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Sluiter, M.M.; Onasanya, A.A.; Oladepo, Oladimeji ; van Engelen, J.M.L.; Keshinro, Myryam; Agbana, T.E.; Van, G.Y.; Diehl, J.C.

DOI
10.1109/GHTC46280.2020.9342953

Publication date
2020

Document Version
Final published version

Published in
Proceedings of 10th IEEE Global Humanitarian Technology Conference (GHTC)

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Merlijn Sluiter
Sustainable Design Engineering
Delft University of Technology
Delft, The Netherlands
merlijnsluiter@gmail.com

Adeola Onasanya
Sustainable Design Engineering
Delft University of Technology
Delft, The Netherlands
A.A.Onasanya@tudelft.nl

Oladimeji Oladepo
Public Health
University of Ibadan
Ibadan, Nigeria
oladepod@yahoo.com

Jo van Engelen
Sustainable Design Engineering
Delft University of Technology
Delft, The Netherlands
J.M.L.vanEngelen@tudelft.nl

Maryam Keshinro
Parasitology
Leiden University Medical Center
Leiden, The Netherlands
M.I.Keshinro@lumc.nl

Temitope Agbana
Delft Center for Systems and Control
Delft University of Technology
Delft, The Netherlands
t.e.agbana@tudelft.nl

G-Young Van
Sustainable Design Engineering
Delft University of Technology
Delft, The Netherlands
G.Y.Van@tudelft.nl

Jan Carel Diehl
Sustainable Design Engineering
Delft University of Technology
Delft, The Netherlands
j.c.diehl@tudelft.nl

2020 IEEE Global Humanitarian Technology Conference (GHTC) | 978-1-7281-7388-7/20/$31.00 ©2020 IEEE | DOI: 10.1109/GHTC46280.2020.9342953

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

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

I. Introduction

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

A. Schistosomiasis

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

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

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

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

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most dominant Schistosoma specie in Nigeria, accounting for 82% of the schistosomiasis infections.

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

B. Diagnostics

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

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

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

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

C. Smart health diagnostics

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

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

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

Fig. 3. Mobile phone and Raspberry Pi based Schistoscopes.

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

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

- Affordable: Low initial and maintenance costs.
- Data collection: Real-time location and diagnostics data sharing for mapping purposes.

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

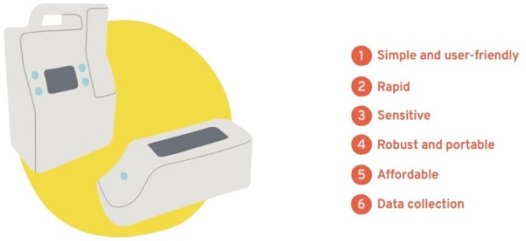

Fig. 4. The main benefits of smart diagnostics.

II. Method

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

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

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

An explorative, qualitative research with semi-structured interviews and observations was conducted in Oyo State, Nigeria. During the field research, 45 stakeholders were interviewed to identify gaps and stakeholders for case management on primary healthcare level and the control and elimination program [13]. By doing contextual research, the interests and needs of the stakeholders could be identified. Furthermore, a better insight into the challenges and limitations of current diagnostics could be obtained. Stakeholders were identified from literature search, expert panel recommendation and snowballing. Using the state as a case study, we categorized stakeholders based on four levels: community level, healthcare level, health system organizational level and policy level. For the field research, a list of questions was prepared based on the framework of Aranda et al. [22] for holistic, contextual design for low resource setting, focusing on individual factors, physical environment, technical factors and systems and structures. For every type of stakeholder, a different interview guide was created. An overview of the diagnostic landscape for case management and the control and elimination program was visualized to help during interviews and to verify and adjust the scenarios to the real situation.

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

The interviews from the field trip were transcribed, and the interviews conducted in Yoruba (local language) were translated. Observations in the health facilities were noted on the health facility observation sheet. Insights from the interviews and observations were translated and visualized into patient journeys, patient and health worker barriers. The context research was concluded with an overview of identified gaps in the healthcare system for case management and control and elimination program. By combining gaps in the current healthcare contexts, specific needs of stakeholders and potential benefits of the new smart diagnostic technologies, 12 use scenarios were constructed (See Fig. 6). In consultation with stakeholders, three promising use scenarios were selected and translated into TPPs.

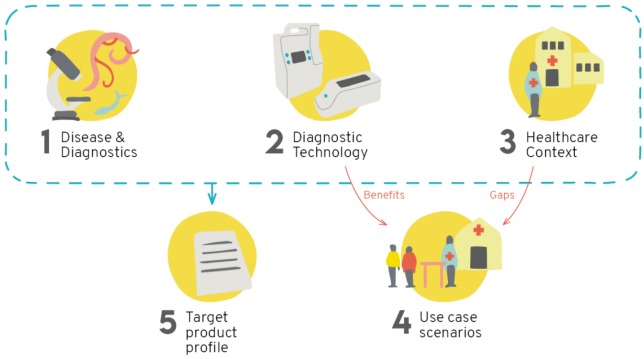

Fig. 6. Approach toward the development of target product profiles.

III. Gaps in Current Scenarios in Nigeria

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

Fig. 7. The two explored diagnostic contexts.

A. Case management

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

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

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

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

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

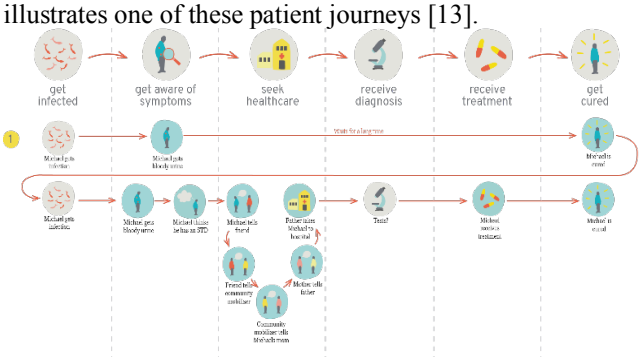

Fig. 9. Example of patient journey in case management context.

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

1. Limited care-seeking behaviour: Infected individuals do not visit a formal health facility when they have symptoms. Due to low awareness on schistosomiasis amongst community members, bloody urine is not perceived as symptom of a medical condition. Most people visit traditional healers, since they are close to the community, or patent medicine vendors, as they are affordable and accessible.

2. No tests in PHC laboratories: There are laboratories available in PHC centres, equipped with microscopes and centrifuges. However, urine analysis is not performed. Suspected schistosomiasis cases are referred to the hospital. Reasons being the proximity to a hospital, lack of skilled laboratory staff, lack of test materials or an unsuitable laboratory environment. In these laboratories, they only test for frequently occurring diseases.

3. Health workers miss cases: The education level of community health workers is low, and they assume a low prevalence of schistosomiasis. Schistosomiasis symptoms are often misinterpreted for other conditions, like STIs or malaria. Case definition of the WHO state that case of urinary schistosomiasis should only be suspected when an infected individual has bloody urine. As a result, wrong treatment is prescribed, and light and asymptomatic cases are never recognized.

4. DSNO guidelines are labour intensive: Once a case is suspected, it should be reported to the disease surveillance and notification officer (DSNO). The DSNO is responsible for getting a sample tested to confirm the case. This often results in extra work, since she or he has to pick up the sample at a PHC facility and bring it to an approved laboratory. In the meantime, the patient is already treated in the facility. Not all suspected cases are reported, and the DSNO does not always have time to get the case confirmed.

5. Few diagnoses in rural areas: Rural communities depend on streams in their daily living, which increases their risk of infection. It is difficult for infected individuals in rural communities to get diagnosed, since there is a limited number of PHC facilities. The health posts and clinics that are available are understaffed and lack resources, so they cannot carry out community-based services. Hospitals are inaccessible due to long distances, poor roads quality and expensive transport fares.

6. No check-up after referral or treatment: The community health worker does not see the patient back after referral to a hospital or administering treatment. There is no check-up or test to confirm cure afterwards. Community health workers do not know if the patient went to the hospital and if the patient has recovered.

7. No follow-up action after confirmed case: Since infected freshwater sources spread schistosomiasis, one confirmed case often means there are more infected individuals from the same community. There are no follow-up actions that take the focal geographical distribution of schistosomiasis into account.

B. Control and elimiation

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

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

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

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

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

1. Limited availability of data on endemicity: The most recent data on schistosomiasis prevalence is the mapping of endemic data from school children between 2013-2015. There is no data available on the prevalence of schistosomiasis among the other risk groups, other than small scale screening results for research purposes.

2. No control program for risk groups: The Deworming initiative targets children from 5-14 years. Other populations at risk - small children and adults who have regular contact with freshwater are excluded from this control program. The Deworming initiative is dependent on support from NGOs and medicine donations. Since pharmaceutical company Merck donates praziquantel specifically for this age group, it cannot be administered to other risk groups. According to the strategy from Federal Ministry of Health (FMoH), in moderate or high-risk areas, adults at risk should receive treatment too.

3. No impact assessment plan for deworming day: According to WHO guidelines, the disease prevalence should be measured 5-6 years after the first mass drug administration round. Since the Deworming initiative started in 2016, the impact of the program should be assessed in 2021-2022. The Federal Ministry of Health is responsible for the initiation of this monitoring survey. Absence or unavailability of information and update on the impact of the program, leads to program fatigue in the target populations, health workers and community volunteers leading to loss of interest in the program, especially in low prevalence communities.

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

5. No field-deployable diagnostics available: Microscopes are fragile and expensive, and filters for sample preparation may not be readily available in Nigeria. As a result, testing for the school-based survey was performed in hospital laboratories instead of at location of sample collection. It required sample transportation by car, which caused logistic problems. This makes epidemiological surveys time consuming and expensive. Dipsticks and questionnaires are available to field-deployable methods, but they lack sensitivity.

6. Control program is short-term focused: The control and elimination strategy in Nigeria-appears to be short-term focused, with the roadmap ending at 2020. Plans should be developed on how to tackle future challenges in anticipation of a reduction in the prevalence and work towards elimination of the disease as a public health problem. A lower prevalence gives different requirements to the control strategy and the role of diagnostics [13].

IV. Use Scenarios

A. *Twelve Use Scenarios*

Next potential benefits of the smart diagnostic technology (See Fig. 4) and gaps in the healthcare system (see above) were combined into 12 most promising use case scenarios for a new diagnostic device to improve case management on primary level and the control and elimination program in Nigeria (See Fig .11).

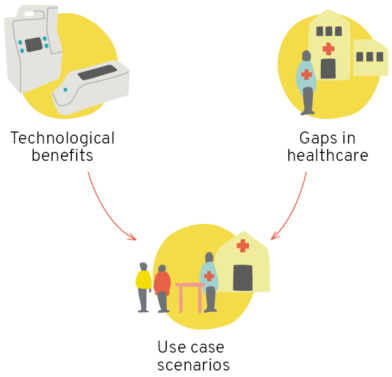

Fig. 11. Development of use case scenarios.

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

B. *Selection of three use scenarios*

An online questionnaire was sent to 6 stakeholders in the field and seven members of the INSPiRED research team. The stakeholders from the field consisted of researchers and community health workers. These stakeholders were involved to obtain feedback and to select the most valuable scenarios through which a diagnostic test can meet the needs of the end-users and stakeholders (See Fig 13).

The following three diagnostic scenarios were selected;

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

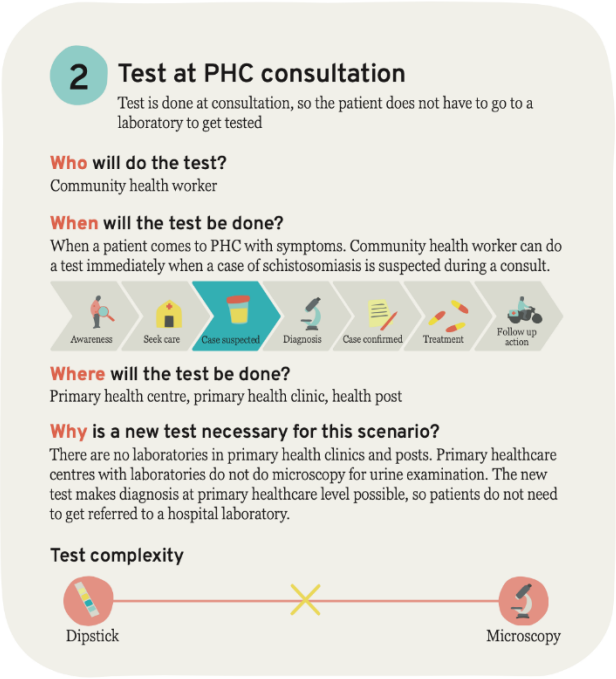

Fig. 12. Example of description of use scenario.

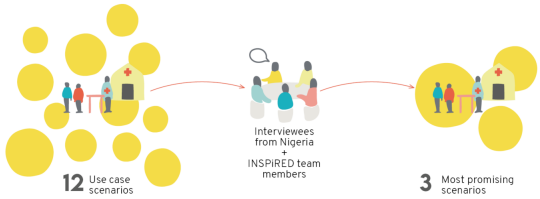

Fig. 13. Selection of three most promising scenarios by stakeholders.

V. TPP and Evaluation

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

Insights from the desk and field research were combined to create target product profiles for the selected use case scenarios. To determine the attributes on the target product profile, desired product qualities were retrieved during interviews in the field, a discussion session with 6 PhD students and a co-creation session with 14 Public Health

master students. This resulted into six scoping attributes, 23 operational attributes, four performance attributes, and two price attributes (See Fig. 14).

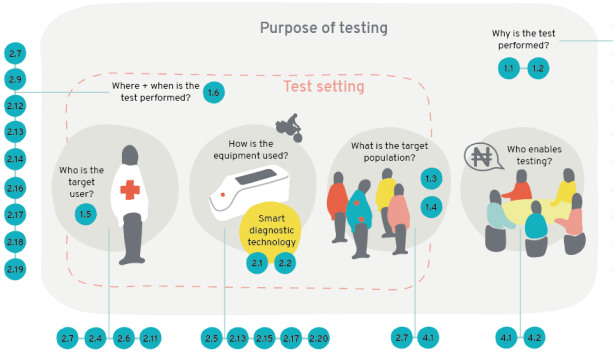

Fig. 14. Characteristics of the product target profile.

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

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

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

TPP for test as sensitization tool – The end users are the community resource people who are not formally trained as health workers. Considering that, the device will not provide official diagnosis, but the test will be performed at the sensitization meetings. The device has a throughput of at least five samples per hour, and the results should be available before the end of the sensitization meeting. Before the results are available, health education can take place to increase awareness. Ideally, the device can save the location data and number of infected samples to identify the location of infected water bodies.

Figure 15 shows five of 35 attributes for the three selected use-scenarios.

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

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

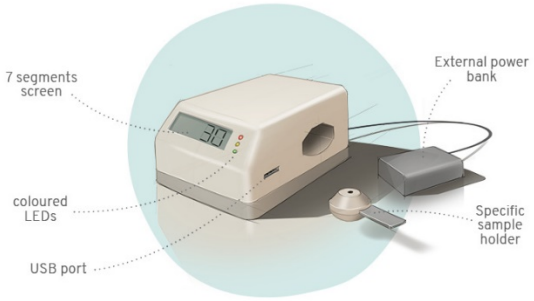

Fig. 16. Design proposal based upon one of the developed target product profiles.

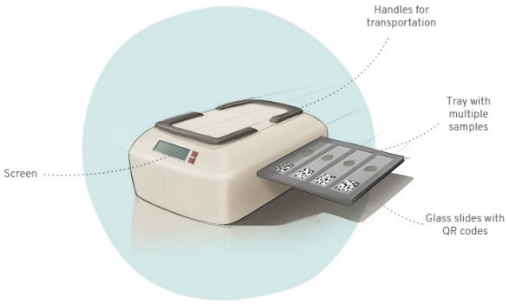

Fig. 17. Design proposal based upon one of the developed target product profiles.

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

Furthermore, meetings were held with the INSPiRED team to explain the context of use and disease

characteristics. The importance of this knowledge transfer process supports designers in their focus on useful TPP, thereby reducing

design time and cost of redundant prototyping, as well as increasing the likelihood of adoption in the context-of-use.

VI. Conclusion and Recommendation

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

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

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

Acknowledgement

We thank Delft Global Initiative and our collaborators within the INSPiRED project who provided valuable support. Special thanks to Opeyemi Oladunni for assistance in coordinating the field research. We thank all the respondents who participated in our study, and Yekinni Fatimat Oyinloluwa for being our translator. Part of the research described has been funded by the NWO-WOTRO SDG programme grant INSPiRED (W 07.30318.009)

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