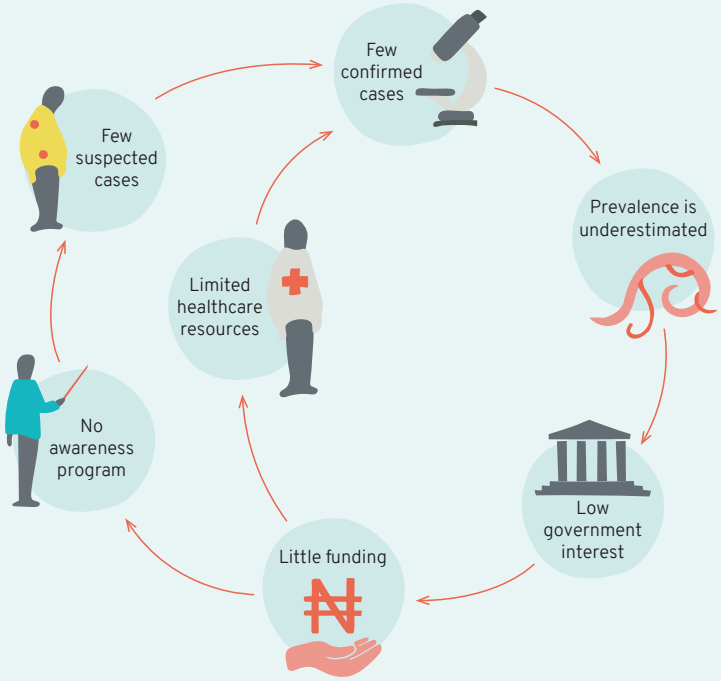


Figure 22. Vicious circle for case management

1 Limited care seeking behaviour

Infected individuals do not visit a formal health facility when they present symptoms. Due to low awareness on schistosomiasis amongst community members, bloody urine is often not perceived as a symptom of a medical condition. Most people visit traditional healers, since they are close to the community, or patent medicine vendors, since 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 still not performed. Suspected schistosomiasis cases are referred to the hospital. Reasons for this are proximity to a hospital, lack of skilled laboratory staff, lack of test material 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 (wrongly) assume low prevalence of schistosomiasis. Schistosomiasis symptoms are misinterpreted for other conditions, like STIs or malaria. Case definitions state that a case of urinary schistosomiasis should only be suspected when an infected individual has bloody urine. As a result, wrong treatment is often prescribed and light and asymptomatic cases are almost never recognized.

4 DSNO guidelines are labour intensive

Once a case is suspected, it should be reported to the disease surveillance and notification officer. The DSNO is responsible to get a sample tested to confirm the case. This often results in extra work, since they have to pick up the sample at a PHC facility and bring it to an approved laboratory. In the meantime, the patient is already being 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

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 do community based services. Hospitals are inaccessible due to long distances, poor road quality and expensive transport.

6 No check ups 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 of 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 schistosomiasis is spread by infected fresh water sources, a single confirmed case often means more infected individuals from the same community. There are no follow up actions that take the focal geographical distribution of schistosomiasis into account.

Chapter 9

CONTROL & ELIMINATION PROGRAM

This chapter aims to answer RQ2: What are the current diagnostic practices and challenges concerning S. haematobium infections within the health care system in Nigeria? and RQ3: Who are the important stakeholders and what are their interests in diagnostics for S. haematobium infections and future implementation of a diagnostic device? A distinction has been made between case management and the control & elimination program. This chapter describes diagnostic practices, challenges and stakeholders for the control & elimination program.

To explore the control & elimination program in Oyo State, five schools, three local government areas and the state government were visited and stakeholders were interviewed. This chapter will elaborate on the steps and diagnostic practices in the schistosomiasis control program. Furthermore, it gives and insight in equipment use in the field. An overview of the stakeholders that are involved in the control & elimination program is given and the chapter will be concluded by listing barriers in the organization and implementation of the control program and barriers that the targeted population has to overcome.

History of control programs

In the past, only sporadic and local control activities took place in Nigeria. The high cost of praziquantel and the low priority of the disease were the main reasons for neglecting the disease. In contrast to soil transmitted helminths (STH) treatment, praziquantel was not donated for a long time. The high cost of praziquantel resulted in restrictive and medicine-saving mass drug administration guidelines. Decisions on treatment were based on individual assessments with reagent strips. [84]

In 2007, German pharmaceutical company Merck initiated the Merck Praziquantel Donation Program in corporation with WHO. Nigeria has been participating in program since 2008. In 2016, Merck supplied a record amount of 34 million tablets for mass distribution in schools in Nigeria – enough to treat 13.6 million school children. [85]

In 2013-2015, the Federal Ministry of Health (FMoH) conducted a nationwide epidemiological mapping. In 2018, Oyo State started with Deworming days. Until now, there has not been an monitoring survey of the control program.

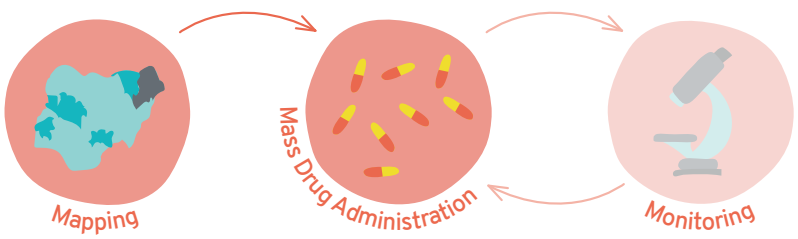


Figure 23. Steps in control program

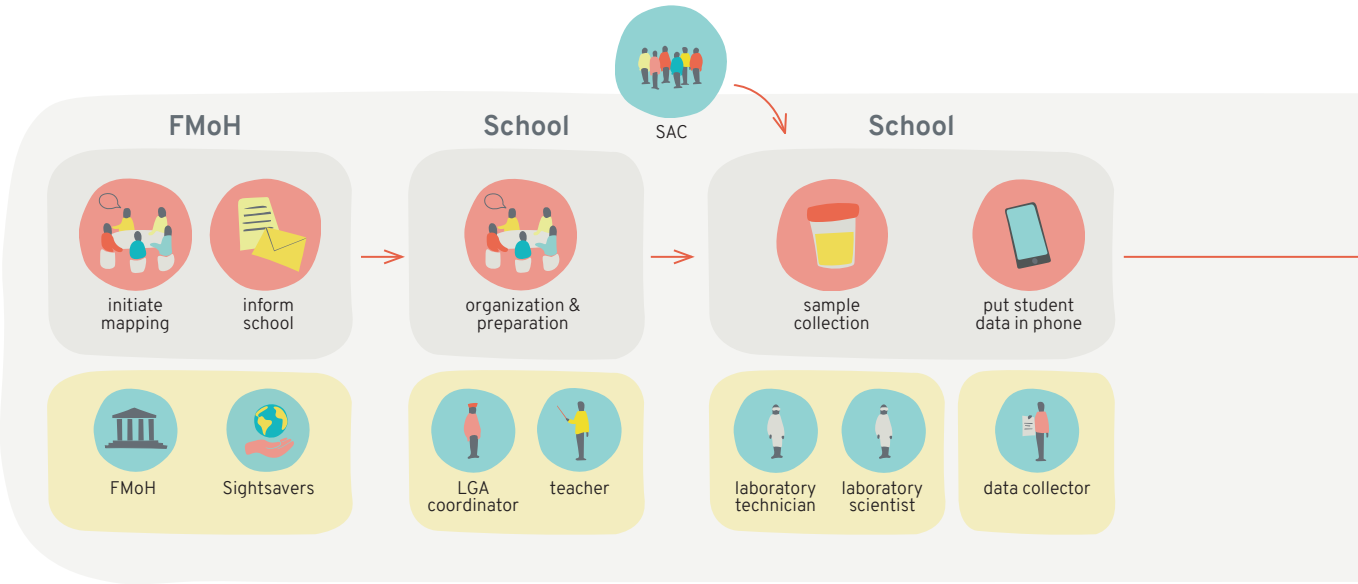


Figure 24. Process map for school mapping

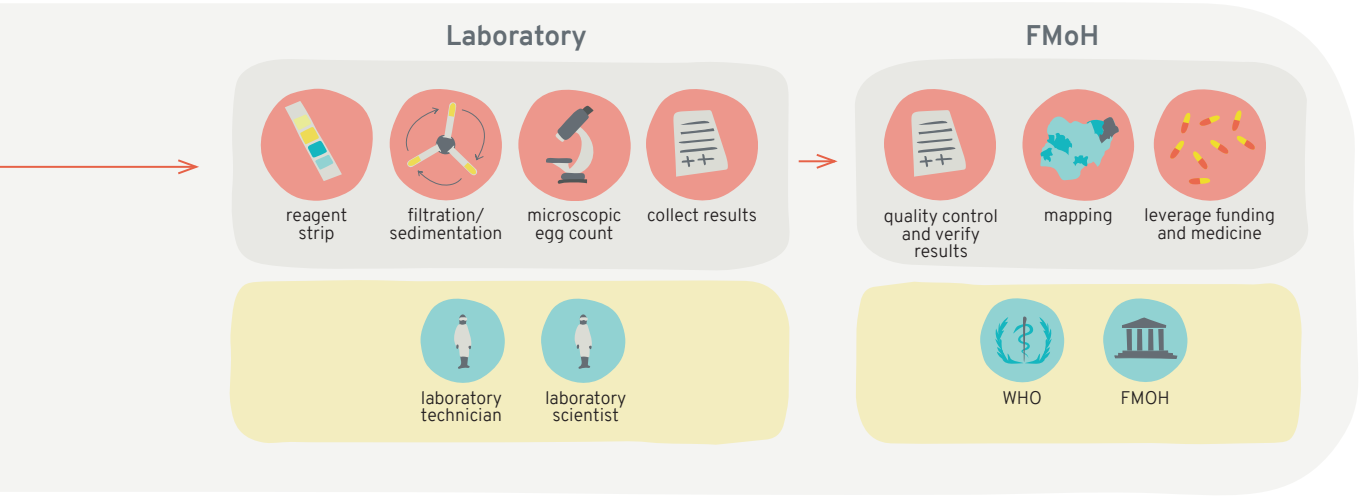
9.1 Mapping

From 2013-2015 epidemiological survey was conducted at schools all over Nigeria, where baseline data was collected on prevalence of soil transmitted helminths (STH) and schistosomiasis. It was organized according to a national protocol based on the WHO guidelines. [22] The NGO Sightsavers completed the epidemiological map in Oyo State, with funding by Children's Investment Fund Foundation. [13][89]

A field team with **LGA coordinators**, **lab scientists, lab technicians** and **data collectors** visited schools to collect samples. Per LGA, five primary schools were randomly selected. Schools in close proximity to fresh water were prioritised in this selection. At every school, urine and stool samples were collected from 50-55 **children** between 5-16 years old. Geographical coordinates of the school were collected and information of the children was put in a phone. Furthermore, water sanitation and hygiene (WASH) information was collected to document the knowledge, attitude and practices of the children. [13]

The samples were transported to laboratories with project vehicles. In Oyo State, samples were examined in four hospital laboratories. The urine samples were tested for microhaematuria with a Combi9 **reagent strip**. Thereafter, samples were **filtered or centrifuged** and S. haematobium ova were counted under a **microscope. Quality control** of the process and verification of the results was done to ensure consistency in sample preparation and microscopic examination. Reagent strip and microscopy results and error reports were shared with FMoH. [13]

Information on the prevalence, disease burden and distribution provided the basis for developing the strategy of the control program. The results of the mapping survey were used as an advocacy tool to leverage government funding and to provide access to donated medicine. [13]



Stories from testing in the community

Sample analysis for this school survey was done in permanent labs in hospitals and the children did not receive individual results. However, for small scale screenings often **temporary labs** are build up in the community. [34]

To explore performing **diagnostic tests in the field** and the corresponding challenges, multiple researchers were interviewed on their field experiences. Insights from these interviews on barriers for health workers are included in chapter 9.4. The story below was based on the experiences from a lab scientist in research for multiple parasitic infections. It represents the procedure during community screening.

Prior to a community screening, the community chiefs should be informed. The chiefs will talk to their community, after which they come back to fix a date.

On the set day, the field team leaves as early as possible. All equipment, apparatus and a generator are brought to the community. Depending on the equipment, it takes about an hour to set up a temporary laboratory. One team is setting up the lab, while another team is preparing and sensitizing the community to gain consent.

According to the lab scientist, usually participants are registered with a laboratory number, which they receive on a piece of paper. Their sex, age and religion is noted, but the names of the participants are not collected. After sample collection, the participant goes home. In the communities where the lab scientist did research, most people were farmers who went to their farm instead. In the meantime, the laboratory staff started testing.

When participants return to the temporary laboratory in the afternoon, they provide their number and the research team looks up the result in register. The results are community verbally, since the majority of people in rural areas are illiterate. The research leaves in time to travel back to the facility. Not everyone comes back for their results in time.

In some field researches, free drugs are provided for people tested positive. In the experience of the interviewed lab scientist, all people take the medicine since community members feel that the researchers are helping them. The people have seen members of their community that are down with certain diseases and cannot work anymore. Since everybody wants to keep making money, they do not want to be sick and will submit themselves for tests. Once they are tested positive, they will take the treatment.

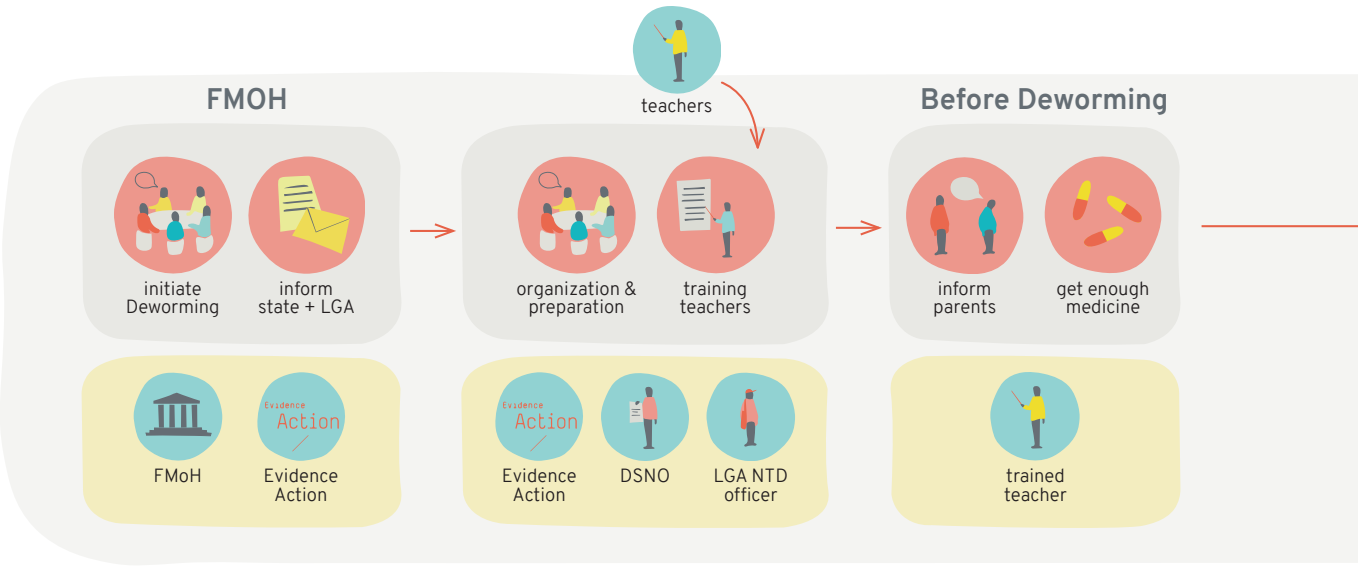


Figure 25. Process map for Deworming day

9.2 Deworming day

Since 2016, the NGO Evidence Action and the Nigerian government have been organizing Deworming days, targeting both STH and schistosomiasis. In 2018, the control program expanded to Oyo State. [55] The frequency of this mass drug administration program depends on the epidemiological data that was collected during the mapping survey, see figure 26. The program targets children from the age 5 to 14 and is conducted at schools. The program is organized by the State Ministry of Health (SMoH), where it is supervised by the **state NTD coordinator**. [90] **Evidence Action** gives technical assistance and provide funding. In Nigeria, the costs of Deworming per child are $0,65. [91]

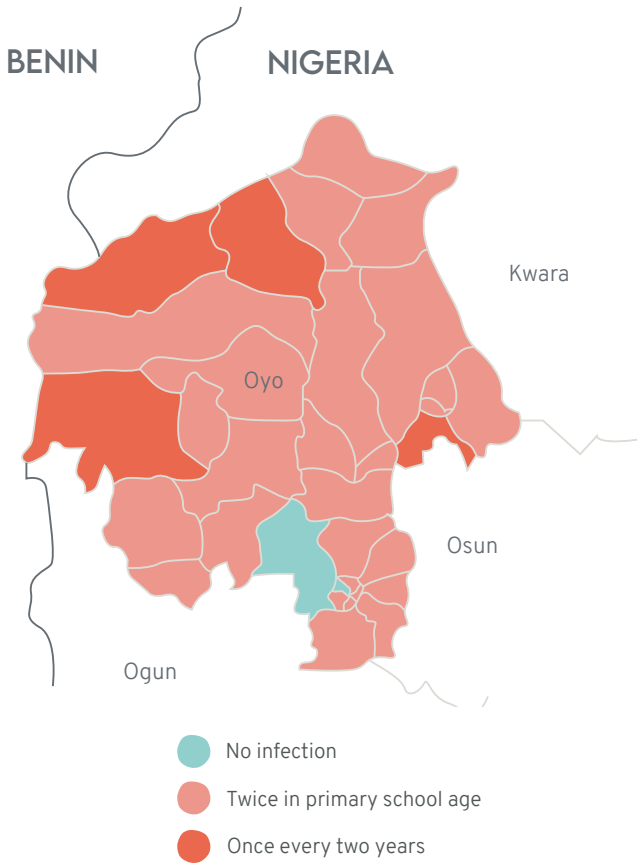
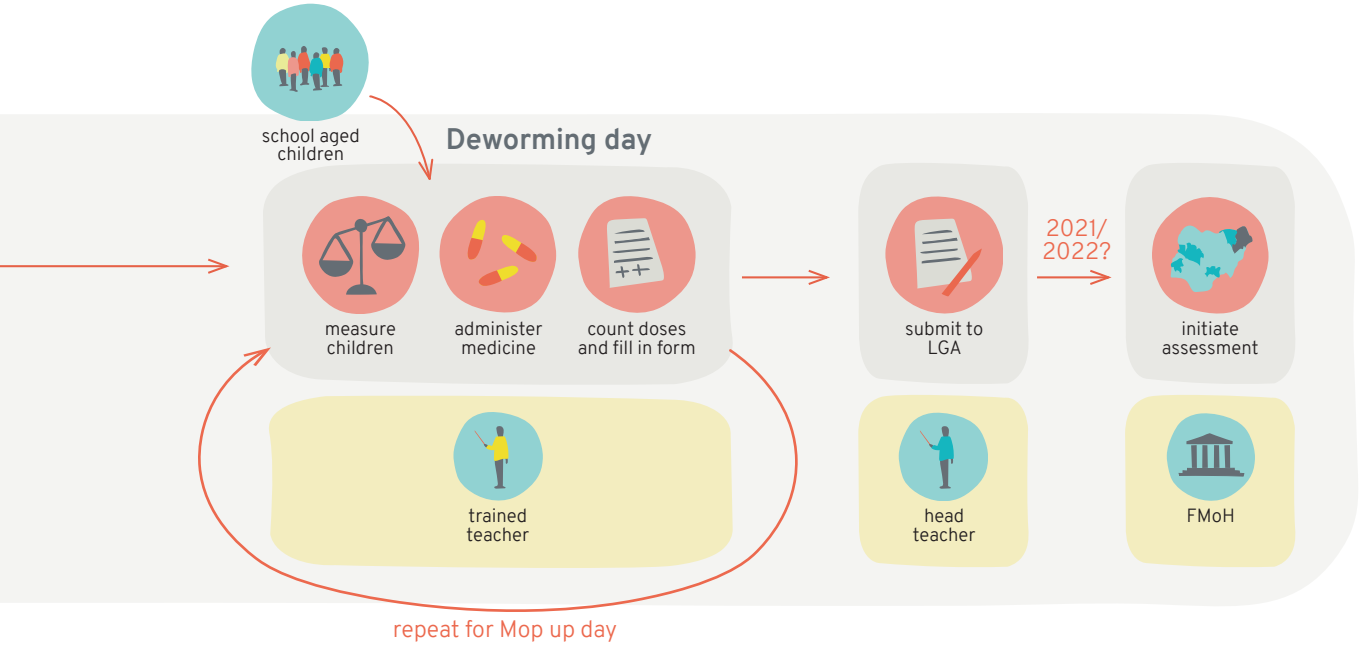


Figure 26. Intervention planing Oyo State



Observations in the field

During the field trip, four primary schools and one secondary school in Ibadan North were visited. All schools were involved in the Deworming Initiative.

The local **DSNO** and **NTD officers** are responsible for the organization of the Deworming exercise in their LGA. They distribute promotional material and drugs to the schools. Prior to Deworming day, they organize a training for **teachers**. Trained teachers are responsible for creating awareness, administering drugs and reporting to the LGA.

Prior to the Deworming day, schools informed the children and their **parents**. The visited schools organized parent meetings or called the parents to inform and sensitize them. In one school they announced Deworming day to the children at an assembly and were asked to inform their parents. The parents had to give consent for the Deworming day.

During the Deworming day, all **children between 5-14 years old** were measured to determine the praziquantel dose, see image 25. Teachers administered mebendazole or albendazole for STH and praziquantel for schistosomiasis. Children below 94 centimetres did not receive praziquantel.

The interviewed teachers made sure that all their children had eaten before they receive the drugs, to reduce the chance on a negative reaction to the drugs. At some schools, free food is provided on Deworming days. Despite these efforts, all teachers had some children that experienced reactions to the treatment. The pupils felt weak and some vomited immediately after taking the drugs. There were a few children that vomited worms. Any child with a severe reaction should be reported to the DSNO or the designated PHC facility.

During Deworming day, schools are inspected by the DSNO and NTD officers. Children that are not enrolled in schools could receive medicine at a designated PHC facility. After Deworming day, one or two mop up days were organized for absent children.

After the program, the teachers send a report along with remaining drugs to the local government.

Image 25. Dose pole and measurements in classroom in primary school

Image 26. Educational material for teachers about Deworming day at DSNO office

9.3 Challenges for targeted populations

The control and elimination program in Nigeria faces major challenges towards eliminating schistosomiasis as public health problem. To understand the motives of community members, the barriers that people at risk can experience in each step of the mapping and MDA are listed. To understand their main challenges in the control program, the barriers are classified into five categories, acceptability, accommodation, affordability, accessibility and availability. [84]

- Acceptability
- Accommodation
- Affordability
- Accessibility
- Availability

Since we did not speak to children who were directly involved in mapping, their challenges and considerations towards **screening surveys** could not be determined. The barriers listed in this chapter are based on the report of the mapping survey [13] and the experience of the Oyo State NTD coordinator. She was involved in the organization of the survey and joined field teams for sample collection. Some barriers are based on experiences from health workers from other screening exercises.

The challenges for the **Deworming initiative** are based on interviews with community members, teachers, community mobilizers, community health workers and stakeholders from the local government. Some insights were retrieved from interviews with public health researchers, the Oyo State WHO tuberculosis coordinator and the Evidence Action country coordinator.

Barriers to give sample

After getting informed about a screening survey there can be several reasons for the targeted population group not to come to action. These reasons are listed below.

Inadequate sensitization of communities led to rejections to participate in the mapping survey. Community members refused to hand in urine samples. In some areas, there were misconceptions about the purpose of the sample collection among community members. [13] A PHC coordinator mentioned that parents in certain communities do not give consent to take children's urine away to an external laboratory, because they have **superstitious beliefs** about voodoo with the samples. According to her, these parents might agree to give sample in case testing is done at location, since that allows them to see what happens with the sample. According to the state NTD officer, sensitization is key. She was involved in a community visit where her team collected 250 samples, after which some community members told them that the samples could not be taken away. She suggested them to join her to the state laboratory, so she could show them what they were planning to do with the samples - but the community members refused. In the school mapping in 2013-2015, some members of the field team were harassed by community members who questioned the implication of taking their children's specimen away from the village. [13]

'There was a fraudster who went around collecting dried stool all over Iseyin to be eaten with bread. This was used for ritual purposes and unfortunately, it was the time that we went out to get samples, that was why they were against us'

State NTD coordinator

Furthermore, for some community members, short term thinking results in a lack of trust in the long term plans of the government to start a treatment program. Two health workers mentioned the importance of **bringing an incentive**. According to them, community members will only provide a sample in case there is a direct benefit for them afterwards. *'If you want to get something from communities, you have to give them something in return. It goes both ways.'* More people might be willing to join mass screening if they will immediately receive treatment after testing positive. When children are screened, one of the PHC coordinators advised to bring incentives like sweets and toys.

Barriers to receive result

In the school survey in 2015, the samples were brought to a state laboratory to get tested. The **individual results were not shared** with the school children, so the children tested positive did not immediately receive treatment. [13]

In the field research experience, described in chapter 9.2, the field team provided the results verbally, to make sure everyone understood. According to the lab scientist, **written results might be misinterpreted due to illiteracy**. Furthermore, he mentioned that not everyone comes back in time from their farm to receive their result before the field team leaves.

Barriers to get informed about MDA

Currently in Oyo State, there is only a control program available for school children. Everyone outside the age range of 5-14 was excluded from Deworming days. Unenrolled school children can receive treatment at designated PHC facility, but there is **no structured way to inform** them about the Deworming exercise.

According to a NTD coordinator in Ibadan North, several people have been asking for a program like the Deworming day for adults. Since the **Merck donation is strictly for school aged children**, the free medicine can not be administered to adults.

Barriers to give consent

Parents have to give consent to let their children participate in the Deworming day. Some parents do not want their children to take drugs and keep them at home. The PHC coordinator in Akinyele and a teacher experienced parents that **refused to let their children participate** in the program. They said their children had been dewormed at home recently and that there is no need to do it again.

Furthermore, there is **suspicion when a new, free program starts**. Community members want to see proof to know that a program is real. One community mobilizer argued '*Most people are not aware of the program and if they can have one or two people go testify that it is real, they will be willing to participate*'. According to a NTD officer in Ibadan North, the people in her community did not understand the importance of the program the first time the Deworming day was organized. She argued that the vomiting and excretion of worms helped the children to see the importance and made them accept it. '*In one of our schools in Akinyele, there was a picture that was taken while the program was on. Initially, the teachers observed that the child was not active in the class, so when they brought praziquantel to the class, the child took the drug and was passing out worms from the mouth, nose and anus, about 40 worms. About two weeks after the program, the previously unresponsive child was not active. Even from that end, we were able to show people the pictures which gave them acceptability that the drug is working.*' The second time, there were no complaints from parents in that school.

If there is a **direct gain from taking drugs,** more community members are willing to take the medicine. The promise that it cures an infection that might be present but is invisible, does not convince everyone to take the drugs. According to one of the teachers, parents would allow their children to use drugs in case it made them add weight. Furthermore, the UCH researcher that had experience with administering drugs for another parasitic disease said '*When they heard that the drug increases libido, the men and women came back to get tested and really,*

I think that was one of the places we had the highest prevalence of lymphatic filariasis and a lot of people got treated.' This might apply to praziquantel as well.

Some community members are afraid of drugs, due to **rumours about possible side effects**. Prior to medicine distribution, gossip is spread that the medicine it not safe to use. According to one of the physicians, there are conspiracy theories that the community members are used for experiments by giving them diseases. In some ethnic groups there is the believe that the government is trying to reduce the population. One teacher mentioned that some communities think that immunization programs are used for family planning and taking drugs will stop them from having children.

'I can remember that about 2-3 years back, when praziquantel came on board, nobody was ready to take it because there were false rumours, but the subsequent years were good. The last one, we had no rejection'

LGA NTD officer

Lastly, the **level of suspicion in the community is related to the person administering the drugs**. One DSNO mentioned that he used to administer the drugs himself, but the community members blamed the local government for reactions to the treatment. From that moment, they decided to involve the teachers in drug administration. One teacher mentioned that some parents did not want their children to be treated in school, but since she was the one administering the drugs, they gave consent. Still, political tension can result in withdrawal from the Deworming exercise. One NTD officer mentioned that people were opposing MDA, because it was organized at schools. '*Last year, they went as far as withdrawing their children from schools because it was a school based exercise.*'

Barriers to receive treatment

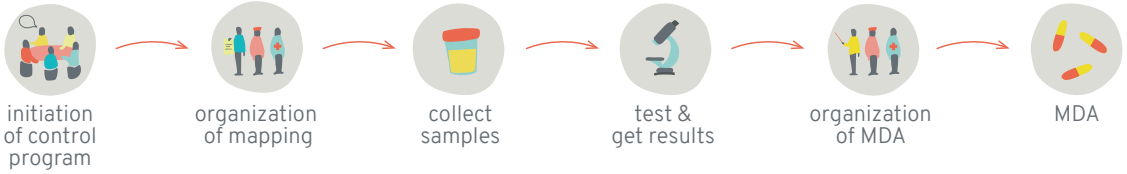
According to WHO guidelines, praziquantel cannot be given children below 94 centimeters. [22] **Children that are too short are excluded** from the drug administration for schistosomiasis.

Multiple teachers mentioned that there were some **children that ran away** on Deworming day since they were afraid, even though their parents gave consent. Furthermore, children are scared of health workers since they associate them with injections. During the community visit in Camp David with a community mobilizer, we observed that children started crying and ran away when they saw him, since he usually visits for immunization purposes.

Furthermore, there are not always enough drugs available to administer to all children. In Ibadan North West there was **not enough praziquantel available** for Deworming day. According to their DSNO, that was caused by the absence of schistosomiasis cases in the area that year.

Lastly, praziquantel is can **only be distributed by teachers on Deworming day and mop up days.** They leftover drugs have to be given back to Evidence Action. One teacher mentioned that there were some children not in school during Deworming day and she was not allowed to give them drugs the day after. In Ibadan North, the people that were unavailable when the drugs were distributed, came to the primary healthcare centre to receive theirs.

9.4 Organizational and executive challenges



Similar to the barriers for targeted populations in chapter 9.3, this chapter lists the challenges for the executive stakeholders (teachers, health workers and local government stakeholders) to organize and execute a control program, based on interviews in the field.

Barriers to organize mapping

There is a **lack of government interest** in the organization of mapping. The state NTD coordinator has to follow the guidelines from FMoH and is not authorized to initiate anything. *'If the federal government wants something done, the state has to follow'*. The school survey in 2013-2015 was organized from federal level and according to Evidence Action, the FMoH is responsible for initiation of an impact assessment of the program. According to a PHC coordinator, the government does not see schistosomiasis as a priority. Mass screening will only be done in communities where a schistosomiasis problem is localized. The government underestimates the prevalence, since they look at hospital records. Reporting more cases will improve the commitment of the government to funding. *'Basically, creating a kind of alert around schistosomiasis will sort of stimulate interest of the government to look at the problem'*.

Epidemiological surveys require a skilled field team, equipment, transport and accommodation, which makes field trips very **expensive**. During the school based survey in 2013-2015 there were logistic problems, caused by fuel and vehicle scarcity and the high price of fuel. [13] According to the state NTD coordinator, carrying out the test in the community would reduce the burden of carrying samples all around. It is considered a welcome method, but it is not affordable and has to be decided on federal level.

Transport of equipment or collected samples requires a car. Poor road quality, rivers and difficult terrain make communities **inaccessible** for cars. During the mapping survey in 2013-2015, field teams had to visit two schools a day. Since the distances were far, teams arrived at the second school late or even took two days per school. Other areas were unsafe to visit due to insecurity and political instability. [13]

Barriers to collect samples

To collect samples, the target populations or their caretakers have to give consent for sample collection. During the 2013-2015 school based survey, a **lack of funding** from the state led to **inadequate mobilization and sensitization** of communities and schools. [13]

Barriers to test and get results

In case of a temporary laboratory, all required material has to be brought to the community. Since laboratory equipment is fragile and road quality is poor, **material can break during transport**. One lab scientist with community screening experience had experience with a microscope lens that broke during transport. As a result, the field research took much longer, since it had to be done with one microscope instead of two.

Furthermore, there are some **limitations to microscopy** as a method, which are listed in chapter 4.2. Microscopy has limited sensitivity and is prone to human error, which can give an inaccurate result or even a wrong diagnosis. **Fatigue** from counting eggs all day influences the quality of the results. Inaccurate results from epidemiological surveys have big impact, since they determine the MDA strategy for a region for several years.

Lastly, during the school based survey in 2013-2015 there were difficulties with uploading data with phones, since the **mobile network was limited**. [13]

Barriers to organize MDA

For the realization of Deworming days, the FMoH is fully dependent on Merck for praziquantel donations and Evidence Action for organization. Without these organizations, the control program could not continue. According to the WHO coordinator, **funding for control programs is an issue**, since funders decide which disease is targeted - the others are neglected.

Secondly, it is important to inform the LGA stakeholders long before the Deworming day, since **organization and preparation of the Deworming day requires time**. The NTD officer in Ibadan North was informed less than a month before and experienced difficulty with preparation, arranging resources and training teachers. The participating schools should be informed in time as well. According to the state NTD coordinator, there was an issue with private schools during the Deworming day. The head of all private schools in Oyo State refused to take part in the Deworming exercise, since he was not informed.

Barriers to administer treatment

There is a **fluctuation in the availability** of praziquantel for Deworming day. According to the state NTD coordinator, in 2019 there was not enough praziquantel to cover all LGAs in Oyo State, so they had to prioritize high risk LGAs.

Deworming medicine can only be administered when parents signed the consent form for their children. Proper sensitization of the community will increase the number of parents giving consent, but often **time is a limiting factor.** Furthermore, **sensitization of communities is difficult**, especially when the people belong to another ethnic group. Teachers in the visited schools mentioned that it was difficult for them to interact with Hausa families, since their culture and language are different from theirs.

Furthermore, there is a lot of **misconception among health workers** when distributing medicine. Some health workers and teachers believe rumours and conspiracy theories and refuse to give treatment to children. One of the community mobilizers in Ibadan North said *'A few teachers have refused to let children get Deworming drugs even after they have received the necessary training. Out of twenty schools, we have about one or two schools that rejected drugs for Deworming.. ... I tried to explain to them that those who brought these drugs for free did so because they love us'* . Furthermore, one researcher had experience with a health worker spreading rumours about the dangers of taking medicine instead of giving drugs to the community.

9.5 Stakeholder overview

This section gives an overview of the involved stakeholders in the organization and implementation of the control & elimination program. Based on insights from the field research, this paragraph describes their current role and needs in the control program and their **potential role in a future scenario with new diagnostics**.

The stakeholders in **initiation of a control program** (the Federal Ministry of Health) and **support of a control program** (NGOs, WHO and Merck) are not included in this overview, since they were not interviewed in the field. One WHO officer was consulted, but he was not directly involved in the control program so could not be included.

Target population and influencers

School aged children

I do whatever my parents or teacher tell me to do, except when it is scary

Parent

I want to understand what is happening before I give consent for sample collection or medicine administration

Organization of control program activities

State NTD coordinator

I want to coordinate NTD related activities in LGAs in line with the national strategy

Strengths + Weaknesses
+ Power over all LGAs
- Obliged to follow guidelines from FMoH

Potential role
Organization of a mapping survey or a new control program

Evidence Action country coordinator

I want to Deworm all children in Nigeria

Strengths + Weaknesses
+ Access to donations
- Depends on WHO and sponsors

Potential role
Organization of mapping survey or a new control program

Deworming implementation

DSNO

I want to Deworm all children in my LGA

LGA NTD officer

Strengths + Weaknesses
+ Contact with schools
- No experience with testing
+ Familiar with NTDs

Potential role
Testing in mapping survey, supervision of testing

Teacher

I want what is best for my children

Strengths + Weaknesses
+ Trusted by community
- No healthcare experience

Potential role
Testing children

Mapping implementation

No stakeholders in mapping implementation were interviewed, so the needs of the field team members could not be determined. The strengths and weaknesses, and potential role are based on their responsibilities in the school mapping survey.

Data collector

Strengths + Weaknesses
+ Experience with data collection
- Does not know community

Potential role
Test during mapping survey

Lab staff

Strengths + Weaknesses
+ Experience with testing
- Does not know community
- Expensive

Potential role
Test during mapping survey

LGA coordinator

Strengths + Weaknesses
+ Knows the community
- No experience with testing

Potential role
Organization of mapping survey in the community

Image 27. At the visited schools in Ibadan north, there were no toilets on school grounds, so the children urinated and defecated outside

9.6 Gaps in control & elimination program

This paragraph summarizes the insights from the context research. Control program guidelines were combined with insights from the field research on diagnostic practices and the stakeholder barriers, into **gaps in the healthcare system.**

The goal of the Federal Ministry of Health is to eliminate schistosomiasis as a public health problem by 2020. To reach that goal, Deworming days are organized for school children. The strategy for mass drug administration is based on a data collected during a nationwide epidemiological survey from 2013-2015.

Currently, here are a lot of challenges in organization and implementation of a control program to reduce the disease prevalence. Next to the school survey, there are no epidemiological surveys where cases are confirmed, so the current disease prevalence in unknown. As a result, the government gives schistosomiasis control programs low priority and depends on donations and NGOs. Since these organizations do not initiate epidemiological surveys themselves, this vicious circle continues (see image 27).

The gaps on the next page were validated and enriched during a co-creation session with public health students in Nigeria, see appendix H. Filling (a few of) these gaps might break the pattern.

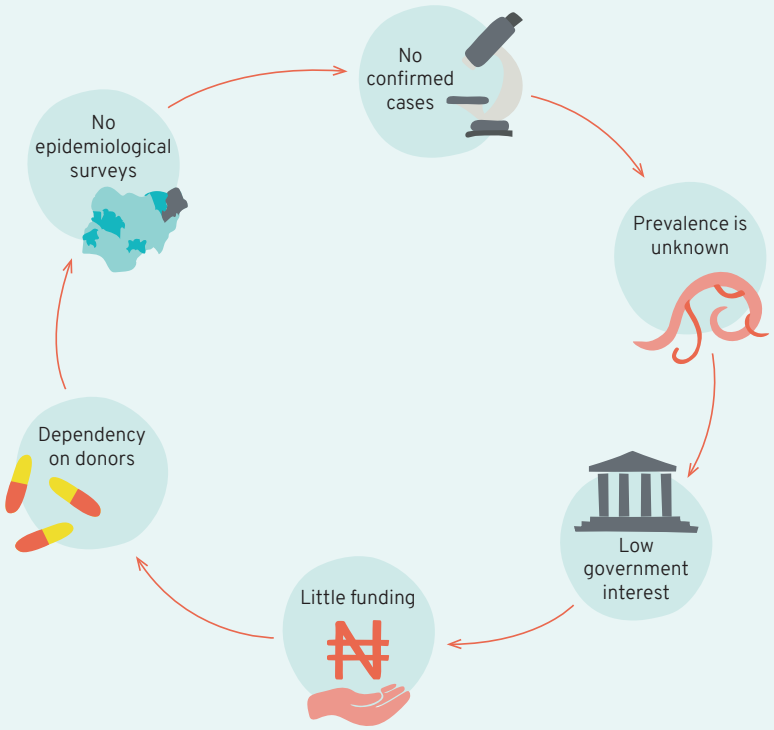


Figure 27. vicious circle for control & elimination program

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 fresh water - 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 FMoH (see table 10 on page 56), 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 should initiate this monitoring survey. According to the state NTD officer and Evidence Action, there is no plan yet. If there is no information available on the impact of the program, target populations, health workers and community volunteers might lose interest in the program, especially in low prevalence communities.[22]

4 Target populations do not give consent

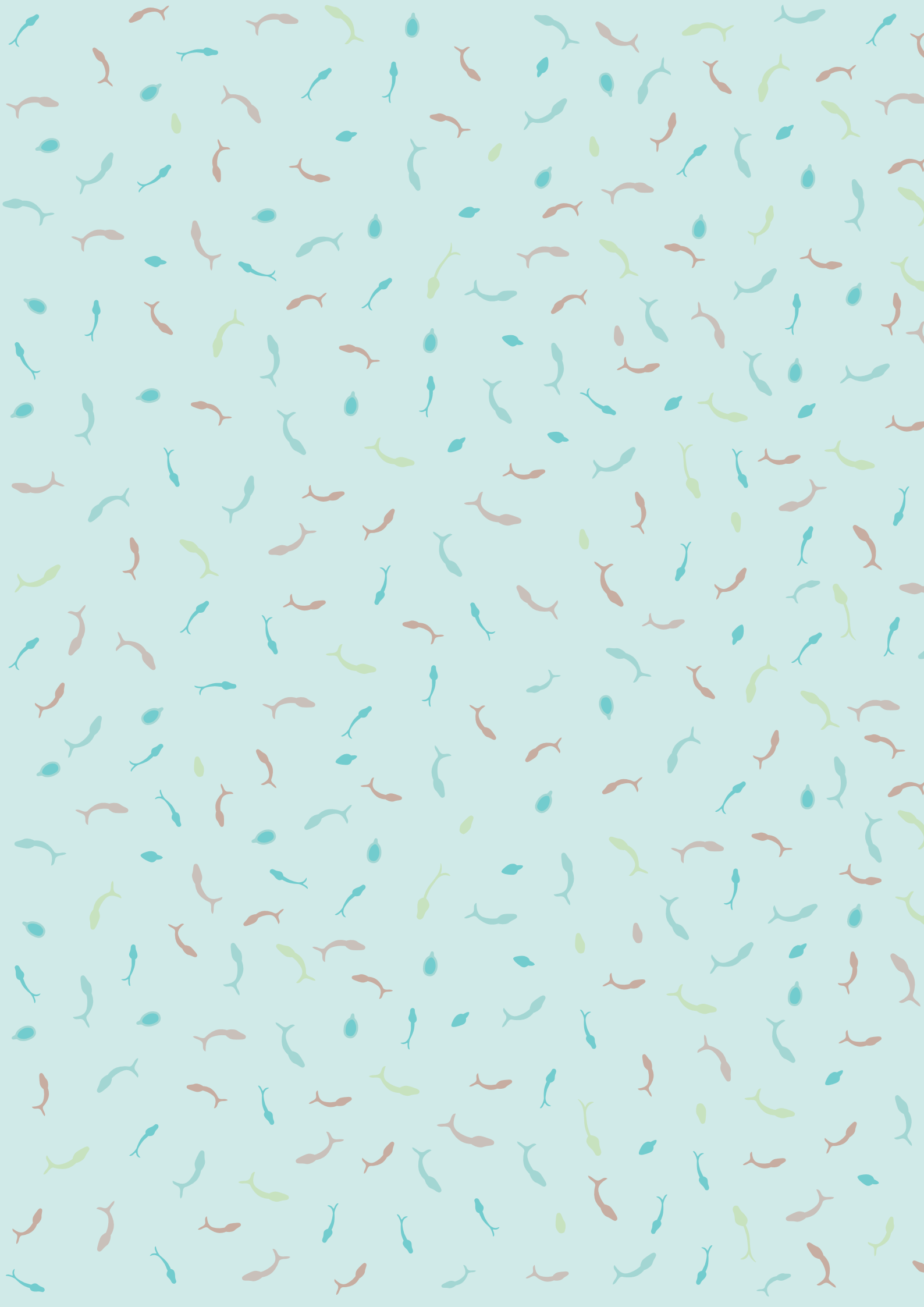
Proper sensitization is key to the control program, but limited due to time or resource constraints. There is low awareness of schistosomiasis in the community and suspicion to free programs. If people do not understand why they have to give a sample, they will not participate. Some community members believe the rumours and conspiracy theories that are spread about sample collection and treatment.

5 No field deployable diagnostics available

Microscopes are fragile and filtration is not widely used 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 field deployable methods, but they lack sensitivity.

6 Control program is short term focussed

The control & elimination strategy in Nigeria is short term focussed. Their roadmap stops at 2020. However, to anticipate on decreasing prevalence in the future and work towards elimination as public health problem, plans should be developed on tackling future challenges. A lower prevalence gives different requirements to the control strategy and the role of diagnostics.



V

TARGET PRODUCT PROFILE

Chapter 10

DIAGNOSTIC SCENARIOS

This chapter aims to answer RQ4: What are the most promising use case scenarios of a new diagnostic device to improve i) case management on primary level, and ii) the control & elimination program?

The **gaps in current diagnostic landscape**, see chapter 8.9 and 9.6, were combined with the **potential benefits of the smart technology**, see chapter 6.3, to create twelve opportunities for new diagnostic scenarios. Inspiration for these scenarios was obtained from the results from the co creation session with public health students, see appendix H-3.

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**. Potential users of the test were defined in chapter 8.8 and 9.5. 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 give an idea of the envisioned test complexity.

The gaps in the context and the technical benefits that created the opportunity are added to each scenario.

For each of these use cases scenarios, the technical requirements for a diagnostic test differs and will pose different technical challenges. A **selection of the most promising scenarios** should be made to determine product specifications for the target product profile.

Image 28. Primary health clinic in the rural community Atan in Akinyele

10.1 Use cases in case management

Figure 28. Stages in case management

Currently, there is a very limited number of confirmed urinary schistosomiasis cases in Nigeria. Seven opportunities are identified to improve case management on primary healthcare level, based on combinations of gaps and technical benefits.

In chapter 8.8 the potential users of the diagnostic test were identified based on their roles, needs and skills. Potential users are community resource persons, community health workers and laboratory staff. The new scenarios apply to different stages of case management, which are visualized in figure 28.

1 Test to sensitize the community

Creating community awareness on schistosomiasis by testing both symptomatic and asymptomatic people and showing visual results

Who will do the test?
Community mobilizer or another community resource person

When will the test be done?
Community mobilizer will do tests during community sensitization meeting or visits.

Where will the test be done?
In the community

Why is a new test necessary for this scenario?
Community awareness on the cause and effects of schistosomiasis is low. As a result, sick people do not visit a health facility and parents do not want their children to get dewormed. Showing that asymptomatic people can be infected too will result in more people visiting health facilities and participating in control activities in the future.

Test complexity

1 Limited care seeking behaviour
3 Health workers miss cases
1 Simple and user-friendly
4 Robust and portable

This scenario tries to increase care seeking behaviour by sensitizing the community. Furthermore, light and asymptomatic cases will be identified that are usually missed by health workers. The simplicity and user friendliness allow diagnosis by a community resource person with very limited health education. The robustness and portability allows transportation to and use in communities.

2 Test at PHC consultation

Test is done at consultation, so the patient does not have to go to a laboratory to get tested

Who will do the test?
Community health worker

When will the test be done?
When a patient comes to PHC with symptoms. Community health worker can do a test immediately when a case of schistosomiasis is suspected during a consult.

Where will the test be done?
Primary health centre, primary health clinic, health post

Why is a new test necessary for this scenario?
There are no laboratories in primary health clinics and posts. Primary healthcare centres with laboratories do not do microscopy for urine examination. The new test makes diagnosis at primary healthcare level possible, so patients do not need to get referred to a hospital laboratory.

Test complexity

5 Few diagnoses in rural areas
4 DSNO guidelines are labour intensive
1 Simple and user-friendly
6 Data collection

This scenario fills the gap of limited resources in rural areas. The simplicity of the smart diagnostics can make the test user-friendly for a community health worker with limited testing experience. The ability to collect and share data does not require the disease surveillance and notification officer to pick up a sample.

3 Test at community visit

Test is done when someone is feeling sick and calls a community health extension worker to visit the community

Who will do the test?
(Junior) Community health extension worker

When will the test be done?
When community health extension worker visits sick people in the community. Community health workers can do a test immediately when a case is suspected

Where will the test be done?
In the community, at patients home

Why is a new test necessary for this scenario?
Currently, people do not get tested because of the long distance to a facility or unavailability of a laboratory, especially in rural areas. The new test does not require a laboratory. Furthermore, by doing the test in the community and sharing the location data, it is easier to localize infected water.

Test complexity

1 Limited care seeking behaviour
5 Few diagnoses in rural areas
1 Simple and user-friendly
4 Robust and portable

This scenario increases care seeking behaviour and allows diagnosis in rural areas, since it eliminates transport to a health facility for the patient. The simplicity of the technology allows the CHEW to perform the test. The robustness and portability allows transportation to and use in communities.

4 Test in PHC laboratory

Test is done in PHC laboratory, so there is no need for hospital referral

Who will do the test?
Lab scientist, lab technician or lab assistant

When will the test be done?
Lab staff can do test when a case is suspected by a community health worker and a patient is sent to the laboratory for a confirmation

Where will the test be done?
Laboratory of primary health centre

Why is a new test necessary for this scenario?
Primary healthcare centres with laboratories do not do microscopy for urine examination. The new test makes diagnosis at primary healthcare level possible, so patients do not need to get referred to a hospital laboratory.

Test complexity

2 No tests in PHC laboratories

5 Few diagnoses in rural areas

5 Affordable

This scenario solves the lack of testing in PHC laboratories. It allows diagnosis on primary healthcare level, so patients do not have to be referred to a hospital laboratory. The affordability of the device will make it an attractive alternative to the microscope.

5 DSNO brings device when case is suspected

When case is suspected at PHC, the DSNO will bring the test device so the case can get confirmed

Who will do the test?
Disease surveillance and notification officer

When will the test be done?
When a case is suspected, the DSNO is informed and she or he will come to the facility with the device to test and confirm the case

Where will the test be done?
At primary healthcare facility

Why is a new test necessary for this scenario?
Currently, when a case is suspected at a PHC, the DSNO comes to pick up the sample and brings it to a lab to get the case confirmed. With the new test, the DSNO does not have to go to the lab for confirmation and sharing the data with the authorities is easy. There is only one device required per local government and only the DSNO needs training.

Test complexity

4 DSNO guidelines are labour intensive

5 Few diagnoses in rural areas

4 Robust and portable

6 Data collection

This scenario decreases the labour intensity for the disease surveillance and notification officer, since it does not require her or him to bring a sample to the laboratory. Robustness and portability allows diagnosis in the whole LGA with only one device, since the DSNO can transport it around. The healthcare data of the case will be automatically saved to keep track of the amount and location of confirmed cases.

6 Community screening after confirmed case

When one case is confirmed, other people in that community will be screened

Who will do the test?
(Junior) Community Health Extension Worker

When will the test be done?
When a case is confirmed in a laboratory

Where will the test be done?
In the community

Why is a new test necessary for this scenario?
When one person is infected, there is probably infected water somewhere in the community and more people are infected. Screening the community can identify asymptomatic infected people with light infections.

Test complexity

1 Limited care seeking behaviour
7 No follow up action after confirmed case
2 Rapid
4 Robust and portable

This scenario solves the lack of a follow up action after case confirmation. The speed, robustness and portabilityof the device allows screening in the community. This will identify light infections and asymptomatic individuals that might not seek care by themselves.

7 Check up after treatment

After a patient is treated, the patient will be tested to check the effectiveness of the treatment.

Who will do the test?
(Junior) Community Health Extension Worker

When will the test be done?
A week after the patient received treatment

Where will the test be done?
In the community

Why is a new test necessary for this scenario?
Not everyone takes treatment or treatment is not effective. Check up afterwards will make sure that the patient is healthy again.

Test complexity

1 Limited care seeking behaviour
6 No check up after referral or treatment
1 Simple and user-friendly
4 Robust and portable
5 Affordable

This scenario allows a check up after receiving treatment from the hospital or primary healthcare centre. Due to the portability of the device, the community health worker can travel to the community to check patients that do not come to the health facility by themselves for a check up. The simplicity allows use by a community health extension worker with limited test experience. The affordability of the device allow this scenario as an addition to the normal healthcare practices of the CHEW.

10.2 Use cases in control & elimination program

Figure 29. Stages in the control & elimination program

At the moment, diagnostics have a minimal role in the control & elimination program. Five opportunities are identified to improve diagnosis for the control & elimination, based on combinations of gaps and technical benefits.

In chapter 9.5 the potential users of the diagnostic test were identified based on their roles, needs and skills. Potential users are data collectors, LGA NTD officer, teachers and laboratory staff. The new scenarios apply to different stages of the control program, which are visualized in figure 29.

1 Mapping of other risk groups

There is only epidemiological data available on school age children. Mapping of other risk groups could help initiating new control programs.

Who will do the test?
Lab assistant or data collector

When will the test be done?
When government or NGO wants to initiate a control program for other risk groups

Where will the test be done?
In community, screening of occupational groups

Why is a new test necessary for this scenario?
Mapping is very important to get insight in disease prevalence and the geographic distribution. However, there is currently no data available on adult risk groups. Mapping is expensive, because it requires a lot of time and high trained staff. Mapping with the new device will be less expensive and the data could initiate control programs to target adults at risk of infection.

Test complexity

1 Limited availability of data on endemicity
2 No control program for risk groups
4 Target populations do not give consent
2 Rapid
4 Robust and portable
5 Affordable
6 Data collection

The ability of the new technology to collect data allows the collection of data on schistosomiasis prevalence amongst adult populations at risk. The speed and portability of the device allows testing in the community, which increases the acceptability of the test. The affordability of the device might leverage governmental interest.

2 Impact assessment of deworming day

Impact assessment is needed for monitoring and evaluation of deworming program

Who will do the test?
Lab assistant or data collector

When will the test be done?
First impact assessment is around 2022, then an evaluation round every 4 years

Where will the test be done?
At schools

Why is a new test necessary for this scenario?
There is no detailed plan yet for the impact assessment of deworming day. The new test will have a higher throughput and easier data collection than microscopy. Expensive lab technicians are not required and the tests can be done at the location of sample collection.

Test complexity

1. Limited availability of data on endemicity
3. No impact assessment plan for Deworming day
2. Rapid
4. Robust and portable
5. Affordable
6. Data collection

This scenario fills the gaps of limited data availability and the lack of a plan for impact assessment of the Deworming day. The price, speed and portability of the technology allow a field deployable method and cheaper alternative to the microscope, which makes this test attractive for FMoH. Since the test rules out human error, the test can be operated by a lab assistant or data collector.

3 Test and treatment at deworming day

When prevalence is too low for deworming to be cost efficient, all children will be tested and only the children with an infection will receive treatment

Who will do the test?
Teacher or LGA deworming coordinator

When will the test be done?
When diagnostic test is more cost efficient than deworming, in a few years when the disease prevalence is lower

Where will the test be done?
At schools

Why is a new test necessary for this scenario?
The new technology makes testing much cheaper than microscopy. Deworming infrastructure can be used, but instead of treating all the children, only the children with an infection receive treatment. This will decrease the dependency on medicine donations. By collecting data and sharing it with authorities, treatment and monitoring can be done at the same time.

Test complexity

4. Target populations do not give consent
6. Control program is short term focussed
1. Simple and user-friendly
2. Rapid
4. Robust and portable
5. Affordable

This scenario proposes a plan for the future of the Deworming control program. Deworming day is dependent on medicine donations by Merck. At a certain point in the future, diagnosis will be cheaper (due to affordability of the technology) than treatment and it is more cost efficient to test and treat only the infected children. The portability, speed and ease-of-use allows teachers without health education to test at schools. The acceptability of the test will be higher when performed by trusted teachers.

4 Monitoring in low-transmission areas

Monitoring of the disease when control program is still going on but prevalence is very low

Who will do the test?
Lab technician or data collector

When will the test be done?
Long term, when prevalence is low

Where will the test be done?
At schools

Why is a new test necessary for this scenario?
There is no fitting diagnostic method to identify hot spots of transmission for intensified intervention when prevalence is low. Microscopy is not sensitive enough. The alternative antibody detection methods are expensive and can not distinguish between past and present infections.

Test complexity

5 No field deployable diagnostics available
6 Control program is short term focussed
3 Sensitive
4 Robust and portable

This scenario anticipates on the future of the control program. The increased sensitivity of new diagnostics makes it useful in areas with low prevalence. Its portability makes testing in the field possible.

5 Assessment of elimination of disease

Device is used to assess the elimination of schistosomiasis as public health problem.

Who will do the test?
Lab technician or data collector

When will the test be done?
Long term, when elimination is close. WHO goal is to eliminate schistosomiasis as public health problem in 2025.

Where will the test be done?
At schools

Why is a new test necessary for this scenario?
There is no fitting diagnostic method to assess the elimination, which is required to make the stopping decision for the control program. Microscopy is not sensitive enough. The alternative antibody detection methods are expensive and can not distinguish between past and present infections.

Test complexity

5 No field deployable diagnostics available
6 Control program is short term focussed
3 Sensitive
4 Robust and portable

This scenario presents a scenario where a diagnostic test is used to determine the stopping decision of the Deworming program. The increased sensitivity of the technology allows detection of light infections. The robustness and portability allows testing in the field.

10.3 Selection of scenarios

To determine which use case scenarios are most promising, feedback was obtained from the interviewees in Nigeria and members of the INSPiRED team.

A **questionnaire** was sent to **people that were interviewed in the field** and **technical, medical and design experts from the INSPiRED team**. Furthermore, the scenarios were **discussed** with **four members of the INSPiRED team**, of which two are experts on Nigerian healthcare and two are experts on technology and design.

The main goal of the questionnaire was to **receive insights in the value of the created scenarios** from stakeholders in the field and experts involved in product development. The sub-goal was to provide an overview of possible end-users and use cases for the members of the INSPiRED team.

To select the most valuable scenario, **promising** is defined as a combination of **desirability, feasibility** and **impact.**

Desirability for government is important for the control and elimination program, since they government is responsible for the initiation, organization and implementation of control programs. **Desirability for patients** is important for case management scenarios, since the scenarios require an active health seeking attitude from patients. **Desirability for health workers** is important, since they are only willing to perform the test if it fits their interest and needs.

Organizational feasibility means to what extent it is feasible to implement the scenario in the healthcare system in Nigeria. **Technical feasibility** refers to what extent the smart diagnostic technologies can fit the requirements of the diagnostic scenario.

Potential impact refers to the result that implementation of this diagnostic scenario can have towards elimination of schistosomiasis.

In the questionnaire, participants were asked to rate each case management scenario on desirability for patients, desirability for health worker, organizational feasibility and potential impact. For each control & elimination scenario, the participants were asked to rate the scenarios on desirability for government, organizational feasibility and potential impact. Since the people in the field do not have knowledge about the possibilities of the technology, feedback on technical feasibility was only obtained from the INSPiRED team members.

To rule out the effect of fatigue of respondent on the result, half of the respondents started with case management scenarios, the other half with control & elimination scenarios.

In the end of the questionnaire the respondents were asked to choose the **most promising scenario for case management** and the **most promising scenario for control & elimination.** This question was also asked to the four respondents during the feedback session.

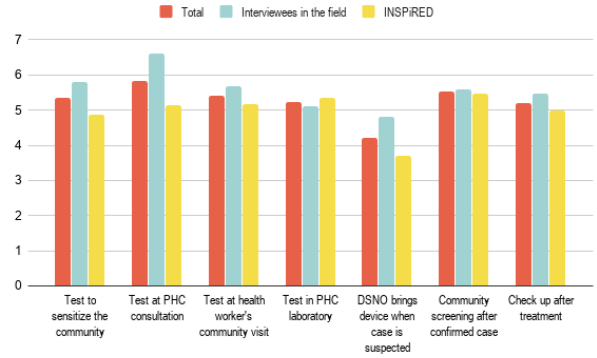


Figure 29. Results from questionnaire

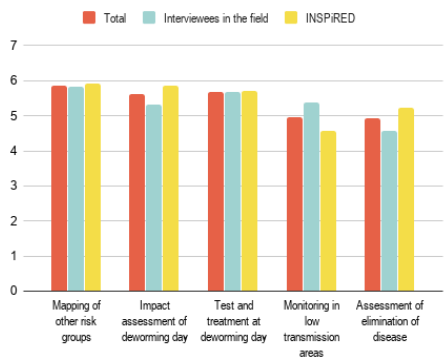


Figure 30. Results form questionnaire

Results

There were 13 respondents to the questionnaire, of which 6 interviewees from Nigeria and 7 members of the INSPiRED team. See appendix K for the details and results of the questionnaire. The feedback on the scenarios from the four experts can be found in appendix L.

Figure 29 and 30 give average ratings for each scenario on a scale from 0-7. The averages were calculated as follows; (average desirability + feasibility + potential impact)/3. Technical feasibility was not included in this calculation, since it was only rated by INSPiRED teammembers. The ratings on technical feasibility can be found in image K1 and K2 in appendix K.

Figure 31 and 32 show which scenarios the respondents to the questionnaire and the feedback session considered most promising.

Discussion topics on this questionnaire and feedback interviews can be found in the discussion in chapter 12.2.

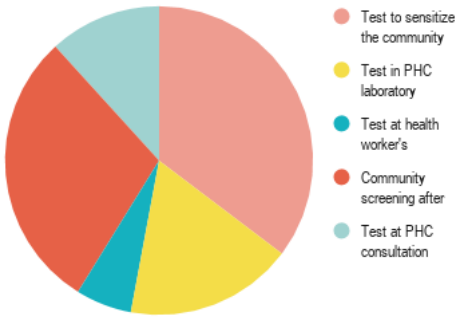


Figure 31. Most promising use cases for case management n=16

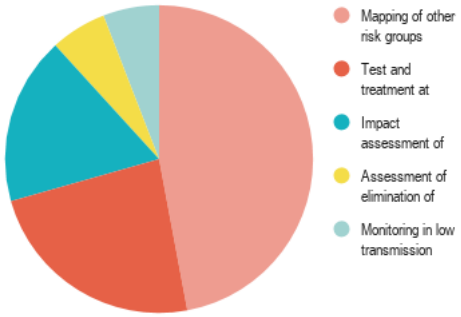


Figure 32. Most promising use cases for control & elimination program n=16

Selected scenarios

Based on the results of the questionnaire and the feedback from experts, three use case scenarios were selected.

1. Test at PHC consult

This scenario was selected, since it was rated highest amongst respondents from Nigeria, see image 29. This scenario will help in early case detection and treatment.

According to the respondents, this scenario is very **desirable for patients**, since it does not require referral to a hospital. The test is more affordable and accessible than current tests, and getting a diagnosis does not require as much time or effort. One respondent mentioned that patients will have more trust in the device than a symptom based diagnosis by the CHEW.

> 'It will boost the morale of the PHC CHEW and it is cost effective for patients'
> Respondent in questionnaire

The scenario is desirable for CHEWs, since it **gives them extra tools and responsibility**. Respondents mentioned that it will reduce the pressure on laboratory staff, who are often busy. An additional effect that was mentioned was the **improved trust of the community in primary health care**. However, the CHEW has limited healthcare training, so the test and the sample preparation should be very simple.

Whether this scenario is feasible, depends on the policy of FMoH. It was recommended by respondents to involve a NGO to increase feasibility of this scenario. They can ensure proper training and data capturing.

The impact of this scenario depends on the prevalence of schistosomiasis in the area. The frequency of use might be too low in low prevalence areas, so the **community first needs to be sensitized**. In high endemic regions the impact will be big. According to a Nigerian respondent, when one case is confirmed, other people from that community will come to get screened.

2. Mapping of other risk groups

This scenario was chosen because it received the highest ratings from both the INSPiRED team and the interviewees in Nigeria that responded to the survey, see figure 30. Moreover, it was chosen as most promising scenario by most respondents, see figure 32.

The respondents during the feedback session recommended organization of the mapping survey through **occupation group meetings**. Since there is an existing structure, it is easy to gather workers together. They mentioned it is not possible to do sex based screening. Only screening women's urine will suspicion about their sexual activities.

This scenario is desirable for the target populations. One respondent mentioned that in some communities, people are upset since children are always being tested and they are ignored. Diagnosis can be done in the community so the participants **see what their sample is used for and they receive results themselves**. However, to increase the acceptability it is **better to involve a community health worker** in testing instead of outsiders. This has been changed in the scenario.

According to the provided feedback, this scenario is especially desirable for target populations when they **immediately receive treatment**. Targeted drug administration prevents drugs wastage and reduces adverse effects.

Furthermore, an additional advantage that was mentioned, it **inclusiveness of testing**. The deployability of the device will enable high coverage, since it is possible to test in hard to reach areas which are otherwise excluded.

INSPiRED members mentioned possible **limitations in technical feasibility** of this scenario. When adults have been infected for a long time, the ova are stuck in tissue. As a result they might not excrete eggs anymore.

Respondents mentioned that the device will reduce costs of an epidemiological survey, so it will be **more desirable for the government** or other potential funders. Nigerian respondents mentioned the political will is doubtful, since the government will only support programs that are in line with their strategy. However, data that is gathered by the device might increase governmental interest and can be used to leverage a new control program. On the long term, it will decrease the disease burden and loss of man hours, which is beneficial for the Nigerian economy.

3. Test as sensitization tool

This scenario was chosen as extra scenario, since low awareness seems to be a major problem towards elimination of schistosomiasis in Nigeria. Overall, this scenario was chosen as most promising scenario by most respondents, see figure 31.

The main reason for respondents to choose this scenario, is that increased awareness is **essential to improve both case management and the control & elimination program**. A diagnostic device can play a valuable role in health education and community sensitization.

> 'I remember that they did an schistosomiasis awareness campaign in the North. Children used to swim and play with snails, no, after sensitization, they know that they shouldn't'
>
> Maryam Keshinro, medical doctor

The scenario is **desirable for patients on the long term**. It increases their knowledge and awareness on schistosomiasis, which increases health seeking behaviour on the long term. The respondents mentioned that providing **visual evidence** - photos or videos - instead of the regular verbal health education makes a bigger impact on the community. Furthermore, it gives them a free testing opportunity and it can identify asymptomatic cases. However, some

patients might shy away from testing in public. According to the respondents, the most important people in the community should be targeted. Sensitizing religious leaders, community elders, chiefs and teachers has the biggest effect on the long term since will influence the rest of the community.

The acceptability in the community is high, since the community mobilizer is **trusted by the community**. As a result the community chief is more likely to give consent for a sensitization meeting. On the downside, respondents mentioned that the community mobilizer is not trained health staff, so will require technical skills using the device. Furthermore, it was mentioned that the increased work demands may be undesirable.

This scenario was rated higher amongst the interviewees in Nigeria than the members of the INSPiRED team, due to a difference in perspective and interest.

10.4 Key insights

- Potential benefits of the smart diagnostic technology and gaps in the healthcare system were combined into opportunities for 12 use case scenarios
- Based on input from stakeholders in Nigeria and members of the INSPiRED team, the three most promising scenarios are selected

1. **Test at PHC consult**, where a 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

Chapter 11

PRODUCT SPECIFICATIONS

This chapter focusses on answering RQ5: What product specifications fit the selected health care scenarios and the needs of the stakeholders best?

In paragraph 11.1, desired product qualities for the diagnostic device are explored. Paragraph 11.2 contains information on the attributes in a target product profile. Paragraph 11.3 -11.5 present the target product profiles that were created for the three selected scenarios.

A creative session was organized to answer the last research question; RQ6: What is the value of a target product profile in communication of context insights and design requirements in a design project? This session is described in chapter 11.6. The test proposals that were created during the creative sessions to proof the value of the TPPs are presented in chapter 11.7.

Image 29. Interview with PHC coordinator/ physician in Ibadan North LGA

11.1 Exploration of product qualities

To discover which product specifications are important, three approaches to determine desired product attributes of a diagnostic test were used during the field trip.

Firstly, during the **interviews in the field,** the stakeholders were asked about their expectation of a new diagnostic test. They were asked what they consider important features for new diagnostics for schistosomiasis, without any further explanation of the technology. The interviews also provided insights in the acceptable price per test. The results are listed in appendix I-1.

Furthermore, to determine the expectation and desired attributes of an automated microscope, a **co-creation session** was organized with 14 Public Health students from the University of Ibadan. See appendix H for the set up and details of this session. Based on a very simple paper mock up of a device, see image 31, they were asked to make a scenario and list corresponding device requirements. Without any technical specifications other than 'it functions like an automated microscope' they listed desired product qualities for their use scenarios. The results of the session can be found in appendix I-2.

Lastly, a **discussion session** was organized with six Public Health PhD students to obtain desired product qualities based on the perception of the diagnostic technology. The prototype of the Schistoscope 2B was used to start a discussion on important device attributes, see image 32. The results of the session can be found in appendix I-3.

An overview of the result is presented in table 12. However, since these product qualities do not apply to a specific diagnostic scenario, insights are taken as general inspiration for the TPPs. The most important qualities were **ease of use** and **affordability**, followed by **limited dependency on power supply** and **rapid testing**

Image 30. Interview to obtain insights in desired product qualities for a new schistosomiasis test

Image 31. Master students discussing desired product qualities for an 'automated microscope'

Image 32. PhD students discussing desired product qualities for the schistoscope

	Product quality	Mentioned in interviews (n=10)	Mentioned in co-creation (n=5)	Mentioned in PhD discussion
Usability	Ease of use	8	1	1
	Automatic reading without human involvement	2		
	Not observer subjective	1		
	Can be operated by low level health worker	2		
	Can not be manipulated	1		
	Voice prompt in multiple languages			1
	Easy sample preparation	2		1
Results	Quantified result to know the severity	2	1	
	Option to upload results	1	1	1
	Option to send results to patient via SMS			1
	Print results			1
	Internal storage of result	2		
	Fast, making diagnosis while patient is still present	2	1	1
Device	Portable	1		
	Limited dependency on electricity or independent power source	4		1
Performance	High level of sensitivity	3	1	
	Specific	2		
	Detect asymptomatic cases	1		
	Detect light infections		1	
	Minimized malfunction, gives instructions in case it happens	1		
	Affordable for community members	7	2	
Extra	Comes with treatment	1		
	Includes Instructions on use the device		1	
	Comes with training that fits education level of operator	3		
	Device should come in a bag with protective foam and space for accessories			1
	Reusable ancillary supplies (filter holder + glass slides)			1
Extra functionalities	Show awareness video with experiences from former patients		1	1
	Video with introduction to disease, symptoms, prevention and treatment		1	
	Provide follow up alert		1	
	Provide suggestion which health centre to visit			
	Can detect multiple diseases	1	1	
	Option to get second opinion	1		
	Save GPS location	1		
	Ability to take pictures of water source	1		
	Includes information to improve knowledge of health worker		1	

Table 12. Desired product qualities

11.2 Target product profile

A target product profile (TPP) lists **desirable characteristics of a product**. The TPP does not only contain technical requirements, but also those that allow **use in a specific setting**. It can be used as guidance in the design and development of a product. [11]

A target product profile describes the **acceptable and ideal characteristics** of a diagnostic test. [93] [94] These ideal values would make the device more attractive. A target product profile is used to ensure that research and design activities are focussed on relevant products and products are designed for the context and needs of the end users. [93] [11]

For the three selected scenarios, three different target product profiles were developed; sensitization tool, diagnostic device for PHC facilities and a diagnostic device for mapping of adult populations at risk. These can be found in chapter 11.3-11.5.

The attributes on the TPP are divided into four categories. The **scope** describes the intended users, location of test and the value proposition. The **operational characteristics** describe the requirements for the use of the device; including requirements on sample preparation and data collection. **Performance characteristics** describe the requirements on accuracy and detection limits of the test. The product features for **pricing** describe the price per test and the price of the device.

Figure 33 gives a visualization of the factors that determine the attributes on the TPP. The number in the blue dots corresponds to the requirement number in the TPP. The scope of the TPP has already been determined for the selected scenarios in chapter 10. Since the purpose of testing, the test setting, target user, target population and test enablers differ for each of the scenarios, the requirements are different for each scenario. Attribute 2.1, the diagnostic marker, and attribute 2.2, (acceptable) sample type, are similar for all scenarios since those are determined by the smart diagnostic technology.

The attributes were determined by combining the insights from part II, part III and part IV of this report. Furthermore, it includes insights from the desirable product attributes presented in section 11.1.

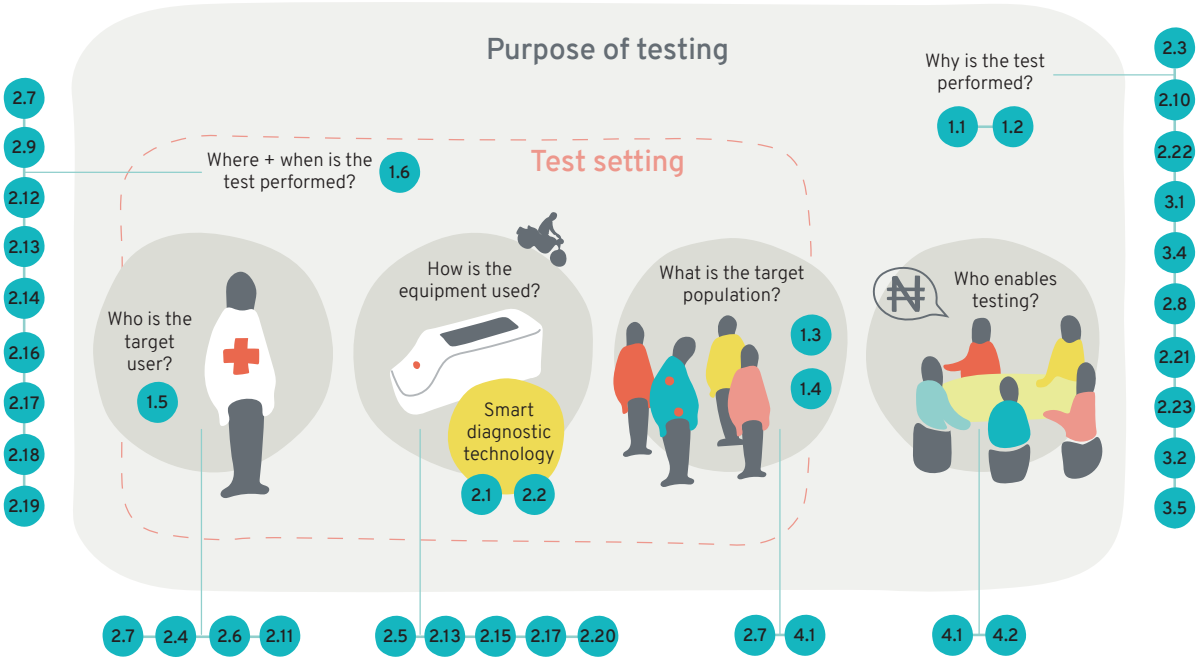


Figure 33. Scope of a target product profile and corresponding attributes

11.3 TPP for test at PHC consult

Table 13 presents the target product profile for a diagnostic device for diagnosing urinary schistosomiasis at a PHC consult. The reasoning behind all attributes and the acceptable and ideal values can be found in appendix M-1.

The device will be used when a patient comes with symptoms to a consult at the PHC facility. Instead of referral to a hospital laboratory, the diagnosis can be made at PHC level. The device is stored inside the facility, and will only be taken out once a case is suspected.

The target population are infected individuals in endemic communities. The test will be performed at public PHC facilities without laboratories, this can either be health posts or clinics. These facilities have no windows, no running water and often not connected to electricity network. The materials present in the facility are limited. Image 33 shows an example of the environment inside a health clinic.

The diagnostic device will be used by a community health worker without testing experience other than RDT, therefore the sample preparation and device interaction should be **as simple as possible**. CHWs often do not have adequate knowledge on urinary schistosomiasis, so the device should include **instructions** on medicine administration and health education.

Confirmed cases should be shared weekly with the DSNO, so the collected data should **correspond with the guidelines** for Integrated Disease Surveillance and Response (IDSR). In an ideal situation, the device would be able to diagnose S. mansoni infections in stool as well, since this allows the data to be a more adequate representation of the schistosomiasis problem in Nigeria. To determine the morbidity and prescribe the right drug dose, results should include infection intensity. Location data can be used to identify infected water bodies.

Sensitivity and specificity of the test should be at least the same as microscopy, since the result should be as trustworthy as laboratory confirmation, to confirm the case officially. To improve the accuracy of the result, it is recommended to test multiple midday urine samples of more than 10 ml, collected on consecutive days. However, since this scenario focusses on passive case detection, it is less likely that asymptomatic people with light infections are tested. As a result, in this scenario it is less important that the device recognizes every single egg.

Image 33. Primary healthcare clinic in Akinyele LGA

The acceptable time to result is one day, which allows sedimentation by gravity as simple sample preparation method. 10 - 30 minutes to result is ideal. A device that gives immediate results will not be trusted.

'Any device that will give results in 5 seconds, I will not trust'

PhD student Public Health

'If the test results take up to 30 minutes to an hour, it is still fine. It will even allow the patient to know the gravity of the disease and you can use this time to enlighten the patient'

Community mobilizer and CHO

Equipment on PHC level is distributed by the SPHCDA. To determine the price for the device, this agency should be involved. The price per individual test is determined by indications from interviewees, see appendix I-1.

	Attribute	Acceptable	Ideal
	Scope		
1.1	**Need (value proposition)**	Affordable and easy to use diagnostics	
		Enables diagnosis at primary healthcare level and sharing of data; referral to hospital labs is no longer required	
1.2	**Use case**	Case management at primary healthcare level	
1.3	**Target population**	Sick people in endemic communities	
1.4	**Target community**	Communities in areas with high prevalence of S. haematobium in Nigeria	
1.5	**Target user of test**	Community health workers (CHEWs and JCHEWs) with minimal training	
1.6	**Location of test**	Primary health facilities without laboratories	
		Inside facilities without windows or with open windows, in a dusty, humid and hot environment	
	Operational characteristics		
2.1	**Diagnostic marker**	Schistosoma ova	
2.2	**Sample type**	Urine	Urine and stool
2.3	**Sample volume**	10 ml urine	> 10 ml urine
2.4	**Sample preparation**	Minimal sample preparation with as little ancillary supplies as possible	Integrated sample preparation
		Precise timing and measuring should not be required	
2.5	**Sample stability**	Time that is necessary to collect, prepare and analyze sample	
2.6	**Steps performed by operator between sample preparation and result**	Test should be easy to use	None
		Less operator steps than microscopy, none of which are timed or labour intensive	
2.7	**Result display and result interpretation**	Instrument should have integrated screen, a simple keypad or touchscreen (compatible with protective gloves)	
		Ability to save results	
		Result should be understandable by healthworkers as well as patients who have no prior knowledge of diagnostic tests and might be illiterate or non English speaking	
		Result and interpretation should not depend on level of knowledge	
2.8	**Nature of result**	Presence and intensity of infection (low or high)	Number of eggs, infection intensity and treatment that should be prescribed
2.9	**Time to result**	Same day result, including sample preparation time	10-30 minutes, including sample preparation time
2.10	**Throughput**	1 sample per day	>1 samples per user per day
2.11	**Training required**	Test should be easy to perform after one training, for an operator with some medical training, but no experience in tests	No training, textual and visual instructions should be sufficient to operate the device
2.12	**Device size and weight**	Table-top device	
2.13	**Power requirements**	Battery power with minimal 8 hour operation between charges	
		Show battery level	
		Battery charged by generator	Battery charged by solar power
			Give indication when battery is almost empty
2.14	**Ancillary supplies**	Ancillary equipment for sample preparation which is not available in standard PHC	None
		Standardized, locally available and reusable parts where possible	

2.15	**Test kit**	Should include all materials for test procedure	
		Should include instructions on test procedure, administration of medicine, maintenance and cleaning of the device	
			Should include urine reagent strips
			Should include material for health education
			Should include urine color card
2.16	**Operating conditions**	Withstand temperature fluctuations between 20-40 degrees and 60-100% humidity	
2.17	**Environmental tolerance of packaged test kit**	Should protect device and ancillary supplies against dust	
2.18	**Cold chain requirements**	No cold chain required	
2.19	**Cleaning**	Device and reusable ancillary supplies should be easy to clean without running water	
2.20	**Maintenance & Calibration**	Calibration is not required	
		Should give indication when unstable, in case of inadequate sample or incorrect procedure	
2.21	**Data acquisition and storage**	Able to add patient ID, operator ID, age, facility, location of patients house, sample quality and color	Able to add patient ID, operator ID, weight or height, date, age, location of patients house, sample quality and color, result of reagent strip
			Able to print results + medicine prescription
		Able to store patient results for at least a week	
2.22	**Connectivity**	N/A	Device is connected with mobile phone network
2.23	**Data export**	Data is shared on paper to disease surveillance and notification officer	Should export data automatically to LGA disease surveillance and notification officer via mobile network
			Should have ability to export data on USB
			Should allow for a second opinion from laboratory on a distance
	Performance characteristics		
3.1	**Limit of detection**	Should be able to detect light infections (<10 ova) and asymptomatic cases (without haematuria)	Should be able to detect the number of eggs in sample (even if there is only one)
		Should be able to distinguish between light and heavy infection	
3.2	**Analytical specificity**	Detects S. haematobium	Detects S. haematobium and S. mansoni
3.3	**Diagnostic sensitivity**	Same as microscopy (≈80%)	Higher than microscopy
3.4	**Diagnostic specificity**	Same as microscopy (≈90%)	Higher than microscopy
	Price		
4.1	**Price of individual test**	Max 800 Naira (including sample preparation)	Max 300 Naira (including sample preparation)
4.2	**Price of device**	Depends on SPHCDA (indication is max 30,000 naira)	Depends on SPHCDA (indication is max 10,000 naira)

Table 13. Target product profile for test at PHC consult

11.4 TPP for mapping of adult populations at risk

Table 14 presents the target product profile for a diagnostic device used for mapping of adult populations at risk. The reasoning behind all attributes and the acceptable and ideal values can be found in appendix M-2.

Farmers and fishermen have daily contact with water, which makes them a big risk group for schistosomiasis. They gather in occupational groups, which makes their group meetings a suitable moment for testing. Those meetings take place in the community, usually outside where resources like electricity and running water unavailable.

The diagnostic device enables the collection of epidemiological data in the field. This mapping involves a lab assistant, if sample preparation is necessary, and a community health worker, since she or he knows the community and can administer medicine. CHWs have very limited experience with medical devices so it is important that the test is **easy-to-use.**

To use the result of the survey for mapping purposes to initiate a new control program, it should follow the **WHO guidelines**. These require testing at least 50 people per sentinel site, a sample of at least 10 ml urine and a quantitative and qualitative result. The data can be used to leverage medicine donation, governmental interest and financial sponsoring for a new control program.

Furthermore, mapping for urinary schisto-somiasis is usually done together with mapping for intestinal schistosomiasis and soil transmitted helminths. Ideally, the device can identify those infections as well.

The results should be available on the **same day**, so the infected individuals can get treated if positive. If there is no praziquantel available, the community members will receive results which can be brought to a health facility where they will receive treatment.

Image 34. Temporary laboratory in rural community

Since the device will be transported from one location to another, the test kit should be able to **tolerate transport stress**. When multiple devices are used at once, transport is done by car. If there is only one device required or test location is hard to reach, the test kit it transported by motorbike. There is no ancillary equipment available at the test location, so everything that is required for testing at least 50 people should be included.

Charging and calibration should not be required during the screening day. It will take up time and disturb the process flow. Preferably, cleaning is of material is not required after every test.

This device should at least have the accuracy of the microscope in the laboratory, since that is the alternative method. A higher sensitivity can be reached with a **larger urine sample** - in case the result should be calculated to the amount of eggs per 10 ml.

Participation in mapping has to be free for the community members. The price per test and acceptable price for the device cannot be determined since they depend on the financial sponsor of the mapping survey. It is more likely that a party will pay for the devices if they are cheaper than microscope.

	Attribute	Acceptable	Ideal
	Scope		
1.1	**Need (value proposition)**	Field deployable, cheaper diagnostic test than microscopy so risk groups can be mapped and treated immediately	
1.2	**Use case**	Mapping of prevalence amongst adults to initiate control program for risk groups other than school children	
1.3	**Target population**	High risk occupational groups: fishermen, irrigation farmers, etc.	
1.4	**Target community**	Communities at risk of S. haematobium infection in Nigeria	
1.5	**Target user of test**	Laboratory assistants for sample preparation (if necessary), community health workers for operating the device	
	Location of test	At occupational group meetings	
1.6		Either inside or outside in dusty, hot and humid environment	
	Operational characteristics		
2.1	**Diagnostic marker**	Schistosoma ova	
2.2	**Sample type**	Urine	Urine and stool
2.3	**Sample volume**	10 ml urine	> 10 ml urine, but can detect ova in smaller samples as well
2.4	**Sample preparation**	Fast sample preparation with as little ancillary supplies as possible	Integrated sample preparation
		Easy to perform for someone with laboratory training	
2.5	**Sample stability**	Time that is necessary to collect, prepare and analyze 50 samples	
			10% of samples should be stored for quality control
2.6	**Steps performed by operator between sample preparation and result**	Test should be easy to use	None
		Less operator steps than microscopy, none of which are timed or labour intensive	
2.7	**Result display and result interpretation**	Test must be simple to navigate	
		Device should have integrated screen, simple keypad or touchscreen (compatible with protective gloves) which functions in various lighting conditions (from direct sunlight to ambient light)	
		Saves results automatically	
			Presence and intensity of infection is given, so drugs can be administered immediately if available
2.8	**Nature of result**	Infection intensity, classify in light or heavy infection and number of eggs/10 ml	
2.9	**Time to result**	Same day result	30 minutes, including sample preparation time
2.10	**Throughput**	>50 samples per user per day	>100 samples per user per day
2.11	**Training required**	Test should be easy to perform after one training by an operator with some medical training, but no experience in tests	
2.12	**Device size and weight**	Small, portable table-top or hand-held device	
2.13	**Power requirements**	Battery power with at least 8 hour operation between charges	
			Battery level should be visible and device gives indication when battery is running low
		Battery charged by generator	Battery charged by solar power

2.14	**Ancillary supplies**	Ancillary supplies packaged as a kit	None
		As little ancillary equipment as possible for sample preparation	
		WHO approved, standardized, locally available and reusable parts where possible	
2.15	**Test kit**	Should include all materials for test procedure	Should include all materials for test procedure and a spare battery
		Should include instructions on sample preparation, how to operate the device and cleaning instructions	
2.16	**Operating conditions**	Withstand temperature fluctuations 20-40 degrees and 60-100% humidity	
2.17	**Environmental tolerance of packaged test kit**	Should be able to tolerate transport stress (motorbike or car) and exposures between 20-40 degrees	
		Should protect device and ancillary supplies against sunlight, dust and rain	
2.18	**Cold chain requirements**	No cold chain required	
2.19	**Cleaning**	Device and reusable ancillary supplies should be easy to clean without running water;	Device and reusable ancillary supplies should be easy to clean without running water
			Cleaning of the device is not necessary during screening day
			In case of filtration, there should be an option to check if a cleaned filter is free from ova
2.20	**Maintenance & Calibration**	Device should give indication when unstable, in case of an inadequate sample or incorrect procedure	
		Calibration should not be required during screening day	Calibration is not required
2.21	**Data acquisition and storage**	Able to add patient ID, operator ID, date, age, location of sample collection	
		Able to store data and results from at least 50 patients	Able to store data and results from at least 100 patients
2.22	**Connectivity**	Device has an integrated GPS module	Device has integrated GPS module and connected with mobile phone network
2.23	**Data export**	Should have ability to store data of mapping in device; number of eggs/10ml, number of cases, location	
		Option to share through USB or mobile network	Share data automatically if there is mobile network, option to share through USB
	Performance characteristics		
3.1	**Limit of detection**	Should be able to detect the number of eggs in sample (detect infections with ≤ 10 eggs)	Should be able to detect the number of eggs in sample (detect infections with ≤ 5 eggs)
3.2	**Analytical specificity**	Detects S. haematobium	Detects S. haematobium, S. mansoni and STH; distinguishes between them
3.3	**Diagnostic sensitivity**	Same as microscopy (≈80%)	Higher than microscopy
3.4	**Diagnostic specificity**	Same as microscopy (≈90%)	Higher than microscopy
	Price		
4.1	**Price of individual test**	Cheaper than filtration + microscopy (approximately $1)	To be determined, dependent on mapping initiator/financial sponsor
4.2	**Price of device**	Cheaper than a microscope (approximately 100,000 Naira ≈ €250)	To be determined, dependent on mapping initiator/financial sponsor

Table 14. Target product profile for mapping of adult populations at risk

11.5 TPP for sensitization tool

Table 15 presents the target product profile for a diagnostic device for a test to sensitize the community. The reasoning behind all attributes and the acceptable and ideal values can be found in appendix M-3.

This device will enable diagnosis as a tool for health education. Testing people from the community and allowing them to see the result with their own eyes will increase the awareness on schistosomiasis. This requires a **visual result** that is understandable to all.

The device is operated by a community resource person, since they are trusted by the community and **experienced with community sensitization**. However, since they are not formal health workers, the device does not make an official diagnosis. They have very limited training, so the number of steps in sample preparation and device operation should be minimized or eliminated.

The test will be performed at sensitization meetings with the most important people in the community. These meetings usually take place outside. The temperatures are high and the environment is dusty. Image 35 shows an example of a sensitization meeting in Nigeria.

Prior to the sensitization meeting, either an infected urine sample should be collected or an infected individual should be invited with help of a CHW. After testing and showing a positive result, the community members have the option to volunteer for testing. Since testing is free and they care for health in the community, the community members should be willing to help.

The device have a throughput of at least **5 samples per hour** and the results should be available **before the end of the sensitization meeting**. The time between the sample collection and result can be used to educate the community about schistosomiasis, symptoms and prevention.

Image 35. Community sensitization meeting in Nigeria

The device will be transported from community to community, so the test kit should be able to tolerate transport stress by motorbike.

Since the device **does not make an official diagnosis**, the healthcare data does not have to be acquired, saved and shared. The infected individuals will receive instructions for referral to a health facility or the DSNO can be informed to pick up the sample. However, ideally the device would save location data and the number of infected individuals to **identify infected water bodies.**

Sensitivity and specificity are not that important for this test. However, the device should be able to detect **asymptomatic cases**, since those are the people that will never seek healthcare by themselves.

The test should not cost any money for the community members. The acceptable price per individual test and the price of the device can not be determined, since they depends on who will pay for this health education program.

	Attribute	Acceptable	Ideal
	Scope		
1.1	Need (value proposition)	Use diagnosis as a tool for health education, to create awareness in the community about the disease	
1.2	Use case	At sensitization meetings	
1.3	Target population	Important people in communities; chiefs, traditional healers, PMVs, teachers, elderly, religious leaders etc.	
1.4	Target community	Communities in endemic areas for urinary schistosomiasis in Nigeria	
1.5	Target user of test	Community resource persons, like community mobilizers or LGA NTD program officers, with minimal training	
1.6	Location of test	At Community meetings	
		Inside or outside in a dusty, humid and hot environment	
	Operational characteristics		
2.1	Diagnostic marker	Schistosoma ova	
2.2	Sample type	Urine	
2.3	Sample volume	10 ml	>10 ml
2.4	Sample preparation	Minimal sample preparation with as few operator steps as possible	Integrated sample preparation
		Requires as little ancillary supplies as possible	
		Precise timing and measuring should not be required	
2.5	Sample stability	Time that is necessary to collect, prepare and analyze sample	> 6 hours
			Should be able to tolerate transport stress
2.6	Steps performed by operator between sample preparation and result	Test should be easy to use for someone with no test experience, except for RDT	None
		Less operator steps than microscopy, none of which are timed, require precision or are labour intensive	
2.7	Result display and result interpretation	Result should be visual	
		Results should be understandable by a user who has no prior knowledge of diagnostic tests. people who are illiterate and in English and local language	
2.8	Nature of result	Presence of infection	Number of eggs, infection intensity and instructions for next steps
2.9	Time to result	Before the end of the sensitization meeting	<30 minutes, including sample preparation time
2.10	Throughput	>5 sample per day	Able to test all people at sensitization meeting (around >30 samples per user per sensitization meeting)
2.11	Training required	Test should be easy to operate after one training for an operator without medical training or experience in tests	
2.12	Device size and weight	Small, portable table-top or hand-held device	
2.13	Power requirements	Battery power with at least 8 hour operation between charges	
			Show battery level and give reminder to charge the battery
		Battery charged by generator	Battery charged by solar power

2.14	Ancillary supplies	Ancillary supplies packaged as a kit	None
		As little ancillary equipment as possible for sample preparation	
		Standardized, locally available and reusable parts where possible	
2.15	Test kit	Should include all materials for test procedure	
		Should include instructions on test procedure, maintenance and cleaning of the device	
		Should contain referral instruction	
2.16	Operating conditions	Withstand temperature fluctuations between 20-40 degrees and 60-100% humidity	
2.17	Environmental tolerance of packaged test kit	Should be able to tolerate transport stress (motorbike on dirt roads)	
		Should tolerate temperature exposures between 20-40 degrees	
		Should protect device and ancillary supplies against sunlight, dust and rain	
2.18	Cold chain requirements	No cold chain required	
2.19	Cleaning	Device and reusable ancillary supplies should be easy to clean without running water	
2.20	Maintenance & Calibration	Calibration should not be required	Should give indication when unstable, in case of inadequate sample or incorrect procedure
2.21	Data acquisition and storage		Able to print the result and/or a referral to health facility
		N/A	Able to add operator ID, date, location, age
			Able to store results
2.22	Connectivity	N/A	Device has integrated GPS module and connected with mobile phone network
2.23	Data export	N/A	Should be able to export data via USB or mobile network to health facility
	Performance characteristics		
3.1	Limit of detection	Should be able to detect light infections (<10 eggs) and asymptomatic cases (without haematuria)	Should be able to detect number of eggs (even if there is only one)
3.2	Analytical specificity	Detects S. haematobium	
3.3	Diagnostic sensitivity	To be determined	Higher than microscopy (>80%)
3.4	Diagnostic specificity	To be determined	Higher than microscopy (>90%)
	Pricing		
4.1	Price of individual test	To be determined, but free for community members	To be determined, but free for community members
4.2	Price of device	To be determined, depends on financial sponsor	To be determined, depends on financial sponsor

Table 15. Target product profile for sensitization tool

11.6 Target product profile validation

To validate the developed target product profiles, two creative sessions were organized with students from Industrial Design Engineering.

Set up

The goal of this sessions was to **validate the completeness of the TPP**, to determine the **value of a target product profile in communication of context insights and design requirements** and lastly, to get some **test proposal ideas**.

Due to time constraints, the creative session included only two out of the three target product profiles. The target product profile for the device as sensitization tool was left out, since it requires the design of a whole health education program. To focus on the diagnostic device itself, the other two TTPs were used, since diagnosis is the main practice in those scenarios.

The sessions took 2,5 hours. Team B consisted out of five students. Team A consisted out of three students. The input that was given to the students can be found in appendix N-1.

Group B first received the TPP for testing at PHC consult and an overview of the patient and health worker barriers in case management. The group had 1 hour to design a device, decide on the components in the test kit and determine the steps in the procedure. After this first design task, group B received the input (barriers and TPP) for mapping of adult populations at risk. Again, they had 1 hour to design a device, test kit and procedure. The session set up for group A was similar, but they started with mapping, and designed for PHC consult in the second part of the session.

After the session, the students filled in a survey where they reflected on the session and shared thoughts on the TPPs and lists of barriers. This survey can be found in appendix N-1.

Image 36. Team B during the creative session

Results

Observations from the session can be found in appendix N-2. The results can be found in appendix N-3. The test proposals are visualized and explained in chapter 11.7.

The test proposals fit the requirements for the use case, but due to time constraints, **not all attributes are included**. All students understood the function and set up of the target product profile without further explanation. Some product qualities required some **extra explanation**, since the students were not acquainted with certain definitions. Furthermore, the participants missed some biomedical knowledge on certain sample preparation attributes and the cleaning possibilities. For some aspects on the list, the students did not understand the difference in acceptable and ideal values.

In the survey, some respondents mentioned that they missed requirements on **repairability, maintenance** and **lifespan** of the device on the target product profile.

In the survey, most of the students thought the second part of the creative session was better than the first part. In both sessions, the results from the second part of the session included more product attributes from the TPP and were more adjusted to its scope attributes, which can be seen in the proposals in chapter 11.7.

The average rating for usefulness of the target product profile is given on the scale below.

The list of barriers was considered very useful for group B, while group A thought its added value was limited, since the list did not contain much new information. The average rating for usefulness of the list of barriers is given on the scale below.

Conclusion

The target product profile was considered to be a **useful tool** for the design of a diagnostic device. The TPPs communicated the context insights and design requirements, since the test proposals fit the requirements. The students were able to realistically balance acceptable and ideal product attributes. However, the target product profiles need to be **accompanied with explanations** that support the decision to include each attribute.

'Having requirements that are based on research frees design time to do more ideation and embodiment'
Participant creative session

The list of attributes on the target product profile was considered to be close to complete. In the future, more research should be done to determine requirements on local repairability and manufacturing - but for this project that was out of scope. Besides that, some product attributes that were unclear have been **revised** and **updated**.

The list of barriers was useful to determine the needs of the patient and test operator, which allowed the students to design from a user perspective. Instead of providing the whole list of barriers as a separate input, it can be considered to **include the user needs** in the target product profile explanations.

Discussion topics for the creative session can be found in chapter 12.2.

'Could a design for the global south methodology come out of this?'
Participant creative session

11.7 Diagnostic test proposals

Case management test A

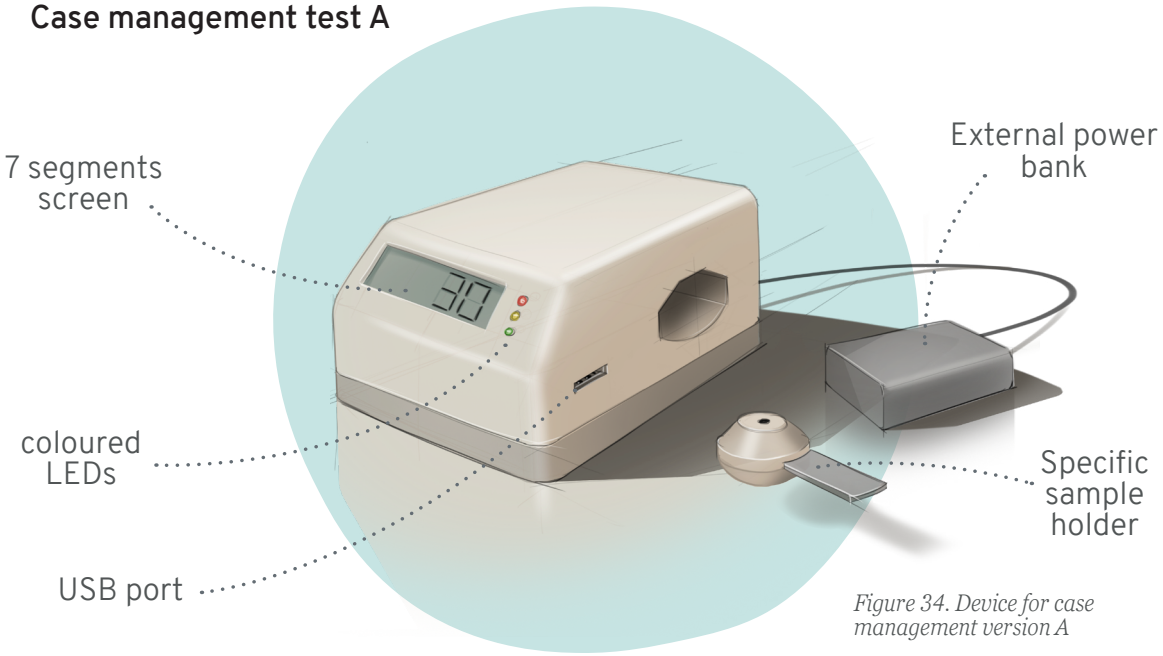


Figure 34. Device for case management version A

The device in figure 34 is designed to be as simple as possible to reduce costs.

Figure 35 shows a simplified version of the test **procedure**. Urine samples are collected in jam jars. Sample preparation is simplified by inserting the whole filter holder into the device, instead of taking out the filter and putting it on a slide. The diagnosis can be started by a switch.

The **device** contains 3 LEDs and a 7 segment screen to show the result of the test. The colour of the LEDs represent the infection intensity - green for negative, yellow for a light infection and red for a heavy infection. The USB port allows data export. The battery pack is external. To save costs, the results are written down on paper.

The **test kit** contains filter holders, filters, gloves, syringes and iodine for sample preparation. There are spare batteries and a logbook to write down patient data. For cleaning, it contains cleaning agents, a small brush and a piece of cloth. Furthermore, there are some replacements for parts that break frequently.

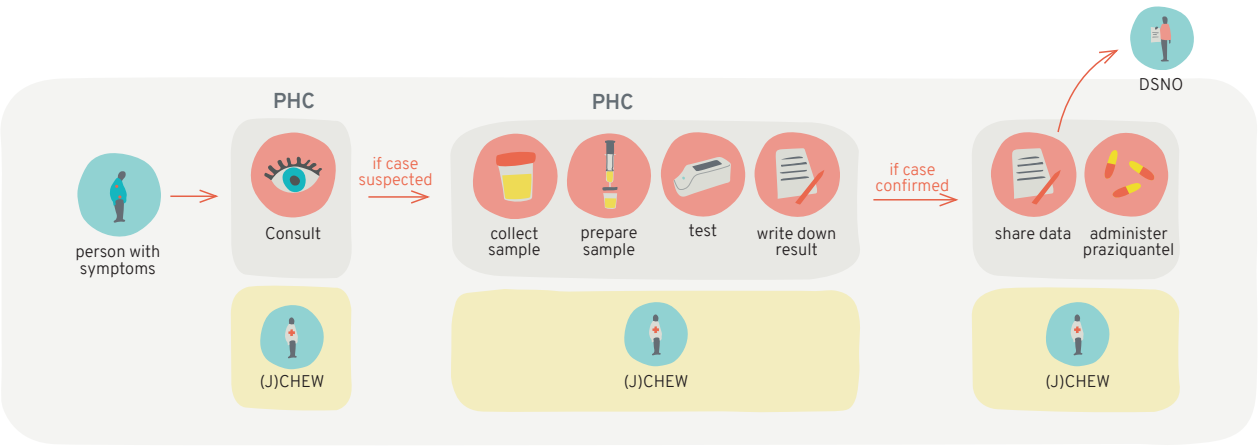


Figure 35. Process map for test

Case management test B

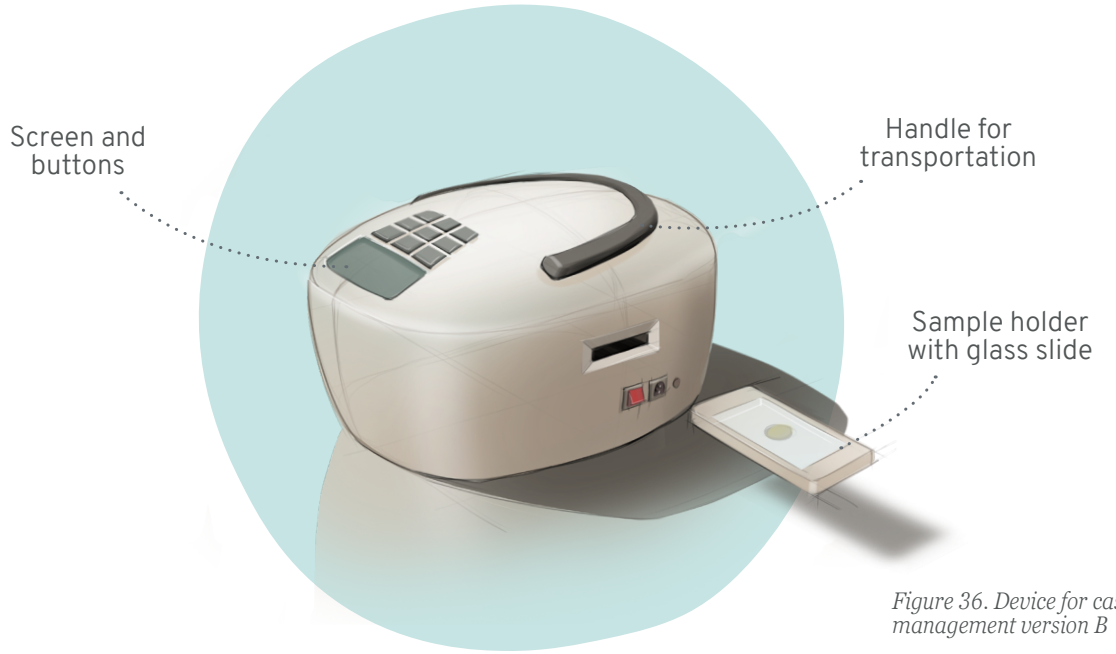


Figure 36. Device for case management version B

The device in figure 36 is designed to analyze both urine and stool samples. The **device** contains a touchscreen, buttons and a handle for transportation.

Figure 37 shows a simplified version of the **test procedure**. Urine samples are prepared by filtration, after which the filter is put on a glass slide. The sample holder is pulled out of the device and the sample is put in. The device is started and the screen shows the test progress. When the test is finished and the results are processed, the screen shows a visual result with the amount of eggs. The intensity of the infection is indicated with a color scale. The result indicated the amount of tablets that should be prescribed. The results can be saved. Afterwards, the slide is taken out of the holder. The sample is stored and the slide is cleaned.

The **test kit** contains enough ancillary supplies for five tests, so there is enough equipment to perform a few tests without cleaning in between. Furthermore, there are disinfectants for cleaning and an iodine solution for increasing the visibility of the ova.

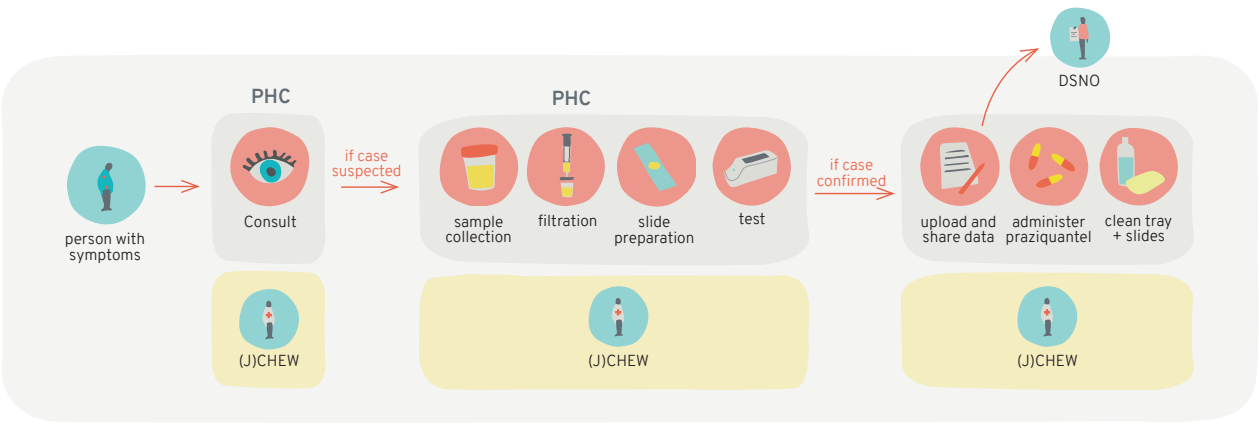


Figure 37. Process map for test

Control & Elimination test A

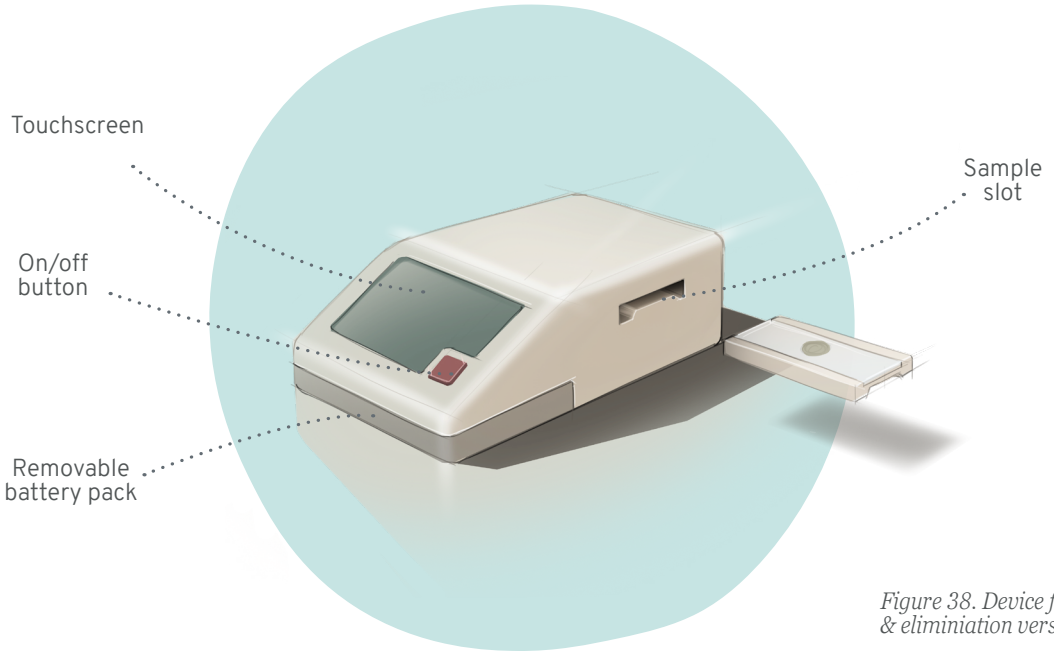


Figure 38. Device for control & eliminiation version A

Th **device** in figure 38 is small in size and has a removable battery pack, a touchscreen and an on/off button.

Figure 39 shows a simplified version of the **test procedure**. Urine is collected, filtered and the sample is prepared on a glass slide. The device is turned on and the patient data is added via the touchscreen. The slide is placed in the sample slot and the device starts analyzing. After processing, the touchscreen shows the test results. After testing, the device is cleaned.

In the **test kit** is material for sample collection - urine containers, filters, iodine, cleaning material and glass slides. The device itself is stored in hard casing box, with some spare parts, an extra battery, a weighing scale and measuring tape. The batteries can be charged with the included solar charger. Furthermore, the kit contains medicine and flyers to distribute in the communities.

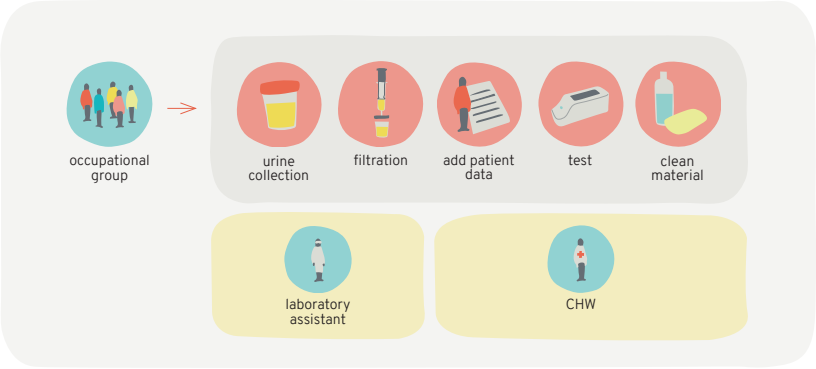


Figure 39. Process map for test

Control & Elimination test B

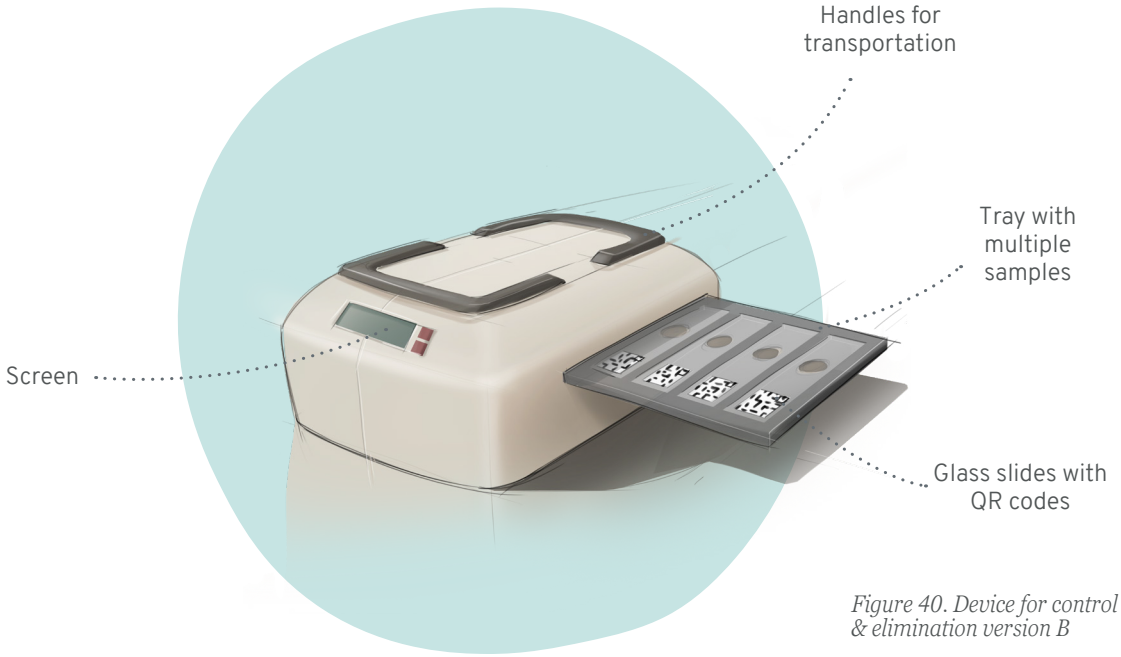


Figure 40. Device for control & elimination version B

The **device** in figure 40 is designed to test multiple samples at once, to increase the throughput.

Figure 41 shows a simplified version of the **test procedure**. The field team consists out of three people. One data collector, one person to prepare the sample and one person to operate the device. Urine is collected and two stickers with identical QR codes are pasted on the urine container. The code is scanned with a phone and patient data is added. The lab assistant takes one sticker and puts it on a slide. The sample is filtered and the filter is placed on a glass slide. The slide is placed in a tray. When the tray is full, the samples will be tested.

The camera in the device scans the QR codes and automatically matches the slide to the patient data. The samples are analyzed and results are uploaded. In case a sample is not recognized, feedback is provided on the screen.

Afterwards the tray is taken out the device. The samples are taken out of the tray, the QR stickers get removed and the sample tray and slides are cleaned.

There is a solar panel on the outside of the **test kit** box and there are three extra powerbanks. The test kit contains material for sample preparation and cleaning. Furthermore it contains a sticker strip with QR codes.

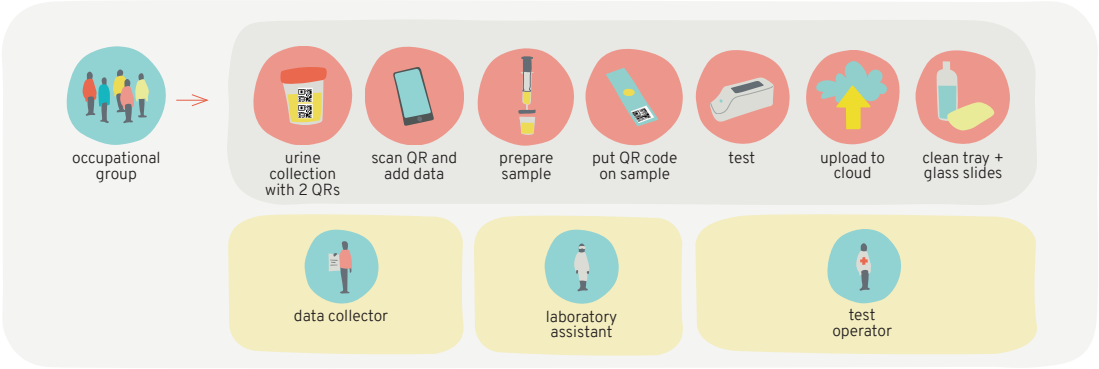


Figure 41. Process map for test

VI
EVALUATION

Chapter 12
EVALUATION

This chapter provides conclusions to the project and answers to the research questions. Furthermore, the discussion section describes the limitations of the study. The last section provides recommendations for further research.

12.1 Conclusion

Combine gaps in the healthcare system and needs from stakeholders with technological possibilities into a target product profile for a diagnostic device for urinary schistosomiasis for specific use case scenarios in Nigeria.

The goal of this project was 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 specific use case scenarios in Nigeria. To reach this goal, six research questions were formulated and answered. The result of this project are three target product profiles for three promising use case scenarios.

II In part II, some basic knowledge about urinary schistosomiasis and the diagnostic possibilities and limitations was gathered. The golden standard for diagnosing urinary schistosomiasis is microscopic egg count. However, it lacks sensitivity, requires high trained laboratory staff and is not field deployable.

III In part III, the smart diagnostic technologies were explored. Basic knowledge on the working principles of the reversed lens, holographic imaging and the classification algorithm was obtained. Moreover, the developed prototypes were evaluated to answer the following research question;

RQ1: What are the benefits and opportunities for the new technical principles for the diagnostics of S. haematobium?

The main benefits of the smart diagnostic technologies compared to microscopy are;

- Simple and user friendly
- Rapid
- Sensitive
- Robust and portable
- Affordable
- Data collection

IV In part IV, desk top research and field research to Oyo State, Nigeria was conducted to answer the following research questions;

RQ2: What are the current diagnostic practices and challenges concerning S. haematobium within the health care system in Nigeria?

RQ3: Who are the important stakeholders and what are their interests in diagnostics for S. haematobium and future implementation of a diagnostic device?

Two diagnostic contexts were explored; c**ase management on primary healthcare level** and the **control & elimination program**.

For **case management**, the stakeholders are divided into healthcare enablers, formal health providers, informal health providers and healthcare receivers. Their interests and potential role in a new diagnostic scenario were identified.

The main problem in case management is the **limited amount of confirmed cases**, which results in **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;

- Limited health seeking behaviour
- No tests in PHC laboratories
- Health workers miss cases
- DSNO guidelines are labour intensive
- Few diagnoses in rural areas
- No check up after referral
- No follow up after confirmed case

For the **control & elimination program** the stakeholders are divided into stakeholders for initiation, organization, mapping implementation, Deworming implementation and target populations. Their interests and potential role in a new diagnostic scenario were identified.

The problem in the control & elimination program is that the **prevalence is unknown**, which results in limited **government interest and funding**. The challenges for targeted populations and for the organization and implementation for each step in the control & elimination program were listed and the following gaps were formulated;

- Limited availability of data on endemicity
- No control program for other risk groups
- No impact assessment plan for Deworming day
- Target populations do not give consent
- No field deployable diagnostics available
- Control program is short term focussed

V In part V, the benefits from part III were combined with the stakeholder needs and the gaps from part IV into twelve use case scenarios. Interviewees from Nigeria and members of the INSPiRED team were consulted to answer RQ4: What are the most promising use case scenarios of a new diagnostic device to improve case management on primary level and control & elimination program?

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

To determine the attributes on the target product profile, desired product qualities were retrieved during interviews in the field, a discussion session with PhD students and a co-creation session with Public Health master students. Insights from part III, IV and V were combined to answer;
RQ5: What product specifications fit these health care scenarios and the needs of the stakeholders best?

The acceptable and ideal values for each product attribute were merged into target product profiles for the three scenarios. A creative session with Industrial Design Engineering students was organized to answer the last research question;
RQ6: What is the value of a target product profile in communication of context insights and design requirements in a design project?

The TPP proved to be **useful** in the design of a diagnostic device, provided that the designers have knowledge about the disease and diagnosis. However, the target product profile should come with an explanation of the chosen values. The TPPs **successfully communicated requirements and context insights**, which resulted in four **test proposals.**

12.2 Discussion

This paragraph provides a discussion of the results and lists the **limitations** of the study.

Scope

The research results and target product profiles are specified for diagnostics of urinary schistosomiasis in Nigeria. This does **not make them directly applicable for other healthcare settings**. Even though the prevalence of urinary schistosomiasis in other sub-Saharan countries might be similar, their healthcare systems are organized differently. They have their own guidelines on health worker responsibilities and data collection. Furthermore, they might be at a different stage or have a different strategy for the control & elimination program. In some countries there is more funding and government interest for the control of schistosomiasis.

The scope of the field research was limited to Oyo State. Even though its disease prevalence is more or less corresponding to the country's average, **not all field research results might be representative for the rest of Nigeria**. Multiple interviewees in the field mentioned the big cultural and political differences between the north and the south, which might result in differences in health seeking behaviour and available resources.

Field trip

During the field trip, three local government areas were visited. However, the **prevalence in those LGAs is not representative** of the rest of the state. Ibadan North and Akinyele were classified as low prevalence areas and Ibadan North West is non-endemic for schistosomiasis. As a result, the health workers in the visited facilities and the disease surveillance notification officers only saw a few cases a year. This might be different in local government areas with moderate or high prevalence of the infection.

The visited **health facilities were not an adequate representation** of the facilities in Oyo State. Five of the six facilities were in urban or peri-urban LGAs in close proximity to each other. The Atan health clinic was located in a rural community in Akinyele. We interviewed only one junior community health extension worker in that clinic, which is not be representative for all rural environments.

Furthermore, **three of the visited facilities were private facilities**, while this is not the target group of the diagnostic device. However, the interviews with health workers gave insights into patient considerations, diagnostic possibilities and use of equipment.

The visited **schools were all located in the same area**. They were all involved in the Deworming day, but not in the mapping exercise in 2013-2015. Results might be more reliable when acquired from teachers from schools in different areas.

None of the interviewees were directly involved in the school based survey, except for the state NTD coordinator. All other information on this survey is based on the report by the Federal Ministry of Health, instead of on experiences by fieldworkers or children involved in the survey.

Furthermore, we did **not speak to schistosomiasis patients directly**. The patient stories are told by caretakers or parents of the patients, and represent their perceptions on the story. The stories lacked detail on considerations and decisions of the patient, the diagnosis and the treatment.

Only one traditional healer and one patent medicine vendor were interviewed, both situated in an urban environment. They might **not be representative of all informal healthcare providers** in Oyo State.

The interviews with community members, community mobilizers, the traditional healer and the patent medicine vendor were conducted in Yoruba. These were translated afterwards,

so during the interviews there was **no chance during to ask follow up questions**. Moreover, there were some interviews in English with stakeholders that did not speak English fluently, which resulted in short answers and **communication difficulties.**

Research question 3 is only partially answered, since there were **no high level stakeholders** from Merck, the Federal Ministry of Health or the State/National Primary Healthcare Development Agency involved in the research.

The gaps were validated during the co-creation session with public health students. Even though they have knowledge about the healthcare system, they are **not direct stakeholders** in case management or the control & elimination program for schistosomiasis. Additionally, due to cultural differences, it was **difficult to receive critical feedback** from the Nigerian students.

Scenario survey

Some scenarios that were included in the questionnaire are **not technically feasible**. However, this was not known at the time of development of these scenarios. Since these scenarios were not selected by the respondents, this was not considered a problem.

Furthermore, the survey **respondents were not an adequate representation** of the stakeholders in the field. Most responses came from public health researchers. There were no respondents from the local or state government or the NGO Evidence Action. Since no community members or no high level stakeholders responded to the questionnaire, the ratings on patient- and governmental desirability are based on expectations which might not reflect reality.

The INSPiRED members that were involved in the questionnaire all have experience with research visits to low resource settings in sub-Saharan Africa, but not all in Nigeria. Dr. van Lieshout from LUMC pointed out that it is difficult to give ratings **without knowing the exact context to which the scenarios apply**. Since most of the INSPiRED members are not acquainted with the healthcare system in Nigeria, their ratings on desirability and organizational feasibility might not resemble reality. However, since the sub-goal of the questionnaire was to inspire them and start a discussion on possible directions of the INSPiRED project, it was of great importance to include them in the questionnaire.

The results from the INSPiRED team did not contradict the results from the interviewees in Nigeria. Meanwhile, the Nigerian respondents perceived the lack of awareness among the community members and the health workers as more problematic.

Desired product qualities

The desired product qualities were **not discussed during every interview** in the field. As a result, there were no insights on desired qualities by laboratory staff - while these might be very useful.

During the co-creation session, the public health students were asked to come up with requirements that corresponded to their created scenario. However, developing these scenarios took a lot of time. As a result, **not all students had enough time** to come up with desired product qualities. Besides, all participants studied Public Health, which resulted in a focus on sensitization in their created scenarios.

Furthermore, the discussion session with the PhD students was not structured. This allowed an informal atmosphere where everyone was discussing the prototype and possible adjustments. However, it was **difficult to catch all their feedback**.

Lastly, the results of these three sessions could not be used as a direct input into the target product profile. The **product qualities did not apply to one of the three selected scenarios**, since they were not developed at the time of the field research.

Image 37. School boy in Ibadan North

Target product profile

Not all attributes on the target product profiles are specified yet, since they require further stakeholder research. Besides, the attributes have **not been validated by end-users.**

The target product profiles were specified for the Nigerian healthcare system. Some adjustments might be required to make the diagnostic tests suitable for other regions or countries.

The target product profiles are specified for three use case scenarios. However, it might be possible that devices that are developed in line with the TPP, are **usable in other test settings** as well. For example, a diagnostic device designed for testing at PHC consult can be used in laboratories as well. This is only possible when moving up in knowledge level of user and available resources at the test location.

Target product profile validation

The participants of the creative session already worked together on a project on the same subject. Discussions they had prior to the session might have influenced the result. Instead of using the input that was given to them, some requirements were filled in from **former knowledge**. When a TPP is provided to a design team with no prior knowledge of the subject, it should come with an explanation of current diagnostic procedure and the new technology.

Besides, team B consisted out of five students, while there were only 3 students in team A. This resulted in more detailed results from team B. Due to time constraints, it was only possible to do creative sessions with **two of the three target product profiles**.

Furthermore, it was not possible for the students to include all attributes on the target product profile into their designs, so the **value of the test proposals** itself might not be very high. However, since the main goal was to validate the TPP as design input, this was not considered a problem. The proposals illustrate possible directions to proceed with in the future.

12.3 Recommendations

This section contains recommendations for further research and some recommended steps in the development of the smart diagnostic technologies and the embodiment. Lastly, there are recommendations for future implementation of a diagnostic device in Nigeria.

Further context research

Since the development of target product profiles is an **iterative process**, it is important to continue with stakeholder research.

It is recommended to **interview the Federal Ministry of Health** to discover their interest in schistosomiasis and plans for the future of the control & elimination program. Furthermore, this can provide insight in governmental support for the scenario mapping of adult populations at risk, and the probability of a new control program.

More research is required to determine whether **testing at PHC consult is feasible**. It requires research into the need of smart diagnostics in areas with a higher prevalence of schistosomiasis. In the visited areas during the field trip, the amount of suspected cases was very low. A diagnostic device for might not be used, unless it comes with a sensitization campaign.

Furthermore, **local manufacturing, repair-ability** and **maintenance** were outside the scope of this project. However, to enrich the target product profiles, additional research is required on these attributes.

Lastly, it might be interesting to **take private facilities into consideration as potential users**. According to multiple interviewees, private facilities in places with a high disease burden will be interested. Since they are not controlled and supplied by the government, it can be easier to implement a new diagnostic procedure. However, the problem is that diagnosis might not be accessible for everyone, since people have to pay for private facilities.

Development of technology

There are several recommendations for the development of the diagnostic technologies.

When urine samples are collected to train the algorithm and test the diagnostic device, it is important to **sensitize the community** and **bring incentives** for the participants.

Secondly, it is recommended to develop the **holographic technology for a sensitization device**, since it does not require sample preparation. It is recommended to adjust the **schistoscope for testing at PHC consult**, since it allows a cheaper device. For the mapping of adults at risk, either one of the technologies can be optimized.

Furthermore, it would bring an huge added value if the device can analyze **both stool and urine.** It is recommended to intensity effort into exploration of this possibility.

Lastly, it is recommended to train the algorithm with samples that are **not stained with iodine.** This saves one step in sample preparation, which makes the procedure to be faster and more user friendly and requires less material.

Design of device

The main recommendation for the design of the device is to use the target product profiles as starting point in designing the next generation of diagnostic devices. After finishing a prototype, it should **immediately be tested with end users in the field**. This test should not only focus on the functionality of the technology, but should include user research as well. The interaction with the device and the acceptability of anew test should be researched. The feedback on the product features can be used in further development.

'Anything you can't dip is gonna be extremely difficult'

Evidence Action country coordinator

Furthermore, the **sample preparation methods should be tested** with potential users. It is unclear whether community health workers and community resource persons have the skills to perform manual sample preparation after one training. This will provide insight in the most fitting sample preparation procedure for the use case - whether it should use filtration, sedimentation by gravity or has integrated sample preparation.

Lastly, the **possibilities in cleaning** of ancillary equipment should be tested. This will influence whether materials can be reused and what needs to be in the test kit. This will have a bit influence on the price per test.

Implementation recommendations

After development, the diagnostic device should be tested exhaustingly to get a proof of concept. For use in Nigeria, the device has to be approved by the National Agency for Food and Drug Administration and Control (NAFDAC). [100]

All scenarios have to be organized top down, since they require approval from the government. According to dr. Keshinro, there is a high level of suspicion at all levels of the government and they feel threatened to be exposed. Consequently, it is difficult to organize something in collaboration with or that is accepted by the government. To avoid difficulty in the future, **the government should be included from an early stage** in the development of the diagnostic device. According to dr. Onasanya, governmental interest can be increased when the use case is relevant to their current NTD strategy and the sustainable development goals, see figure 42. [52]

In case of choosing to develop the device into a **sensitization tool**, it is recommended to collaborate with a NGO involved in health education. This scenario requires the development of a health education program, which can be developed together. They can provide diagnostics and training to community resource persons, so they can independently sensitize their communities. The PHC coordinator should be included in the implementation of the education program from an early stage, since they are the key to the community chiefs which have to give consent. According to dr. Keshinro, media is crucial for the success of the diagnostic device. Radio should be used to spread jingles about the awareness campaign.

In case the diagnostic device is optimized for **testing at PHC consults**, it is important to involve high level stakeholders from an early stage in product development. The Integrated Disease Surveillance and Response protocol should be changed and the device should be approved as a standard laboratory test. This requires official approval from the Federal Ministry of Health. Furthermore, it is important to involve the State Primary Healthcare Development Agency from an early stage. They provide the resources to the public PHC facilities in the whole state. Moreover, the PHC coordinators should be involved from an early stage in implementation. The diagnostic device should be presented to patients and health workers as an **automated microscope** instead of a completely new device. This will lead to more acceptance among the health workers and the communities.

Mapping of populations at risk, requires collaboration with the FMoH and possibly a NGO. Sightsavers might be an interesting party, since they were involved in the mapping survey for school aged children. To implement a new diagnostic method, approval from the World Health Organization and/or the Federal Ministry of Health should be obtained. To implement mapping surveys in the community, the LGA government and community chiefs should be involved.

Figure 42. Sustainable Development Goals targeted by NTD interventions [52]

Chapter 13
REFLECTION

It has been a great pleasure to work on this project for the past five months. I learned a lot during this project. On the one hand I learned about the context, especially about the complexity of eliminating schistosomiasis in Nigeria. Furthermore, I developed myself as design researcher through the field trip and by collaborating with other researchers from different fields.

Process

There was a very short time to prepare for the field trip, since it was planned only two weeks in advance and we did not know who we were going to interview until we arrived. As a result, there were certain questions that I did not ask during the interviews which might have been valuable for the product specifications. It would have been better to have some more knowledge about the technology and the healthcare structure and guidelines prior to the field research. On the other hand, since I was not guided by former knowledge, I had an open view during the interviews and it allowed me to critically review the technological developments.

The first half of the project was filled with the field trip, interesting symposia, feedback sessions and inspiring meetings with the INSPiRED team members. The end of the project was a bit less exciting due to the corona pandemic. Since everyone was obliged to work from home during the last 1.5 month of my project, I had less contact with the others within the project. This made me realize the value of collaborations, real life discussions and feedback sessions. I was lucky enough to be able to organize the creative sessions in time.

Since my thesis was part of the INSPiRED project, it was sometimes difficult to feel complete project ownership. At times, the process was a bit slowed down, since I was dependent on other people. On the other hand, it was an nice opportunity to work with people from different fields from all over the world towards the same goal. I think the results of my research are valuable for the INSPiRED project. I hope insights from this report can guide as inspiration or spark a discussion about the future direction of the project.

Image 38. Field research team; Adeola Onasanya, Merlijn Sluiter, Oladimeji Oladepo, G-Young Van and Opeyemi Oladunni

Personal experiences

Without a doubt, the field trip was one of the most interesting experiences of all my years as a student. It was such a different experience to visit a country as researcher instead of as tourist. The field trip challenged my flexibility and patience, but I had the opportunity to talk to so many inspiring and interesting people. Those conversations and interviews did not only teach me about the healthcare system, but about the Nigerian culture as well. It also triggered me to reflect on my own cultural values and habits.

It is rather unusual to graduate from a master Integrated Product Design without designing a product. However, I discovered that I am more of a design thinker than a design doer.

Furthermore, I heard a lot of stories from peers who struggled a lot with their graduation projects. To avoid making the same mistake, I decided to put the same gravity on this project as I did on my other master projects. For me, this means working hard and reaching a result with which I am happy, without getting stressed in an attempt to reach the (impossible!) perfect result.

During my other master projects, I focussed on concept design and embodiment design. This project emphasized on the research phase of the design process. With this master thesis I feel like I have finished the design trilogy and I am ready for the real world.

Chapter 14
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Image references

Image 5. S. haematobium ova, obtained from https://mcdinternational.org/trainings/malaria/english/dpdx5/html/frames/S-Z/Schistosomiasis/body_Schistosomiasis_mic1

Image 6. Schistoscope 1, obstained from S. Lluch, A. Choza, J. Hooft Graafland, J. Faber, S. Patel, and S. Jujjavarapu, "Schistoscope."

Image 7. Schistoscope 2A, obtained from R. Aarts, S. K. Freire, D. Leeger, B. Vermaat, I. Vester, and J. De Vos, "Advanced Embodiment Design - Final report Schistoscope 9A," 2019.

Image 8. Schistoscope 2B, obtained from M. Gieskes, T. Ekhtiar, T. Brenninkmeyer, C. XU, M. Yang, and J. van Lent, "Advanced Embodiment Design - Final report Schistoscope 9B," 2019.

Image 9. Schistoscope 3, obtained from S. Jujjavarapu, "Automating the Diagnosis and Quantification of Urinary," 2020.

Image 13. and 14. SODOS, obtained from M. Hoeboer, "Smart Optical Diagnostic Of Schistosomiasis," 2019.

Image 34. Temporary laboratory in rural community, obtained from . Gieskes, T. Ekhtiar, T. Brenninkmeyer, C. XU, M. Yang, and J. van Lent, "Advanced Embodiment Design - Final report Schistoscope 9B," 2019.

Image 35. Sensitization meeting, obtained from WHO Nigeria https://www.instagram.com/whonigeria/

All other images in this report are made during the field trip by G-Young Van or the author (Merlijn Sluiter)