A ROADMAP FOR DEVELOPMENT OF A SMART MALARIA DIAGNOSTIC DEVICE

Use and acceptance of the Excelscope by healthcare professionals in Nigeria.

JULIA STOEVELAAR

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healthcare professionals in Nigeria.

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Master Design for Interaction
Delft University of Technology
Faculty of Industrial Design Engineering

Suporvisory team
Dr. ir. J.C. Diehl
B.S. Groeneveld

Support
Prof. O. Oladepo
O. Abiona

University of Ibadan
Faculty of Public Health
Ibadan, Nigeria

ABSTRACT

SUMMARY OF THE CONTENT OF THIS REPORT

This document reports the graduation project into acceptance of a smart malaria diagnostic device by healthcare professionals in Nigeria. It consists of three parts: technology, context and user and is concluded with a roadmap that combines the insights and translates the connections into suggestions for further development of the device.

Malaria is a life-threatening parasitic disease and the leading cause for high morbidity rates in developing countries. In Nigeria, the chosen context of this study, over 90% of the population is at risk of malaria infection, leading to 60% of the outpatient visits in Nigerian healthcare facilities. Accurate diagnostics are not available for the mass and drugs can be bought without prescription, leading to misdiagnosis, overtreatment and drug resistance.

The Excelscope is a smart malaria diagnostic device that leverages the functionalities of a smartphone to capture magnified images of a blood smear and provide a remote or automated diagnosis. The concept was developed by students from the faculty of Industrial Design Engineering and is currently under development of a research consortium. The Excelscope aims for increasing accessibility to accurate malaria diagnostics. Three scenarios for the diagnostic analysis of a blood sample (remote, semi-automated and automated) were the starting point of this research.

The technology analysis evaluated the three defined scenarios for remote or point-of-care diagnostics. Based on an initial analysis, the assumption was made that the semi-automatic scenario was most feasible in the context and best accepted by healthcare professionals (doctors, nurses, lab scientists). Furthermore, the technology analysis briefly discussed definitions related to eHealth, resulting in several ideas for applications for the Excelscope. Finally, a study into similar technologies for malaria diagnostics was done. An integrated system for imaging and automated parasite detection has not been launched on the market yet, although several organizations and companies are working on similar technologies.

The context analysis consists of four chapters: Nigeria, her healthcare system, malaria and-diagnostics. Next to literature research and expert interviews, Insights were gained during a one-month field study in Ibadan, Nigeria. During the field study, healthcare facilities were visited and caregivers participated in semi-structured interviews. The context analysis resulted in a country profile (including general aspects about economy, living standard and health), an overview of the healthcare system and insights on each tier of the healthcare system. Coverage of malaria diagnostics can significantly increase when a device is implemented in primary healthcare centres, pharmacies, medicine stores or medical outreaches. However, the Excelscope has to meet the minimal infrastructure at these places: little or no access to reliable water, lack of internet connection, low-level medical staff and ‘robust’ environments.

Current ways of diagnosing malaria were studied as well and evaluated according to WHO’s ASSURED checklist. Microscopy and rapid diagnostic tests are the recommended methods for confirmation of a suspected case of malaria. However, both methods lack on different aspects, such as affordability, availability or accuracy. In development of the Excelscope, the checklist can be used as guidelines for basic requirements. However, aspects related to context (infrastructure and accessibility) and user (behaviour, attitude and trust) are essential in order to develop an effectively used device.

Throughout this project, emphasis has been placed on the user. The goal of this study was to find barriers and enablers for use and acceptance of the Excelscope by healthcare professionals in Nigeria. During the interviews with stakeholders in Nigeria, the different scenarios were discussed, as well as local perspectives on malaria management in general. Through the interviews, six potential target groups were defined: patent medicine vendors, pharmacists, medical doctors, nurses, laboratory scientists and medical volunteers (community health workers). For each of the target groups, suggestions have been given for smartness of the device, values and mHealth applications.

The study is concluded with a ‘roadmap’ wherein all findings are connected in a framework of technology, context and user. The framework can be used for defining a target group or anticipating on necessary developments in order to increase

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INTRODUCTION

TECHNOLOGY

CONTEXT

USER

CONCLUSION

APPENDICES

1

INTRODUCTION

AN INTRODUCTION INTO THE GRADUATION PROJECT

This study shows how technology, context and user intertwine in the development of a smart malaria diagnostic device, the Excelscope (figure 1.1). It gives recommendations on further development for the device by showing the connections between technological developments, required infrastructure, and user values and needs.

Malaria is a parasitic disease with high morbidity and mortality rates in developing countries. The symptoms of malaria are non-specific, hence clinical diagnosis via microscopy or a rapid diagnostics test of a blood sample is recommended [1]. However, these diagnostic methods are faced many challenges, among which a lack of competent medical staff, duration of the procedure, affordability and accessibility [2].

Student team Excelsior (faculty of Industrial Design Engineering) reported these problems during a field study in Uganda. They came up with a concept for a smart malaria diagnostic device: the Excelscope. A simple smartphone-based microscope would be able to take magnified images of a blood smear, after which a diagnosis could be provided by either a (remote) pathologist or deep learning algorithms. Coincidentally, researchers at the TU Delft's department of Systems and Control were working on parasite detection as well. Similar incentives from different fields of expertise led to the Smart Malaria Diagnostic research consortium of TU Delft faculties Industrial Design Engineering and Mechanical Engineering, in collaboration with Leiden University Medical Centre (Parasitology & eHealth) and the Nigerian University of Ibadan (Public Health).

The collaboration with the university in Nigeria opened doors for research within another context. Nigeria is, with 182 million inhabitants, the most populous country of Africa [3]. Over 90% of the population is at risk of malaria infection, leading to 60% of the outpatient visits in Nigerian healthcare facilities. This project focuses on the implementation of a smart diagnostic product-service system in the health system in the area of Ibadan (South-west Nigeria). For a new technology to be effectively implemented and used, the gap between technology, context has to be bridged.

Effectiveness of a new technology in healthcare practices is dependent on many factors. Tugwell et al. [5] developed a framework for the evaluation of an innovation in healthcare, the 'Technology Assessment Iterative Loop' (appendix 1). Although the tool cannot fully be used yet (due to the early stage of development, no specific context), elements of the loop show the influencing factors on the impact of an innovation. The tool will not elaborately be used in this project, but states the importance of taking contextual and user-related aspects into account when working on innovation.

Tugwell states that effectiveness of the device in a community is a multiplication of different factors: *Community effectiveness = efficacy x diagnostic accuracy x medical professional compliance x patient compliance x coverage.*

The model indicates that, if one of the aspects is equal to zero, effectiveness is not addressed at all. With regard to the Excelscope, effectiveness is dependent on accuracy of the device, but on the provision of appropriate care, treatment and referral as well. Thereby, the effect on the healthcare

FIGURE 1.1
A visual presentation of the Excelscope, a concept for a smart device for malaria diagnostics developed by student team Excelsior. [6]

provider has to be taken into account. Will the device bring benefits in terms of usability, time and resources? And what about the patients, will they be able to seek for care, do they have trust in caregiver and the technology? Will they adhere to the given diagnosis or advice? Besides effectiveness, efficiency is an aspect to be evaluated or anticipated on. It is dependent on perceived benefits of paying for a test. What is the cost-effectiveness for both patient and caregiver (compared to e.g. buying/selling antimalarials over the counter)?

Although many aspects relate to patients, this study mainly addresses healthcare professionals. Professional caregivers have been defined as potential users, since the Excelscope needs clinical actions such as blood sample collection and provision of a diagnosis. An explorative research aims to find barriers and enables for acceptance from medical professionals towards use of the Excelscope.

By defining the opportunities and challenges for acceptance and feasibility of the Excelscope in Nigeria, suggestions for further development of the device can be given on the level of technology, context and user. Therefore, it anticipates on essential elements related to the final effectiveness of the innovation in the field of malaria diagnostics.

TECHNOLOGY

CONTEXT

USER

TECHNOLOGY

2

THE EXCELSCOPE

2.1 TECHNOLOGY AND USE

THE CONCEPT AS A STARTING POINT FOR FURTHER RESEARCH

This study focuses on the use and implementation of the 'Excelscope', a low-cost smartphone-based microscope for malaria detection. Parallel to this project, the technology is being developed and new prototypes are being made (Excelscope 3.0 and 4.0) by the research consortium of the TU Delft and LUMC. This section describes the intended use and procedure of the Excelscope 2.0 and the possible different scenarios for malaria parasite detection.

2.1.1 Smartphone-based microscope

The Excelscope uses the abilities of a smartphone to capture images and process data (figure 2.1). A small glass ball in front of the smartphone's camera provides the possibility to take high resolution magnified images [6]. The lens module is placed in a 3D-printed piece that can be attached to the smartphone and aligned with the camera. Currently, research is being done on the best way to mount the lens module tightly, robust and in a cheaply manufacturable way.

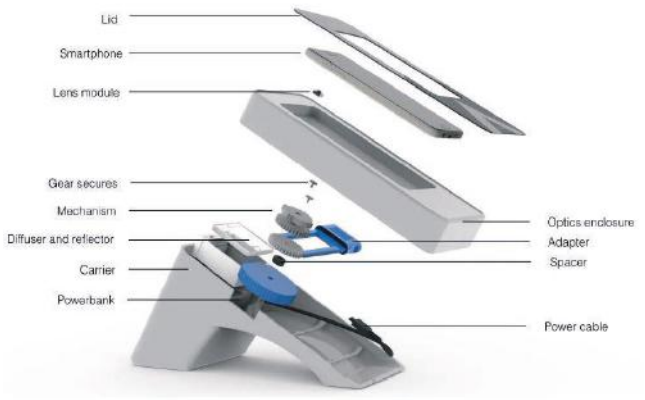


FIGURE 2.1
Exploded view of all elements of the Excelscope 1.0

2.1.2 Blood sample collection and preparation

Blood sample collection and preparation – fixing it to a glass slide and staining the smear – is necessary in order to capture the sample in such a way that it can be analyzed by either a laboratory scientist or computer software. This task is similar to conventional microscopy. The stain makes the parasites visible by the colour that it contains (figure 2.2). Chapter 8.3 describes the procedure for conventional blood sample preparation into detail. Since this procedure requires skills and equipment, a toolkit for support of the (low-medium level) medical professional (figure 2.3) has been proposed by Team Excelscior.

2.1.3 Include patient data

The patient's clinical and geographical information can be added to the digital sample. Adding patient data brings opportunities for patient monitoring at the point-of-care and large scale data analysis for national or global malaria management.

2.1.4 Capturing the image

The user places a prepared blood sample in an adapter and slots it into the Excelscope. By use of knobs on the side of the device, the slide can be moved in the x-, z- and y-direction for camera alignment and focus adjustment. To provide an accurate and quantitative diagnosis, at least 100 fields-of-view (the visible magnified area when looking through the microscope) have to be analysed [1]. Therefore, the user has to move the slide along the camera to capture a sufficient part of the blood sample.

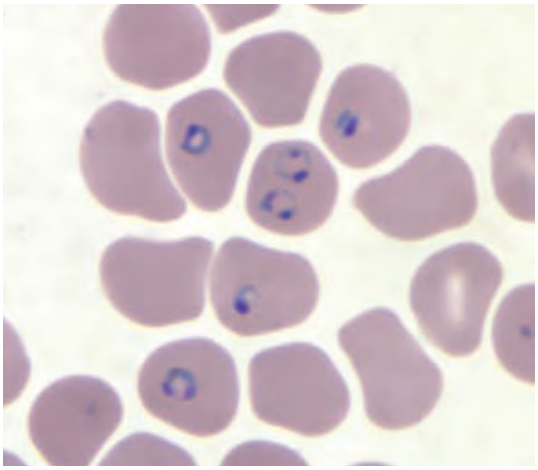
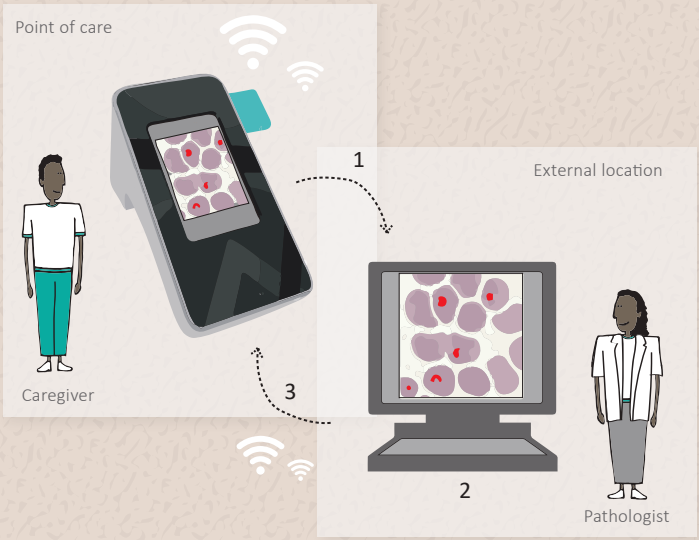


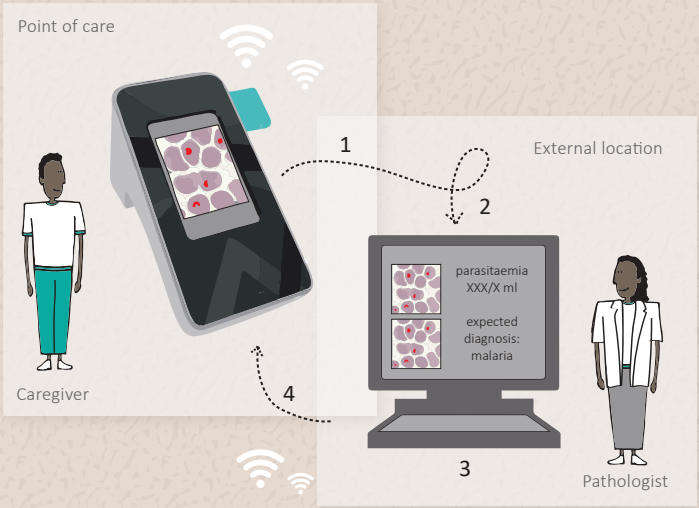
FIGURE 2.2
A stained and maginified blood sample. Parasites are coloured blue by addition of a Giemsa stain.

FIGURE 2.3
A prototype of a designed toolkit that supports the healthwoker in the staining procedure.

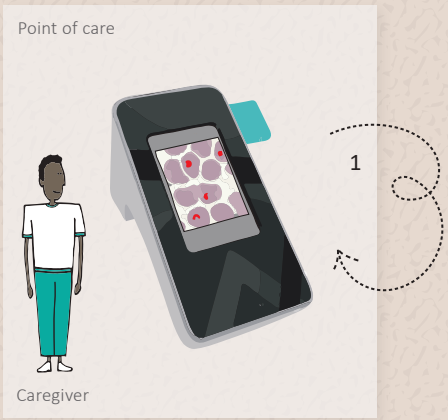
manual analysis



semi-automatic analysis



automatic analysis



2.1.4 Malaria detection: three scenarios

It has not yet been decided how 'smart' the Excelscope will be in terms of the diagnostic blood sample analysis. Three scenarios for the analysis have been defined, which are different in involvement of human expert and computer analysis. A brief explanation of the scenarios is being given below and visualized in figure 2.4. In all scenarios, it is intended that the blood sample preparation can be done by (low-medium level) medical staff at the point-of-care.

2.1.4.1 Manual analysis

This analysis is most similar to conventional microscopy, but sample collection and image analysis are divided over different locations. The images are taken at the point of care, after which they can be digitally transferred to an available pathologist (1). The expert can analyse the digital images on a computer (2) and provide the diagnosis to the point of care (3). Internet connection is required for data transmission, the diagnosis is in hands of the human expert.

2.1.4.2 Semi-automatic analysis

Similar to the first scenario, the images will be transferred to an external location (1). Through algorithm software on the PC, an automated report can be provided to the laboratory technician (2). The algorithm recognizes blood cells and parasites, resulting in a quantitative report. The pathologist can inspect a selection of images (3) in order to conclude on a diagnosis and provide it to the point of care (4). The diagnosis is based on the combination of computer analysis and a human expert. The latter is responsible for the decision.

2.1.4.3 Automatic analysis

The last option for malaria analysis is fully automated and can be done at the point of care. The Excelscope provides the analysis through automated algorithms on the smartphone (1). In this scenario, a human expert is involved in sample collection only.

2.1.5 Acceptance of the technology

The three defined scenarios will be taken as a starting point for the evaluation of the Excelscope in Nigeria. Acceptance of the device will be studied by discussing the three different scenarios with potential users. A full setup of the study can be found in chapter 10.2.

FIGURE 2.4
Three proposed scenarios for the diagnostic analysis of a blood sample by the Excelscope.

2.2 PRELIMINARY EVALUATION

FIRST ASSUMPTIONS ON THE THREE DIAGNOSTIC SCENARIOS

To kickstart the evaluation and comparison of the three defined scenarios for blood sample analysis, a preliminary study on the advantages and disadvantages of each of the options has been done.

2.2.1 Goal and participants

The study was kickstarted through a short brainwriting session in order to a quick overview of insights from different perspectives in the limited available time. Members of the consortium participated in the session (TU Delft; Mechanical Engineering and Industrial Design Engineering and the LUMC; E-health department).

2.2.2 Method

All participants were given a canvas with one of the three scenarios, on which an advantage, disadvantage and open question could be written. Consequently, the canvasses were handed to the next person. The goal was to avoid double statements and let others be triggered by the already stated pros and cons. All statements were rewritten and clustered. For each of the scenarios, similar topics were used, so that the gaps can easily be found. The template was complemented with new insights from literature readings and individual analysis of the insights.

2.2.3 Results

The results are clustered in a table in which advantages and challenges for the general elements of the Excelscope are being given as well (Figure 2.5)

Based on this first evaluation, the semi-automatic analysis is expected to be best acceptable and implementable. The method increases efficiency by analyzing the report automatically, yet leaves the control to conclude on a diagnosis in hands of a human expert. This might not only be more accepted by the medical staff, but easier to implement within current regulations as well.

	ADVANTAGES	CHALLENGES
GENERAL		
	- Collection of data can be used for training - No laboratory (technician) needed at the point of care - Easier to repair or replace than a microscope	- Power supplies / battery power - Data storage and safety - Implementation - Robustness - Keeping the technology up to date
MANUAL		
	- Human expert is responsible for diagnosis (easier to regulate) - High specificity - Easy to implement in current system - Might increase efficiency - Assessment on display instead of microscope has usability advantages	- Resolution of image - Transferring data - Laboratory technician needs to be available - Laboratory technician needs a computer - Skills of laboratory technician (human errors)
SEMI-AUTOMATED		
	- Human expert is responsible for diagnosis (easier to regulate) - Improves system performance over time - Makes the procedure more efficient - High sensitivity and specificity - Might increase confidence - Processing can be done at the computer instead of in the smartphone	- Resolution of image - Transferring data - Accuracy - Algorithms for parasite detection - Laboratory technician needs to be available - Laboratory technician needs a computer - Skills of laboratory technician - Interpretation of report
AUTOMATED		
	- Point-of-care testing: reduced patient loss, less stakeholders needed - Deployable to remote areas - Efficient - No human expert needed - Minimal human error	- Reliability and accuracy - Certification needed - Loss of control - Interpretation of report - Acceptance / motivation for use - Computer errors / failure

FIGURE 2.5
Results of the initial evaluation of the three scenarios. Results were gathered through brainstorming, brainwriting and a literature study.

3

E-HEALTH & SMART DEVICES

3.1 E-HEALTH

DEFINITIONS, EXAMPLES AND OPPORTUNITIES

The Excelscope is a smart device that can be integrated in an eHealth system. 'Smart devices' and 'eHealth' are trending terms that are used in the field healthcare provision and patient's self-management. How is eHealth related to terms as telemedicine and m-health? All concepts aim for improvement of healthcare services in efficiency and quality, but differ in applications. This section defines the concepts and gives opportunities and ideas with regard to development of the Excelscope; the next section defines and compares smart diagnostic devices.

eHealth and mHealth

eHealth (electronic health, also written as 'e-health') is a broad term and can shortly be defined as 'supporting healthcare through electronics'. According to the WHO [7], 'eHealth is the combine use of Electronic Information and Communications Technology (ICT) in the health sector for clinical, educational, research and administrative purposes, both at the local and distant region'.

eHealth can have a positive impact on healthcare services in low- and middle income countries, since it can improve efficiency, accessibility, accuracy and workflow. It brings possibilities for digital patient data management (therefore increasing access to patient data and reducing pressure of manual documentation), support of healthcare professionals (providing information, decision making support) and tailored care [8].

The terms eHealth and mHealth (mobile health) are often interchanged. Although having similar goals (improving healthcare through electronics) mHealth is only related to mobile devices, such as smartphones and tablets. Therefore, is a component within the umbrella of e-health applications. mHealth includes the use of mobile device functionalities such as messaging services, camera, Internet and global positioning system (GPS) [9]. In comparison, e-health also refers to systems that cannot be stored on mobile applications (yet), such as electronic health records.

What is telehealth?

Telehealth can be accommodated to eHealth and has been described as "the use of telecommunications technologies to deliver health-related services and information that support patient care, administrative activities, and health education" [10]. Telehealth can be confused with the term 'telemedicine'. The terms are often used interchangeably, but telehealth covers a broader range of applications. Telemedicine refers to remote clinical support for diagnosis and treatment and can improve access to care in regions where the availability of physicians is scarce. It can be used for remote interaction between healthcare professionals, or between physician and patient, and is specifically related to patient care [11]. Telehealth is a broader term and includes non-clinical services, such as online learning, the provision of information and helping patients to adhere to medication [10,12].

Although the field of telehealth is growing, it is questionable whether it is applicable to all regions and intended areas of use yet. How will eHealth fit in rural areas without network connection? Fortunately, telehealth and -medicine do not always necessarily require internet connection. The services can also be designed in other networks, such as SMS, GPS or Bluetooth [13].

Figure 3.1 visualizes the 'umbrella' of eHealth, to which mHealth, telehealth and telemedicine can be appointed.

Impact of eHealth

Exact numbers or qualitative impact of eHealth is difficult to measure. According to the WHO, approximately 1.5 billion people make use of e-health services. Furthermore, the use of mobile technology increases quickly in low- and middle-income countries: from 82 mobile subscriptions per 100 inhabitants in 2005 to 7 billion (over 120/100) by the end of 2015. In African rural communities, mobile access increases much faster than access to computers [14]. Therefore, there are many opportunities in the field of m-health and the coverage of mobile health will probably increase even more.

Opportunities for the Excelscope

The two scenarios for remote diagnostics, as described in section 2.1.4, can be categorized as telemedicine practice. Besides, the Excelscope brings opportunities for other eHealth applications. Labrique et al. (2013) described 12 common mHealth applications. Among the applications are education, point-of-care diagnostics, supply chain management and electronic health records, which are relevant to the Excelscope [4]. In chapter 11-13, different applications will be discussed with potential users of the smart device.

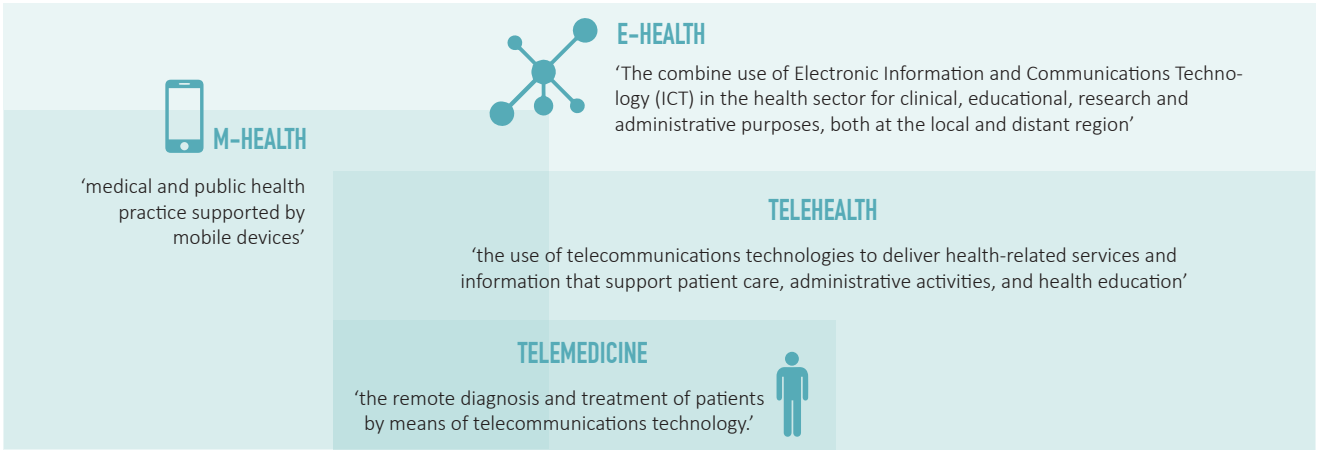


FIGURE 3.1
Visualization of the 'umbrella' of e-health, to which m-health, telehealth and telemedicine can be appointed. The definitions (gained from the WHO) explain each term.

3.2 SMART MALARIA DIAGNOSTIC DEVICES

EXPLORATION INTO SIMILAR TECHNOLOGIES

This project does not focus on improving the Excelscope's technology and hardware, but on implementation and acceptance. However, a brief study into similar diagnostic devices can be useful in order to place the Excelscope in the perspective of other (developing) technologies. The devices can be compared on technological aspects and implementation strategies.

3.2.1 What is a smart device?

In general, smart devices can have the ability to connect, share and interact with its user, or operate autonomously to a certain extent. Often, they are connected to a network (e.g. Internet, Bluetooth, NFC) or other devices. A smart device therefore is the combination of hardware and software, and cannot only be a mobile application or a device that can just be connected to the Internet. Other possible characteristics of a smart device are remote/external access, portable and cordless, internal autonomous operation, plug-ins or dynamic components. The most used smart devices are personal electronics, such as smartphones, tablets and smartwatches.

The Excelscope makes use of a smartphone, can connect to a network, share data and can possibly provide an autonomously generated test result; it is therefore considered being a smart device.

3.1.2 Smart malaria diagnostics

For several years already, smart devices for malaria diagnostics are being developed. A study into this field of innovation lead to an overview of several devices and applications that are still under development. The selection is being made on relevance and comparable elements to the Excelscope. The technologies have been found through a literature research and a recent overview given by Unitaid [15]. A more extensive explanation of each device is given in appendix 2.

Autoscope [16], Sight diagnostics [17], MOMALA [18] and xRapid-malaria [19] develop an automatic analysis of a blood sample, similar to the automatic analysis scenario of the Excelscope. According to Ince and McNally (2009), an automatic analysis has many advantages, such as standardization of tests, diagnostics operated by unskilled staff at the point-of-care and increasing the number of people that can run the analyses. When sample preparation is eliminated from human effort (included in the device) and the same level of accuracy can be achieved compared to conventional diagnostic methods, an automatic analysis can be time- and labor-saving as well as cost-effective [20]. Nonetheless, acceptance of the user and compliance to the result is an essential element in the implementation of the technology.

Although a variety of different technologies can be found in publications and by online searches, only a few project have shown progress or updates of later stages recently. More research on any recent developments, reasons for failure and clinical studies of the technologies is recommended.

3.2.4 Comparison

Figure 3.2 gives a schematic comparison of the selected devices. The characteristics of the devices have been chosen and rated in terms of being beneficial (green) or not (red):

- The optical system used for imaging
  Microscopy has been chosen to be disadvantageous because of immediate extra costs.
- The level of automation
  Automated analysis is more efficient and cost-effective.
- Qualitative or quantitative results
  A quantitative/qualitative result (the severity of the disease and species) is more accurate than a qualitative (malaria/no malaria) only.
- The need to prepare the sample through staining
  Eliminating blood sample preparation reduces human error and will be more efficient.

For the quick comparison, the characteristics are not weighted. Costs are not included in the table, since the costs for each test or device have not all been defined yet. Conventional microscopy and RDT have been added to the table as a comparison, although not being smart devices. An extensive comparison of the conventional techniques can be found in chapter 8.3.

3.2.4.1 Insights

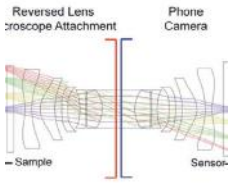
The first column of the table includes devices that provide a qualitative result, such as antigen- or hemozoin-based tests. The devices that provide quantitative results as well have been placed in the other columns. Most devices have been placed in the last column; automated analysis. Whereas Momala and xRapid focus on the software only (therefore require a microscope), the Autoscope and Sight Diagnostics make use of an integrated optical system too. Since Sight Diagnostics has excluded sample preparation in the procedure, this technology scores best in this quick qualitative evaluation. If the device can be made low-cost and available for low resource settings, it will bring many benefits for malaria diagnostics at the point-of-care.

Sight diagnostics Ltd

- X **automated**
- measure parasite load
- smartphone based
- low-cost
- X **blood sample preparation**
- X **integrated imaging**

Autoscope

- X **automated**
- measure parasite load
- smartphone based
- ? low-cost
- blood sample preparation
- X **integrated imaging**



Cellscope

- automated
- measure parasite load
- X **smartphone based**
- X **low-cost**
- X **blood sample preparation**
- X **integrated imaging**

MOMALA malaria diagnostics

- x **automated**
- x **measure parasite load**
- x **smartphone based**
- low-cost
- x **blood sample preparation**
- integrated imaging

xRapid-Malaria

- x **automated**
- x **measure parasite load**
- x **smartphone based**
- low-cost
- x **blood sample preparation**
- integrated imaging

MOPID malaria diagnostics

- automated
- measure parasite load
- X **smartphone based**
- X **low-cost**
- X **blood sample preparation**
- X **integrated imaging**

QuantuMDx

- x **automated**
- measure parasite load
- smartphone based
- ? low-cost
- blood sample preparation
- integrated imaging

Magneto Optical device (MOD)

- x **automated**
- measure parasite load
- smartphone based
- x **low-cost**
- blood sample preparation
- integrated imaging

Fionet automated RDT reader

- x **automated**
- measure parasite load
- smartphone based
- x **low-cost**
- blood sample preparation
- integrated imaging

3.2.4.2 Compete or collaborate?

Different researchers and companies are working on the development of smart devices for malaria parasite detection. The technologies are still under development and not yet (widely) available. A low-cost device that integrates both digital imaging and automated blood sample analysis does not yet exist. The Excelscope adds on the developing technologies and the team can learn from innovations such as automated/simplified blood sample preparation (Sight diagnostics), the automated algorithms (MOMALA, xRapid) and interface designs.

Thus, the Excelscope can distinguish from other technologies by developing an automated smartphone-based device. Nonetheless, it is questioned whether competitiveness is demanded on this field of research: researchers from different consortiums could also collaborate in order to increase capabilities in the development of a smart malaria diagnostic device. On the other hand: competition might enhance and motivate organizations to develop the technologies faster, resulting in earlier implementation of smart solutions.

3.2..3 Acceptance from the user's perspective

It has not been found whether the developers of the highlighted technologies have been done (or do) research on user acceptance of their devices, but it is expected that most organizations or companies focus on technology. More research can be done on the involvement of context and user in comparable research and development projects.

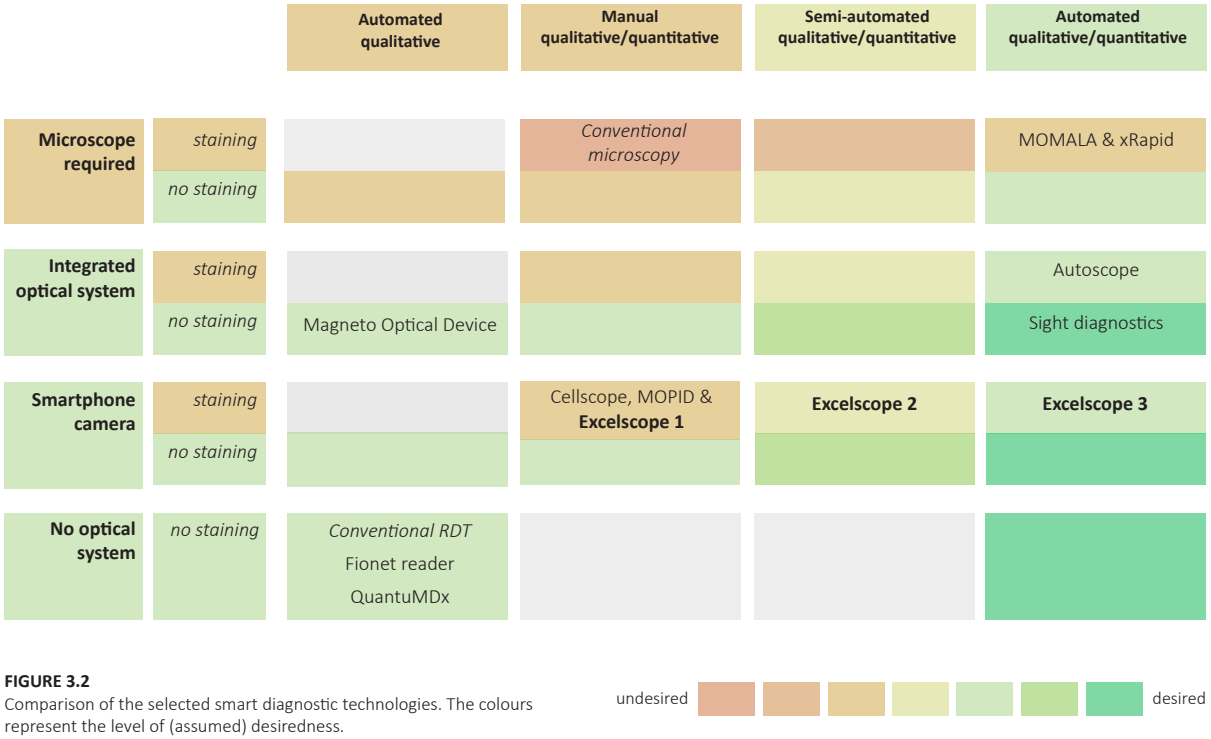


FIGURE 3.2
Comparison of the selected smart diagnostic technologies. The colours represent the level of (assumed) desiredness.

4

SUMMARY

FINDINGS FROM THE TECHNOLOGY ANALYSIS

The brief analysis on e-health and smart devices lead to directions for the Excelscope and questions for further research. The main insights have been summarized.

Chapter 2.2 - Preliminary evaluation of the diagnostic scenarios
It is assumed that a semi-automated scenario is most feasible in terms of implementation in the current system and acceptance by the user.

Chapter 3.2 - eHealth
eHealth, mHealth, telemedicine and telehealth are definitions that are used interchangeably, but which can be distinguished. Applications for the Excelscope can be addressed to each of the categories, and mthe many possible applications will further be studied and defined in part 'user'.

Chapter 3.3 Smart devices
Aspects that are being developed in different ways are blood sample preparation, an integrated optical system and the level of automation. An integrated system for imaging and diagnostics has not been developed yet.

There is a knowledge gap on context feasibility and user acceptance of smart malaria diagnostics. This study aims to bridge the gap between the technology, context and user. Research will be done on contextual feasibility (facilities, access, equipment, staff) and user acceptance (desired smartness and interaction).

CONTEXT

5

CONTEXT ANALYSIS SET UP

5.1 INTRODUCTION

THE CONTEXT

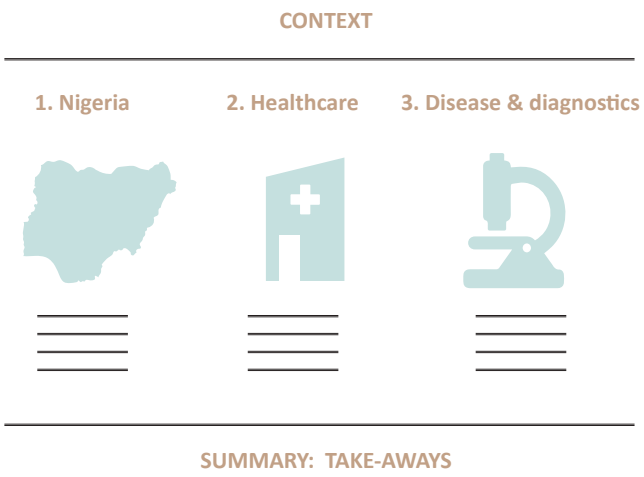
Currently, the Smart Malaria Diagnostics project aims to develop the Excelscope for use in a healthcare facility by medical professionals. More specifically, this study focuses on implementation of the device in Nigeria. Therefore, the following chapters in this section – related to healthcare and malaria – will be addressed to this country.

The context analysis will be reported from a broad perspective- Nigeria in general- to more specific topics. A country profile of Nigeria will be given to paint the picture and get insights in the Nigerian living standards and culture, which can be relevant for development of the Excelscope for this context.

The healthcare (system) within the country will be studied to find opportunities and challenges. The level of infrastructure and accessibility will be addressed.

The origin, symptoms and treatment for malaria will be explained. More specifically, the current diagnostic methods will be compared and evaluated by use of the World Health Organization's ASSURED checklist (3). The chapter about disease and diagnostics is complemented with insights from the context and perspective from Nigerian citizens and healthcare professionals, since effectiveness of technology is not only dependent on technical aspects, but on culture and behaviour as well.

All chapters together lead to a summary of the context analysis and take-aways for further development of the Excelscope.



5.2 RESEARCH GOALS AND METHODS

NIGERIA – HEALTHCARE – MALARIA DIAGNOSTICS

For each of the topics as described in the introduction, research goals and-questions have been defined. The questions were studied parallel to each other through literature and field studies. This section elaborates on the goals and methods of the whole study; in each chapter, a brief summary of the approach will be given.

5.2.1 Research goals

The following research goals (RG) have been set up for each of the aspects.

5.2.1.1 Nigeria

A brief study will be done in order to get general insights about Nigeria's political system, economy, living standards and cultural beliefs that have to be taken into account when developing the Excelscope for use in Nigeria.

5.2.1.2 Healthcare system

The goal of this study is to create an overview of challenges and possibilities per tier of the healthcare system with regard to implementation of the Excelscope. Therefore, subgoals are:

RG1 Understand Nigerian healthcare and map the healthcare system
RG2 Identify differences per type of health centre in terms of facilities, equipment, staff, accessibility, diagnostic abilities

5.2.1.3 Disease and diagnostics

The aim of this part of the study is to learn from malaria and diagnostic methods in order to translate the insights into key messages for the development of the Excelscope. The subgoals are:

RG3 Get understanding of basic terminology of disease and diagnostics
RG4 Get understanding of malaria (disease, prevention, treatment)
RG5 Find advantages and limitations of different malaria diagnostic methods
RG6 Get insights in the local perspective on malaria and diagnostics.

5.2.2 Research questions

Several research questions (RQ) have been derived from the research goals. No questions were defined for the chapter about Nigeria: the findings are a summary of general readings about the country, from which relevant aspects have been pointed out.

5.2.2.1 Healthcare system

RQ1 How is the healthcare system organized and regulated?
RQ2 Which levels of health centres does the system consist of?
RQ3 What are the differences between these health centres in terms of equipment, facilities, diagnostic abilities and accessibility?

5.2.2.2 Disease and diagnostics

RQ4 What causes malaria, how can it be prevented and treated?
RQ5 What are the advantages and limitations of malaria diagnostic methods?
RQ6 Where do Nigerian people go whenever they suspect Malaria?

5.2.3 Methods

Different methods have been used in order to understand the healthcare system and malaria diagnostics.

5.2.3.1 Literature

A literature study has been conducted throughout the analysis. In advance of the field study, literature has been conducted in order to immerse and prepare. The study has been continued later on, by being able to specify the keywords for finding appropriate information. Literature has been found through Google Scholar, PubMed, NCBI and news websites, by using keywords related to Nigerian (primary) healthcare, challenges, barriers, development, community pharmacies and patent medicine vendors.

5.2.3.2 Open online questionnaires

Open questionnaires were sent out to Nigerian inhabitants in order to get better understanding of the local perspective on the Nigerian healthcare system in advance of the field study. Next to questions about healthcare, the online interviews were done to get better insight in people's perspective towards malaria (section 8.3.4). Seven Nigerians from Lagos, Ibadan and Ile-Ife participated through online communication tools. Follow-up questions were asked based on the first responses.

5.2.3.3 Field study

During the field study in Ibadan, the healthcare system was studied through observations and interviews. Through semi-structured interviews, 29 different healthcare professionals shared their opinion and view on the healthcare facilities and their jobs within these facilities. Furthermore, four students and staff members from the University of Ibadan were closely involved in the analysis and provided feedback on the results.

5.2.4 Results

The results of the analysis can be found in chapter 6, 7 and 8.

6

NIGERIA

Nigeria is the chosen context for research on implementation of the Excelscope. Therefore, the following chapters in this section – related to healthcare and malaria – will be addressed to this country. This chapter gives an overview of relevant insights about Nigeria. The findings from the country analysis will be used to find necessary insights for development of the device with regard to the environment and users on an abstract level.

FIGURE 6.1
A local market place in Ibadan, Nigeria.

6.1 A COUNTRY PROFILE

SOCIO-ECONOMIC, POLITICAL AND CULTURAL ASPECTS

Nigeria is situated in the Western part of Africa and is the most populous country of the continent. The 186 million inhabitants account for almost half of the West-African population [3]. This section brings a brief overview of Nigeria's political system, economy, culture and health.

6.1.1 Political system and economy

After years of slave trade (Nigerians being sent to America) and colonization (by the United Kingdom), Nigeria regained her independence in 1960 and became a federal republic. Since then, the country has developed her political system into a system that exists of 36 states (regulated by democratically chosen governors) and 774 local government areas (LGAs). The president of Nigeria is Muhammadu Buhari, who has been elected in 2015, as the first candidate from the opposition to win a presidential election.

Nigeria's economy is the largest in Africa, but suffers from a high income inequality. Currently, the country belongs to the world's 20 poorest countries and is classified as a low-middle income country. Nigeria is highly dependent on her oil industry, since it accounts for 90% of the export and 75% of government revenues. Nonetheless, the sector does not bring much local employment or wealth and is in recession since the oil prices dropped in 2014. Next to the oil sector, agriculture is one of the main sources of income, accounting for 20% of the total GDP in 2013 [3,21,22].

The government allocates 75% of her expenditures on economic affairs and general public services and invests minimally on social facets such as health, education and social protection. Consequently, the social outcomes for Nigerians are poor: more than 10 million children do not go to school and almost half of the population is illiterate [32,33]. The average income per citizen is 5.740 dollars, far below the world's average of 16.100 dollars [3,21,23]. Thus, although the country is rich in resources and has a fast growing economy, basic needs of the population cannot be met.

6.1.2 Urban and rural areas

There are several large cities in Nigeria, where about 50% of the population is situated. The rest of the population lives in rural areas. The definition for rural and urban areas differ per country, but 'rural' is in this study referred to small towns in the country side; cities are considered being urban areas. An exact definition is not relevant for this explorative research, but might be necessary in further studies.

Due to a lack of – among other things – infrastructure and healthcare, Nigerians tend to move to urban areas, leading to less (focus on) development in rural areas. Urban areas in Nigeria are more attractive to healthcare professionals for their social, cultural and professional advantages [24].

6.1.3 Language, habits and values

Language

English is the official language spoken and being taught in Nigeria and next to that, there are over 250 linguistic groups. Sixty percent of the population is covered by the three major groups: the Igbo, Hausa and Yoruba. The latter is the biggest ethnic group, situated in the southwestern part of Nigeria (including Ibadan) as well as a part of the neighbouring country Benin. These regions are called Yorubaland [25]. Although English is the official language, uneducated people do barely speak this language.

Cultural values

According to Hofstede's cultural 6-D Model, Nigerians are short-term oriented and relate to standards and traditions. They are more focussed on achieving quick results and relatively less on projecting on the future. Furthermore, there is an emphasis on hierarchy in Nigeria, meaning that there is power distance and centralization within organizations [26]. With regard to the development of the Excelscope, these findings are interesting to take into account: short-term focus might be related to the perspective on benefits of diagnostics (chapter 8). Hierarchy might influence the acceptance for use in different levels of the healthcare system or healthcare facility. However, assumptions about possible cultural influencing factors need to be verified.

Mobile phones and Internet

In Nigeria, everyone is always on the phone. Cellular subscriptions are rising every year. In 2015, there were 82 registered subscriptions per 100 inhabitants [27]. According to the World Bank, 26% of the population made use of Internet, but other sources indicate that about half of the population is on the Internet. Use of Internet is probably best accessible and used in urban areas. Social media is popular, especially among the youth. Nigerians use their phone mainly for social activities, such as calling, messaging and social media. Wi-fi is not commonly available, but data packages can be bought.

FIGURE 6.2
The city centre of Ibadan is crowded and noisy due to traffic.

6.1.4 Health

In Nigeria, the life expectancy at birth is 54,5 years, which is 17 years below the world's average and 5,5 years below the average life expectancy in Africa [28]. In 2015, the mortality rate for children under five was 186 per 1000 live birth [29], of which 30% is caused by malaria [21]. Malaria is a major problem in Nigeria, to which the government has set fighting as one of her top priorities [30]. More than 90% of the Nigerian population is at risk of malaria infection, leading to 60% of the outpatient visits in Nigerian healthcare facilities [21,31]. Together with the republic of the Congo, Nigeria counts for a third of the malaria cases and deaths [24]. The prevalence of malaria parasites (plasmodium Falciparum) is the highest in middle, south and south-west areas of Nigeria. An elaborated explanation of the disease and its burden can be found in chapter 8.

Next to malaria, there are several health problems in Nigeria. Some of the most prevalent diseases and health problems are malnutrition, hypertension, respiratory infections, HIV/AIDS, stroke and trauma (due to road traffic accidents). In chapter 7, the healthcare system of Nigeria is further being explained, based on a literature study and findings from the field.

FIGURE 6.3
Corn is one of the main agriculture products. Roasted corn is a common snack that is being sold everywhere in Ibadan.

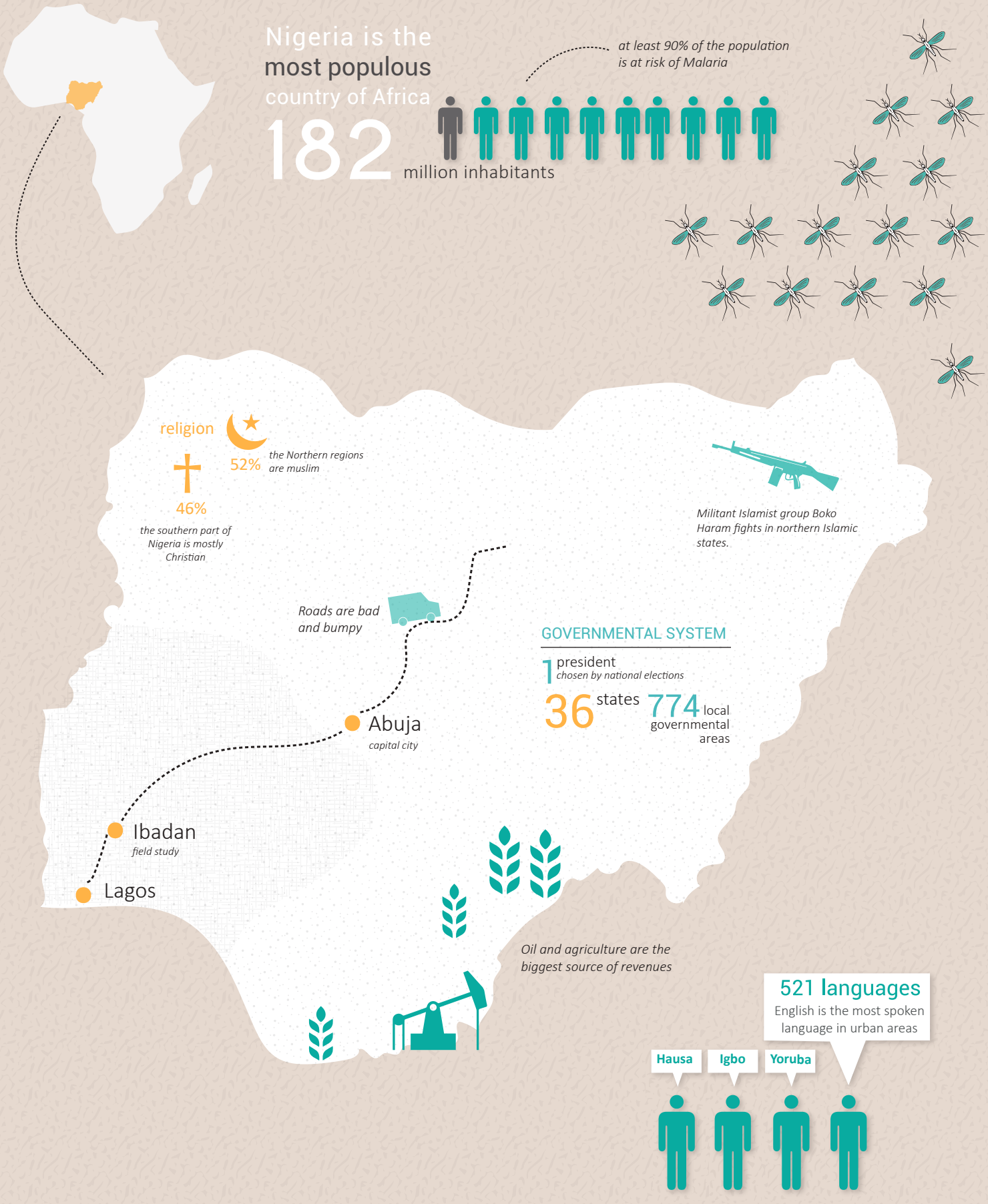


FIGURE 6.4
The infographic gives a visual overview of Nigeria's main characteristics.

FIGURE 6.5
In Ibadan, taxis, motorbikes and tricycles ('kekes') are the most common public transport

My experiences in Ibadan

The field study of this project is conducted in Ibadan, a city in the South-West region of Nigeria. It is the widest city of Africa: the total area is three times as big as Lagos, while the population density is eight times as small. I stayed for a month in this lively, colourful, friendly city and gain a lot of insights into the Nigerian culture.

First of all, the population density is indeed striking. By daylight, people are everywhere. On the streets, in the many cars, taxis, tricycles (figure 6.6) and on market places. It creates a lively atmosphere (and a lot of traffic jams). Ibadan is a big city, but feels more like a large town. Within Ibadan, there are a lot of slums and low developed areas.

I stayed in Ibadan during the rainy season, which means that the rain can poor down heavily all of a sudden (and that happens quite often). Nigeria's climate is warm and humid during the rainy season, but warm and dusty druing the dry season.

Power often fails, resulting in the noise and pollution of generators that are being turned on. Air pollution is an issue in general, derived from all motor vehicles that are driving around.

People in Ibadan are friendly and talkative. The general attitude is open; they often start conversations with each other in for example the public taxis. There are no tourists and some people had never seen an 'oyinbo' (white person) before, resulting in greetings from everyone and a lot of conversations.

Nigerian students are entrepreneurial and ambitious: a lot of them apply for internships or grants abroad. However, this is partly due to the challenges Nigeria is facing. Universities are often on a strike and many young people cannot find a job once being graduated. These problems cause a brain drain. However, I have also met a lot of people who were proud of their country and aimed for solving these problems.

The stay in Ibadan has been inspiring and valuable for understanding of the context and getting insights in the Nigerian culture and healthcare system.

FIGURE 6.6
Enjoying a daily drive in the tricycle.

FIGURE 6.7
These girls sell apples on the corner of the street every day.

NIGERIA | TAKE-AWAYS

The country analysis lead to several take-aways (T) for the development of a smart malaria diagnostic device for Nigeria.

T1 Nigeria is a low-middle income country and belongs to the poorest countries of the world. Therefore, the device (and an individual test) has to be **affordable** for healthcare providers and-seekers.

T2 An increased number of people tend to move towards urban areas, since urban infrastructure and healthcare services are better facilitated. Organizations working in rural areas are based in urban areas. Therefore, initial **implementation of the Excelscope in urban areas** is recommended, after which the use can be extended.

T3 Although English is the official language, illiterate people mainly speak **traditional language**s. This has to be taken into account when designing the interfaces for the Excelscope.

T4 From a cultural perspective, Nigerians are **short-term focused**. With regard to malaria, it could mean that people focus on quick recovery and the 'better safe than sorry' habit to take medicines regardless of test results, instead of taking risks of overtreatment and resistancy into consideration.

T5 Trust in healthcare is relatively low and care is expensive. Instead of seeking for care, a lot of people try **self-medication** first.

T6 Infrastructure in general is quite poor, power often fails. **The climate is humid and warm**. A device has to be robust in order to withstand extreme circumstances.

7

HEALTHCARE IN NIGERIA

The healthcare system in Nigeria has being studied in order to get better understanding of the accessibility to healthcare, availability of equipment and challenges with regard to malaria diagnostics. A literature study in combination with observations and (online) interviews in Ibadan, Nigeria, lead to an overview of different healthcare facilities and their characteristics. Information with regard to local malaria diagnostics can be found in chapter 8.

7.1 THE HEALTHCARE SYSTEM

OVERVIEW OF HEALTHCARE CENTRES AND FACILITIES IN NIGERIA

This section gives an overview of the complex healthcare system in Nigeria, wherein public and private healthcare facilities interlace. The analysis is based on findings from the field study in Ibadan, supplemented with findings from the literature study and online interviews.

7.1.1 Development of healthcare in Nigeria

In the pre-colonial era, healthcare was delivered through traditional medicine, by herbalists, traditional healers, spiritualists, bone-setters and mental health therapists [34]. Western style health care was introduced in Nigeria by Western doctors who had to care for the colonialists. It only became available for the local people via church missionaries, in return for tribute to the church. The first hospital in Nigeria was the Sacred Heart Hospital in Abeokuta, built in 1885 342]. Since then, the healthcare system has developed into a complex combination of traditional medical practices, private health care facilities and public health centres.

7.1.2 Current healthcare system

As visualized in figure 7.1, the healthcare system exists of private and public healthcare facilities, from which patients can be referred to another. According to Welcome (2011), the referral system from one facility to another is poorly managed. People do not need to be referred from primary care to higher levels, but can go to each of the facilities directly for a consult, laboratory test or drugs [35].

7.1.2.1 Public healthcare sector

The government subsidizes and regulates the public healthcare facilities on primary, secondary and tertiary level. Primary health centres are regulated by the Local Government Areas and State Governments are responsible for secondary centres. The Federal Government is responsible for health care at tertiary level (university hospital) as well as general policy and regulations.

Primary health centres

The primary health centres (PHCs) get minimal funding, leading to a poorly developed base of the system, mainly because 85% of the health facilities are primary care centres [35,21]. PHCs often lack in (laboratory) equipment, which leads to diagnoses solely based on clinical symptoms. There are many differences in infrastructure: some primary health centres have a laboratory and the possibility to monitor inpatients, while other centres are minimally equipped. According to a study of the General Household Survey (2016) most Nigerians have geographic access to PHC (<30 minutes travel distance), but do not have financial resources to actually afford healthcare [36].

Secondary health centres

Secondary health centres (SHC) normally have more equipment and facilities than PHCs, but do not always have a laboratory. In that case, patients have to be referred to a private laboratory or lab in a university hospital if a blood test is required. In urban areas, secondary health centres are small hospitals with different departments for e.g. children, a laboratory and/or inpatient care.

Tertiary health centres

University hospitals can be addressed to the tertiary level and count for only 0.2% of the health centres in Nigeria [21]. These hospitals have many facilities, such as operating rooms and laboratories, research departments and many different staff members. From primary and secondary centres, patients can be referred to the tertiary hospitals for the more severe cases. Since PHCs and SHCs often lack proper equipment, people tend to go to the tertiary hospitals right away whenever they are sick. It leads to many primary care cases to be attended to in the hospitals, causing high workforce for the tertiary staff.

7.1.2.2 Private healthcare sector

The majority of private clinics focuses on primary health care or diagnostics, such as malaria care or ultrasound consultation. In private hospitals, surgeries can be done. In severe cases or in case of a lack of proper equipment, patients can be referred to public tertiary hospitals. Since private clinics are profit-oriented and need to attract patients, the personal care and hospitality is generally better compared to public health centres and the waiting time is shorter. However, the equipment in the private facilities is limited, as little hands as possible are employed and the staff often has limited expertise.

> in short | aim & approach

Goal

RG1 Understand Nigerian healthcare and map the healthcare system

Main research questions

RQ1 How is the healthcare system organized and regulated?

RQ2 Which levels of health centres does the healthcare system consist of?

RQ3 What are the differences between these health centres in terms of equipment, facilities, diagnostic abilities and accessibility?

Data collection

Data was collected by a literature study and supplemented by insights from an open online questionnaire and a field study.

Results

The Nigerian healthcare system is a complex system of public and private healthcare facilities, regulated and funded by different parties. The majority of the system lacks equipment, infrastructre, staff and resources.

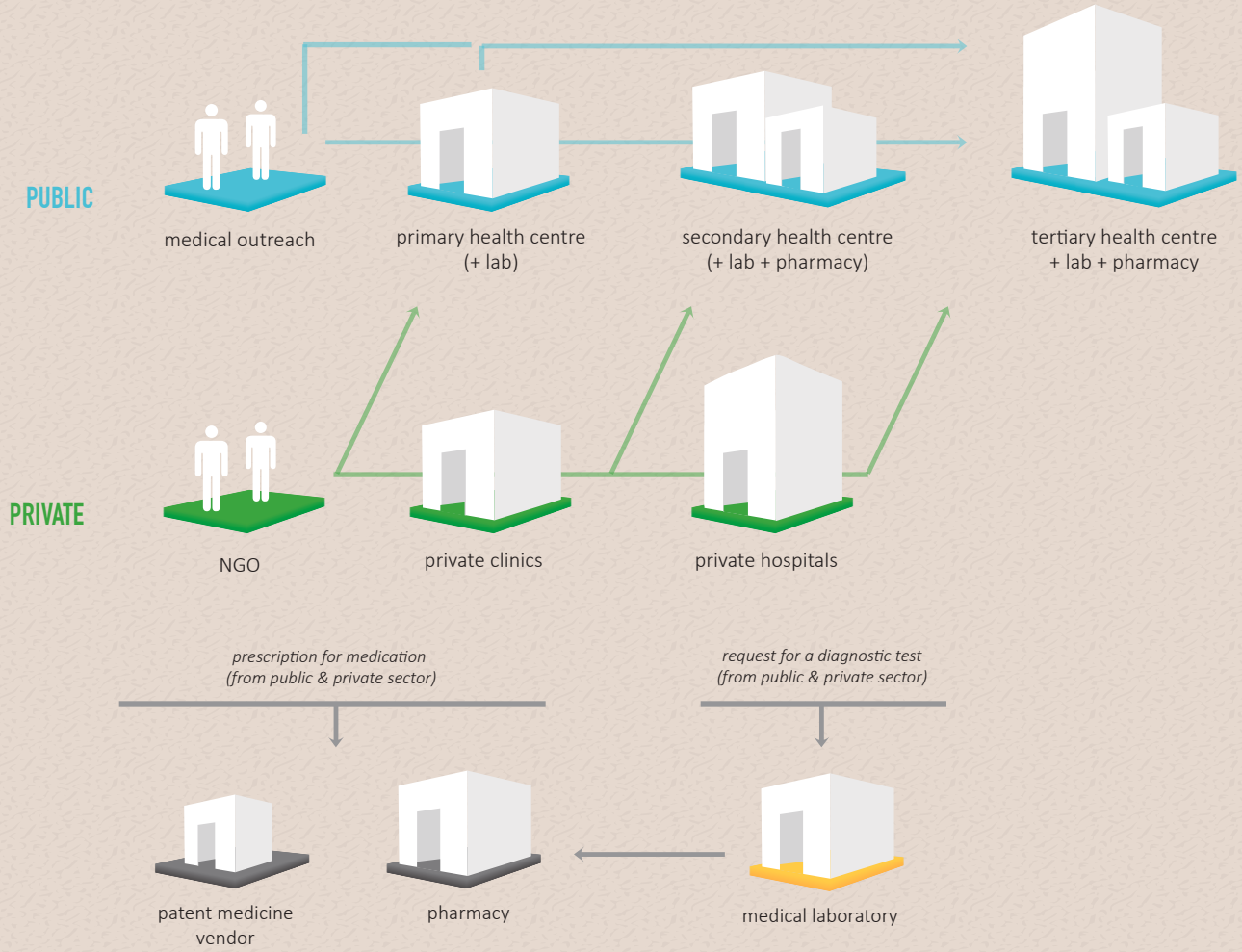


FIGURE 7.1
Visual representation of the healthcare system in Nigeria, giving both public as private sector, laboratories and medicine facilities. The overview has been developed in collaboration with students in Public Health and a medical doctor.

7.1.3 Other healthcare services

The Nigerian healthcare system consists of healthcare centres as well as several other healthcare services which be visited without referral.

7.1.3.1 Non-governmental organizations

Several NGOs go to communities for primary care outreaches. The organizations take diagnostic equipment (e.g. blood pressure monitors, glucometers and RDTs) as well as medication to the field. All care and treatment is provided for free. Often, medical students work as volunteers for non-governmental organizations.

7.1.3.2 Patent Medicine Vendors (PMV)

In the patent medicine shops, drugs can easily be bought without prescription. PMVs are the first point of call for 30-40% of the people and the main source of medicine for acute complaints [37-39]. Next to medicine, the shops sell daily groceries. The shops are easily accessible to the majority of the people in both urban and rural areas, which makes treatment (a.o. anti-malaria drugs, paracetamol) accessible to those who can afford it. In general, medicine prices are lower at PMV shops, compared to community pharmacies. Since the medicine vendors are often low educated and profit focused, health services are poor and overtreatment can easily be caused.

7.1.3.3 Community pharmacies

At community pharmacies, low-impact diagnostic tests can be done, among which tests for typhoid fever, cholesterol, blood glucose and blood pressure measurement. Pharmacies are especially accessible to the urban population.

Diagnostic abilities differ per pharmacy: some pharmacists emphasize the patient's health and try to monitor their customers, while others tend to sell drugs over the counter and are profit-oriented. Several community pharmacies collaborate with public health centres and can get governmental funding on e.g. rapid tests for malaria diagnostics.

7.1.3.4 Medical laboratories

Since laboratory facilities are not always available in health centres, public and private clinics can refer patients to a private medical laboratory for a diagnostic test. It depends on the laboratory whether a test can be done without referral from a doctor. The laboratories conduct blood and urine tests for different diseases by use of microscopy. Based on estimations, there are most probably more than 10 000 medical laboratories throughout Nigeria, although less than one-third is being registered in the national database.

	no infrastructure *rural areas / home*	minimal infrastructure *rural / urban areas*	moderate infrastructure *urban areas*	advanced infrastructure *urban areas*
Electricity	Not available	Not reliably available	Available	Available
Clean water	Not available	Not reliably available	Available	Available
Physical infrastructure	None	None or minimal laboratory	Poorly equipped laboratories	Well equipped laboratories
Staff	No expertise	Nurses (minimal expertise available)	Nurses, some physicians, poorly trained technicians	Nurses, physicians, well trained technicians

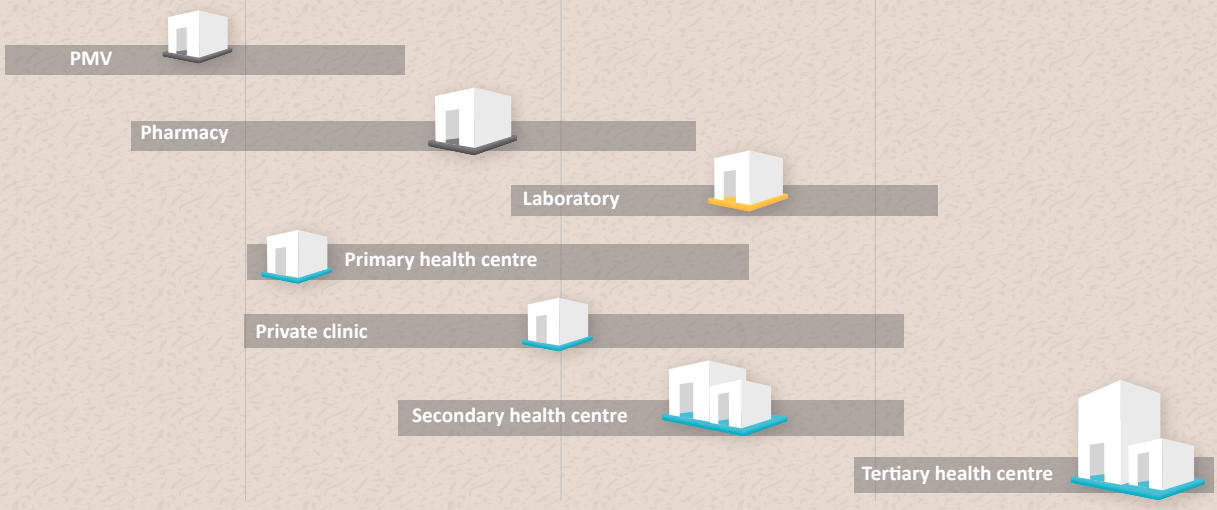


FIGURE 7.2
When mapping the healthcare facilities in the infrastructure level model of Girosi et al. [40], the differences and overlap between different healthcare facilities is visualized. A secondary centre can have less infrastructure than a primary centre, based on the (non)governmental investment.

7.1.4 Infrastructure levels

As described by Girosi et al. (2006) health centres can be categorized in infrastructure levels in terms of staff, facilities and equipment (figure 7.2) [40]. The three levels of public healthcare facilities do not specifically correspond to the infrastructure levels, since there are many differences between rural and urban centres and the level of infrastructure is dependent on local investors as well (figure 7.3). Yet, in general, primary centres are more likely to have minimal infrastructure (no laboratory, unreliable water and energy supply) whereas the tertiary centres are more advanced. When developing a smart device for a specific location, the level of infrastructure has to be taken into account; or vice versa: the available resources have to be considered when defining a context of use.

FIGURE 7.3
Microscope in a medical laboratory of a primary health centre (left) and a laboratory in a secondary health centre (right), which is less advanced. The centres are categorized in terms of governmental regulations, which does not specifically give a hierarchy in level of infrastructure.

7.1.5 Challenges in Nigerian healthcare

The result of this analysis show that Nigeria has several challenges to come in order to facilitate efficient and accessible healthcare. According to Adeyi (2016) underperformance of the health system is caused by a variety of factors, including a lack of good education, poor infrastructure, unhealthy environment, but moreover a system in which the different parts do not work well together [41]. The complexity makes it hard to regulate the system, financing is not based on prospected outcomes (but on inputs such as the number of health centres or-workers) and projects are short-term focused [3]. Several challenges have been highlighted.

7.1.5.1 Lack of staff

According to the WHO, the amount of nurses, midwives and doctors (1.95 per 1000 people) is too low to effectively deliver essential health services [24]. Most of the healthcare professionals work in urban tertiary health care institutions, and the highest concentration of health workers is found in Lagos. In rural areas, there is a lack of caregivers. The inequality is caused by e.g. underperforming management in public and private sector, bad work environments, an inequity in amount of health workers per section [32].

The lack of staff is partly due to the emigration of skilled healthcare professionals to other countries, a so called 'brain drain'. Exact numbers are unclear and not validated, but alarming: different sources report that 60 up to 88 percent of the doctors seek work abroad. Most Nigerian doctors emigrate to the USA or UK.

7.1.5.2 Accessibility

Accessibility to healthcare remains a problem in Nigeria, in both rural and urban areas. Accessibility is the sum of different aspects: the ability to perceive health constraints, seek and reach healthcare, pay for the service and engage in the procedure and treatment [42]. On different levels, challenges exist.

First of all, the availability of health facilities is low in Nigeria. For every 1000 people, there are 0,9 hospital beds: far below the global average of 2,3 beds per 1000 inhabitants. More striking, the amount of intensive-care beds is dramatically low: 0,07 per 100.000 inhabitants. To compare to another low-middle income country: Kenya has 0,3 intensive-care beds per 100.00 people [24].

The healthcare sector is financed by different sources of income: governmental funding, out-of-pocket spending, external grands, charities and insurances. From all these sources, out-of-pocket spending makes up 70% of the total health expenditure in Nigeria. Less than 5% of the population is enrolled in the National Health Insurance Scheme (NHIS) of the government [43]. The subscriptions are mostly covered by the upper-class and federal government employees.

The implementation of the healthcare insurance scheme is slowly implemented through both public and private insurance programmes [44,45]. Without an insurance, the need to pay for care creates financial barriers for the poor and makes healthcare inaccessible for a large part of the Nigerian population [44,46].

7.1.5.3 High workload at tertiary level

As stated before, healthcare is poorly developed at the primary level. Therefore, people tend to seek for care in tertiary health centres immediately, leading to an overload of minor outpatient cases in higher levels of the healthcare system. Better equipment or diagnostic abilities at the primary level might reduce the workload at tertiary levels where doctors are being educated for treating severe cases, instead of taking care of minor complaints.

7.1.6 Objectives and solutions for better healthcare

To fight the challenges and improve access to healthcare, the governmental expenditure on primary health centres has to increase, brain drain has to be managed actively and health insurance schemes have to be made accessible to the mass. The WHO [24] emphasized on the potential use of telemedicine for improving healthcare and the importance to collaborate with other countries through financing arrangements. The Excelscope can have impact on healthcare by enhancing access to diagnostics to a disease with the highest burden of illness. Nonetheless, it has to fit the healthcare system and infrastructure in order to be usable.

7.2 PATIENT JOURNEY FOR MALARIA DIAGNOSTICS

DIFFERENT OPTIONS FOR A PATIENT IN ORDER TO GET TESTED AND TREATED

The analysis on the healthcare system is related to malaria diagnostics. Based on the findings of the study, an abstract patient journey has been made. In Nigeria, there are different possibilities to get tested and to obtain antimalaria drugs. This chapter relates to diagnostic methods in chapter 8.

7.2.1 The gold standard: referral and prescription

The standard and possibly most accurate way of getting diagnosed and (if necessary) obtaining treatment, is through screening and diagnostics via a doctor in a health centre (figure 7.4). The doctor can decide on a laboratory test request based on clinical symptoms. A private laboratory can be attended to if there is no laboratory available at the specific health centre. More information about the gold standard for malaria testing can be found in chapter 4.

The patient takes the result of the laboratory back to the doctor, who can decide on treatment. Based on the diagnosis, the patient undergoes another test, goes home or takes a prescription to the pharmacy.

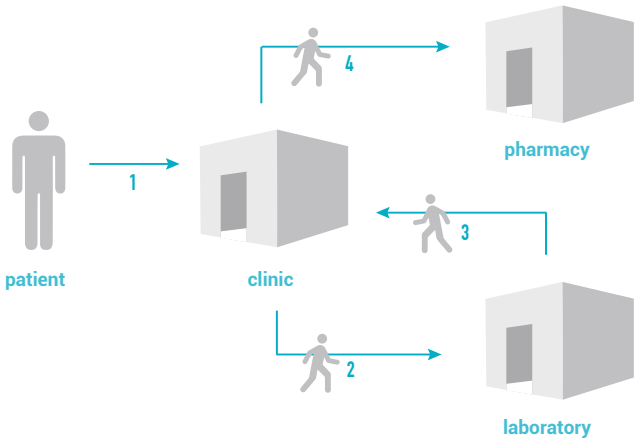


FIGURE 7.4
Diagostics and treatment via a clinic, laboratory test and prescription.

7.2.2 Direct prescription or rapid diagnostic test result

The diagnostic procudure for malaria is often conducted without a laboratory test. In some cases, doctors base their diagnosis on clinical symptoms or the patient's own assumptions and demand for a prescription. More accurately, rapid diagnostic tests are used in (especially primary) health centres to diagnose quickly. Similar to the first scenario, the patient takes the prescription to the pharmacy or PMV (Figure 7.5).

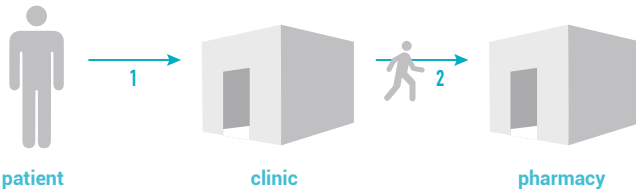


FIGURE 7.5
Diagostics and treatment via a test or screening in a clinic and prescription.

7.2.3 Over the counter

In most PMV shops and many pharmacies, drugs can be purchased without a prescription. Several pharmacies provide rapid diagnostic tests, yet not all people have geographical or financial access to tests. When someone suspects having malaria, a visit to the closest drug supplier is the quickest patient journey to get treatment. However, this is the worse scenario in terms of reliability and chance on overtreatment (figure 7.6).

A smart diagnostic device would possibly suit in any of the three scenarios, by either reducing the procedure time, improving accuracy or decreasing overtreatment and misdiagnosis. The next chapter elaborates on malaria and the avantages and limitations of different diagnostic methods.

FIGURE 7.6
(Diagnostics and) treatment directly at the pharmacy or medicine shop.

7.3 ADVANTAGES OF IMPLEMENTATION

FOR EACH HEALTHCARE FACILITY

Figure 7.7 shows the potential advantages for use of the Excelscope in different healthcare facilities. Private centres have not been included, since they are similar to primary healthcare centres on the given aspects. The advantages have been derived from the healthcare system analysis.

	Primary centre	Secondary centre	Tertiary centre	PMV	Pharmacy	Laboratory
Increase access to diagnostics	X			X	X	
Reduce workload			X			X
Improve diagnostic abilities	X			X	X	
Reduce waiting time	X	X	X			X
Provide point of care test & treatment		(X)	X	X	X	
Consult a lab technician for verification	(X)	(X)	X			(X)
Use available advanced infrastructure	(X)	(X)	X			(X)
Shorten patient journey	X			X	X	

FIGURE 7.7
Potential advantages of implementation of the Excelscope for different healthcare facilities. An X indicates that the advantage is applicable to the centre; an (X) means that the statement is applicable to the facility when the specific aspect (e.g. medicine, lab scientist or advanced facilities) is available; within the tiers, differences in infrastrucutre exist.

HEALTHCARE SYSTEM | TAKE-AWAYS

The Nigerian healthcare system is complex due to the interlace of public and private healthcare facilities and a lack of clear regulations. People can go to a hospital for primary care complaints, or even go to a pharmacy directly to buy drugs without prescription. The lack of regulations on healthcare is one of the causes for bad malaria diagnostics and overtreatment.

Analysis of the Nigerian healthcare system brings insights for implementation of the Excelscope and the challenges to overcome.

Primary healthcare

T6 A smart device would suit in both public and private primary healthcare settings, since they are relatively accessible to the majority of the people. Diagnostic abilities are limited in these centres and diagnoses are often based on clinical consultation. Improving diagnostic abilities in the lower level facilities can reduce the workload in hospitals. Overtreatment or misdiagnosis can be solved by providing better diagnostic possibilities in primary healthcare facilities.

A lack on facilities such as running water, electricity and internet have to be taken into account when developing the device for primary healthcare.

Pharmacies and Patent Medicine Vendors

T7 The pharmacies and PMVs are accessible to people in rural and urban areas and often the first point of call. Use of a diagnostic device in these centres decreases unnecessary medicine intake.

Profit focus of these facilities, limited medical knowledge and a lack of facilities such as running water, electricity and internet have to be taken into account when designing for pharmacies or drug vendors.

NGOs or public medical outreaches

T8 To increase access to diagnostics in (rural) communities, the Excelscope can be used by medical outreaches from NGOs or public healthcare facilities.

In the field, facilities are limited. Furthermore, the device must be applicable to be transported on the bad roads in Nigeria.

8

DISEASE & DIAGNOSTICS

8.1 TERMINOLOGY

DISEASE AND DIAGNOSTICS – RELATED TO MALARIA

To understand all aspects of this project, some core terms and definitions related to diseases and diagnostics will be explained, in particular related to malaria. The terms and definitions will be used throughout the rest of the report.

8.1.1 Infectious and communicable diseases

Infectious diseases are caused by a pathogenic micro organism and can be transferred in different ways to individual 'hosts'; these can be communicable or non-communicable:

- A communicable disease can be transmitted by infectious bacteria or viruses.
- A contagious disease is a rapidly spreading communicable disease, by being transmitted via close contact between individuals.
- A non-communicable disease is for example caused by toxins, from the environment or food-poisoning [47,48].

Malaria is a communicable disease, but an infection does not necessarily have to lead to a disease. Severity of an infection ranges from asymptomatic (free from symptoms) to severe diseases or fatal consequences [49]. More details about malaria can be found in chapter XXX.

8.1.2 Screening and diagnosis

The difference between screening and diagnosis is visualized in figure 8.1. In theory and practice, a *screening test* (which identifies (asymptomatic) people who might have the disease, e.g. based on risk factors or demographic characteristics) and *diagnostic test* (determines the presence or absence of a disease) are distinguished. The diagnostic test is performed after a positive screening test. Examples of screening tests are blood tests, mammography or cholesterol measurements. A diagnostic test can be laboratory tests (evaluation of biomarker samples such as blood, salliva or urine), imaging scans or biopsies [50,51].

Both screening and diagnostic test might be harmful, e.g. by exposure to high radiation doses, psychological harm, unnecessary medical procedures. A screening test is usually more acceptable to patients and staff, whereas a diagnostic test might have more impact, be expensive or more invasive [52]. On the other hand, diagnostic tests generate more detailed information about possible diseases.

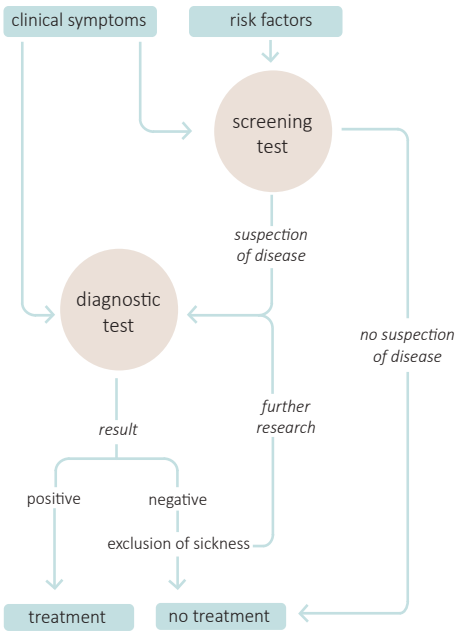


FIGURE 8.1
Flowchart for screening and diagnosis of diseases. Clinical symptoms are the main reason for a screening or diagnostic test for malaria.

> in short | aim & methods

Goal

RG2 Identify differences per type of health centre in terms of facilities equipment, staff, accessibility, diagnostic abilities

Main research questions

RQ4 What causes malaria, how can it be prevented and treated?

RQ5 What are the avantages and limitations of malaria diagnostic methods?

RQ6 Where do Nigerian people go whenever they suspect Malaria?

Methods

Data was collected by a literature study and supplemented by insights from an open online questionnaire and a field study.

Results

General knowledge about diagnostics has been gained as well as specific information about malaria diagnostic methods. Microscopy and rapid diagnostic tests for malaria have been compared: both methods have advantages, which ideally have to be combined in a smart device. Trust in diagnostic methods from caregivers and patients is not always sufficient, leading to limited adherence to test results.

Besides detection of disease, a diagnostic test can be done for [53]:

- monitoring treatment effectiveness
- enabling surveillance programs
- selection of appropriate treatment
- avoidance of inappropriate treatment

8.1.3 Diagnostic yield

Whether the result of the tests is correct, depends on competence of the healthcare provider and accuracy of the test. In diagnostic testing in general, four scenarios are possible, as shown in figure 8.2.

[a] True positive	Patient has the disease, the test result is positive. *A proper and suitable treatment can be advised.*
[b] False positive	Patient does not have the disease, but the test result is positive. *Chance on unnecessary intake of medicine.*
[c] False negative	Patient has the disease, but the test result is negative. *Chance on serious burden of the disease.*
[d] True negative	Patient does not have the disease, the test result is negative. *The specific disease is excluded from diagnosis.*

The diagnostic yield of a test is the likelihood that it will provide the necessary information to define a diagnosis. This is dependent on the sensitivity and specificity of the test, which together determine the test's validity [52, 54-57].

8.1.3.1 Sensitivity

The ability to identify the 'true positives', those who have the disease (a) from all individuals with the disease (a+c). A screening test is usually chosen towards high sensitivity to find those who might have the disease.

8.1.3.2 Specificity

The ability to identify the 'true negatives': those who do not have the disease (d) from all individuals free from the disease (b+d). A diagnostic test is generally focused on high specificity.

8.1.3.3 Gold standard

In general, highly sensitive tests have a low specificity and vice versa. However, a perfect diagnostic method would have a 100% sensitivity ad 100% specificity. In that case, everyone with a positive test result actually have the disease, while a negative test result accurately indicates that the patient does not have the disease. The most accurate test (highest sensitivity and specificity) that is available for diagnosing a specific disease is called the 'gold standard' [57].

8.1.4 Point-of-care-testing

Point-of-care-testing (POCT) is executing a test for clinical decision making at or near the location of patient care (e.g. during a consult, in an ambulance or at the patient's bedside). For POCT, a laboratory and laboratory technicians are not needed. Examples of point-of-care-tests are dipsticks (chemically sensitive sticks), portable glucose meters or home pregnancy tests [54,58].

Point-of-care-tests are normally less advanced than laboratory based tests. However, technologies are in development and the demand for POC devices is increasing. The pros and cons of both types of tests are given in figure 8.3, based on the overview created by Bioventures [53].

8.1.5 Microscopy

Since microscopy (figure 8.4) is the gold standard for malaria diagnostics, there are several specific terms that will be used throughout the report. More details about malaria microscopy can be found in chapter 8.3.

8.1.5.1 Parasitaemia

The presence of parasites in blood; often given in an amount per high power field or severity on a scale of three + signs (+; ++; +++) [58].

8.1.5.2 Field of view

In microscopy, the field of view (FOV) is the diameter (in mm) of the image view. The larger the FOV, the bigger the area that can be seen through the microscope (in the same level of magnification). The field of view is indicated by the field number on the microscope eyepiece [19]. The field of view can also be called 'high power field'.

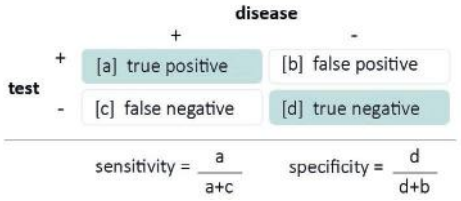


FIGURE 8.2
The specificity and sensitivity are based on the chance on false/ true negative- and false/true positive results of a diagnostic test.

	Advantages	Disadvantages
Point of care tests	Increasing diagnostics in regions without lab access	Lower sensitivity/specificity
	Reducing patient loss by test ant treatment at one place	Higher costs per test (on average)
	Reducing inappropriate use of antibitoics and antimalarials	More waste from packaging and disposables
Laboratory tests	Higher sensitivity and specificity	Not readily accessible by rural patients
	Monitoring where immediate action is not required	Requires investment, infrastructure and equipment
	Less waste from packaging and disposables	Possible patient loss due to time between test, result and treatment

FIGURE 8.3
The advantages and disadvantages of point-of-care-tests and laboratory based tests (Based on the model of BioVentures, [53]).

FIGURE 8.4
Microscopy is the gold standard for malaria detection.

8.2 MALARIA

ORIGIN AND DISEASE

Although the serious burden of malaria in developing countries is common knowledge, information about the origin, symptoms and diagnostic methods are needed in order to get better understanding of the disease and perspective on malaria (diagnostics). Via a literature study and expert interviews, a complete overview of these topics has been given. Consequently, opportunities and threats for the future interaction with the smart device can be drawn.

8.2.1 Burden of illness

Malaria is a life-threatening parasitic disease and the leading cause for high morbidity rates in developing countries. Per year, malaria causes an estimated 429 000 deaths, of which most occur in sub-Saharan Africa. Especially children under five and pregnant women are at risk of malaria. Africa itself carries the biggest burden, counting 90% of the malaria cases and 92% of malaria deaths in 2015 [30, 60-62]. Although the amount of malaria infections has reduced and the mortality rates decreased for about 60% worldwide over the last decennia, the disease remains one of the major problems in developing countries in tropical areas [30]. The WHO aims to decrease the global mortality rate for malaria with 90% by 2030 compared to 2015 [63]. As described in chapter 6.1, malaria is one of the main health issues in Nigeria too.

8.2.2 Disease

Malaria is caused by parasites of the genus Plasmodium, a single-celled organism that is being transmitted via bites of female Anopheles mosquitos. There are five species that infect human (figure XXX), of which Plasmodium Falciparum is the most common species in sub-Saharan Africa. This parasite causes the most severe type of malaria. Plasmodium Knowlesi mostly infects animals, but has caused human malaria as well [1].

The early symptoms of malaria are non-specific and the disease is mostly suspected by a history of fever. Severe malaria can lead to liver failure, coma or even be fatal. Since there is no combination of symptoms that reliably indicates malaria, a diagnosis based on only clinical symptoms has low specificity. A false positive diagnosis causes overtreatment, resulting in the economic burden of buying unnecessary drugs, the chance on drug resistance and the missed opportunity to treat the actual disease. Therefore, there is need for effective and accurate diagnostic methods in order to diagnose malaria and reduce mortality from this disease [64,65].

7.2.3 Prevention

The Nigerian government promotes malaria prevention via different media, such as television, newspapers and drama plays. Insecticide-treated mosquito nets are being distributed to rural areas and training about the use is being provided. However, the rural population is often not aware of appropriate use of mosquito protection tools or do not accept them.

"Even though treated malaria nets are frequently being distributed to people to prevent malaria, they rather use the nets as fishing nets, window nets or curtains."

- MSc student in Public Health, Ibadan

8.2.4 Treatment

According to the WHO treatment guidelines, malaria has to be treated by an artemisinin-based combination therapy (ACT), of which different types exist. Based on the patient's weight, a specific dose can be prescribed [66]. The ACTs are highly effective and uncomplicated malaria can be treated successfully by three days' treatment. In the past, chloroquine was the recommended drug for malaria treatment, but an increased drug resistance made the treatment unreliable and ineffective. The different ACT combinations were introduced to delay further resistance. However, information about drug resistance and new recommendations or national policies are not always up-to-date, increasing risks on mistreatment and mortality [67].

"Chloroquine is widely used in Nigeria to treat malaria and many peole do not bother again to visit a hospital when they are down with malaria."

- Health educator, Ibadan

8.2.5 Alternative causes for fever

The symptoms for malaria are non-specific, which means that the symptoms can be caused by other diseases. Next to that, co-morbidity such as typhoid or respiratory infections might occur and give similar symptoms to malaria. Hence, access to accurate diagnostics is essential in order to treat effectively.

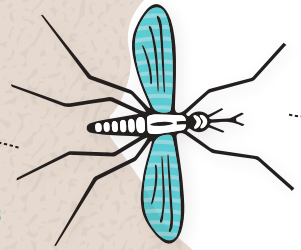
8.2.6 Malaria management

Figure 8.5 visualizes the 'journey' from a parasite to severe malaria. The included table shows different stages that a malaria infected person goes through. For each of the stages, challenges are given. This study focuses on malaria diagnostics, therefore taking accessibility, affordability and accuracy of a diagnostic test into account. Nonetheless, the whole journey and related problems are taken into consideration, since a diagnostic device does not eliminate malaria.

FIGURE 8.5
The infographic shows the different stages of malaria, from infection to symptoms.

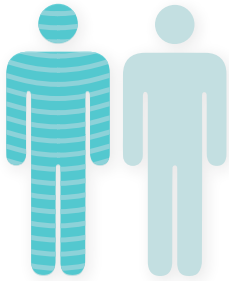
Plasmodium parasites

Falciparum	Vivax	Ovale	Malariae	Knowlesi
dominant in sub-Sahara Africa	dominant out of sub-saharan Africa	represent a small percentage of infections		mainly infects animals
causes most severe malaria	can stay in the liver for years without invading the blood			



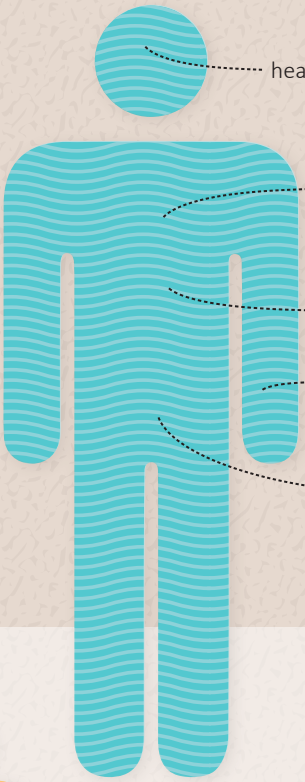
transmission via Anopheles mosquito bites

after infection, the parasite travels to the liver



almost half of the world's population is at risk

AFRICA counts for **90%** of the estimated malaria cases



early stage of disease

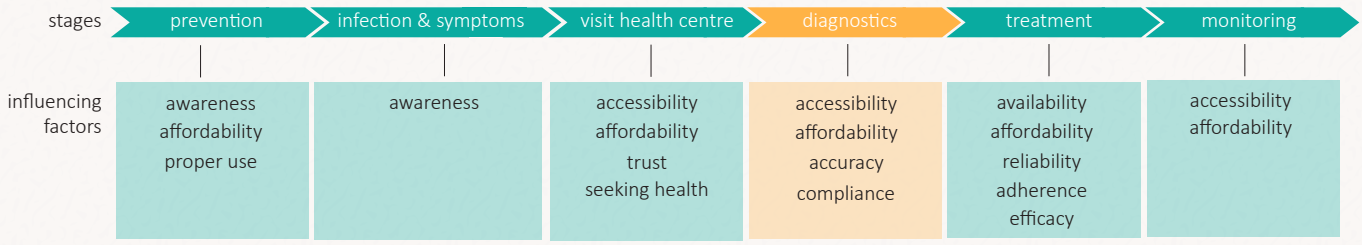
The early symptoms of malaria are non-specific, but quick and full recovery is possible with anti-malarial drugs

but if not being cured, malaria can lead to..

respiratory distress | liver failure | severe anemia | brain infection | shock, coma, stroke

Malaria causes an estimated **429 000** deaths per year worldwide

Malaria: from prevention failure to treatment effectiveness



8.3 MALARIA DIAGNOSTICS

DIFFERENT DIAGNOSTIC METHODS

To prevent misdiagnosis, every suspected case of malaria has to be confirmed via microscopy or a rapid diagnostic test of a blood sample [66]. Other diagnostic methods are limited available or still in development, and since light microscopy and RDTs are the common and recommended technologies, these have been further elaborated.

8.3.1 Rapid diagnostic tests

Rapid diagnostic tests (RDTs) are 'lateral flow immunochromatographic' tests, for which only a finger-prick of blood is needed. The drop of blood is added to the paper strip, which can detect the antigens produced by the human immune system in response to a malaria infection. Throughout Nigeria, the RDTs are widely used in healthcare clinics, pharmacies and even in laboratories- to do a screening or emergency test. The tests were first implemented in urban public healthcare centres, after which its use was extended to pharmacies and rural settings.

RDTs are qualitative tests: they do not distinguish species or measure parasitaemia (the amount of parasites per microliter blood). At low parasitaemia, the sensitivity of the test is low, potentially leading to a false negative result. This can have fatal consequences. Moreover, RDTs detect the antigens, which can still be present even after the parasites have cleared out, leading to false positive results.

The exact use of the test kits differs per brand, which might cause errors when a different RDT is being used (e.g. adding one drop of acid instead of two, figure 8.9). The variety of rapid tests know a wide range of quality in terms of sustainability, shelf life and accuracy.

Although the tests have many advantages (being relatively cheap, quick in use, limited training needed), the tests should only be used when microscopy is not available or feasible due to the limited accuracy [1,61,67-70].

8.3.2 Microscopy

Microscopy remains the oldest and still most accurate method for diagnosing malaria, and considered to be the gold standard. In order to detect the plasmodium parasite, a blood smear has to be prepared and stained on a glass slide. Via microscopy, the parasitaemia and the species can be identified via different ways [24]. Malaria diagnostics through microscopy requires different tasks, equipment and facilities in good condition. One must know the details in order to fulfill the procedure properly.

8.3.2.1 Procedure

A blood sample of 2 milliliters is needed for microscopy (figure 8.6). The lab technician has to make a smear and fix it to a slide. The slide has to dry, which can be done in an oven, under a heating lamp or in the open air. The latter will slow down the process, but can be unavoidable when electricity facilities are limited.

A thin blood smear enables analysing the morphology of the parasite, since the blood cells are fixed on the thin film. However, when the parasitaemia is low, there is a chance that the parasites will be missed. Therefore, thick blood smears are recommended to screen, since these are 20-40 times more sensitive for the identification of plasmodium parasites (Figure 8.7) [64].

When the smear is dry, it can be stained. The WHO recommends use of a Giemsa stain, which is being done by the visited laboratories in Ibadan. When the stain has dried, it can be washed (figure 8.8) and placed under the microscope. For parasite detection, one must zoom in to 100x objective magnification. At least 100 fields of view have to be viewed in order to confirm a magnification. The lab scientist needs to search through the whole slide to confirm a negative slide or low parasitaemia [1]. Sometimes, a diagnosis can be made quickly if parasites can be seen all over the slide.

Lab scientists need to be trained for several years before being able to identify parasites, distinguish them from other artefacts (such as colour grain particles), recognize parasite stages and count parasitaemia. It is important to identify species and parasite stage for a proper diagnosis and treatment advice. Parasites can most easily been found in the schizont and trophozoite stage; the infective stage. The Plasmodium Falciparum parasites can be recognized by the ring shape.

FIGURE 8.6
A drop of blood is taken from a patient and put on a glass slide.

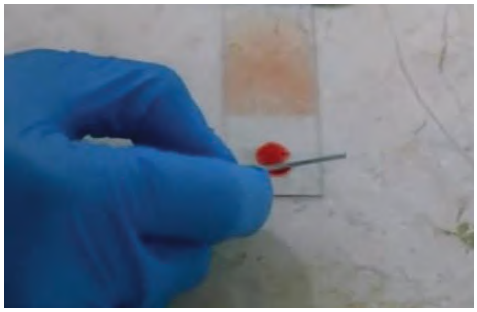
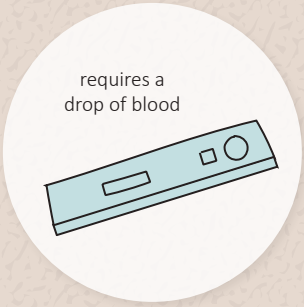


FIGURE 8.7
On one slide, both a thin (upper) and thick (lower) smear can be made. A thick smear is 20-40 times more sensitive than a thin smear.

FIGURE 8.8
After the stain has been fixed, dried and stained, it needs to be washed to get rid of redundant stain. Giemsa adds the blue colour to the smear and enables parasite detection.

Image source: A. Berbudi, YouTube.



	RAPID DIAGNOSTIC TEST	MICROSCOPY
AFFORDABILITY	✓ cheap tests often provided for free by the government to public healthcare	consultation fees traveling costs laboratory costs
SENSITIVE	low sensitivity: false negatives false positives, quality differences between different tests	✓ high sensitivity human expert
SPECIFIC	no species identification no parasiteama count	✓ species identification parasitaemia count
USER FRIENDLY	✓ low skills needed	skilled staff needed
ROBUST & RAPID	✓ 5-15 minutes	30-60 minutes requires running water, electricity, (oven)
EQUIPMENT FREE	✓ rapid test kit acid	microscope slides stain maintenance
DELIVERABLE TO THOSE IN NEED	✓ available in most health centres, pharmacies, laboratories and often used by NGOs	available in laboratories, (some) PHC/SHC tertiary facilities

FIGURE 8.10
Comparison between rapid diagnostic tests and microscopy, based on the ASSURED checklist of the WHO.

FIGURE 8.9
A medical doctor in a primary health centre shows the use of an RDT. In primary healthcentres, the test is being conducted in the consultation room by doctors.

"My RDTs only gave negative results, I didn't trust it. I found out that the use of this brand was different from what I was used to: instead of two drops of acid, I only have to add one. Since then, the RDT is giving me reliable results." - *Medical doctor, Ibadan*

FIGURE 8.11
Parasite detection via the 'QBC' method does not require difficult sample preparation, but is an expensive method.

In theory, the presence of species and parasitaemia assessment can be done easily and within an hour, including the smear preparation and a 30 minute microscopic evaluation. According to parasitologist dr. van Hellemond, a lab technician needs to analyse 150-200 fields of view, which would only take 10 minutes in total [71]. However, it requires a competent laboratory technician, equipment and other facilities [62,69]. Therefore, microscopic diagnostics bring different challenges and do not meet WHO's ASSURED checklist for diagnostics in remote areas, as visualized in figure 8.10 [60, 62, 68-72].

8.3.3 Other technologies

Next to RDTs and microscopy, there are other methods for malaria diagnostics:

- Nucleic acid test (detection of parasite DNA), for example polymerase chain reaction (PCR) and loop-mediated isothermal amplification. These tests are very sensitive, yet only used in research settings.
- Hemozoin test (a by-product of parasites, which can be detected)
- Spectroscopy (detection of the optical signature of molecules associated with parasites)
- Serology (detection of antibodies to malaria parasites)
- Urin malaria tests
- Quantitative Buffy Coat (QBC); parasite detection through centrifuging blood in a capillary tube under ultraviolet microscope light (figure 8.11)

Although these methods are highly sensitive, they are still in development or only available for a niche market. Furthermore, these tests are not (yet) suitable for field deployment, but more focused on reaching extreme sensitivity and specificity, or detecting malaria at the lowest parasitaemia possible [66].

8.3.4 Attitude and impact

According to Burchett et al. (2017), healthcare providers often emphasize clinical symptoms in the decision making process rather than relying on the result of an RDT, especially when the test result was different from the expected outcome [73]. Despite a negative test result, anti-malarial drugs are often given anyways since other diagnostic possibilities or treatments are not available [74,75]. This was confirmed in the field study during interviews with medical professionals. Moreover, the patient's attitude causes little compliance to diagnostic tests. People do not seek for diagnostics or demand antimalarials, since they assume to be infected when having fever. Even professionals in the field of health care were convinced of their self-diagnostic abilities: "I know myself, I know the symptoms." Although the assumptions might be correct in many of the suspected cases, one has to be aware of other causes for fever and the risks of overtreatment.

Thus, the introduction of a smart diagnostic device does not necessarily overcome problems related to malaria diagnostics, even if the device meets the ASSURED checklist. Although accuracy and availability are essential, behaviour from both healthcare providers and the community play a role in the actual effectiveness of the tool [76]. Behaviour and trust can for example grow through the provision of training in use and interpretation. For RDTs, the incorporation of training and awareness programmes led to an increase in trust amongst healthcare providers [73].

"I just take anti-malarial drugs since I'm already so familiar with the symptoms. Besides, I don't have to spend so much paying for the test at the hospital."

- Freelancer, Ibadan

"If I was tested negative to malaria parasite, I will still go ahead with malaria treatment to be 100% sure I am malaria free, but will not bother myself with laboratory test on another disease."

- Health educator, Ibadan

DISEASE & DIAGNOSTICS | TAKE-AWAYS

This study briefly described the origin of malaria and ways to prevent and treat the disease. The two recommended diagnostic methods were compared by use of the ASSURED model of the World Health Organization. Some take aways:

T9 Rapid Diagnostic Tests (RDTs) are point-of-care tests that are easy to use, affordable and quick. However, they lack in sensitivity ad specificity compared to light microscopy.

T10 Caregiver and patient compliance to the test results are often limited to positive results, since negative results are not always trusted.

T11 Probably many people rely on their self-diagnosis, since malaria is endemic and antimalarials are available over-the-counter. Awareness for the need for diagnostic tests and risks of overtreatment are necessary.

T12 Based on the ASSURED checklist (WHO), it is recommended to reduce the need for facilities and equipment, create a user friendly procedure and make a test robust and rapid.

9

SUMMARY

FINDINGS FROM THE CONTEXT ANALYSIS

This section concludes the context analysis by summarizing all key insights for the development of the smart device. The findings state different problems and goals.

The context analysis has defined different causes for problems in malaria management, misdiagnosis and overtreatment. Major problems are:

- Diagnostic tests are not available, too expensive or not properly used, while antimalarial drugs are widely available.
- There is little awareness about the need to confirm a suspected case of malaria via a diagnostic test and little knowledge about the risks of overtreatment. Drugs are being taken without prescription.
- Negative results from diagnostic tests are often ignored and diagnosis are based on clinical symptoms instead. It results in unnecessary prescription of anti-malarial drugs and the economic burden of purchasing the drugs.

It can be stated that different aspects have to be taken into account when developing or introducing a new technology for malaria diagnostics, among which accessibility of healthcare facilities, feasibility of the device in the infrastructure and patients/caregivers' attitude in the malaria test and treatment procedure.

With regard to development of a smart malaria diagnostic device, the following design goals have been derived:

1. Create awareness for the need to confirm a suspected case of malaria via a test as well as for the risks caused by overtreatment.
2. Create caregiver and/or patient compliance to a diagnostic method by creating a trustworthy interaction.

The second goal (with regard to caregivers) has been chosen to focus on during this project, since it is more related to direct interaction and acceptance of the device. A study into awareness and motivating people to get tested is recommended in a later stage of the project. Next to that, regulation and control of antimalaria drug policies might reduce the unnecessary intake of these drugs, but this aspect is out of scope of the project.

The following chapter continues the research from the user perspective.

USER

10

USER RESEARCH

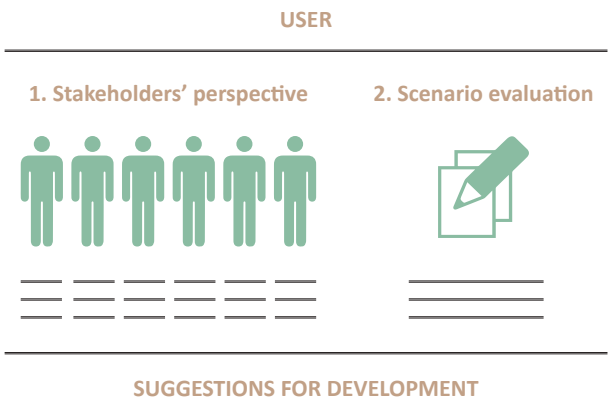
10.1 INTRODUCTION

THE USER

The technology and context analyses led to questions about use and interaction of the device. Whenever the technology is developed well and the Excelscope can be used according to the available facilities in a healthcare centre, it does not immediately mean that it will fit the needs of a healthcare professional. How can the device best be designed to match these needs and be used properly? This chapter will study the barriers and enablers for use and acceptance of the Excelscope.

Through semi-structured interviews with medical professionals in Ibadan, six different potential target groups have been defined. Healthcare professionals on each level of the healthcare system have various perspectives towards the Excelscope and malaria management, resulting in different ideas for development of the device and services around it.

These perspectives and ideas will be described in separate chapters about the six stakeholders. A brief digital evaluation study of the improved user scenario and mHealth solution will be described, leading to a summary of all results at the end of this chapter. The summary will give suggestions for development and define the most interesting target group to focus on.



10.2 RESEARCH GOALS AND METHODS

SEMI-STRUCTURED INTERVIEWS AND QUALITATIVE RESEARCH TOOLS

From the preliminary analysis on context and local perspectives on malaria and diagnostics, research goals and questions were derived. In advance of the field study, different research tools were designed and storyboards were made. This section gives research goals, questions and a description of all methods.

10.2.1 Research goals

The goal of this part of the study is to find barriers and enablers for acceptance of the Excelscope by medical professionals. Different sub-goals have been defined in order to gather the right information.

RG7 Define (a) potential target group(s) for use of the Excelscope
RG8 Define the desired smartness of the Excelscope
RG9 Define desired interaction qualities for use of the Excelscope

10.2.2 Research questions

The following questions (RQ) have been derived from the research goals:

RQ7 Which of the three scenarios for the smartness of the device (remote, semi-automatic or automatic analysis) is desired by healthcare professionals?
RQ8 Which elements are important for healthcare professionals with regard to a smart diagnostic device?
RQ9 What would be the benefits of the Excelscope according to the healthcare professionals?
RQ10 What can be learned from the healthcare professionals' perspective on current diagnostic methods?

10.2.3 Hypothesis

Based on the initial analysis, it is assumed that healthcare providers prefer to have human control on the diagnostic procedure, but will benefit from a more efficient procedure. Therefore, the semi-automated scenario is probably most desired. Concerning RQ8, a mindmap with values for the user and device has been made (figure 10.1), but since the questions are rather open, hyptheses has not been made for the other questions.

10.2.4 Methods

Semi-structured interviews were conducted, for which a questionnaire and different tools were designed. Since the interview setting, available time and motivation of the participants were not known on beforehand, the procedure of the interviews could be adjusted according to the possibilities. The duration of the interviews varied from 25 to 75 minutes, according to the available time and responsiveness of the participant. All interviews were recorded on audio and pictures were taken, both with permission of the participant via a consent form.

10.2.4.1 Semi-structured interviews

A list of questions was prepared and used to guide the interviews in a semi-structured way (appendix 3). The healthcare professionals were asked to introduce themselves and their work in the particular healthcare facility. Specific questions were asked about malaria diagnostics: whether and how malaria is being diagnosed by the participant as well as his/her opinion about microscopy and rapid diagnostic tests (RDTs). A mock up of the Excelscope was shown to explain the use of the device (figure 10.2).

10.2.4.2 Choosing adjectives

Secondly, a list of 32 adjectives was presented (appendix 4), from which three words had to be chosen according to the participant's opinion of what would be important for a diagnostic device. This tool was used to ask further questions and a trigger to get information about important aspects of a diagnostic device. The list included adjectives such as 'pleasant', 'empowering', 'controllable' and 'reliable'. It was presented in advance of an extensive explanation of the Excelscope, to not bias the participant.

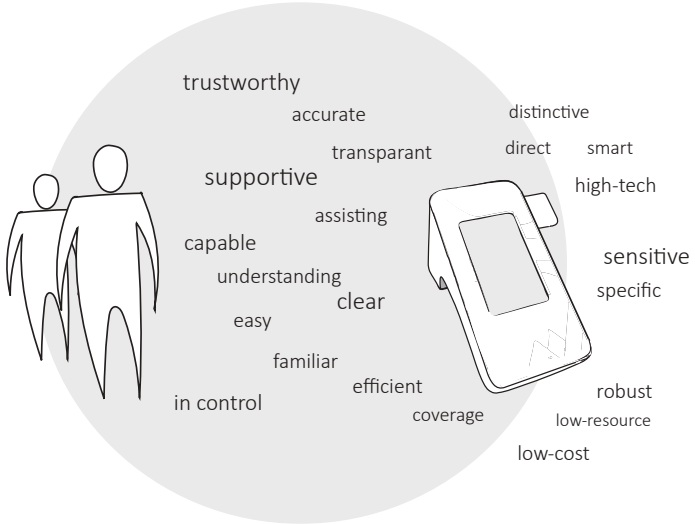


FIGURE 10.1
A mindmap was made to map assumptions for potential important values and interaction qualities. The mindmap lead to the research tools.

FIGURE 10.2
Storyboards were used to explain the scenario of use and different diagnostic options, in combination with a mock up of the Excelscope.

10.2.4.3 Storyboards

Storyboards were used to explain and clarify the three different scenarios for the malaria analysis (figure 10.2, appendix 5). After the explanation, the participant was asked to give his or her opinion about the device and preferred scenario. The storyboards were low fidelity drawn images to indicate that the technology is still under development.

10.2.4.4 Rating adjectives

To compare the different scenarios, a short questionnaire was given (appendix 6). Seven adjectives had to be rated on a 7-point scale, giving two opponent adjectives (figure 10.3). The answers were instantly used to ask further questions about the participant's comparison, such as 'can you explain the difference in transparency between the second and third scenario?'. It was used as a conversation starter for topics on which information was desired, but difficult to gain through regular questions.

10.2.4.5 Feelings

In the last week of the field study, one tool was added to get more information about people's feelings and experience, instead of solely information about the device. Seven different images of feelings were presented, of which the participant could pick the one (or more) that were most relevant to him or her (figure 10.4, appendix 7). The cards were presented before introducing the Excelscope (to ask how participants wanted to feel during work) and/or after the discussion (to ask how the Excelscope made participants feel). Again, the tool is used as a trigger to get more information about the professionals' needs.

10.2.4.6 Interface designs

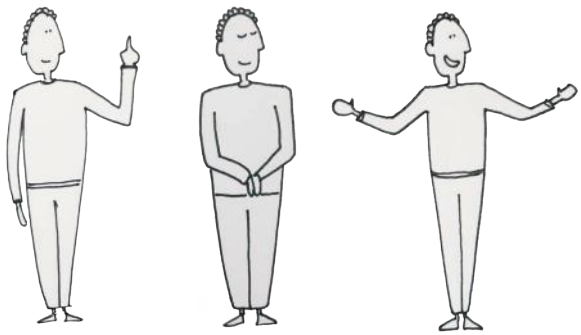
Interface designs (figure 10.5) were used to clarify the use of the device, as well as to discuss the needed information. The ideation process towards these designs can be found in appendix 8. The interfaces were programmed by use of the application Invision App, which was installed on the phone in the prototype. This made it possible to navigate through the procedure or let the participant navigate in order to review potential user errors.

10.2.5 Participants

In total 29 healthcare professionals from 22 different healthcare facilities were included in the qualitative study to cover a variety of perspectives on the smart device. Amongst the participants were patent medicine vendors, community pharmacists, medical laboratory scientists and medical doctors. The education level and expertise of the participants varied from little medical knowledge to professor on malaria pharmacology. Figure 10.6 shows an overview of the participants.

	+++	++	+	+/-	-	--	---	
Reliable	○	○	○	○	○	○	○	Unreliable
Time-saving	○	○	○	○	○	○	○	Time-consuming
Transparent	○	○	○	○	○	○	○	Ambiguous
Practical	○	○	○	○	○	○	○	Impractical
In control	○	○	○	○	○	○	○	Out of control
Supportive	○	○	○	○	○	○	○	Unsupportive
Secure	○	○	○	○	○	○	○	Insecure

. Figure 10.3
. The questionnaire that was given to the participants for comparison of the three diagnostic scenarios. The answers were discussed immediately during the interview.



. Independent . Relieved . Motivated

. FIGURE 10.4
. Three images of the 'feeling' card sort too. The participants were asked to choose which of the cards did meet their desire when conducting diagnostic tests.

Health centres	*HCs*	*MP**
PMV	5	5
Private pharmacy	4	4
Private laboratory	3	3
Private primary health centre	1	2
Private clinic	1	1
Public primary healthcentre	1	4
Public secondary healthcentre	3	4
Public tertiary healthcentre	1	3
NGO	1	1
Medical shop	1	1
Ministry of health	1	1
Profession		
PMV chemist	5	
Pharmacist	4	
Pharmacy assistant	1	
Medical doctor	4	
Laboratory scientist	8	
Nurse	1	
Medical director	2	
Public health lecturer	1	
Pharmacologist	1	
Salesman	1	
Policy employee	1	
Sector		
Private healthcare	16	
Public healthcare	12	
NGO	1	
Gender		
Male	13	
Female	16	

. *MP = amount of medical professionals interviewed per type of health centre. In some HCs, multiple stakeholders were addressed.

. Figure 10.6
. An overview of the interviews per sector, type of health centre, profession and gender. In total, 29 professionals from 22 different health care facilities were interviewed.

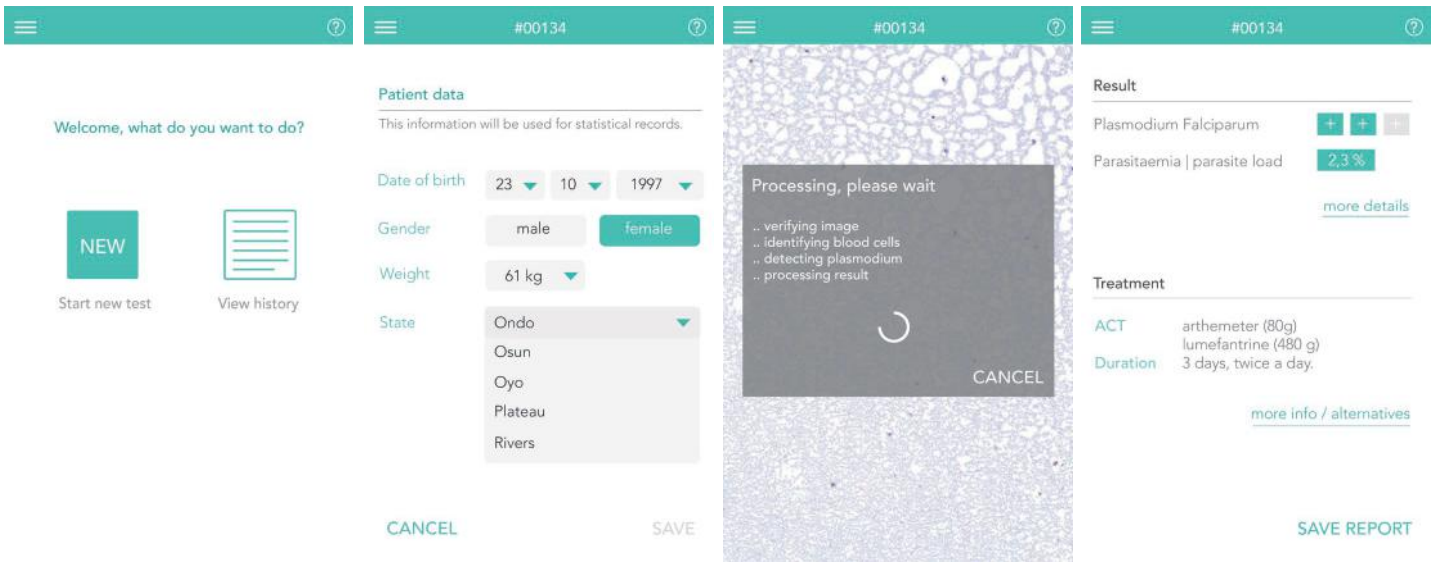


FIGURE 10.5
A selection of the interfaces that were included in a prototype of the application. The interface designs were used to explain the procedure of the Excelscope and to discuss the necessary information that should be included in the application, according to the participants.

11

THE USER'S PERSPECTIVE

FIELD STUDY RESULTS

11.1 GENERAL RESULTS

AN OVERVIEW OF THE FINDINGS FROM THE INTERVIEWS

An overview of the most striking results from the research tools are presented. Since answers were different per profession, the chapter will be folllowed by more extensive results for specific target groups in separate chapters.

11.1.1 Choosing adjectives

Since the interview structure was adjusted according to the possibilities of the setting and participant, not all tools where used for every participant. Out of the 29 participants, 21 were asked to choose three important aspects out of the list of 32 adjectives.

Since some words were closely related, these have been combined in the analysis (reliable/trustworthy and time-saving/quick). The similarity between the words will be discussed in chapter 14.2.

The following words have most often been chosen:

Easy to use	10
Reliable/trustworthy	9
Cheap	7
Time-saving/quick	7
High quality	5

Although the most chosen words seem to be obvious in terms of importance, it gave the chance to ask further questions and relate to these topics in a later stage of the interview. Furthermore, it gave insights in the importance of a quick and cheap procedure (merely with regard to patient's compliance to a test). In all cases, an explanation for the chosen words was asked to get the reason behind the choice. Some people interpret words differently, which makes further explanation essential in the interviews and result analysis.

Two interpretations of 'easy to use':

"What you want to teach me, can it be easy for me to do? Without stress, without spending much money on it? That is why I say easy to use"
- PMV chemist

"It must be easy to use, simply because malaria is the most common diagnosis at primary health centres in Nigeria. This makes diagnosis faster."
- Medical doctor

The whole list of chosen words can be found in appendix 9.

11.1.2 Preferred diagnostic scenario

Most of the participants of this study preferred the automated scenario (as described in section 2.1): an analysis that is being done by computer software only. Despite differences per group of healthcare professionals (laboratory scientists being more sceptical towards the technology in general, while others mentioned the risk on human errors in the manual scenario), the majority of the healthcare professionals desire an automated analysis because of the quick procedure, the point-of-care solution and being able to handle the diagnostic procedure independently. More reasons for this preference will further be explained in the results of the study.

> in short | aim & approach

Goal
Find barriers and enablers for acceptance of the Excelscope by medical professionals by defining (RG7) target group, (RG8) desired smartness and (RG9) the interaction qualities for use of the Excelscope.

Research questions

RQ7	Which of the three scenarios for the smartness of the device is desired?
RQ8	Which elements are important with regard to a smart diagnostic device?
RQ9	What would be the benefits of the Excelscope according to the healthcare professionals?
RQ10	What can be learned from the healthcare professionals' perspective on current diagnostic methods?

Methods
Semi-structured interviews, using different tools to get deeper insights in stakeholder's perception and opinion of the device.

Results
The automatic scenario was preferred by the majority of the participants, mainly because of being able to provide a diagnosis at the point of care independently. The results are different for different stakeholder groups.

Read more
> Research tools (chapter 10.2, appendix 3-7)
> Results per profession (chapter 11.2-11.7)

11.1.3 Insights from the adjective questionnaire

Similar to the list of adjectives, the questionnaire has not been used in all interviews: 23 participants rated the list of the seven adjectives or discussed their preference by use of the list. The data cannot be used for quantitative analysis, because of the limited sample size, the different interpretation of the adjectives and the aim to collect qualitative data by use of the questionnaire. Nonetheless, the most striking results can be given to get a general idea of the participants' perspective on the different scenarios. Answers with regard to reliability, supportiveness and peception on secure and practical will be given in the separate chapters about the different stakeholders.

11.1.3.1 Time

The most explicit result from this tool has been found on the aspect of time. Major concerns on the remote and semi-automatic scenario were given on this aspect and all participants rated these options on the 'time-consuming' side of the scale. The concerns were related to availability of a human expert, the time for analysis or result confirmation and delays due to bad internet connection.

11.1.3.2 In control

An interesting result is the perspective on being 'in control'. It was assumed that healthcare professionals feel less in control in case of an automatic analysis. However, this third scenario was rated as in control by most of the participants. As some of the healthcare professionals mentioned, they would feel more in control when the whole diagnostic procedure can be done at the point of care, without having to consult another medical professional. Especially lower educated caregivers had that opinion, which can also be related to the perception of independence.

"The machine can explain what is happening, so you will be in control."
- Patent medicine vendor

"The automatic scenario makes me in control since it's not dependent on an external factor"
- Community pharmacist

Laboratory scientists and some medical doctors mentioned to be in control when having the possibility to inspect the images. Furthermore, doctors had their concerns about remote diagnostics, because 'you don't know who will do the diagnosis'. The latter is closely related to transparency of the procedure. In general, several words were used interchangeably or interpreted in multiple ways.

11.1.3.3 Transparency

Similar to 'in control', the opinion about transparency of the analysis was different from the initial expectations. The automated option was mentioned to be more transparent by the majority of the participants, mainly because the analysis is being done at one place. If the images or result has to be sent to someone else, the perceived transparency decreases because of the unknown competence of the human expert 'at the other side'. The automatic scenario was also mentioned to be transparent because both healthcare provider and patient will see the same result.

Transparency would increase when the pathologist is someone familiar to the caregiver at the point of care. Yet, participants think it is more important that the diagnosis is provided quickly.

11.1.4 Information on the interfaces

The interfaces were used to discuss the user flow with regard to (a) the required steps in the diagnostic procedure, (b) necessary information in e.g. patient dossier and result presentation and (c) clarity of the interfaces and workflow. Since this part was discussed briefly with only some participants, more research- or an evaluation study- on this aspect is recommended.

11.1.4.1 Clinical test results

Although opinions about the necessary information as a test result differed, most participants mentioned to prefer the 'plus-system', a three-point scale (+++) to indicate the severity. Lab scientists use this system to communicate the result to doctors. When an actual number is assigned to the severity, parasitaemia has to be given in amount of parasites per high power field instead of percentages, according to the lab scientists and some doctors. When designing for a specific stakeholder, the visualization of results (clear and visual versus advanced and detailed) has to be considered.

11.1.4.2 Patient data

Incentives for adding or leaving patient data were different. Some medical professionals want to keep the procedure as short as possible, while others want to make use of data that can be saved and analyzed. In general, most participants agreed on the benefits of saving test number and/or name with date of birth in order to recall the data and monitor a patient's health.

11.1.4.3 Usability

A usability study has not been conducted because of the low fidelity of the interface prototype. Yet, a selection of participants have been observed in interaction with the device. No immediate severe user errors have been defined. Design iterations were done immediately after each interview by feedback of the participants, by e.g. adding a confirmation of actions (figure 11.1). A usibility study is highly recommended in each stage of the design process, in order to anticipate on the needs, understandibility and actions of potential users.

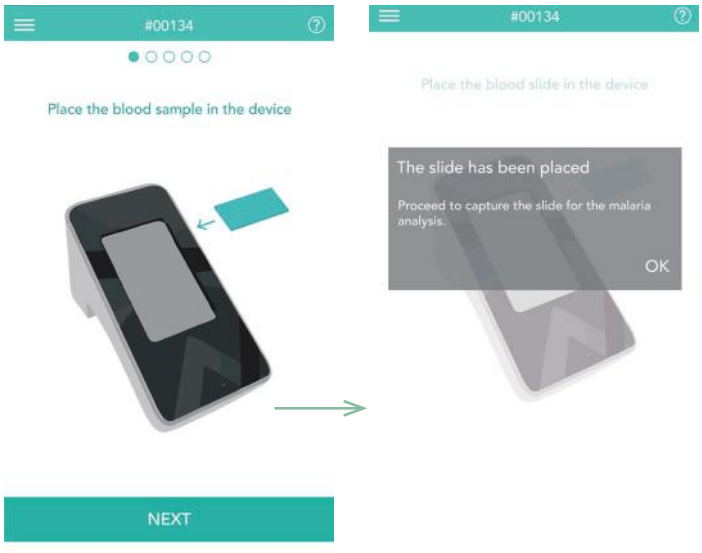


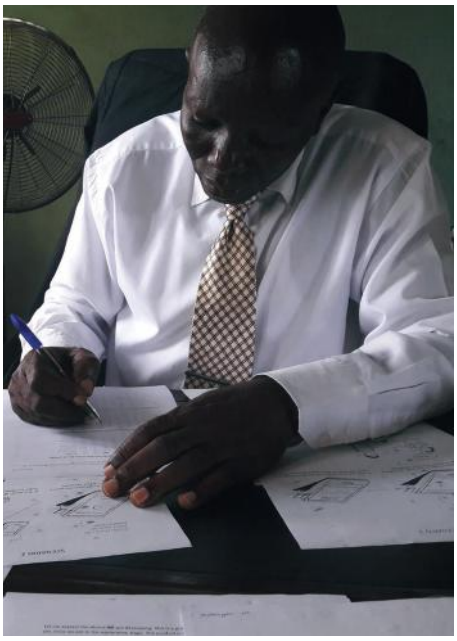
FIGURE 11.1
Iteration step during the field study. A confirmation of actions (e.g. placing the slide into the Excelscope) has been added to clarify the procedure to the user and enhance confidence in use.

11.1.5 Differences per profession

As stated before, many differences between the healthcare professionals have been found. Although the sample of participants is relatively small, results per profession have been generated and suggestions for development of the Excelscope will be given. For each target group, points of attention, possible barriers and enablers and interface designs are proposed.

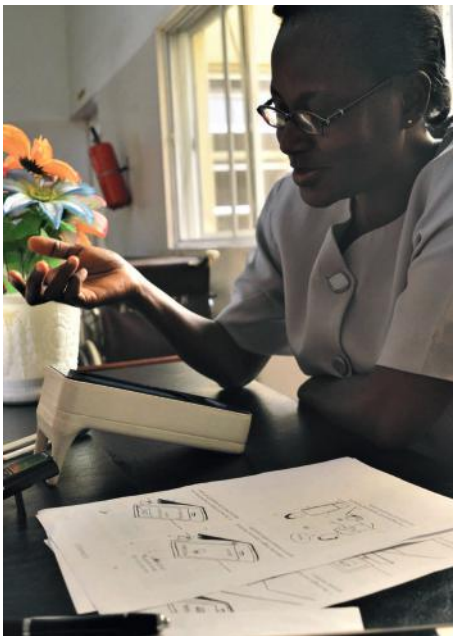
Chapter 11.2- Patent medicine vendor

Chapter 11.3- Community pharmacist



Chapter 11.4- Medical doctor

Chapter 11.5- Medical laboratory scientist



Chapter 11.6- Nurse

Chapter 11.7- Medical volunteer

11.2

PATENT MEDICINE VENDOR

"Can you teach me how to use it, and encourage me how to treat?"

FIGURE 11.2
A patent medicine vendor shows her medicine store.

Five patent medicine vendors from different areas in Ibadan participated in this study.

On average, there are 24 PMV shops per 100.000 population, spread over rural and urban areas [3].

PMVs have often no medical background. Knowledge on malaria diagnosis and treatment is poor [1].

11.2.1 Patent medicine vendors & malaria diagnostics

PMVs (or PPMVs: patent and proprietary medicine vendors) are defined as: "persons without formal training in pharmacy who sells orthodox pharmaceutical products on a retail basis for profit" [1]. PMVs can sell a selection of pre-packaged medicines over the counter, but are not allowed to sell prescription medications or conduct invasive medical procedures. Anti-malarial drugs can be sold by PMVs since a change in regulations of the Pharmacist Council of Nigeria in 2005 [1,2].

PMVs are located in urban communities and rural areas, and especially a primary source of care for the poor and rural population [1,3]. In general, the vendors know their local customers and sell drugs, drinks and food to them. Since malaria is highly endemic in Nigeria, people often assume to be infected with malaria when having fever, resulting in a visit to a PMV or pharmacy to buy drugs over the counter (instead of going to a clinic or laboratory and pay for a test). More than half of the Nigerians visit a PMV shop when having malaria symptoms. Moreover, PMVs are consulted for treatment advice and diagnosis by people with limited access to healthcare, although PMVs often have not had clinical education [1,3].

Most PMVs sell their drugs based on what the customer requests [4]. During the interviews, some PMVs mentioned to not sell their antimalaria drugs without a prescription and provide vitamins or paracetamol instead. They are aware of the right policy. However, the vendors admitted that, if clients are convinced of malaria infection or keep on demanding the medication, they will sell the drugs without prescription. Others are more profit-oriented anyway, and mention to always sell drugs according to the demand of the client.

The medicine vendors are affiliated with local associations, overseen by the National Association of Patent and Proprietary Medicines (Nappmed). The study of Oladepo et al. [1] states that the local associations have potential to be involved in training and awareness programmes on malaria management, since their monthly meetings are well attended by the PMVs. Thus, patent medicine vendors can play a role in decreasing misdiagnosis and overtreatment by providing the possibility to test on malaria before taking antimalarials. Besides, the medicine vendors can create awareness on the importance of accurate diagnostics among community members and encourage them to get tested. If the Excelscope can be used in their shops, accessibility to diagnostics would increase.

"The person that doesn't have money to do the test. I will first give him maybe like.. pain relief. After some days, if it is still doing.. Maybe it is malaria. I am now giving malaria drugs, so that the person will be okay. Anybody that buy here will be okay."

11.2.2 Patent medicine vendors & the Excelscope

The participating PMVs are enthusiastic about the device and would like to do tests. They are eager to get training and provide diagnostic tests to people within the community. Different barriers, challenges and opportunities for the use and acceptance of the Excelscope have been identified. This section describes the attitude and concerns from the PMVs towards the smart device.

11.2.2.1 Scenario: Automated analysis

The PMVs prefer to have an automatic device. If the analysis is fully automatic and can be done at the point of care, the user will be in control of the whole procedure: the device can be used, protected and maintained at one place by one user. According to the medicine vendors, parasite detection through computer software is more *transparent* than remote analysis, since both PMV and client will get to see the same procedure and result.

"It is transparent, you can see the result. The person conducted the test can see it. And the person provided the service can see it."

11.2.2.2 Time

The amount of time has been given as a barrier for use. The PMVs explained that clients are often on the go and do not want to wait for a test result. Thus, a time-consuming device would not be beneficial for the PMV's business. In case the procedure is too time-consuming, a messaging service could be included. Via the Excelscope, a text message can be sent to the client to inform about the result and possible need for treatment or visiting a clinic.

11.2.2.3 Tasks and use

The PMVs are aware of their limited clinical knowledge and medical skills, and place importance on feeling competent and confident in use of the Excelscope, which can be achieved in different ways.

The device has to be easy in use and limited to the necessary actions, explained in a step-by-step procedure or manual. It will be best understandable if the application is being provided in a local language (e.g. Yoruba in the southwest region of Nigeria), since not all PMVs speak and understand English properly (Figure 11.3, 11.4) This will enhance confidence and proper use.

A too extensive procedure, including manual imaging, cleaning the lens and preparing a blood slide, will probably lead to rejection of the device by PMVs. These tasks should be automated as much as possible. Although training on these tasks can be provided, the extra time it takes and need for extra facilities are major barriers in acceptance of the device. Safety, accuracy and hygiene with regard to blood sample taking and preparationwill thereby be hard to manage when being done by these non-medical professionals.

In certain ways, PMVs will be likely to be proud on their device, therefore motivated to maintain the Excelscope. However, it should be quick, easy and clear how to manage this task. A modular device (easy to disassemble) and a maintenance guide in the application will support the vendors to manage the quality of their Excelscope.

"I am the one that is going to manage it, I will protect it, I will clean it. If there is any error, I will quickly through my seminar or training."

"It's an expansion of the business. People will be come: that woman has a machine! They will come and buy it from me."

11.2.2.4 Clinical knowledge
It is most important to know whether a patient has malaria and if referral to a clinic is needed. If patent medicine vendors can be qualified to provide treatment, they should either be trained on prescribing the right drugs or a treatment advice should be integrated in the application (figure 11.5, 11.6). The participants mentioned to be in need of training in order to feel competent and be confident about the provided diagnosis: *"we can be encouraged to do tests, but need training"*.

An integrated module can include information about malaria parasites, diseases with similar symptoms, treatment and which cases need to be referred. More research on how to empower PMVs to use digital information guides has to be done.

11.2.2.5 Business strategy
The profit orientation of patent medicine vendors causes a focus on selling drugs. Negative test results may reduce revenue from antimalaria drugs. This might cause limited adherence to the test results. On the other hand, the Excelscope can have a positive impact on the business: if community members can be empowered to test before taking drugs, Excelscope owners might attract more customers. From this perspective, it is interesting for both community health and PMV businesses to promote diagnostic tests in communities.

To sustain use and a the positive impact of the device, a proper business strategy has to be developed. How to motivate PMVs to use the device and participate in awareness programmes? It brings challenging new questions, related to e.g. the costs of the device, costs for a single test and maintenance service. Ideas for business strategies include lease of the Excelscope (which brings opportunities for maintenance and quality control) or a reward system for PMVs (e.g. discounts on drugs or disposables when the Excelscope is being used or data is being shared).

Although rapid diagnostic tests are provided for free to some PMVs and pharmacies by the government, it is questionable whether the Excelscope has to be given out for free to the medicine vendors. If the PMV obtains the product from own expenses, motivation to use and maintain a device might be higher. More research on this aspect is needed to draw proper conclusions.

11.2.2.6 Policy & regulations
Although the government allowed the use of RDTs by medicine vendors, the policy on this aspect has badly been managed and the tests are barely being used by this stakeholder group. The government does not only need to allow PMVs to provide diagnoses by use of the Excelscope, but has to manage this policy, promote the changes and motivate PMVs to make use of the device.

11.2.2.7 The patient's perspective
If PMVs get more qualifications for diagnostics, their image might change from medicine vendor to healthcare professional. They might perceive the PMVs as doctors, while they are not educated as medical professionals. As long as enough training on malaria and diagnostics has been provided, increased authority of a PMV might not be a problem. Research on the perception of community members towards the PMVs has to be done.

11.2.2.8 m-Health opportunities
The study into patent medicine vendors lead to several ideas about m-health possibilities. As mentioned, a step-by-step guide can be integrated in the application, information about malaria (and similar diseases) can be provided, text message services can be a solution to overcome waiting time. Furthermore, decision making support on proper treatment or referrals can be given, based on national guidelines (Figure 11.5, 11.6).

11.2.3 Conclusion
The results lead to several aspects to take into account and new ideas for development of the device. These aspects, as well as barriers and enablers for acceptance, are given in figure 11.7.

To match the Excelscope with the PMVs' needs, the procedure has to be quick, easy to understand and provided with essential malaria management information. The government has to support the PMVs by giving them the right to diagnose. If the responsibility is being given in combination with training, PMVs are likely to adopt the device and maintain it properly. Nonetheless, because their focus on making profit, a business strategy has to be developed to enhance user- and client compliance to the device.

With regard to a smart malaria diagnostic device, PMVs want to be
Competent: by knowing how to handle the device
Confident: in providing the right diagnosis to their customers
Proud: about owning the device and the ability to use it

Figure 11.9 shows several elements and ideas for development of the Excelscope within the context of community pharmacies.

"I went for the meeting from the government to introduce this thing (RDT) for us. But the policeman is giving us problems. That we don't have a certificate for this. So if you could help us to get a device that can recognize the malaria, we would like that."

FIGURE 11.3
A patent medicine vendor explains his experience with RDTs and perspective on use of the Excelscope in English and Yoruba language.

FIGURE 11.4
Local language and limited features to keep the procedure easy and understandable.

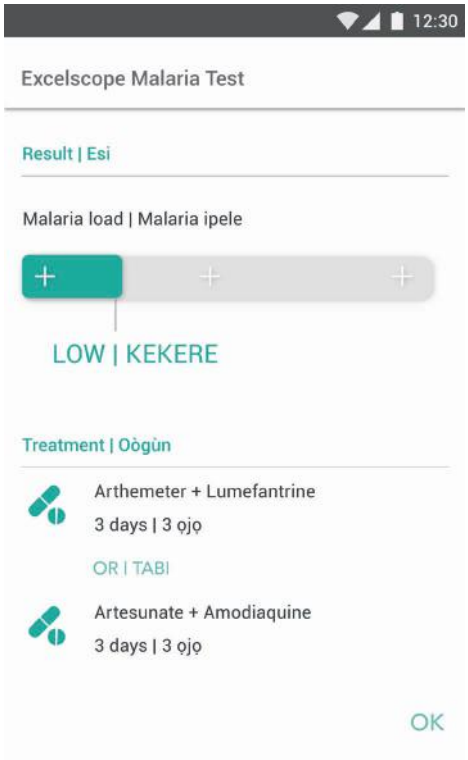


FIGURE 11.5
The result is visualized in a bar chart including the standard +++ system for severity indication. Treatment advice is given based on national guidelines.

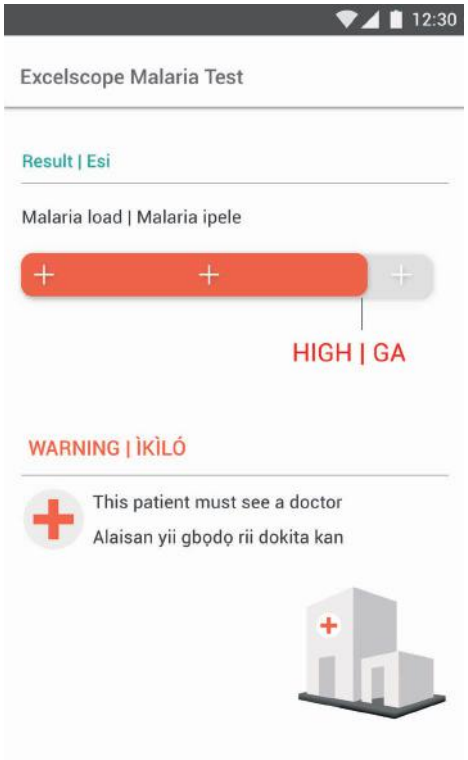


FIGURE 11.6
Since proper referral is one of the concerns for use by PMVs, warnings can be included in case someone has severe malaria, is pregnant or high probability for co-morbidity. In those cases, someone has to be referred to a doctor.

ENABLERS

Quick procedure
Profitable product-service system
Point of care diagnostics

Competence
- Provide training

Confidence
- Include clinical information
- Provide a manual
- Local language & visual information
- Treatment and decision support
- Acceptance & qualification

BARRIERS

Time
Difficult procedure
Costs
Remote diagnostics

Tasks
- Blood sample preparation
- Imaging

OPPORTUNITIES

Engage PMVs in awareness programmes about malaria diagnostics.

m-health solutions
- Decision support (treatment and referral)
- Use: digital manual
- Transfer result to clients

CHALLENGES

Clinical knowledge on disease, diagnostics and treatment.

Keeping knowledge up to date.

Acceptance of government.

Focus on making profit.

FIGURE 11.7
Summary of the findings from the field study.

FIGURE 11.8
A community area in Ibadan, where PMVs are normally located and better accessible than healthcare centres.

FIGURE 11.9 >
A visual presentation of the interaction between patent medicine vendor and the Excelscope

COMPETENT & CONFIDENT

MANUAL

A step-by-step procedure within the application or a manual alongside.

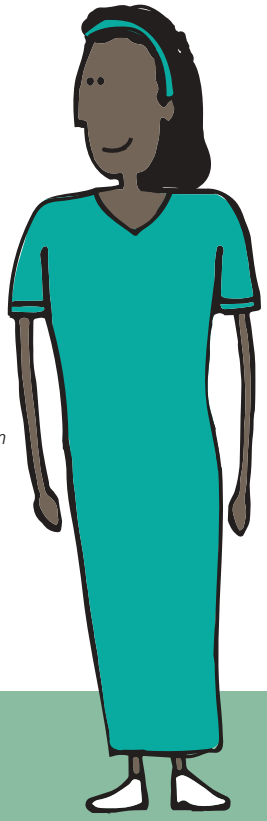
DECISION SUPPORT

Instructions about interventions or referral in case of high severity.

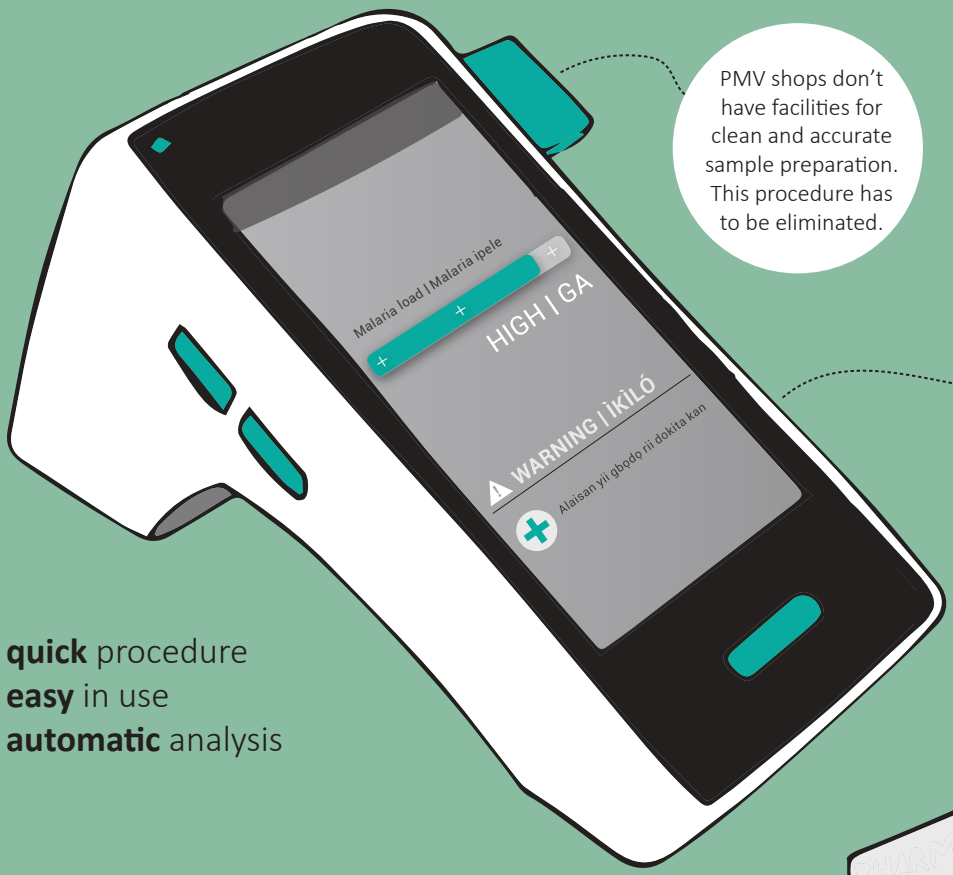
TREATMENT ADVICE

Advice for adequate treatment based on national guidelines. A text message can indicate the need for an update.

"If you can teach me, or if you can encourage me to go for how to treat. And they give me the certificate for it. In case of anything, they will know that I went for training."



PROUD *"I am the one that is going to manage this device. I will clean it and protect it"*

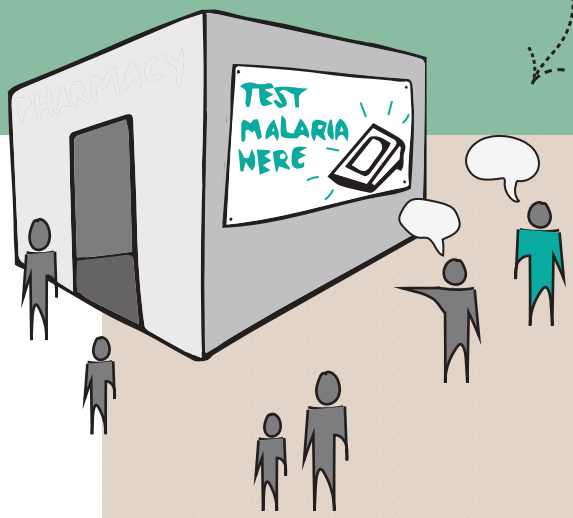


PMV shops don't have facilities for clean and accurate sample preparation. This procedure has to be eliminated.

Visual information and local language to be understandable for the illiterate user.

quick procedure
easy in use
automatic analysis

"it's an expansion of the business. People will be come: that woman has a machine! They will be come and buy it from me."



BARRIERS & CHALLENGES

Taking a blood sample and staining the slide.

Acceptance and regulations by the government.

Clinical knowledge and proper malaria management.

11.3

COMMUNITY PHARMACIST

"healthcare is business"

FIGURE 11.10
A community pharmacist in his pharmacy .

Four community pharmacists and one pharmacy assistant from different areas in Ibadan participated in this study.

Community pharmacists already monitor or screen patients' health by different diagnostic devices.

"It will only work if the computer works, the smartphone works, the people in charge have background knowledge and are around.."

11.3.1 The community pharmacist & malaria diagnostics

Community pharmacies are accessible to most people in urban communities and often a first point of call for malaria care. Pharmacists often work in private shops in a small team of pharmacists and assistants. Based on the insights from the interviews It is assumed that most pharmacists have had formal education and have knowledge about malaria, the different anti-malaria medicines and health risks as a result of overtreatment.

In general, pharmacists provide health monitoring services and basic diagnostic tests, such as blood pressure monitoring, blood glucose checks and diabetes screening. Moreover, RDTs are commonly used by pharmacists, which – at least in Oyo state – has been the influence of a governmental programme, executed by the Association of Community Pharmacists in Nigeria. The programme provided the RDTs, training and promotional banners for free, in order to make tests better accessible and create awareness amongst pharmacists and community members. The pharmacists express to be happy about the service they can provide to their clients and proudly showcase the banners (figure 11.11). The programme is in line with a study of Offu et al. (2015), who stated that 'community pharmacists could be used to promote and deliver various public health interventions' [81]. Yet, although these programmes are running, antimalaria drugs are still being sold without prescription. Adherence to RDT tests and results are dependent on the clinical knowledge and profit-orientation of the pharmacist. These aspects will be discussed into detail in the following sections.

Nonetheless, based on the access and ability to conduct basic diagnostic tests for different complaints already, positioning a smart diagnostic device seems to be a logical choice.

11.3.2 Pharmacists & the Excelscope

During the discussions with the five participating pharmacists, different barriers, challenges and opportunities for the use and acceptance of the Excelscope have been identified. This section describes the attitude and concerns from the pharmacists towards the smart device.

The pharmacists in this study were open towards the device and eager to learn more about it. Different from the PMVs, they were more confident about being able to use the device, yet slightly more sceptical about the technology or system. The major concern was the system to become cumbersome, by having too many influencing factors, taking too much time or be in need of internet connection.

11.3.2.1 Automatic scenario

Overall, the automatic analysis was seen as an opportunity to conduct accurate diagnostic tests at the point of care, especially in comparison to RDTs. However, the pharmacists would like to have the option to either ask for a second opinion or be trained to analyse the images themselves. The latter will be difficult, since parasite detection is a rather specialized task that needs hours of training on microbiology. It needs to be a statistically proven technology before the pharmacists want to make use of it.

If the device can be fully operated at the point of care by the pharmacist, it will lead to confidence that can be shown to the client: showing the ability and competence to do a somewhat advanced task. However, if the results need to be send to a lab scientist, they have the feeling that they fail; they cannot provide the result themselves. "The patient might feel: he's relying on a third party, maybe he's not very good". The device has to give the pharmacist a feeling of independence and competence that can be shown in the interaction with customers.

FIGURE 11.11
The banner provided by the Association of Community Pharmacists of Nigeria during the 'test & treat' malaria programme, in which RDTs and trainings were provided for free to the community pharmacists.

11.3.2.2 Time
All pharmacists mentioned time as one of the major concern: "Patients are always in a hurry, if it takes too long, you'll lose customers". One of the pharmacists notes the phone numbers of her clients in case they cannot wait for the result of a certain test, so that she will be able to inform them through mobile phone. It might be something to include in the (future versions of the) Excelscope: sending out a text message to the specific client to communicate the result. However, if the Excelscope will give more sensitive results in comparison to the current RDTs, a longer waiting time would be acceptable, according to the pharmacists. "At least, the patient does not have to go to the lab, wait there and come back to me again".

11.3.2.3 Tasks and use
The pharmacists were convinced of their ability to properly use the device as long as some training or a manual can be provided. The pharmacists want to be confident and communicate their confidence to their clients. Therefore, the device should not be too advanced or technical in use, yet look advanced in order to be presentable and convincing to customers.

It can be developed in line with other devices such as glucometers and blood pressure monitors that are currently being used in these facilities. If different laboratory-related steps are required (using needles, imaging, blood sample preparation), it might scare some pharmacists and lead to rejection of the device.

"It looks like the lab stuff we actually want to run away from."

11.3.2.4 Clinical diagnosis and test result interpretation
full clinical analysis based on the patient's symptoms. Training can be given on the aspect of malaria screening and diagnostics, but not all cases can be treated by the pharmacist. Severe or specific cases (pregnancy, comorbidity, infants) need to be referred to a hospital, which need to be recognized by either the device or the pharmacist. Decision support on the device can improve the pharmacists' confidence about providing proper treatment without losing a perception of being independent in the diagnostic process.

The result can be given in a combination of qualitative (for quick understanding of the severity) and quantitative (for patient monitoring) data. The pharmacists were especially familiar with the 'plus-system', but it is assumed that they can easily be trained on interpreting quantitative results as well (parasites per high power field).

To facilitate easy prescription, including a treatment advice was proposed to the pharmacists. The participants were sceptical towards this feature, by having concerns about changing policies, their drugs in stock and specific cases (comorbidity, allergies, resistance). The pharmacists do not want to keep control on their own practices and do not want to be restricted by a certain advice. A basic recommendation or advice to refer to a doctor would be more feasible and possible to be accepted. Figure 11.15 shows a visualization of the interface design of the test result.

"Poverty is a major disease. If people don't even have money for food, how are they supposed to pay for a test? I have to provide them the drugs without doing a test."

11.3.2.5 Business strategy and costs
Most pharmacies are profit-oriented healthcare facilities, aiming for selling drugs. The pharmacists emphasized the importance of a valid prescription, but some of them admitted (or showed, figure 11.12) to not always demand a doctor's note or test result. This inconsistency is caused by empathy for the poor, confidence in their own clinical diagnostic abilities ("If the symptoms are clear, it's not necessary to test") or complying to their customer's demand ("some people say: 'I know myself, I know it's malaria"). This might be a challenge to overcome in compliance to the Excelscope, related to a business strategy: can pharmacists provide the tests for free, or do clients have to pay for it? If there are costs associated with each test, will it improve accessibility to accurate diagnostics? Will accurate diagnostics tests reduce revenues from antimalaria drugs when they are not just being sold over the counter anymore? The mixture of business-

PROVIDING DRUGS WITHOUT PRESCRIPTION
A pharmacist assistant claims to only provide antimalarials with prescription or positive RDT result. During the interview, a customer walks into the pharmacy and asks for antimalaria drugs. The assistant sells her the drugs without any other question, in contradiction to what she argued. The incident showed that theory and practice do not always meet, and that observations are needed in order to strengthen insights from interviews.

FIGURE 11.12
A pharmacist sells antimalaria drugs to a client without asking her for a prescription or test result.

"I'm a business man, I don't want to overbuy or underbuy. Recording data can change the way I practice. I just need to know what's happening in the community, and I can ask colleagues what they see in their area."

oriented pharmacists, customers' limited resources and compliance from both sides in a health-related product/service creates a complex challenge for a business strategy rather than user interaction. However, in combination with training and information programmes, the engagement of pharmacists in fighting misdiagnosis and overtreatment might be possible. The Excelscope will bring marketing opportunities and could attract new customers to the pharmacies.

11.3.2.6 mHealth opportunities

One of the main opportunities identified by the pharmacists, is keeping track of data and/or monitoring patients' health. It is something that is already being done by these medical professionals, whether or not on paper records. When including a patient's name and date of birth, a test can be recalled upon from the history saved in the application (similar to blood pressure monitoring devices). This can be used in order to monitor parasite clearance or look at a patient's malaria (treatment) history. Moreover, data can be saved for statistical analysis, to be used later on to e.g. forecast the necessary amount of antimalarials in stock during a certain time of the year.

Figure 11.13 and 11.14 show examples of the interface designs, in which the possibility for patient monitoring and statistical records have been visualised.

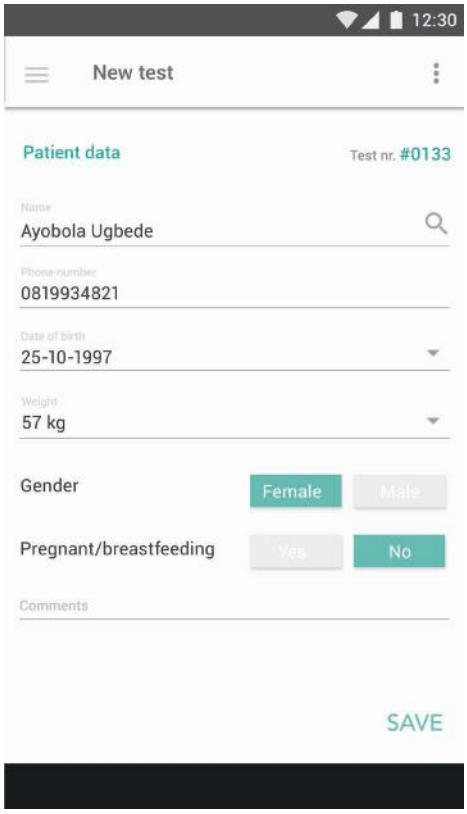


FIGURE 11.13
A limited selection of patient data can be filled in, in order to (a) contact the patient, (b) monitor the patient's health, (c) make statistical records of all test results.

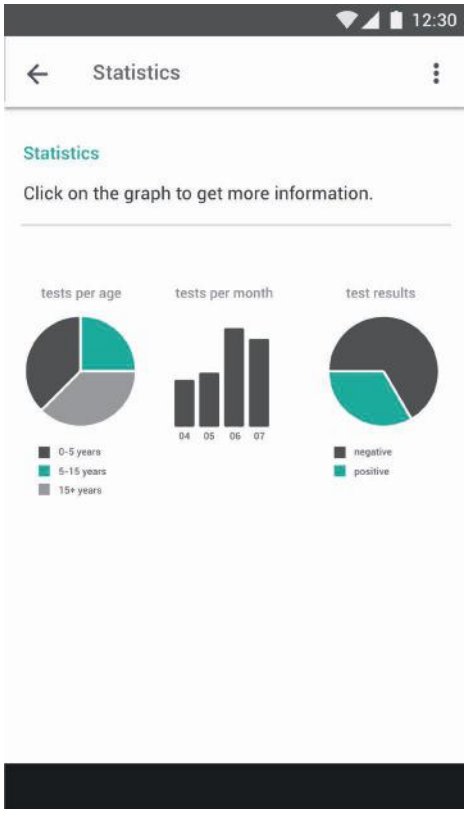


FIGURE 11.14
A report can be made from all or a selection of test results, to compare with results of colleagues in the area, to anticipate on the amount of drugs to buy, or to share with e.g. the World Health Organization.

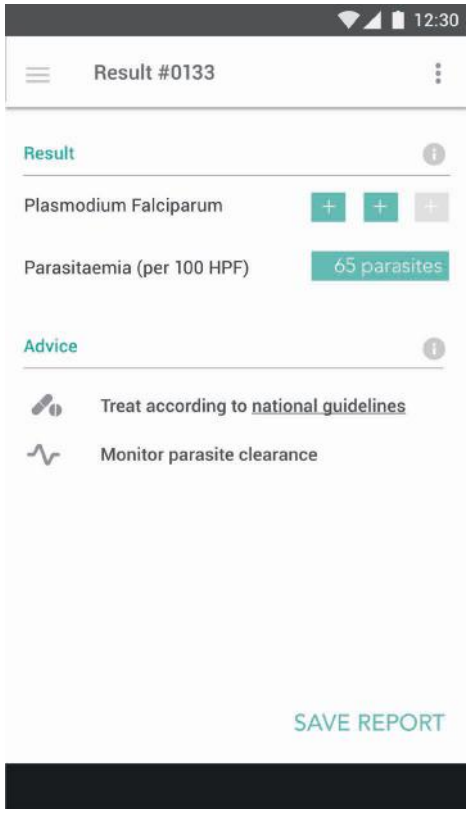


FIGURE 11.15
The Excelscope gives both qualitative and quantitative result for easy interpretation and health monitoring. Information about treatment advice or how to monitor can be found online.

11.3.3 Conclusion

The results led to several aspects to take into account and new ideas for development of the device. These aspects, as well as barriers and enablers for acceptance, are given in figure 11.16.

According to the interpretation of the pharmacists' input, interaction with the device must be quick and easy, yet advanced in how it can be communicated to clients. It should give the pharmacist the control of doing the complete test at the pharmacy, from blood sample collection to prescription of medicine, without being dependent on an external lab scientist or doctor.

Pharmacists will most probably be eager to participate in training programmes to learn about how to use the Excelscope and provide their customers with accurate tools. Nonetheless, because of pharmacies being part of the private sector and profit-oriented, a business strategy has to be developed to enhance user- and client compliance to the device.

With regard to a smart malaria diagnostic device, pharmacists want to be
Independent: to conduct the whole procedure independently
Confident: in having knowledge about malaria and advising customers
Proud: about owning the device and the ability to use it

Figure 11.17 shows several elements and ideas for development of the Excelscope within the context of community pharmacies.

ENABLERS	BARRIERS	OPPORTUNITIES	CHALLENGES
Quick procedure Profitable product-service system Personalize the device; adding a feature related to the pharmacist's practice *Independent* Point-of-care diagnostics Automated analysis *Confidence* Include clinical information Provide a manual Acceptance & qualification *Competence* Provide training	Time Costs Remote diagnostics *Tasks* Difficult procedure Blood sample preparation Imaging	Supply chain management Electronic health records Engage pharmacists in enhancing community awareness for diagnostic tests. Point-of-care diagnostics & treatment	Clinical knowledge on disease, diagnostics and treatment (and keeping it up-to-date). Maintenance Business strategy

FIGURE 11.16
Summary of the findings about community pharmacists.

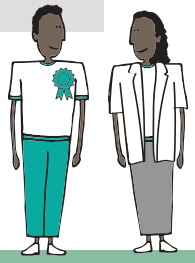
FIGURE 11.17 >
A visual presentation of the interaction between pharmacist and the Excelscope.

TRAINING

Provide training on recognizing symptoms for malaria and distinguishing diseases, as well as for the use of the device.

IDEA

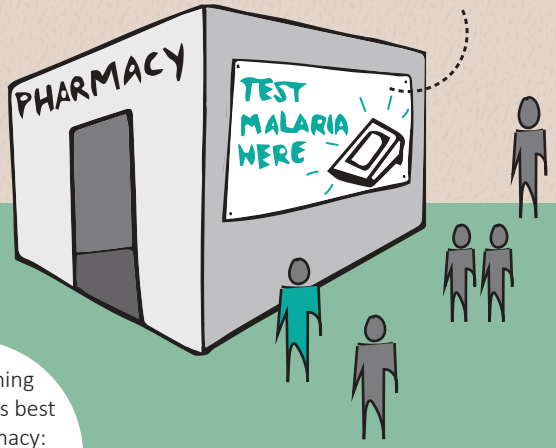
Bring lab and pharmacy together: employ a lab scientist for preparing the smear, staining the slide and potentially needed second opinion tests.

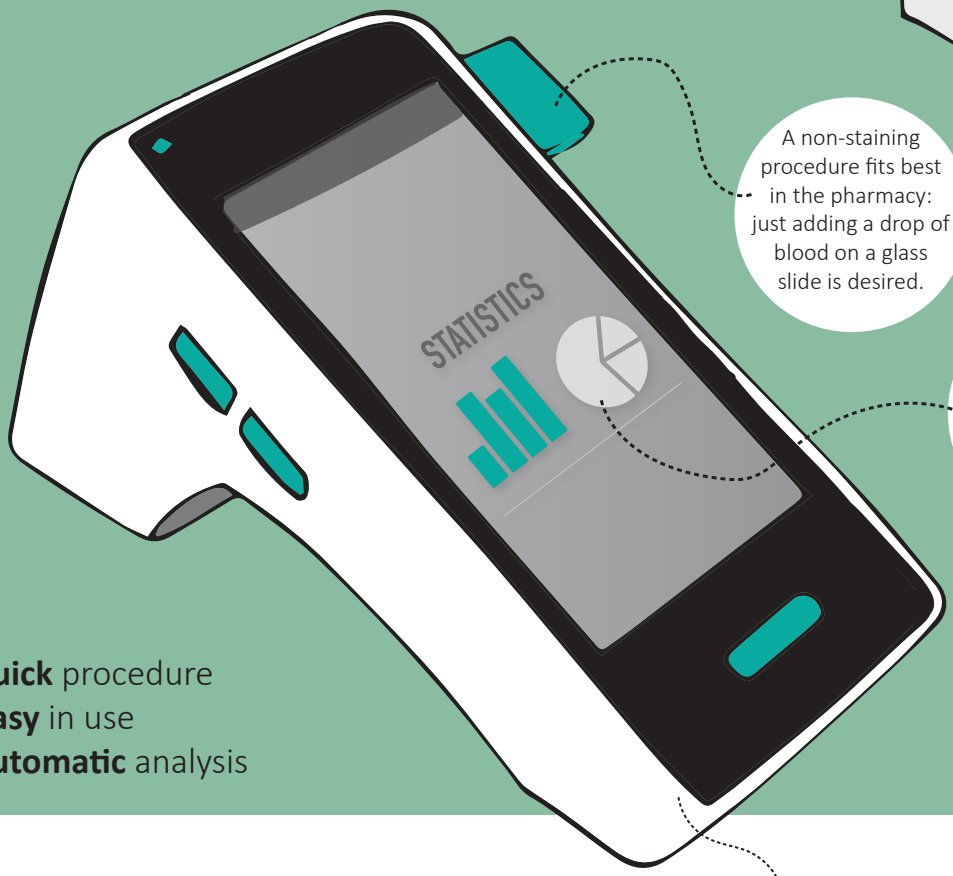


INDEPENDENT
PROUD
CONFIDENT

My clients will come back, since I can offer different diagnostic services independently

promotional banner to attract new customers

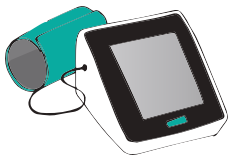




A non-staining procedure fits best in the pharmacy: just adding a drop of blood on a glass slide is desired.

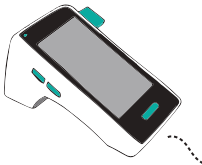
Keep track on data to e.g. anticipate on the necessary amount of drugs in stock.

quick procedure
easy in use
automatic analysis



blood pressure

blood sugar



malaria

DIAGNOSTIC DEVICES

The Excelscope fits within the current diagnostic devices that are being used in pharmacies. Form language and usecues can be identified in order to develop the Excelscope and fit within this product category.

BARRIERS & CHALLENGES

Staining
Taking a blood sample and staining the slide

Time
Long procedural time might be a barrier for pharmacists and clients

11.4

MEDICAL DOCTOR

"It's a device, I don't know what's happening inside."

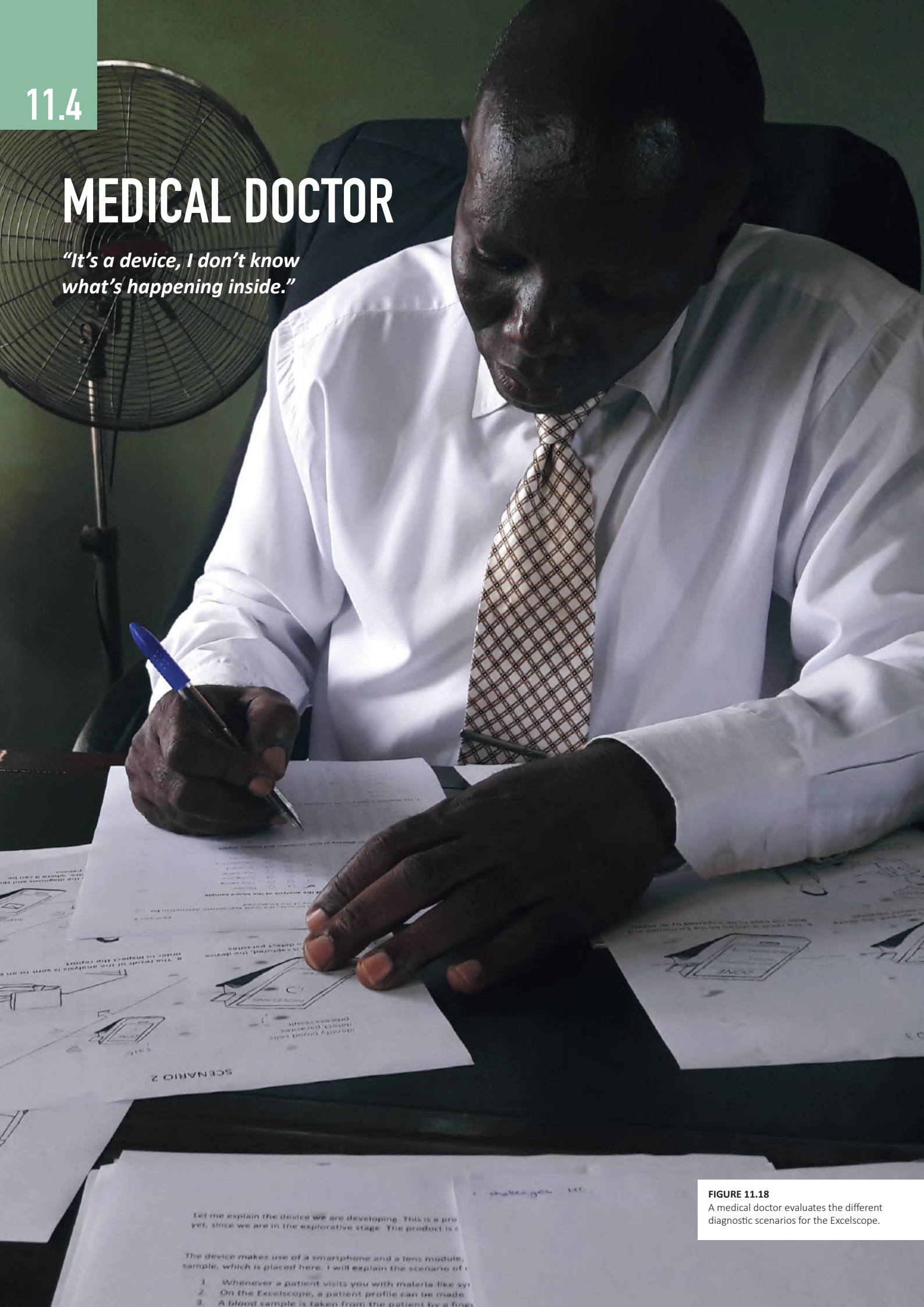


FIGURE 11.18
A medical doctor evaluates the different diagnostic scenarios for the Excelscope.

Five medical doctors in public healthcare facilities from different areas in Ibadan participated in this study.

"I would feel independent, because I don't have to tell the patient to go to another lab and wait. I can actually generate the results here, don't have to depend on reagent, the microscope... Once I have this and it belongs to me or the consult room, I am good to go."

11.4.1 Medical doctors & malaria diagnostics

This field study focused on public healthcare centres in an urban area, where the infrastructure is more advanced than rural areas. The visited health centres had laboratories and lab scientists available. Implementation of the Excelscope in this area seems to be less urgent, however, doctors in urban areas (often closely related to university hospitals) are likely to be the 'early adopters' of new technologies. Although doctors and laboratory scientist often work together in malaria diagnostics in these settings, this study evaluates the needs and concerns of doctors when using the device independently – in order to be applicable at minimal infrastructure (primary) healthcare centres too.

In primary healthcare centres (PHCs), doctors attend to patients with a variety of complaints, such as hypertension, typhoid, bacterial infections and malaria. According to the General Household Survey (2016), 28% of the population are most likely to visit a hospital for the first point of care, whereas on average 33% goes to a chemist first [36]. One of the participating medical doctors, working in a primary healthcare centre, mentioned that many patients initially try to get better through traditional healing, self-treatment or over-the-counter drugs from PMVs. As a result, their complaints could have become more severe by the time they come to the hospital.

In PHCs, malaria is mostly diagnosed by RDTs. If a laboratory is available, a second opinion can be done via microscopy. Amongst the participating doctors, there are different opinions about the RDTs. RDTs are easy to use ("even an illiterate can use it") and available, but the sensitivity is being criticized. The doctors complained about false negatives (it does not pick low parasitaemia) and false positives (if someone has been treated already, the antigens can still be detected by the RDT). Therefore, microscopy is being preferred for accurate diagnosis or complicated cases, but not always possible due to a lack of equipment, time or financial resources.

"If a test is negative, we use our judgement as a doctor. We decide to treat such patients sometimes, especially if the patient has not taken anti-malaria medicine yet. Most patients will go home better."

Whereas people can buy antimalarials without prescription at PMV shops or community pharmacies, medical doctors are more likely to search for the actual disease. "If the RDT cannot tell us that the patient has malaria, we cannot treat for malaria". The doctors seem to be less sensitive for the patient's demand for a prescription or the self-diagnostic ability of patients and want to decide on treatment themselves. They prioritize a combination of clinical consultation in combination with a diagnostic test, and do not solely want to rely on the test result. Therefore, patients are still often being diagnosed on clinical symptoms, instead of on an accurate test result, which includes the risk on misdiagnosis.

11.4.2 Medical doctors & the Excelscope

During the discussions with the participating medical doctors, advantages as well as barriers for use of the Excelscope were expressed by the participants. In general, the Excelscope was perceived positively for the use in primary healthcare settings, although the accuracy of a computer analysis was being questioned. This section elaborates on the attitude and needs from doctors towards the Excelscope.

11.4.2.1 (Semi)-automatic scenario

The doctors participating in this study were enthusiastic about an automatic diagnostic device, since it is accessible and beneficial for quick patient management. However, the accuracy and transparency of an automatic analysis were questioned; a cross-check from both human expert and computer is preferred with regard to accurate diagnostics. At least, having the possibility to do a second opinion in case of doubt was mentioned by several participants.

"If you can do a cross check, it's a plus. Sometimes you just feel that a patient has malaria, you don't want to trust the device. At the same time, you have two options."

Although verification by a human expert was preferred, a remote diagnostic scenario was rejected by all medical doctors for several reasons (time, availability of pathologist, bad internet connection); "it is ambiguous to send it somewhere and send it back..". Instead of sending the images remotely, the doctors prefer to be able to analyse the slide themselves or have someone around to do the analysis. The doctors consider themselves competent enough to learn how to detect parasites in a blood smear, yet would still have more trust in the analysis of a laboratory scientist. However, being able to do the whole procedure in the consultation room was perceived as an advantage, since it will give the doctor the possibility to combine a clinical analysis with the test result and therefore total control on the diagnosis, which "makes a rich decision". The doctors would feel in control and independent when they are able to provide a diagnosis in that

When discussing the Excelscope with regard to reliability, the doctors desire to cross check the result or have a look at the images themselves. It is interesting to find out whether they would actually want this, or express the desire because they have become aware of possible computer errors when discussing the three scenarios. One of the doctors said: "I have actually never questioned the result of a blood pressure monitor or glucometer..". Another study, by for example only presenting the automatic scenario (or letting them conduct a test with a working device) is recommended to study the need for transparency in the procedure.

"To me, this is still the same as conventional a microscope, up to the point of inserting the slide. This is just a substitute of a microscope. You still need the technical aspect of blood collection, smear, staining, drying.. That makes it very difficult.."

way. Thus, the doctors were slightly indecisive in which of the three scenarios had their preference: all of them had pros and cons that have to be measured in actual use of the device.

An opportunity for better equipped health centres is an increased efficiency between the in-house laboratory scientist and the doctor. The doctor can send the generated result (through e.g. internet, Bluetooth or a USB connection) to the lab scientist, by whom the diagnosis can be provided.

"We don't want to go back to a system where we have to wait."

11.4.2.2 Time

Similar to the other stakeholder groups, procedural time can be a barrier for use of the Excelscope. Since the Excelscope is a smart device and can be related to blood pressure monitors and glucometers, people do not expect the procedure to take much time. Furthermore, RDTs are being used by medical doctors as well, which have made them used to providing a diagnosis quickly. Yet, in contrast to on-the-go places like the PMV shops and pharmacies, patients might be more willing to wait for a test result at a health centre. Waiting rooms or seats are available and the diagnostic procedure in general is already more elaborated than a visit to a pharmacy of drug store.

11.4.2.3 Tasks and use

Primary health centres (in urban areas) are better suitable for extra tasks such as blood sample preparation or maintenance of the device, because of a better infrastructure and more assistance (from nurses). Within the consultation room, some room can be prepared with necessary tools for staining a blood sample. Thereby, doctors expressed more acceptance towards this kind of tasks, but still have their concerns with regard to time, required resources and quality of the stain: "The malaria parasite, the biology is such a complex ting. If you don't have high quality input to the test, you are not likely going to get round in diagnostics." A doctor can be assisted by a nurse, who can be trained on how to stain accurately. The doctor can continue attending to patients while the nurse can run the test on the Excelscope. The result can be communicated to the doctor and provided to the patient. A feasibility study needs to be conducted on the aspect of the nurses' abilities on accurate staining and motivation to include these tasks in their workflow.

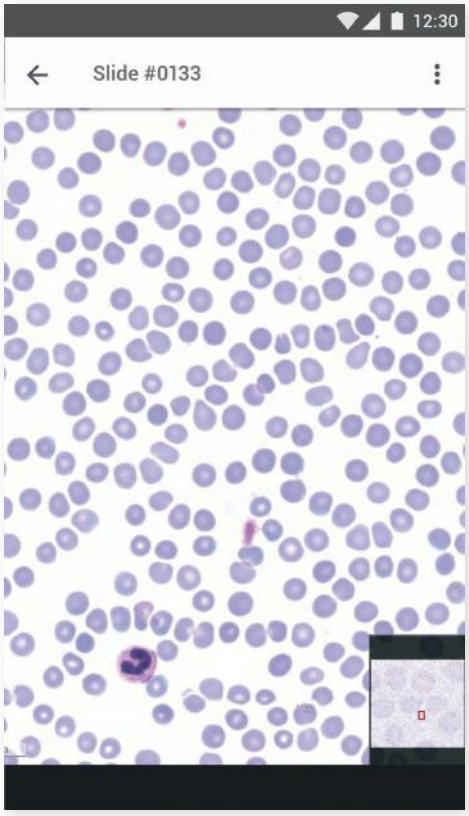


FIGURE 11.19
The possibility to confirm or inspect a diagnosis leads to a perception of control and transparency in the procedure. Doctors need to be trained or a pathologist has to be involved.

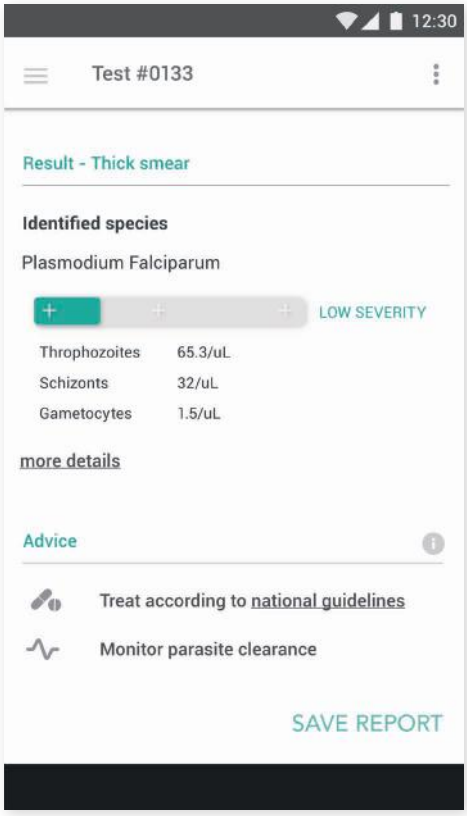


FIGURE 11.20
The test result contains both a visual interpretation and absolute values for monitoring treatment effectiveness and providing transparency.

11.4.2.4 Test result interpretation
The participating doctors want to have detailed information about the test result. They are familiar with the plus-system and find it convenient, yet want to have actual numbers on parasitaemia for precise monitoring of the patient's health. Furthermore, species identification was mentioned to be important, and one doctor desired to be able to have a look at the images of the blood slide in order to see the parasite stage. There is need for a more elaborated study on the amount of required information. Would doctors be able to distinguish parasites from artefacts on a (selected) image after some training (figure 11.19)? The discussion about test result visualization lead to ideas and desires, but it is questionable whether the doctors actually need and will use this information, or whether they just express what they know about malaria parasites. Regardless of that discussion, a combination of a visual presentation and test result in significant numbers will most probably be best for the doctors for quick interpretation and health monitoring (figure 11.20)

Besides the test result, an automatically generated treatment advice was presented to the participants. Even though the doctors were surprised and interested in this feature, they do not want to be dependent on this. Prescriptions are normally being made on a clinical screening of the patient, including the level of hydration and other symptoms. The doctors want to be in control of both diagnosis and treatment, and attach value to their own abilities as healthcare professionals.

11.4.2.5 Business strategy and costs
When the Excelscope is being used by doctors, the business strategy is dependent on implementation in the public or private health sector. Medical doctors in private clinics – if being the director of the clinic – might need some training on setting up their margins. A product-service system (including provision of disposables and maintenance) or pre-paid test package (one can buy and install a certain amount of tests through voucher codes) seem to be relevant for doctors. It relieves them from the burden of maintenance and allows them to properly focus on the patient's healthcare in an easy way.

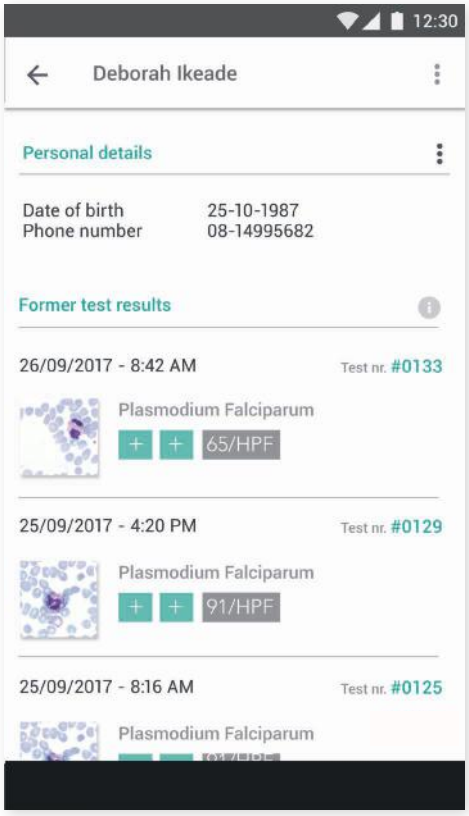


FIGURE 11.21
The Excelscope can be used for electronic records of malaria tests in order to monitor on parasite clearance. Patient data has to be limited to essential information in order to keep the procedure short.

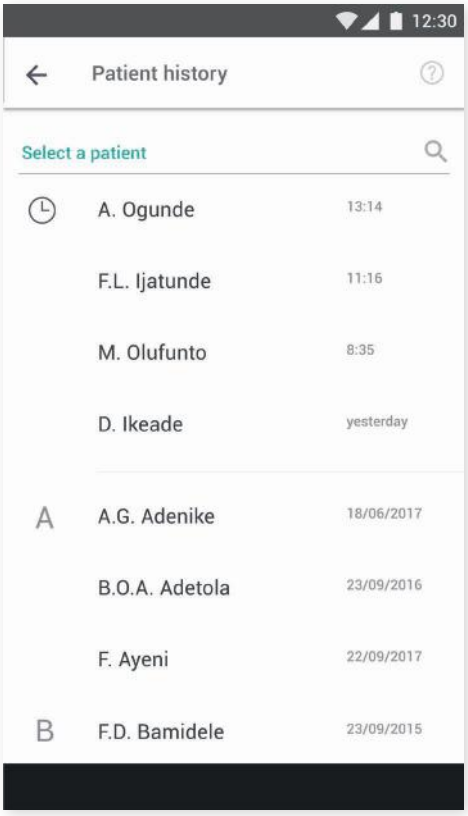


FIGURE 11.22
The Excelscope can be used for electronic records of malaria tests in order to monitor on parasite clearance. Data that needs to be inserted, has to be limited to the necessary data in order to keep the procedure short.

FIGURE 11.23
Patients are normally being given a registration card, on which personal data, vital signs and test results are written (left image). The right image shows the patient record storage of a primary healthcare centre. No data is stored online yet.

11.4.2.6 mHealth opportunities

One of the advantages of the smart device being used in clinical settings, is the doctor's ability to screen the patient's health in general. Furthermore, some primary centres have the infrastrucutre to keep patients for two to three days and monitor their health. The possibility to monitor on parasite clearance would be beneficial (figure 11.21).

In that case, including name, date of birth and/or patient registration number have to be included in the device. Normally, a patient registration card is used on which a registration number is written (Figure 11.23). The patient keeps this card at home and a record of the data is stored in the hospital too. If the information can be digitalized, it will reduce time for registering information or looking for the right patient's record. However, the amount of information that is currently being stored might be too extensive for an m-health application on this device (extensive patient data including information about other diseases and wellbeing). The aim of including patient data must be clear (e.g. only for quick malaria management or monitoring) to avoid a cumbersome collection of patient data at different places.

If electronic patient records are being made, it can easily be used for data reports to governmental institutions.

11.4.3 Conclusion

The results lead to several aspects to take into account and new ideas for development of the device. The barriers, enablers, opportunities and challenges for use of the Excelscope by medical doctors are given in figure 11.24.

The medical doctors prefer to be independent in the diagnostic procedure and base their decisions on both clinical symptoms and the test result. Use of the Excelscope can increase accuracy of diagnostics in low resource facilities (where diagnoses are based on RDT results or clinical symptoms) or efficiency of test procedures in more advanced health centres. In the latter, a collaboration between lab scientist and doctor would fasten the procedure without the need for sending images through internet. In that case, a semi-automatic analysis would be most suitable and will be accepted by doctors, since they express the desire for a cross-check from computer and human expert.

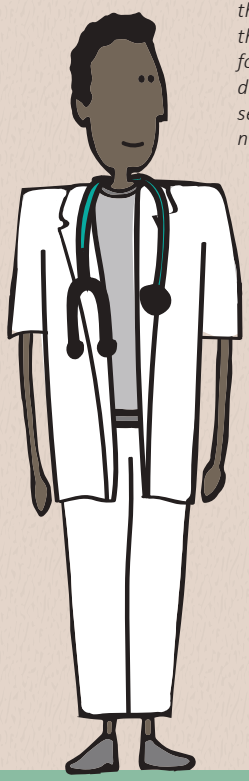
In endemic – low infrastructure areas, an automatically generated result will provide the possibility to diagnose on the point-of-care independently. The device has to be designed in a transparent way (e.g. providing some images of clean/infected blood cells) and leave the final decision to the doctor: being in control is highly important for the physicians.

Implementation of the Excelscope in primary healthcare brings the opportunity for efficient patient health monitoring. In future practices, the Excelscope can be linked to electronic patient dossiers to manage electronic health records.

ENABLERS	BARRIERS	OPPORTUNITIES	CHALLENGES
Independent Automated analysis Point of care diagnostics	*Tasks* Staining	Electronic health records	Maintenance
In control Possibility to cross-check a result (by pathologist or individually)	Time Remote diagnostics Ambiguous procedure	Close collaboration between doctor and nurse Enhancing efficiency by collaboration between laboratory technician and doctor in more advanced settings.	Being more beneficial in comparison to RDTs (in terms of time, costs and effort)

FIGURE 11.24
Summary of the findings from interviews with medical doctors.

FIGURE 11.25 >
A visual presentation of the interaction between doctor and the Excelscope.



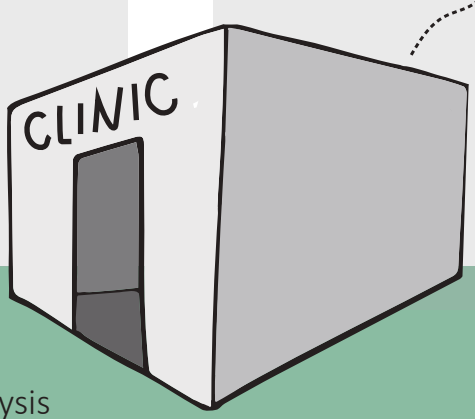
"As a doctor, you will have the patient, so you can use the patient's symptoms to fortress the diagnosis. The device or lab scientist only sees the sample, but does not see the patient."

SUPPORTED & IN CONTROL

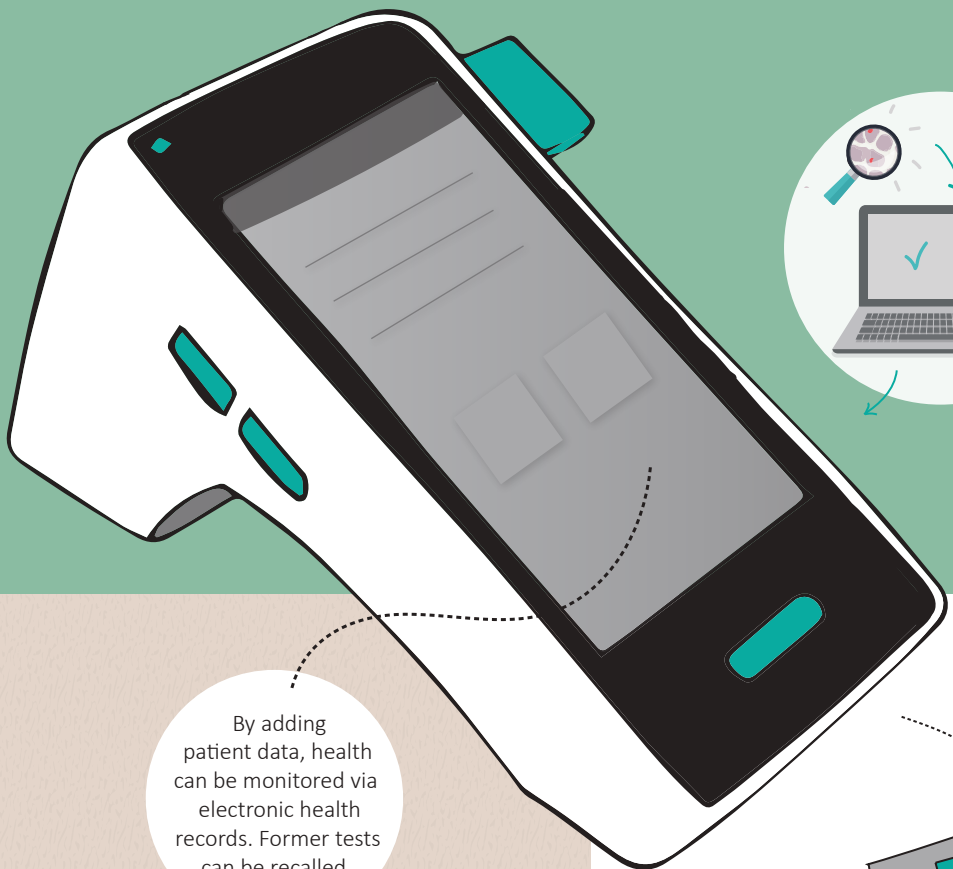
Be supported by the Excelscope in decision making, but base the diagnosis on clinical symptoms as well.

INDEPENDENT

Being able to provide an accurate diagnosis at the point-of-care without the need to send the patient to a laboratory.

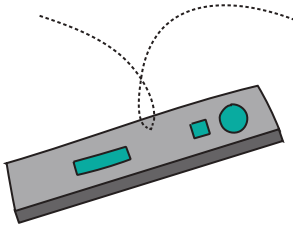


low infrastructure settings: **automatic** analysis
advanced settings: **manual/semi-automatic** analysis



Doctors value the possibility to verify the result (ask for a second opinion or self-verification). This is possibly more accepted in advanced settings or lower endemic areas.

By adding patient data, health can be monitored via electronic health records. Former tests can be recalled.



BARRIERS & CHALLENGES

Being perceived more beneficial compared to RDTs in terms of:

TIME TASKS COSTS

11.5

LABORATORY SCIENTIST

"I love my microscope, I don't want to use any other device."

FIGURE 11.26
A laboratory scientist is proud on her microscope.

Eight laboratory scientists (five from the public sector, three from private labratories)

If I could go through the picture and there are parasites, according to the machine.. I would believe it. I can go through the slide again to be sure that the machine is okay and perfect. I go through the slide. And if it is giving me the same result, that means the machine is perfect. So I don't need to bother myself and start using the machine.

11.5.1 Medical laboratories & malaria diagnostics

Medical laboratory scientists (or 'lab scientists') work in either public healthcare centres or private laboratories. In the public centres, lab scientists normally attend to patients with a request form from the doctor of that specific health centre. In private laboratories, patients often come on advice of a doctor, but sometimes go straight to the lab. Officially, the laboratories can only test based on a request from a doctor, but sometimes run a test without this form as well.

Laboratory scientists (or their assistants, figure 11.27) take blood samples in the waiting or consultation room, and conduct the requested test in their laboratories. Concerning malaria, Giemsa stain microscopy is the main method being used in laboratories. In some laboratories, RDTs are used to do a first screening in case of emergency, after which the result is being quantified through microscopy. Malaria microscopy is being described in chapter 8.3.

Laboratory scientists provide a test result which can be taken to the doctor. They cannot prescribe any drugs. In case the result is positive, some patients do not go to the clinic anymore: they will go straight to a pharmacy to get antimalarial drugs.

Since laboratories are equipped with microscopes, the use of a smart device might be cumbersome. Nonetheless, microscopy can be exhausting and it might be difficult to detect the parasites in case of low parasitaemia or early parasite stage. Therefore, the Excelscope could support and assist laboratory scientists in their work.

11.5.2 Medical laboratory scientists & the Excelscope

In this study, eight laboratory scientists from both public and private sector were involved. Although being critical towards a new technology, some of the participants were open for a smart device that could relieve their workload. One of the lab scientists thinks the device is promising, since microscopic malaria diagnosis can become in reach of primary healthcare facilities, *"since malaria can best be managed close to home".* This section gives more insights on the laboratory scientists' perspective on the Excelscope.

11.5.2.1 Manual or semi-automatic or automatic analysis

The lab scientists were rather sceptical about the reliability of an automatic smart device, since they think it is of high importance to have a human expert involved in malaria diagnostics. Nonetheless, when they are able to do a comparative study of the Excelscope and their own microscope, and the results turn out to be equally sensitive and specific, the lab scientists would consider the use of the smart device. In that case, an automatic analysis might eventually be accepted by the medical laboratory scientists, but should leave the option to verify the images manually. In any case, they want to be in control of the procedure and analysis.

According to the participants, the advantages of the manual analysis are not significant enough or perceived at all, especially if blood sample preparation, and manual adjustment and imaging of the slide are needed.

A semi-automatic analysis can save time compared to conventional microscopy and would relieve the burden of looking through the microscope over and over again. However, according to the lab scientists, this would only be suitable for positive slides. In case the device gives a negative result, the scientists still want

FIGURE 11.27
In private laboratories, a laboratory assistant attends to patients by filling out registration cards, managing payments and collecting blood samples in the waiting- or consultation room.

to go through the whole slide manually, in case one parasite has been missed by the computer analysis. The semi-automated analysis would 'reduce human error, but keeps the controlling aspect."

Similar to the semi-automatic analysis, one of the main reasons for laboratory technicians to make use of a smart device, is the relieve of fatigue caused by microscopy, which was mentioned by several participants.

Acceptance
Although there are opportunities for use by laboratory scientists, there is a way to go in terms of acceptance and perceived reliability. As some pharmacists said: "there is no way the device can be as good as expert microscopy (…), we don't want this to replace the microscope in lab settings" and "I don't trust devices like that. Even if it is reliable, it's not!". The scenarios in which the images have to be send to an external location are perceived to be cumbersome. The device might better be used in the laboratory itself.

Yet, the laboratory scientists were interested in the development of the device and eager to be involved in the project; most of them offered to do a comparative study to statistically check the accuracy of the technology.

"I find it very exciting and want to be the one that tests it and standardizes it. It's very exciting."

11.5.2.2 Time
Malaria microscopy takes 30 to 60 minutes. Sometimes, patients wait at the lab for their result; others come back later. It is therefore expected that patients are more willing to wait for their result (or expect having to wait) from a laboratory than at the other healthcare facilities that have been discussed. On the other hand, when decreasing procedural time, more tests can be done. Efficiency and access to diagnostics increase.

11.5.2.3 Tasks and use
Lab scientists and-technicians are skilled in fixing and staining a blood smear. They are used to technical procedures for preparation, cleaning and maintenance of their tools and microscopes. The tasks can be continued in use of a smart device, but the Excelscope will only be adopted if the rest of the procedure (analysis of the slide) has advantages compared to normal microscopy. When removing time-consuming tasks, such as staining and changing fields, the device will be supportive.

By creating a more user friendly way of looking at the slide, on a (computer) display instead of through the microscope eyepiece, the lab scientists would be supported too. In that case, a tablet-sized display might be more suitable than a smartphone.

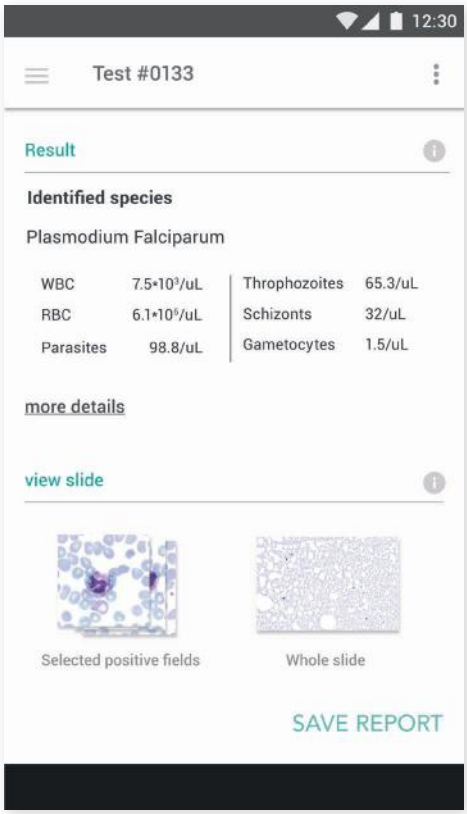


FIGURE 11.28
The result gives the option to analyse the whole slide or view a selection of fields in order to confirm or inspect the diagnosis.

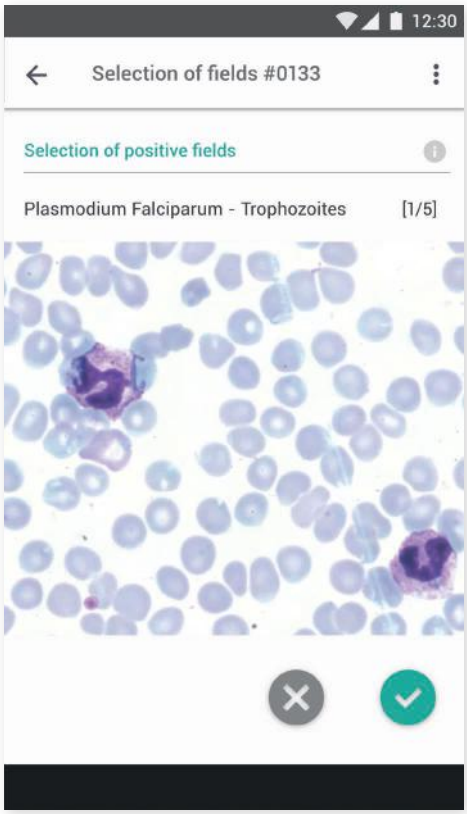


FIGURE 11.29
In a semi-automatic analysis, the lab scientist is asked to confirm the diagnosis by looking at five fields of view. Human input can improve the algorithms over time by deep machine learning.

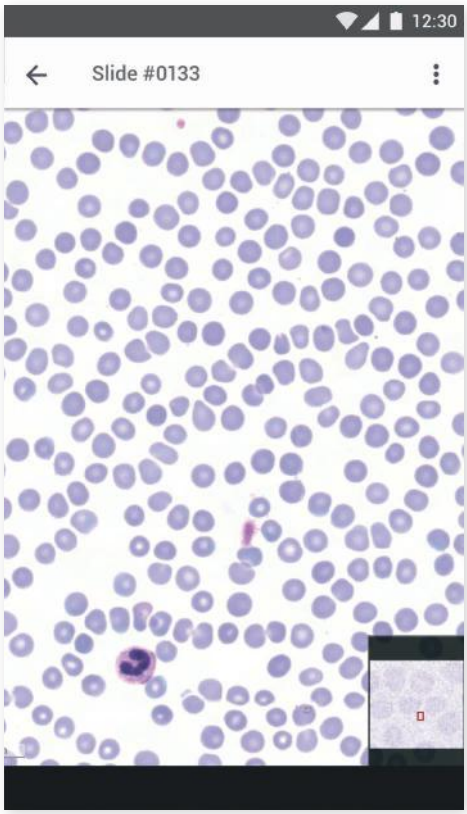


FIGURE 11.30
If doubt is present, the lab scientist can swipe through the whole slide to look for parasites.

"It will just process the sample. So if there is any mistake, you may noat know. So the third one is out of control. (..) When you have used it several times, you know if it is better than another device. It would be very interesting if it will work and it is working perfect."

FIGURE 11.32
A lab scientist gives her opinion about an automated analysis.

FIGURE 11.31
Step-by-step guide about making a blood smear and staining the slide. Secondary public health centre laboratory.

11.5.2.4 Clinical knowledge and test result interpretation
Malaria diagnostic test results are normally provided to the doctor in amount of parasites per high power field or microliter, often together with an indication of the severity on the scale of three plusses. Laboratory scientists make the report themselves by counting all cells and counting the parasites in different stages. When the Excelscope processes the slide automatically, the report has to include this detailed information in order to gain trust from the lab scientist. The images have to be available for inspection. When discussing the designed interface of a blood test result, the lab scientists were critical towards the provided image and proposed result ("I cannot analyse this picture." "Why do you give parasitaemia in percentages?"). Since the visualization was not designed in collaboration with a lab scientist, the information did not meet realistic values or standards. However, that evoked discussions about the necessary information. Lab scientists want to have information about at least the presence of parasites, the species and the stage of the parasites' life cycle.

Figure 11.28 proposes an interface design of the test result for laboratory scientists. It provides the possibility to view a selection of (positive) fields or going through the whole slide manually. It will bring transparency and therefore gives the lab scientist the perception of being in control.

11.5.2.5 mHealth opportunities
Telemedicine is one of the m-health opportunities in a remote scenario. In that case, lab scientists have to be available to analyse the images or test result. The role of being the remote pathologist has been discussed with the participants.

The lab scientists are open to be involved in this process of doing the analysis or confirm the result, although the workload in some laboratories might be too high to incorporate extra tasks. The role of 'expert' might better suit the less occupied laboratories in public health centres. A (business) strategy has to be developed for the reimbursement of the lab scientists' involvement in the process: who is going to pay for the work, or should it be done voluntarily? Could it be organized by a laboratory equipped public health centre that does medical outreaches in the field, in order to keep everything under supervision of one organization?

It would be good if the device has already done the analysis partly, so that it only has to be confirmed by the lab scientist. Extra training is needed to analyse the images digitally, since it will most probably look different from the analogue slide analysis.

11.5.3 Conclusion
The results lead to several aspects to take into account and new ideas for development of the device. The barriers, enablers, opportunities and challenges for use of the Excelscope by laboratory scientists are given in figure 11.33.

Laboratory scientists want to be in control of the diagnostic procedure, which has to be transparent and detailed to be trustworthy. If the device can be proven to be as sensitive and specific as conventional microscopy, the lab scientist might accept a semi-automated or automated device. At least, the possibility to inspect the images has to be included. A positive test result will be easier to be confirmed in a semi-automated scenario than a negative result. More research has to be done on validation and trustworthiness of negative test results.

The Excelscope can support lab scientists in reducing workload, increasing efficiency and relieving them from the exhausting task to look through the microscope. Figure 11.34 visualizes the interaction of lab scientists with the Excelscope.

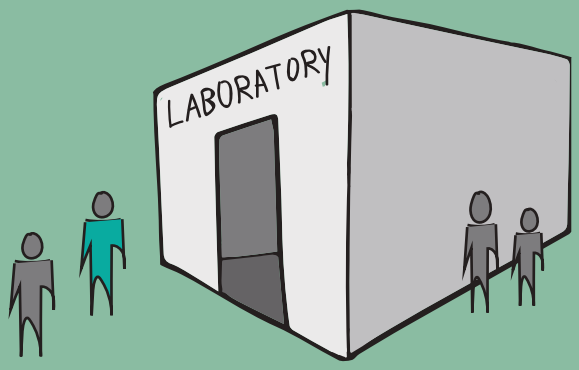
ENABLERS	BARRIERS	OPPORTUNITIES	CHALLENGES
In control Being able to compare the result with conventional microscopy	*Out of control / ambiguity* No control on the test result (the feeling of) being replaced by technology	Increase efficiency	Gain acceptance amongst laboratory scientists concerning the trustworthiness of the device
Supported Feeling supported by technology	*Tasks* A procedure that is similar to conventional microscopy in tasks and time consumption	Reduce workload	
Relieved Improved usability compared to a microscope Reduced workload		Design a tablet size device for a user friendly interaction	
		Limited equipment needed allows lab scientists to work as a malaria expert in low resource health centres or pharmacies.	

FIGURE 11.33
Summary of the findings from interviews with laboratory scientists.

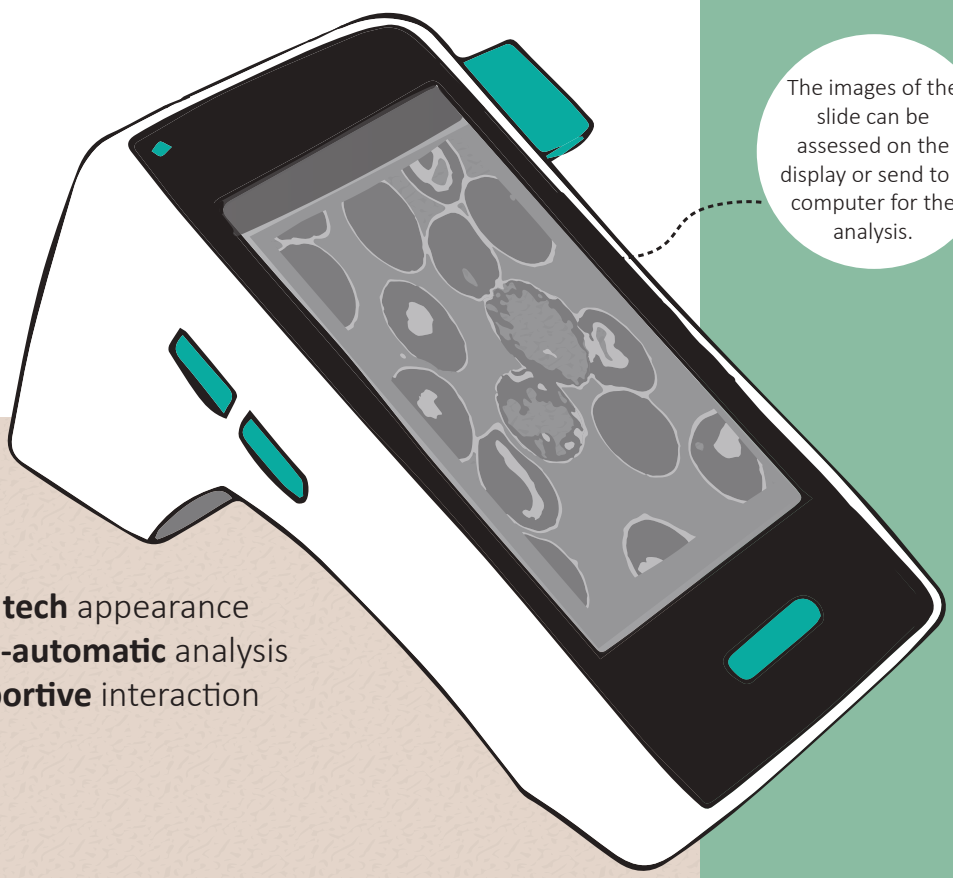
FIGURE 11.34 >
A visual presentation of the interaction between lab scientist and the Excelscope.

IDEA

Design a tablet sized device, to increase user friendliness when looking at the slide. Lab scientists can easily assess the blood sample from the bigger sized display.



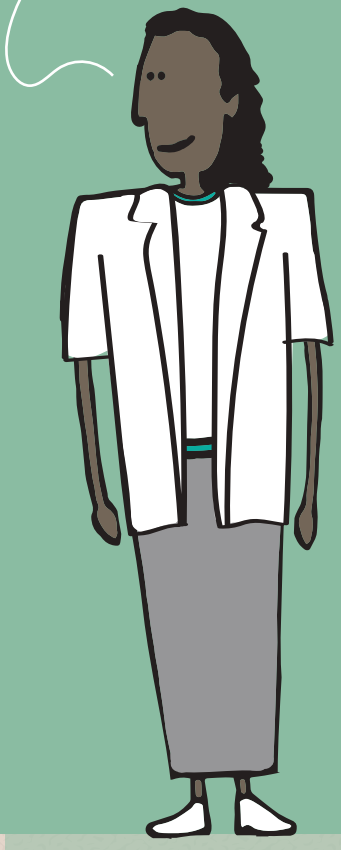
public
private



The images of the slide can be assessed on the display or send to a computer for the analysis.

high tech appearance
semi-automatic analysis
supportive interaction

"I would just sit and relax with my computer and view it there.."



SUPPORTED & IN CONTROL

The advantages of a new device have to be significant to replace the microscope. The lab scientist wants to be in control of the diagnosis instead of feeling replaced by a smart device.

RELIEVED

The Excelscope can reduce workload, stress and eye complaints by providing a time-saving and ergonomic scenario of use.

BARRIERS & CHALLENGES

Creating benefits compared to the use of microscopy

Feeling out of control or replaced by a computer.

11.6

NURSE

"Due to the policy of the hospital, we are not allowed to do malaria diagnostics tests ourselves."

FIGURE 11.35
A nurse evaluates the Excelscope in a primary health centre.

Two nurses participated in the study. One of them works in a primary health centre, the other nurse works as a lecturer in Public Health.

11.6.1 Nurses & malaria diagnostics

According to the WHO, the density of nurses is 1.03 per 1000 population [82]. In comparison, there are approximately 8.51 nurses per 1000 inhabitants in the Netherlands [83]. They work in both public and private centres and assist doctors. Little information could be found on exact tasks, responsibilities and the balance between nurses and physicians in both rural and urban health centres.

The responsibilities of nurses are based on the policy of each health centre [84]. In one of the visited primary healthcare centres, it is the policy that doctors test the patients by use of RDTs. The nurses are not allowed to do the tests, but dispense the drugs and take care of the patients. The nurses attend to patients when they come in and hand out the patient registration card.

In the primary healthcare centre, patients can be hospitalized for three days, and treated for minor causes, such as malaria. Nurses monitor take care of the patients, dispense drugs and monitor their vital signs. By being able to operate the Excelscope, malaria monitoring can be added to their tasks. It increases their (sense of) responsibility and relieves the doctor's workload.

11.6.2 Nurses & the Excelscope

The Excelscope 1.0 was developed for use by nurses and community health workers in rural areas in Uganda. Since this study focused on a variety of healthcare professionals, only one nurse and a former nurse have been interviewed. Although the results are not significant enough to draw conclusions on interaction and desires, some insights can be taken into account and lead to recommendations for further research.

11.6.2.1 Automated scenario

An automatic device will extent the abilities of nurses in (rural) primary healthcare: in doctors are not available, the nurse can provide an accurate diagnosis; in more advanced centres, the device can be used for monitoring (in) patients' health. The Excelscope extends the nurses' abilities and can provide a sense of competence and confidence in their jobs as medical professionals.

By the time you diagnose your patients and you are able to treat appropriately, you will be confident about what you have done.

11.6.2.2 Time

The nurses prefers a quick diagnostic test, in order to help the patients as good as possible. Although a manual diagnosis from a laboratory might be more reliable, it is important to help the patient as fast as possible; "People don't want to wait, they don't have patience". Therefore, rapid diagnostic tests have an advantage, according to one of the nurses. "The rapid test will show you that the patient has it. But here you can really see if the patient is having one plus, two plusses or more. Which is even more reliable."

11.6.2.3 Tasks and time

As stated before (section 11.4.2.3), nurses could be trained to prepare a blood sample in order to assist the doctor in use of the Excelscope. Yet, similar to other medical stakeholders, eliminating the tasks from the procedure is probably preferred. Not enough information was gathered from this study to draw conclusions about acceptance and motivation from nurses towards (being trained on) blood sample preparation.

The nurses prefers a quick diagnostic test, in order to help the patients as good as possible. Although a manual diagnosis from a laboratory might be more reliable, it is important to help the patient as fast as possible; "People don't want to wait, they don't have patience". Therefore, rapid diagnostic tests have an advantage, according to one of the nurses. "The rapid test will show you that the patient has it. But here you can really see if the patient is having one plus, two plusses or more. Which is even more reliable." Besides reliability and the patient's demand for quick tests, a fast procedure will probably fit better in the daily routine of nurses. Especially in private clinics, limited staff is employed in order to save costs, resulting in a higher workload.

According to one of the nurses, it is possible to handle the device by herself. She would feel confident and relieved if she is able to diagnose and treat patients appropriately. The Excelscope will support nurses when the procedure is concise and quick.

11.6.2.4 Clinical diagnosis and test result interpretation

Nurses have basic clinical knowledge about malaria diagnostics and treatment. The participants were familiar with the plus-system, but were not able to interpret the parasitaemia in numbers. One of the nurses was happily surprised about a treatment advice that was included in the procedure; it would support her in the diagnostic procedure since she currently does not prescribe any drugs. In remote health centres without physicians, a treatment advice could help nurses in providing appropriate care.

11.6.2.5 mHealth opportunities

As an addition to the Excelscope's ability to detect malaria parasites, the possibility to monitor patients can be included. Furthermore, a telemedicine application can be added to provide the possibility to ask for decision support on diagnosis or treatment in case of doubt or limited clinical knowledge.

11.6.3 Conclusion

More research on nurses and their perception towards the use of a smart malaria diagnostic device is recommended.

Based on the insights from the two interviews, the Excelscope will probably can extend nurses' abilities in healthcare provision and make them feel confident and supported in their daily practice. Because of their limited clinical knowledge, sufficient training and/or a decision support module has to be provided. A telemedicine application might support nurses in providing diagnosis. Since regulations on conducting tests and prescribing treatment differ per health centre, it is recommended to do more research on this aspect.

11.7

MEDICAL VOLUNTEERS

"We can buy five of these devices, and take it to the communities. We can have five people running the tests. But if we have to wait to get the results from the experts for 1000 people.. It's not possible."

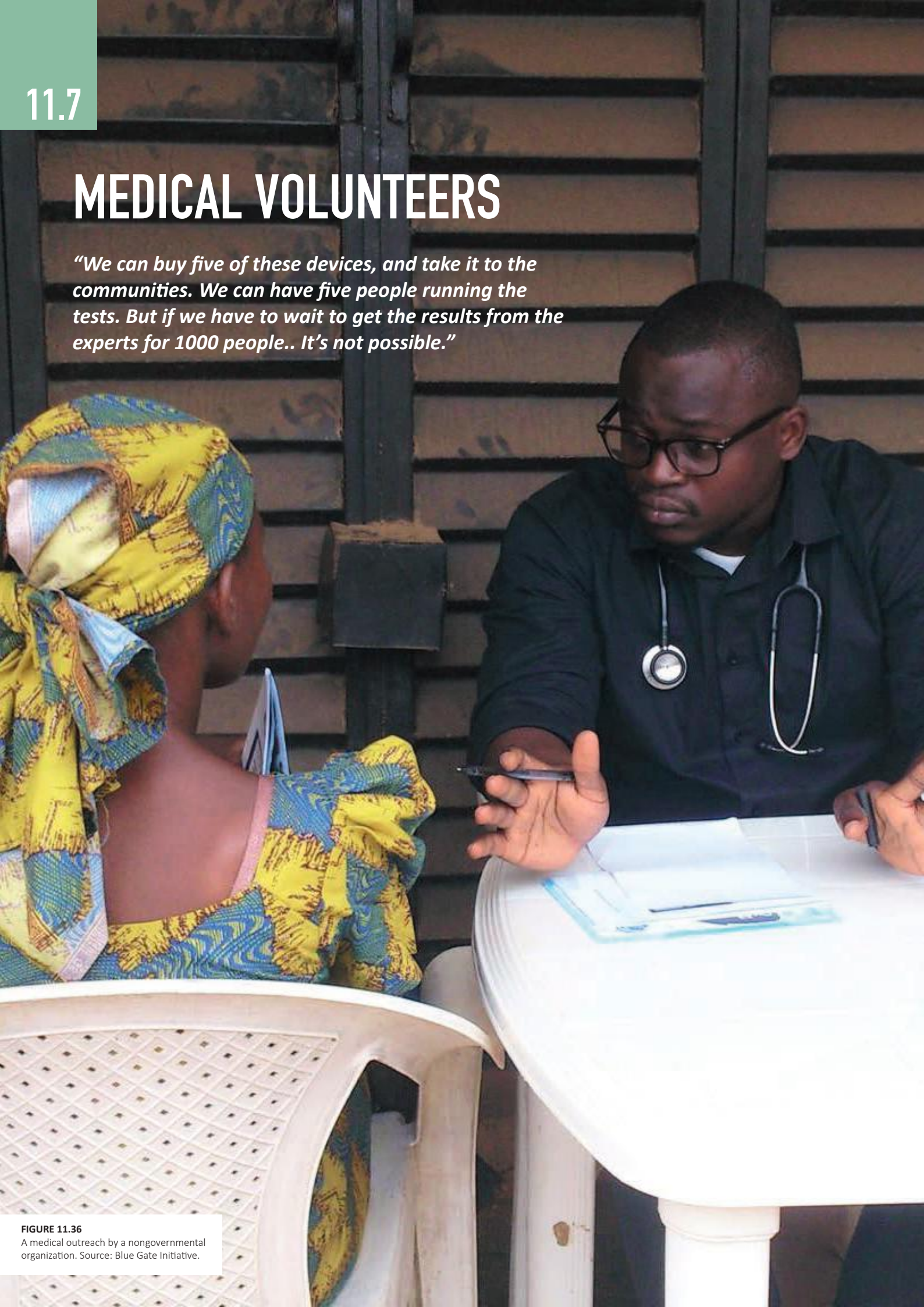


FIGURE 11.36
A medical outreach by a nongovernmental organization. Source: Blue Gate Initiative.

The CEO of one nongovernmental organzation on public health participated in this study. The participant is a medical doctor.

11.7.1 Medical volunteers at nongovernmental organizations

During the field study, one nongovernmental organization (NGO) has been visited for a discussion about the use of the Excelscope during medical outreaches to communities. In this section, 'medical volunteers' and 'community health workers' are used interchangeably.

NGOs have been defined as 'private organizations that pursue activities to relieve suffering, promote the interests of the poor, protect the environment, provide basic social services, or undertake community development' and operate on local, national or global level [85]. Nongovernmental organizations have become major stakeholders in the provision of social (health) services, and often work together with governments and companies [86]. Exact data on the amount of NGOs and their impact on public health has not been found.

The NGO 'Blue Gate Initiative' does different things on the field of public health, such as promotion and intervention programmes, as well as medical outreaches. During an outreach, community members are screened, tested and treated by the doctors, nurses and social workers of the organization. Depending on the community, the available personnel and time, hundreds up to a thousand patients can be seen. All tools and drugs will be taken to the field and can be provided for free.

The NGO does malaria testing through RDTs, although the sensitivity is not that high. "If the RDT cannot tell it's malaria, we cannot treat for malaria." During an outreach, there are limited facilities for testing on another disease."

11.7.2 NGOs and the Excelscope

Since only one NGO has been addressed for this study, the results are limited and cannot be used to draw conclusions about the perception from NGOs towards the Excelscope. Nevertheless, understanding of the medical outreaches leads to ideas about development of the device for this sector.

11.7.2.1 Automated scenario

In rural areas or on community level, internet connection is limited. Therefore, an automated scenario will be best suitable for NGOs. Furthermore, this allows a quickly generated result, which is necessary in order to provide results in the most efficient way.

11.7.2.2 Time and tasks

A quick procedure is being desired for use at medical outreaches, similar to use of an RDT. Within this procedure, the need to stain will not be applicable due to large patient groups to attend to, limited time and a lack of facilities. Furthermore, the outreaches are being done by volunteers- often students in the field of healthcare- who then need to have more training before being able to go into the field.

The device would be beneficial to RDTs if the result can be provided immediately. Currently, the results of RDTs can be mismatched to the patient if they are not properly managed: *"In RDTs, we make errors. Because, we take five samples and put it down to wait for the result. By the time we get the results, we don't know which patient has this result, or that one. If you can get an immediate result, you can document it."*

The CEO of the organization explains that time is an important factor, not only for the organization to work efficiently, but also for the patients. "If we cannot provide the result immediately, next time I come, they will not participate."

11.7.2.3 Clinical knowledge and test result interpretation

Depending on the user (medical professional or trained volunteer), the result has to be detailed or visual. The device could be developed in different variations or give the option to get more details about the result. Since use of the Excelscope during medical outreaches has to be quick and efficient in general, a visual presentation of the result is recommended.

Next to that, information about follow-up actions (treatment, referral to a hospital) can be included in order to support the community health workers.

11.7.2.4 mHealth opportunities

Depending on how long the NGO is going to stay in a certain community, the healthcare providers will stay for multiple day. Patients can be monitored on vital signs or recovery. Use of the Excelscope would provide qualitative information about parasitaemia and will provide the possibility to monitor parasite clearance. In that case, it might be interesting to register patient data in order to keep track of the recovery.

11.7.2.5 Robustness

Since the device will go along with the medical team, it has to be robust and portable. Roads in Nigeria are bad, the climate is humid.

11.7.3 Conclusion

The device must be kept as simple as possible, providing quick results, be robust. Potentially the feature of monitoring health can be added, but quick patient management is of main importance. The Excelscope can be supportive in providing accurate results and local malaria management. Furthermore, its use can be linked to awareness programmes on malaria diagnostics.

More research needed on needs and requirements of healthcare providers and volunteers in order to develop it for use during medical outreaches.

12

EVALUATION OF USER SCENARIOS

12.1 USER SCENARIOS

DIFFERENT SCENARIOS FOR THE STAKEHOLDERS

Based on the insights from the field study, the user scenario has been adjusted and modified per profession. The scenarios were made for further discussion with a selection of medical professionals. An explanation of the adjusted scenario and differences per stakeholder will be given.

The new user scenario (figure 12.5) has been drawn according to the conclusions of the field study into the users' needs and values. In the scenario, emphasis has been placed on information on the interface and the automated analysis. Blood sample preparation has still been included, since it is not sure whether this task can be elimated. Moreover, more insights about healthcare professionals' perspective on staining a slide was desired.

The procedure has not changed much from earlier presented procedures. The main difference is based on the choice for the automated blood sample analysis and adjustments per medical profession. The evaluation of the specific scenarios has been conducted via digital communication tools. The set up and results of this study are described in the next section.

The following adjustments or added applications have been made for each group of medical professionals, as already explained in the previous chapters:

PMVs	Decision support for treatment/referral (figure 12.1)
Medical doctors	Possibility to monitor patients' health (figure 12.2)
Pharmacists	Supply chain management module (figure 12.3)
Lab scientists	Result validation- inspection of images (figure 12.4)

Besides, the visualization of the test result differs per stakeholder: more detailed for pharmacists and doctors, more visual for pharmacists and PMVs.

FIGURE 12.1
Decision support for PMVs

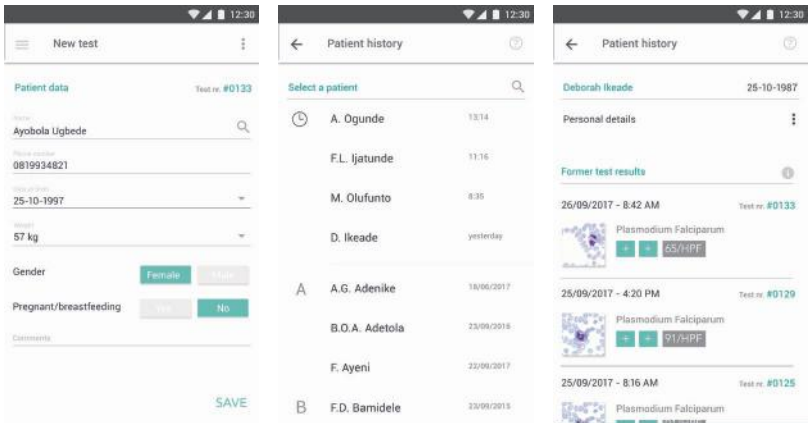


FIGURE 12.2
Electronic health records, the possibility to monitor patient's health by storing test results in the application.

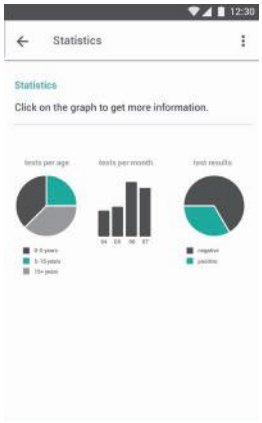


FIGURE 12.3
Supply chain management by recording test result data

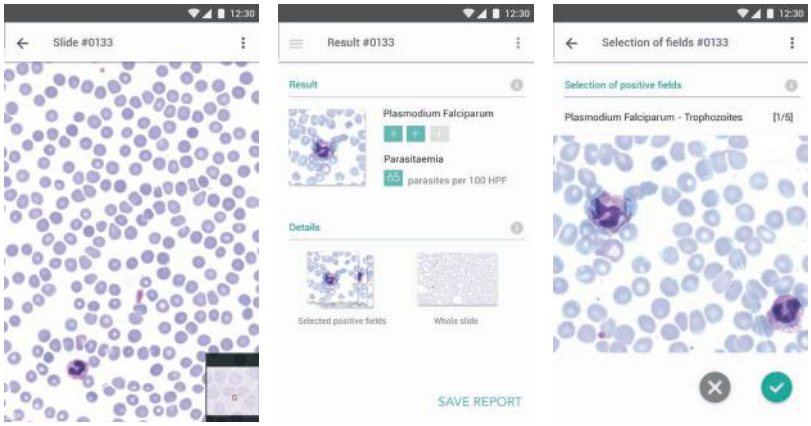


FIGURE 12.4
The possibility to validate results on the display after the Excelscope has generated the result automatically. The whole slide or a selection of positive fields can be inspected.

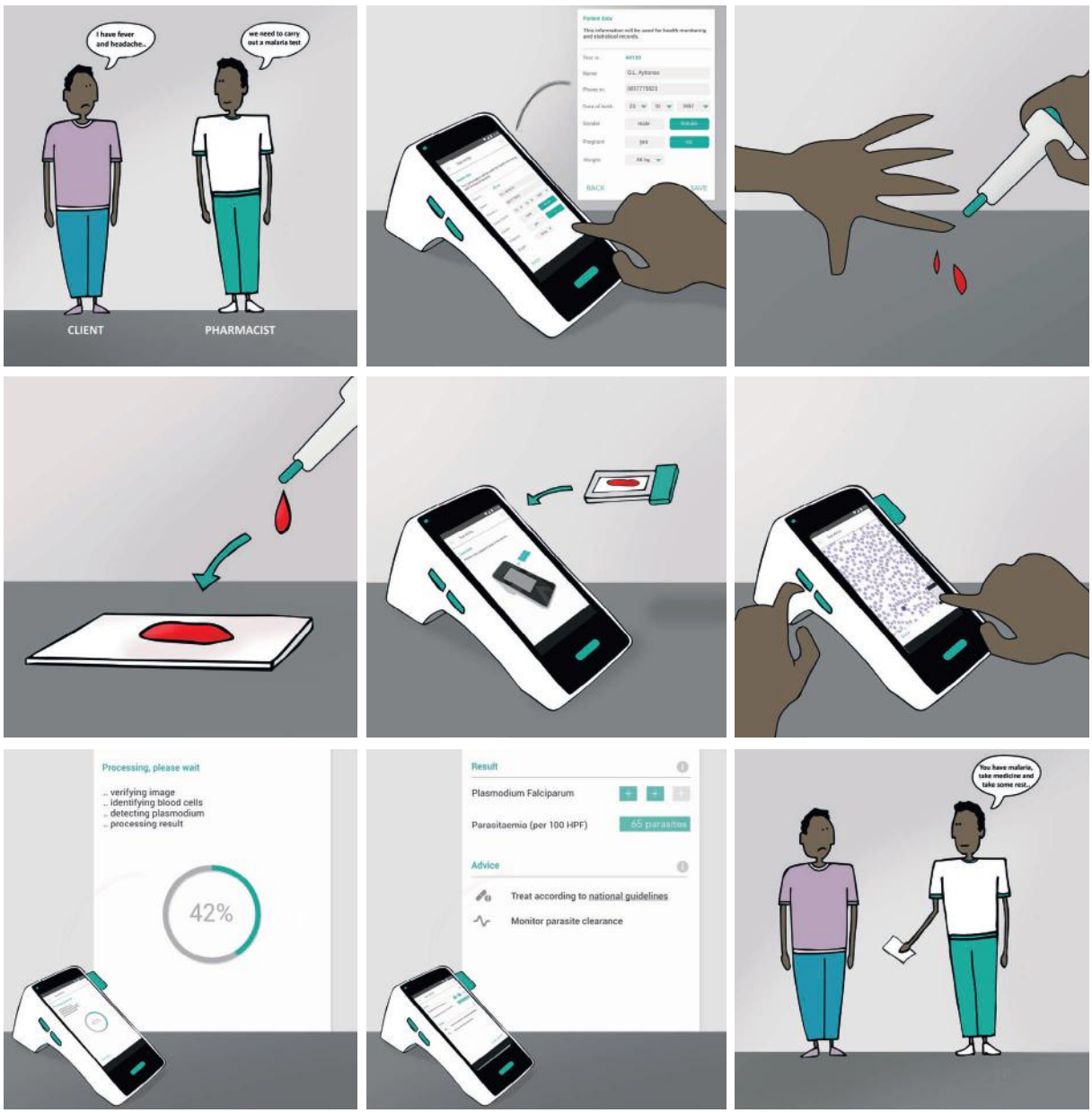


FIGURE 12.5
User scenario for the pharmacist. Scenarios for the other stakeholders differ in result visualization and mHealth application (figure 12.6). Per image, a short explanatory text was provided.

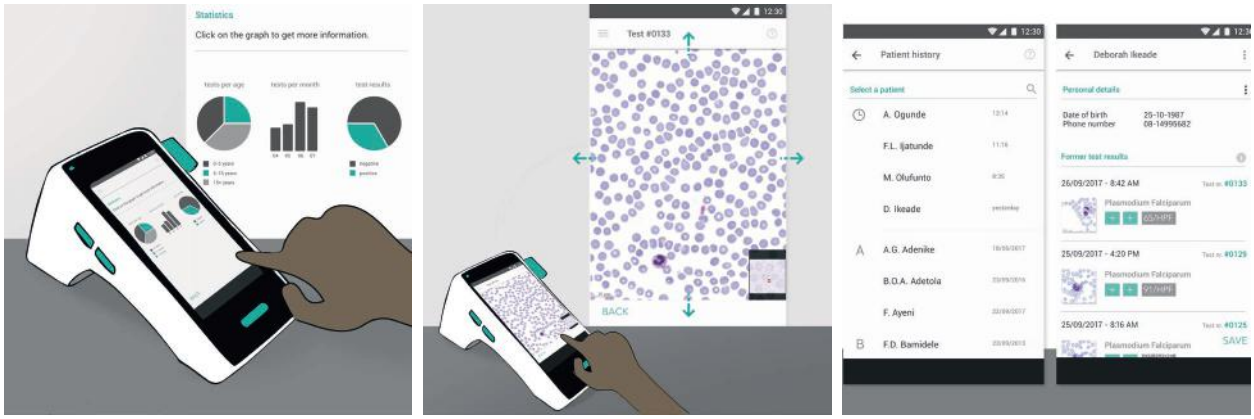


FIGURE 12.6
Different applications visualized in the user scenario for the pharmacist (left), lab scientist (middle) and doctor (right).

12.2 EVALUATION OF USER SCENARIOS

ONLINE INTERVIEWS WITH MEDICAL PROFESSIONALS

Several healthcare professionals were approached to give their opinion about the new user scenarios and information on the interfaces. The study was conducted through whatsapp and e-mail. This section describes the goal, method and results of the study.

12.2.1 Research goal

RG10 The goal of this brief evaluation study is to gain essential feedback on the improved user scenarios from different stakeholders.

12.2.2 Research questions

RQ11 What can be improved on the current scenarios?
RQ12 Do the participants understand the clinical test result?
RQ13 What do different stakeholders (pharmacists, doctors, lab scientists) think of the added modules? (health monitoring, statistics, inspecting the images)

12.2.3 Method

Participants were approached through e-mail and asked for their preference to participate via e-mail or WhatsApp. WhatsApp is the main online communication method in Nigeria. Since the majority of the Nigerians have a smartphone, it is a convenient and quick way of getting feedback. Advantages: sending images, asking questions and follow-up questions, start a discussion, refer back to previous messages.

The user scenarios- related to the profession of the participants (section 12.1) were sent to the medical professionals. The participants were asked whether anything needed to be clarified or questions already arised. Secondly, statements were given, based on the SUS questionnaire (appendix 10). The statements were adjusted in order to fit the identified interactions for the different stakeholders.

1. I need to learn a lot before being able to use the device
2. The device emphasizes the importance of my responsibility as a medical professional
3. The device helps me to provide the patient with an accurate diagnosis
4. I think that I need the support of another medical professional to be able to diagnose malaria
5. I think the device gives me enough information in order to provide a true diagnosis

(1- competent, confident; 2- confident, proud; 3- supported, trustworthiness; 4- independent, confident; 5- trust, in control)

Based on the answers of the participants, follow-up questions were asked and a discussion was started. Questions were related to the preference for information on the interfaces, the feasibility and necessity of the added modules per stakeholder and concerns with regard to the procedure.

12.2.4 Participants

Participants from the field study were asked to participate and a new group of medical professionals (doctors and pharmacists) were approached. Eight medical professionals participated in this study.

Participants from field study:	2 medical doctors
	1 nurse / lecturer public health
	2 laboratory scientist
New participants:	1 medical doctor
	2 pharmacists

12.2.5 Results

The medical professionals gave useful insights on the user scenario designs and shared their opinion about several aspects with regard to the given statements. Briefly, the most useful insights are presented.

12.2.5.1 Statements

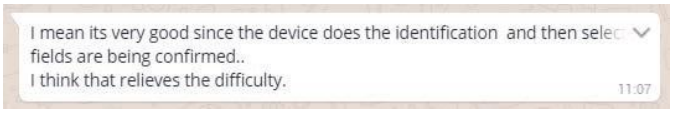
The following results were gained from the statements.

1. Usability and competence

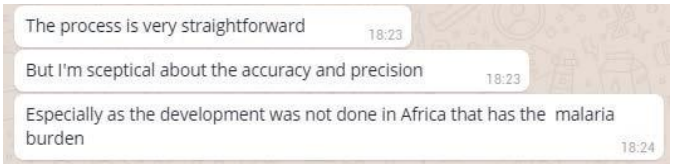
All respondents disagreed on the first statement 'I need to learn a lot before being able to use the device'. They perceive the Excelscope easy in use and consider themselves competent enough to operate it properly.

One medical doctor thought the procedure was easy, besides capturing the slide: *"Training is needed on how to capture very well. How to adjust the focus of the camera might need little explanation. I have to use it before I conclude".*

A lab scientist was concerned about the need to stain and identifying parasites. After explanation of the automatic scenario with the possibility to confirm the diagnosis, the lab scientist was enthusiastic: 'that is fantastic' and:



Although usability was not perceived as a problem, some participants had their concerns about the accuracy, as this pharmacist explained:



Development of a device in another country might be a barrier, but can be taken away when collaborating with experts in Nigeria or proof of concept within the country.

2. Confident and proud

Responses on the second statement ('the device emphasizes the importance of my responsibility as a medical professional') differed. The doctors and lab scientist disagreed on the statement, whereas the nurse and pharmacists agreed. One of the pharmacists partly agreed, *"based on the fact that a science laboratory technician can also make use of it. Which is their core responsibility".*

The two doctors mentioned that the device is so easy to use, that it can be used by any healthcare professional or even non-medical professionals (at home). Use of the device does not particularly make them proud, since being able to handle or owning it should be something that is possible for anyone.

"This helps to distribute work burden and give room for independent assessment thereby reducing bias."
- medical doctor

Although the small amount of participants is not suitable for drawing conclusions, the answers are in line with the field study: stakeholders with a less medical background tend to feel proud in use of the device, while higher educated professionals place less importance on this value.

3. Supported and trustworthiness
Most participants agreed on the statement 'The device helps me to provide the patient with an accurate diagnosis'. One of the pharmacists was concerned about co-morbidities that might exist, wherefore referral to a doctor is necessary. When the Excelscope indicates the need for referral, the perception of being supported by the device can be increased.

4. Independent & confident
The participants perceived confidence with regard to independent use of the Excelscope. One of the pharmacists mentioned the importance of a laboratory scientist in the diagnostic procedure, but only if he suspects more than just malaria present. The other pharmacist and nurse emphasize on the importance of the device being self-explanatory in order to be used independently. The doctors and laboratory scientist were condifent about using it by oneself.

5. Trustworthiness & in control
This statement is similar to statement three, although emphasis is now placed on clinical information. Not all participants agreed. One doctor mentioned the need for a diagnosis based on the combination of test result and clinical symptoms. Although use of the Excelscope would still give the control of combining the two sources, the answer on this statement shows that technology only is not trusted yet through evaluation of a conceptual user scenario.

12.2.5.2 Malaria report - clinical test result
The interviews lead to discussions on the visualization of the test result: which information needs to be shown, what is understandable, which information is used? Some responses were expected: the laboratory scientist wanted to see the parasite and did not understand the (from internet selected) given picture (figure 12.7), the doctors and pharmacists said it was all clear and alright in the first place (figure 12.8).

However, severity of the disease and parasitaemia is not yet recognized by some participants to be important on providing treatment or a follow-up. "An indication of parasite load is not necessary. If there's no improvement when the patient has taken drugs, then the patient will be given injection", as one doctor explained. This statement was given to another doctor, who disagreed. He repeatedly mentioned the need for severity or parasitaemia indication as the result of a test. The different answers show that knowledge and approach from stakeholders of the same profession can already differ a lot. Therefore, more in-depth interviews with medical professionals have to be conducted to develop the right information and training. Figure 12.9 shows different interfaces that were discussed with the participants as well as their response to it.

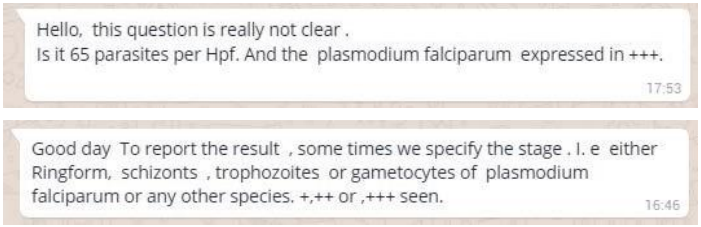


FIGURE 12.7
A laboratory scientist did not understand the given result, and (the next day) explained how a result is normally reported.

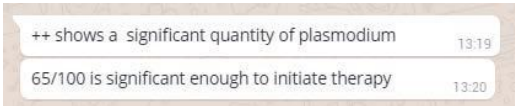


FIGURE 12.8
A pharmacist was asked to interpret the visualization of the clinical test result.

12.2.5.3 mHealth applications
Three mHealth applications were discussed: verification of test result (lab scientists), electronic health records (medical doctors and nurses) and supply chain management (pharmacists). The applications have been proposed in order to build incentive or increase acceptance from medical stakeholders for use of the Excelscope.

With regard to patient's health monitoring, a doctor and nurse preferred to leave the function out of the device, since it is just an addition to the main advantage of the Excelscope: parasite detection. They did not see the significant value from the applications to the main function. A similar answer was given by the pharmacist, who mentioned that statistical records can be useful for research, but there is no other reason to do so.

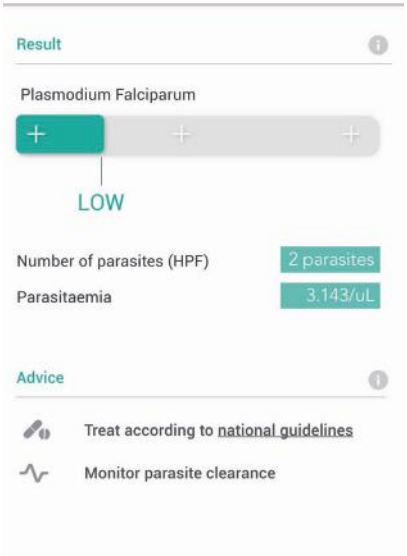
The addition of extra modules needs further discussion. Although it might be interesting for some stakeholders, accurate parasite detection must be the key focus in the development. Integration of a smartphone provides the possibility to develop and add extra applications easily in later stages. Nonetheless, it is important to get a grasp on possible enablers in advance of large implementation of the device. For example, supply chain management might not be interesting for one pharmacist, but can motivate another pharmacist to actually obtain the device.

12.2.6 Discussion
The small sample of participants does not provide significant result to state conclusions about the user scenarios. The variety of answers showed that the interpretation of a smart device differs per person. It cannot be stated which aspects causes the difference; whether this is caused by level of education, type of health centre, cultural values or other influences. It is recommended to do more research on stakeholders' perception on a larger scale.

To overcome different needs, the application can be developed personalizable: giving the possibility to add modules and make it as advanced as desired. This partly answers RQ11 and RQ13: the scenarios can be improved by not specifically designing the applications for each stakeholder, but create more generic modules that can be added later on.

Discussion about the clinical test result visualization lead to different opinions about the amount of information [RQ12]. Yet, healthcare providers might not be aware of the importance of specific clinical information. The Excelscope can complement the health worker's clinical knowledge. Therefore, more expert interviews have to be conducted in order to find the most important information that should always be given to the user.

A discussion about the method of this study will be given in the overall discussion in chapter 14.2.

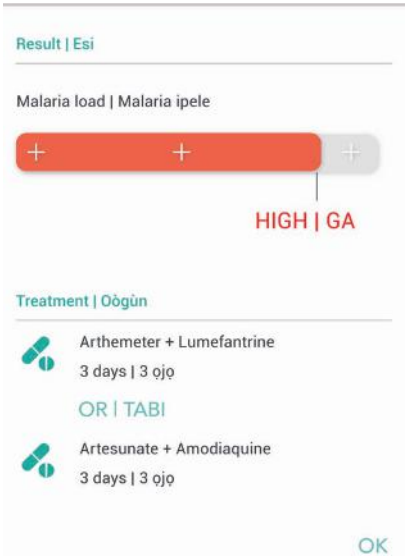


Doctor: "The expectation is that Excelscope will reveal the parasite if present.. and quantify the load of the parasite. Those information are adequate for any health care giver to decide on diagnosis of malaria"

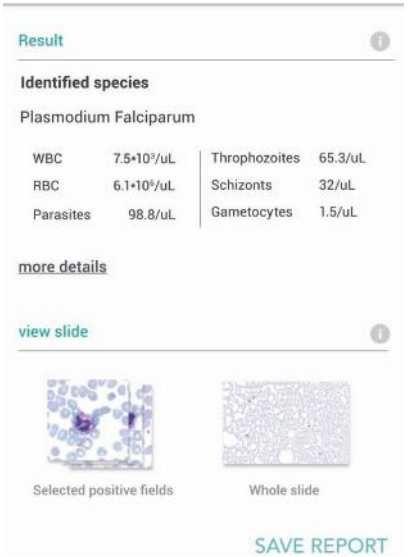
Doctor: "Is fine....But my concern is just that.....At what number of parasites will patients start taking antimalarial...

Doctor: "The device like other investigation are complimentary to clinical evaluation and not a stand-alone for diagnosis."

Pharmacist: "At low parasite level the person might not develop symptoms. The reason is this, our country is malaria endemic region."



Pharmacist :It's not necessary to indicate the treatment,because drugs might keep changing due to some factors like resistance.Or else you'll need to keep modifying your device from time to time..



Doctor: As long as the device is standardized... and giving accurate results... It builds trust... Which is the most important. ...it's only doctors or laboratory scientists that may want to probe further by requesting for the images....

Lab scientist: "Please , i don't understand this image. Can you put an arrow to show the parasite"

FIGURE 12.9
Different result visualizations were sent to the participants of the study, who gave their opinions about the designs and included information.

13

SUMMARY

SUMMARY OF THE INSIGHTS FROM THE USER STUDY

The perspective of all defined stakeholder groups have been combined and summarized in a visual overview. The conclusions can be used for further research and recommendations on development and implementation of the Excelscope.

13.1.1 Summary

Figure 13.1 gives a summary of the findings and shows differences and similarities between the healthcare providers. Both laboratory scientists and doctors are for example seeking for support and control in the procedure, while lab scientists thereby mainly want to be relieved from the stress in their work. Healthcare providers with less medical education (nurses, pharmacists, PMVs) want to feel competent and confident in use of a smart device.

The expressed values lead to product development ideas, mHealth opportunities and insights in specific training that needs to be provided when designing for a specific group of healthcare professionals. Besides the opportunities for implementation and further development of the Excelscope and service around it, there are several challenges to overcome for specific target groups or development of the device in general.

13.1.2 Stakeholders

This study elaborated on four of the six described stakeholders. More research on use by nurses and medical volunteers is recommended in order to give a total analysis of healthcare professionals in Nigeria.

Use of the Excelscope by PMVs will increase access to malaria diagnostics in rural and urban communities. However, the product, service and policy have to undergo development and many changes before it can be feasible for PMVs. To gain acceptance and make it easy scalability, it might be better to focus on medical doctors in the first place. From there on, the use can be extended to nurses, pharmacists, NGOs and PMVs.

13.1.3 Smartness of the Excelscope

In general, an automated analysis is more preferred than a (remote) manual or semi-automatic analysis, for the sake of time, effort, available resources and facilities. A remote analysis through telemedicine was rejected due to concerns about the availability of pathologists and time-consumption. However, a semi-automated analysis was preferred by lab scientists and medical doctors if it could be confirmed in person at the point-of-care.

As stated in the context analysis, use of the Excelscope would be most suitable in primary healthcare settings, pharmacies/medicine stores or by medical outreaches. In that context, the Excelscope has to be developed into an automated point-of-care device in order to be valuable and accepted by the user.

13.1.4 Applications

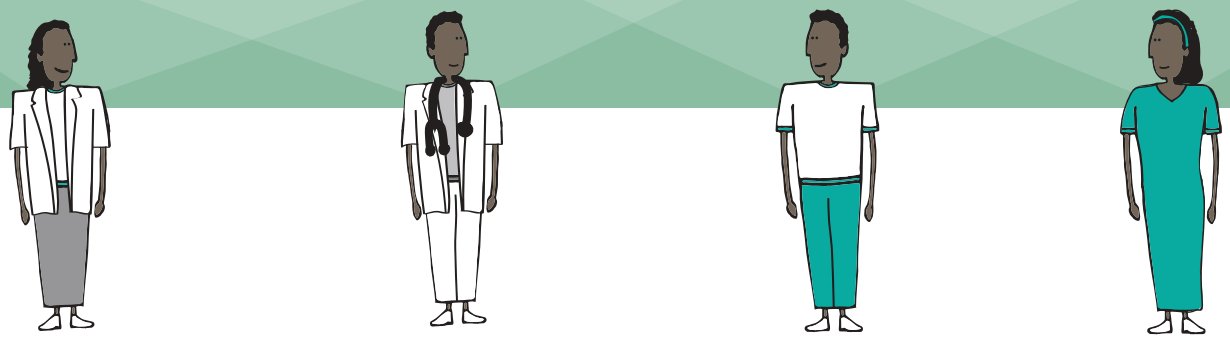
Acceptance towards- and incentives for use of the Excelscope might increase when applications, suiting the stakeholders' interest and practice, are added. mHealth applications such as decision support on treatment and referrals, electronic health records and supply chain management can be developed.

Therefore, it extends the device's abilities in line with main purpose of clincial tests, as described in section 8.1.2, and supports tasks such as monitoring treatment effectiveness and selection of appropriate treatment. This could also increase a sense of confidence and support. Nonetheless, the aim of the device is to enhance access to accurate malaria diagnostics, which should always be the main goal of development of the device. Whether applications can enhance acceptance from different stakeholders needs further research.

FIGURE 13.1
Summary of the challenges and opportunities for development of the Excelscope for different stakeholders.

VALUES

RELIEVED IN CONTROL SUPPORTED INDEPENDENT PROUD CONFIDENT COMPETENT



laboratory scientist | medical doctor | community pharmacist | PMV

CHALLENGES

TRUST

Especially lab scientists are sceptical about specificity and sensitivity of an automated diagnostic analysis.

TASKS

The procedure has to be as effortless and quick as possible in order to gain maximum acceptance from different stakeholders.

TIME

COSTS

A business model has to be developed to make testing affordable for caregiver and patient.

KNOWLEDGE

Knowledge on clinical symptoms, treatment and referral is required for proper malaria management.

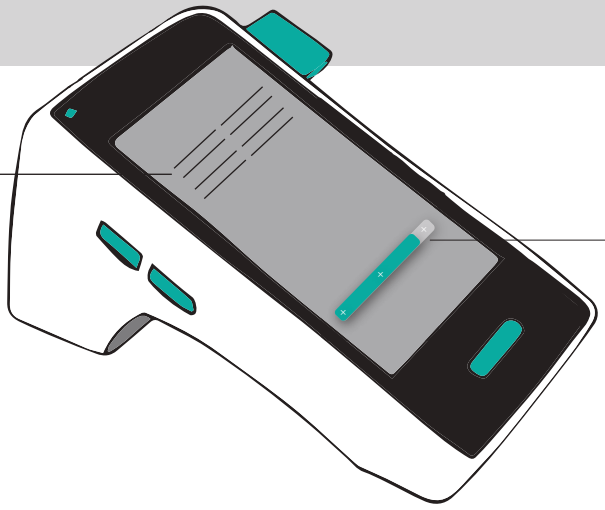
REGULATONS

Regulating use of an automated device in general is a challenge; use by non-medical professionals will be another challenge.

DETAILED INFORMATION

Provide detailed information about the test result to doctors and lab scientists

The test result can add on the doctor's clinical knowledge and improve diagnostic decisions.
(12.2.5.2)



PICTORIALS

Include visuals to explain procedure and test result to low level healthcare providers

Result validation

A semi-automated analysis increases efficiency and reduces workload in medical laboratories.

Electronic health records

The Excelscope can be used to monitor the patient's health efficiently by recalling former test results.

Supply chain management

Add the possibility to save results and record statistical data for supply chain mangement of antimalaria drugs.

Treatment support

Develop a module that generates treatment advice based on patient data and the test result for users without a medical background.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CONCLUSION

14

CONCLUSION

This study showed that acceptance and use of a device does not only depend on its accuracy and accessibility, but on the attitude, incentives and behaviour of the user as well.

The findings of the three analyses lead to a roadmap that captures all findings and shows the connections between technology, context and user. The roadmap is being provided in a digital, interactive way, through which the connections can be discovered. The tool can be used by all stakeholders in the research, development and implementation processes of the Excelscope.

Besides the interactive version, a hardcopy roadmap is provided. The poster does not show direct cause and interaction between the elements, but gives an overview of all things that have to be considered in the process. It visualizes the main elements related to technology, context and user.

The results of this study will be discussed in chapter 14.2. Next to the results, the impact of the Excelscope, research approach and relevance of this study will be discussed. The project will be concluded with recommendations for further research and development of the Excelscope.

14.1 ROADMAP

CONNECTING TECHNOLOGY, CONTEXT AND USER

A roadmap has been developed to summarize all findings of the study in a visual overview. The overview can be used in further development of the Excelscope, by giving recommendations related to contexts of use and users, including barriers to overcome and m-health opportunities. Therefore, it captures insights from the three parts: technology, context and user.

The roadmap is divided into the three main parts of the research: technology, context and user, and shows how all elements intertwine and influence each other. It is available in an online interactive version as well as a physical poster. The roadmap invites the reader to choose for a point of focus: developing for a specific context or user, or taking the state of technology development as a fist focus point. Consequently, the relation with other elements can be discovered.

14.1.1 Interactive and hardcopy roadmap

The two versions of the roadmap are different in use and understanding.

14.1.1.1 Interactive roadmap

The interactive roadmap can be viewed in a web browser (https://invis.io/U7EB8WZVA). By hovering over the different icons, more information about that element can be read. Furthermore, the relationship between the categories will be shown. The roadmap can be discovered step by step, by (de)selecting the categories on the left side.

Technology

When hovering over a technological aspect (e.g. one of the given tasks), the possible context(s) of use and user will be shown. It gives the influence on technological development on feasibility and coverage. The attitude from healthcare professionals towards the task or development is visualized in thumbs up/down or hearts (to visualize that caregivers 'love' the development).

Context

Choosing for focus on a healthcare facility (e.g. hospital) highlights the required technological developments. It shows how the technology has to be developed in order to make the device usable in a specific infrastructure level. Hovering over a healthcare facility provides a short description about the infrastructure and healthcare professionals working at the facility.

User

Hovering over a user group (e.g. pharmacist) gives the most information. Besides technological developments and contexts of use, a persona is generated including values, incentives and required training. Ideas for product development and business strategies are added.

11.1.1.2 Hardcopy roadmap

The poster (provided with this report) includes most of the information that has been given in the interactive roadmap, but shows it all in one picture. By following arrows, the relationships between the different elements can be discovered. The richness of the interactive model could not be reached in the poster version.

This section provides conclusions about each level of the roadmap and explains the visualized connections.

14.1.2 Technology

14.1.2.1 Diagnostic analysis scenario

This study aimed for finding the preferred and most accepted scenario for slide analysis: manual, semi-automatic or automatic analysis. Overall, the automatic scenario was preferred by the medical professionals participating in this study. Besides the opinion of the participants, the automatic scenario brings most opportunities for use in low resource settings and projects on the future in terms of similar innovations in the field of point of care devices.

14.1.2.2 Tasks

Three tasks in the workflow of the current concept have been highlighted in the roadmap. If the tasks can be eliminated, time will reduce accordingly and acceptance will increase, since the stakeholders want to have a device that is easy to use and time-saving. Short procedural time is mostly desired by pharmacists, PMVs and by volunteers in medical outreaches.

Imaging

It is highly recommended to automate the imaging process or reduce the amount of steps (move the slide, take a picture, move the slide, etc) as much as possible. The most preferred scenario is a one-shot image of high resolution, to capture the slide at once and zoom digitally. However, this requires more advanced technology.

Sample preparation

Blood sample preparation requires precision, time and equipment. Although it brings opportunities for the design of an easy-to-use staining kit, innovative solutions for quick staining and drying methods and providing training, it will probably be a barrier in acceptance of the Excelscope.

Cleaning and maintenance

The glass slide will touch the magnifying lens, wherefore it needs to be cleaned on a regular basis. Cleaning requires precision and motivation for maintenance, and is expected to be a barrier in use. This task might be not a problem in less endemic areas, where tests are not being done regularly, therefore reducing the necessity to clean the device on a daily basis. Since this element has not been taken into account during the field study, more research on usability and acceptance on this part is recommended. Other maintenance tasks might have to be defined and – if possible, reduced to a minimum. This will enhance use at low infrastructure settings and improve acceptance from users.

14.1.3 Context

Development of the Excelscope opens possibilities for use in lower infrastructure levels and lower (medical) skilled staff. Reducing the amount of tasks- therefore the amount of necessary resources- makes it possible to move from advanced settings (where internet and water are available) to minimal facilities in urban and rural areas. In the latter, there is often a lack of skilled medical professionals. However, an automated device that needs limited actions or facilities will allow any health worker to use the device (after having done the necessary training).

14.1.3.1 Remote or point-of-care analysis
In a manual or semi-automatic analysis, a human expert is involved in the diagnostic process. This expert can be available on the point-of-care, which will most probably be limited to advanced or moderate settings. Remote analysis or confirmation is possible to, yet difficult in terms of internet connection and availability of the expert on an external location. Both scenarios are time-consuming.

14.1.3.2 Coverage
Coverage will increase significantly when the Excelscope can be used in minimal or low infrastructure settings (in urban and rural areas).

14.1.4 User
The roadmap gives different incentives for the stakeholders to make use of the device. Whereas doctors want to be independent, PMVs are seeking for a feeling of competency in use of the device. These aspects can be taken into consideration in further development of the device and application. Different concerns and values of stakeholders are added to elements of the roadmap.

14.1.4.1 Training
In all possible scenarios of use, training is required for appropriate use of the Excelscope. Training can and has to be provided on different topics, depending on the user's (clinical) knowledge).

Interpreting digital images of blood slides
Digital images will probably be different than a view through the microscope. Laboratory scientists have to be trained on how to interpret the images and learn about the possible differences. More reseach about the differences has to be done.

Blood sample preparation
If conventional staining techniques are required for use of the Excelscope, training has to be provided to each stakeholder besides lab scientists. It is passumed that Pharmacists, NGOs and PMVs will only use the device in a non-staining procedure, so training does not have to be developed for these caregivers.

Community awareness
Caregivers play an essential role in providing information about diagnostics, empowering community members to get tested and creating awareness for the importance. A training programme can include workshops about community sensitization towards the smart device and how to communicate the working principle or accuracy to (potential) clients or patients.

Clinical knowledge
When targeting healthcare providers with less clinical skills (such as pharmacists, community health workers), training on clinical knowledge about malaria and related diseases has to be provided. Healthcare providers have to be able to distinguish low and high severity for proper referral to other facilities.

Treatment
Related to training on clinical knowledge, information about how to treat according to national guidelines has to be given. This includes: treatment for uncomplicated and severe malaria, treatment for special cases, risks and presence of drug resistance, quality control and awareness for future changes in treatment guidelines [66].

Pricing and business
Depending on the business model, healthcare providers might be able to price the tests themselves. It is recommended to organize a workshop on how to manage costs for use of the device and disposables versus test fees for patients, yet keeping it affordable for community members.

14.1.4.2 Applications
The Excelscope can leverage the advantages of the smartphone and include mHealth applications. The applications can enhance motivation for use of the Excelscope by providing support in business or practice. The solutions can extend the knowledge and abilities of the user, and add to the training.

Online training and info
A digital manual can provide clinical information and info about use.

Electronic health records
Patient data can be saved to the device for monitoring parasite clearance, recall former test results and make statistical diagnostic records.

Supply chain management
Keep track of test results in order to manage the antimalarials in stock.

Telemedicine
Since a(n external) lab scientist is not involved in the clinical procedure anymore when the diagnosis is provided automatically, it can be interesting to add a telemedicine option. In case of doubt about a patient, a remote physician can be consulted. This will bring benefits to rural areas, if (internet) connection is available. However, physicians need to be available too.

Decision support
Clinical decision support could also be included in the application by automatically generated instructions about clinical interventions: a warning for referral in case of high severity or pregnancy, for example.

Treatment support
Similar to decision support, treatment advice according to national guidelines can be given, based on the test result and patient characteristics. However, the device has to be connected to the inernet regularly to update treatment policy with regard to drug resistance.

14.1.5 Business strategies
The project did not focus on business strategies, but ideas with regard to business models were generated throughout the study. They have not been included in the roadmap, since the acceptance and feasibility have not been evaluated. However, some ideas can be given for future development on this aspect.

Compatability
Make the device compatible with disposables, if these are needed. It will provide a constant revenue stream for the supplier and the possibility to build on customer relationship.

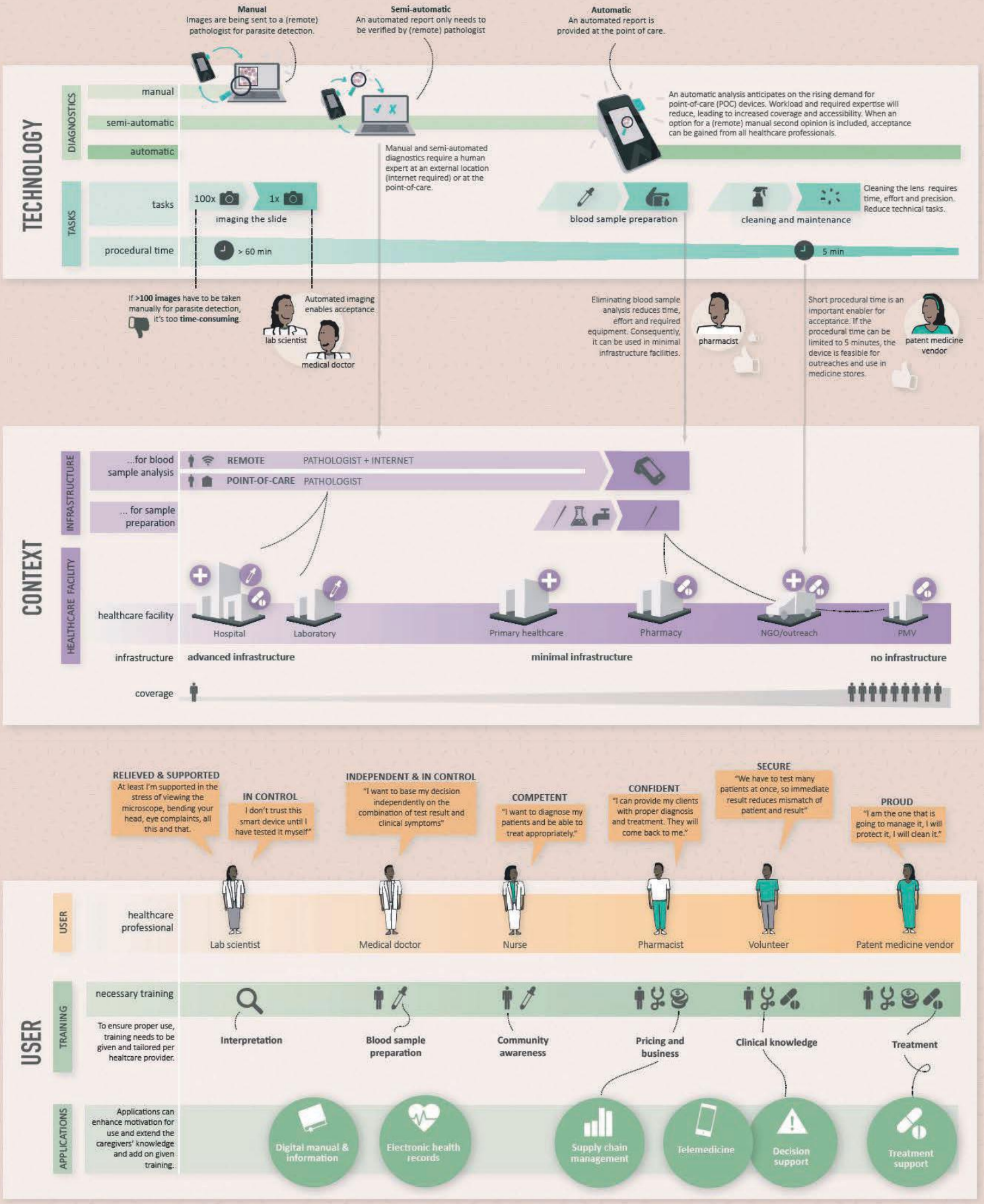
Fee per (prepaid) test
A package of tests can be bought through a prepaid service, or tests can be bought individually. The caregiver/facility can decide on the fee for patients.

Reward system
To motivate caregivers to use the Excelscope, rewards can be given if a certain amount of tests has been conducted.

Lease
A product-service system asks for a fee per month or year, and provides the user with disposables, maintenance and training.

Add ons
Applications can be added according to the user's desire. The caregiver can personalize the device by buying different 'add ons'.

14.1.6 Conclusion
The roadmap visualizes all defined aspects that are importnt to take into account when developing the Excelscope for a specific healthcare facility or caregiver. More elements can possibly be defined when doing more research or development on the project. Elements can be added to the roadmap's framework of technology, context and user. Potentially, 'business' can be added as a fourth tier.


TECHNOLOGY
DIAGNOSTICS
manual
semi-automatic
automatic
Manual
Images are being sent to a (remote) pathologist for parasite detection.
Semi-automatic
An automated report only needs to be verified by (remote) pathologist
Automatic
An automated report is provided at the point of care.
An automatic analysis anticipates on the rising demand for point-of-care (POC) devices. Workload and required expertise will reduce, leading to increased coverage and accessibility. When an option for a (remote) manual second opinion is included, acceptance can be gained from all healthcare professionals.
Manual and semi-automated diagnostics require a human expert at an external location (internet required) or at the point-of-care.
TASKS
tasks
100x
1x
imaging the slide
blood sample preparation
cleaning and maintenance
Cleaning the lens requires time, effort and precision. Reduce technical tasks.
procedural time
> 60 min
5 min
If >100 images have to be taken manually for parasite detection, it's too time-consuming.
Automated imaging enables acceptance
lab scientist
medical doctor
Eliminating blood sample analysis reduces time, effort and required equipment. Consequently, it can be used in minimal infrastructure facilities.
pharmacist
Short procedural time is an important enabler for acceptance. If the procedural time can be limited to 5 minutes, the device is feasible for outreaches and use in medicine stores.
patent medicine vendor
CONTEXT
INFRASTRUCTURE
...for blood sample analysis
REMOTE PATHOLOGIST + INTERNET
POINT-OF-CARE PATHOLOGIST
... for sample preparation
HEALTHCARE FACILITY
healthcare facility
Hospital
Laboratory
Primary healthcare
Pharmacy
NGO/outreach
PMV
infrastructure
advanced infrastructure
minimal infrastructure
no infrastructure
coverage
USER
RELIEVED & SUPPORTED
At least I'm supported in the stress of viewing the microscope, bending your head, eye complaints, all this and that.
IN CONTROL
I don't trust this smart device until I have tested it myself"
INDEPENDENT & IN CONTROL
"I want to base my decision independently on the combination of test result and clinical symptoms"
COMPETENT
"I want to diagnose my patients and be able to treat appropriately."
CONFIDENT
"I can provide my clients with proper diagnosis and treatment. They will come back to me."
SECURE
"We have to test many patients at once, so immediate result reduces mismatch of patient and result"
PROUD
"I am the one that is going to manage it, I will protect it, I will clean it."
USER
healthcare professional
Lab scientist
Medical doctor
Nurse
Pharmacist
Volunteer
Patent medicine vendor
TRAINING
necessary training
To ensure proper use, training needs to be given and tailored per healtcare provider.
Interpretation
Blood sample preparation
Community awareness
Pricing and business
Clinical knowledge
Treatment
APPLICATIONS
Applications can enhance motivation for use and extend the caregivers' knowledge and add on given training.
Digital manual & information
Electronic health records
Supply chain management
Telemedicine
Decision support
Treatment support

14.2 DISCUSSION

ASSUMPTIONS, METHODS AND RESULTS

This study aimed for getting insights in the Nigerian healthcare system and finding barriers and enablers for acceptance of a smart malaria diagnostic device. An explorative, qualitative research approach was conducted through semi-structured interviews and observations. The study lead to a roadmap wherein connections between technology, context and user are visualized. A discussion for the findings and approach for each of the three parts of the project will be given.

TECHNOLOGY

FINDINGS

14.2.1 Comparison to assumptions and the research in Uganda
In advance of the field study in Nigeria, the three scenarios for blood sample analysis were already evaluated. Furthermore, the study proceeded on knowledge from the study in Uganda (by team Excelsior). Briefly, the preliminary knowledge and analysis will be compared to the final results.

Based on the preliminary evaluation of the three smart scenarios, it was assumed that a semi-automated analysis would be most accepted by healthcare providers in Nigeria. Since little was known about the healthcare system in Nigeria, a specific user had not been defined yet. However, the assumed users were doctors, nurses and remote laboratory scientists. This project identified more potential target groups and studied their values and concerns with regard to the Excelscope.

JMP Team Excelsior developed the concept for the Excelscope by doing research in Uganda. The device was developed for use by community health workers and nurses, who can be trained on staining blood samples. Although this research did not focus necessarily on use of the Excelscope by nurses and community health workers, it is doubted whether blood sample preparation can be done accurately and will be accepted by these healthcare providers. Besides the skills of the health workers, staining is dependent on the facilities' infrastructure and amount of time that a) the caregiver wants to spend and b) the patient wants to wait.

Several disadvantages and concerns that were given by Team Excelsior meet the findings from the field study in Nigeria: internet connection, procedural time and checking all fields-of-view are barriers for use of the device. Furthermore, an automated analysis via artificial analysis algorithms has been suggested to be the most applicable by the research in Uganda and this study in Nigeria.

APPROACH

14.2.2 Preliminary analysis
The preliminary analysis existed of a literature study, several interviews and a comparison on the different scenarios. The analysis on different aspects (focus on technology and context) was useful to immerse in the topic and get understanding of malaria diagnostics. However, the analysis could have been done somewhat more effectively and efficiently, since some elements of the concept, ideas and technology where missed upon. A more extensive session with the JMP team who developed the concept as well as the team that currently works on the technology could have been scheduled in order to understand the concept completely. Instead of proceeding the analysis phase throughout the whole project, a final analysis report could have been finished earlier in the process. Yet, some 'naiveness' about the concept might have led to new ideas, instead of being directed too much from the beginning.

14.2.3 eHealth and smart devices
Chapter 3.1 distinguished the different definitions related to eHealth and clarified the different applications. The study was useful to create consistency and clarity in the project, as well as generating ideas for Excelscope applications.

A brief technology comparison was been done in order to place the Excelscope in perspective of the innovation concerning malaria diagnostics. It was found that an integrated device does not exist yet. Although the study might not seem to be extremely relevant for the study into user acceptance and implementation, the study shows the knowledge gap on user research. Furthermore, the overview can be used by future stakeholders (students, researchers) working on development of the Excelscope.

CONTEXT

FINDINGS

14.2.4 Implementation
This research focused mostly on public healthcare centres. When developing for the public sector, it is recommended to focus on acceptance from the federal government and implementation in tertiary levels first. Besides organizational and regulatory reasons, doctors in higher levels of healthcare might feel passed if the Excelscope is being introduced in lower levels or pharmacies first. This question requires more research to be answered.

Initial implementation can be a slow process due to the hierarchical structure. However, once the device is accepted by the government and ready to be used, it can be scaled quickly. The private sector, at the other hand, is easier for quick implementation, yet more difficult to scale.

This study could have focused more on the private sector to get more knowledge and insights on the challenges and opportunities in private clinics and perspective of caregivers working in these facilities. Private clinics might have different incentives, since they are more profit focused and normally employ less people. The Excelscope can attract patients and reduce workload in the clinics. However, these assumptions were made after the field trip and have not been studied yet. More research has to be done on potential implementation of the Excelscope in private clinics.

14.2.5 Impact
The study into malaria and malaria diagnostics was done by preliminary online interviews, literature research and the field study. Besides general insights on the disease and burden of illness, the most striking results were related to people's perspective towards malaria diagnostics and treatment. For several reasons, people take antimalarials without getting tested. Reasons are limited (financial) access to diagnostic tests, not trust in test results or being convinced of self-diagnostic abilities. The government promotes rapid diagnostic tests through community pharmacists.

Malaria management is a complex system of awareness and adherence on different levels (prevention, diagnostics, treatment). Furthermore, the availability of over-the-counter drugs and resistance to several antimalarials make management of this device even more difficult. When the Excelscope is being introduced, it can best be provided in combination with awareness and promotion programmes. A diagnostic device only will not bring sufficient enough impact: when access to diagnostics is maximized, it will not necessarily mean that the coverage of people that let themselves getting tested is maximal as well.

Nonetheless, the Excelscope can actually have a great impact and the device can be used for creating awareness and empowerment for malaria test, especially when this is done at community level in urban and rural areas.

APPROACH

14.2.6 Nigeria
Preparation for the field study
The field study was conducted in Nigeria. To immerse in the context, Nigerians were approached through social platforms and interviewed about their perspective on the Nigerian healthcare system and malaria. The interviews were useful to get insights, make assumptions and shape the research questions. During the field trip, the (on beforehand approached) locals were helpful and hospitable in showing the city and their lives. It is recommended to get into contact with some people beforehand, especially when travelling alone. The warm replies lead to a comfortable stay. Preparation for observations and interviews will be discussed in section 14.2.11.

Country profile
The country profile was made in order to give an image of the context of this project. Initially, a more extensive study was conducted. However, extensive information about the political system and economy is not relevant for the goal of the project. Therefore, the analysis was reduced to a general overview and aspects that might be relevant for the research. Although some interesting aspects were identified, these have not further been elaborated on. The country profile indicates that it is useful to define potential cultural influencing factors, but could have identified earlier in the process in order to be tested in the field.

USER

FINDINGS

14.2.7 User
This study aimed for defining users for the Excelscope in Nigeria and discover barriers and enablers for acceptance of the technology. The comparison of three levels of smartness for the diagnostic procedure was one of the main aspects of the study. Since the study has been explorative and the sample of participants was relatively small, the conclusions have to be interpreted as suggestions for further development and research.

Based on the preliminary evaluation of the three smart scenarios, it was assumed that a semi-automated analysis would be most accepted by healthcare providers in Nigeria. Since little was known about the healthcare system in Nigeria, a specific user had not been defined yet. However, the assumed users were doctors, nurses and remote laboratory scientists. The field research identified pharmacists and patent medicine vendors as potential users as well, and brought a new perspective on the lab scientist as the main user (instead of being an external expert). More research has to be done on nurses and community health workers.

14.2.8 Tasks
JMP Team Excelsior developed the concept for the Excelscope by doing research in Uganda. The device was developed for use by community health workers and nurses, who can be trained on staining blood samples. Although this research did not focus necessarily on use of the Excelscope by nurses and community health workers, it is doubted whether blood sample preparation can be done accurately and will be accepted by these healthcare providers. Besides the skills of the health workers, staining is dependent on the facilities' infrastructure and amount of time that the caregiver wants to spend and the patient wants to wait. This study suggested to eliminate technical tasks as much as possible. It will enable use by low-level medical professionals.

Although specific suggestions for eliminating the tasks have been given, the actual acceptance of these tasks has only been discussed with the stakeholders. The feasibility and accuracy could not be tested due to the low prototype fidelity. If technical tasks, such as blood sample preparation or manual imaging cannot be eliminated from the procedure, more research has to be conducted in order to develop the device and user scenario in such a way that it can be used by the intended user.

14.2.9 Interpretation of negative test results
During interviews and a digital evaluation study, interpretation of clinical test results has been discussed. However, although adherence to negative test results was defined as a problem in the initial analysis, little emphasis has been placed on interpretation and interventions on a negative test result. When discussing test result visualization, more attention was given to the necessary elements (e.g. parasitaemia, species). More focus could have been placed on how to communicate negative test results in a trustworthy way, or how to improve caregiver compliance on these diagnoses.

14.2.10 Barriers and enablers
For each target group, barriers and enablers for use of the Excelscope were defined. These elements were derived from the research approach and a selection of qualitative tools. More barriers and enablers could be identified by use of different methods or more specific research into one of the stakeholder groups.

APPROACH

14.2.11 Preparation
It was difficult to prepare the field study in advance very well, since the context was not familiar. Some tools were designed and adjusted when after arrival in Ibadan and getting feedback from students and staff on the faculty of Public Health. Because of limited knowledge on the context, targets for participants and the amount of interviews had not been defined yet. It would have been good to think this through in advance or discuss it with supervisors in Delft, instead of relying too much on the help and initiative from the faculty of Public Health. Although 29 interviews have been conducted, the feeling remains that more interviews and observations could have been done.

14.2.12 Semi-structured interviews
An interview guide with questions related to the research goals was prepared for the interviews. It gave some guidance during the interviews, but left room for going into other topics or discussing subjects that were not yet included. For explorative and qualitative research, the semi-structured interview is a good method for gaining diverged information on a topic.

Yet, only 1-on-1 interviews were held, which gave a lot of different views on malaria diagnostics and the device. It would be interesting to conduct a focus group session with different stakeholders, in order to respond to each other's ideas and potentially find consensus on e.g. the kind of information that is needed for a proper diagnosis.

Throughout the study, most of the tools and interview structure were kept the same. At the end, the interface design was included in the interviews. It might have been good to set up an initial target for a first and second 'round' of interviews with some time for analysis in between. In that way, more knowledge gaps might have been found and interview questions could have been developed more specifically.

14.2.13 Storyboards
The three scenarios for blood sample analysis were explained by use of storyboads. They were always given in the same order, since it is a logical way of explaining the concept and different options. However, this might have influenced the perception of the participants (e.g. increase of the smartness might lead to respective perception of a better solution). The sample is too small and various (many different professions) to have been able to conduct a comparative study on this aspect. Yet, it is something to keep in mind in folow-up or similar studies.

The scenarios were not completely consistent. The first scenario included an image in which the result was communicated to the patient, while the second scenario missed this image. This might have confused or influenced participants' perception of the procedure.

In all interviews, all three storyboards were presented. It would have been interesting to only show (e.g.) the second scenario, to discuss the procedure, before presenting the other options. This would leave room for the participant to express concerns or give ideas that might somewhat be related to other scenarios.

14.2.14 Adjectives
In advance of describing the different storyboards, a list of 32 was presented to the participants, from which the three most important ones had to be chosen. This tool enabled some discussion about the values of the caregivers with regard to diagnostic devices. Some remarks have to be given on this tool.

- First of all, the list contained some words that were rather similar (e.g. cheap / affordable, easy / easy to use). Although the words can be perceived differently, it was confusing for some participants. The tool can be improved by reviewing the whole and eliminating (almost) similar adjectives.

- The adjectives were interpreted differently, which makes it more difficult to compare the answers. Although quantitative analysis of these results is not possible, the tool was valuable for further questions and qualitative analysis in combination with sayings from the particpants.
- The given answers were relatively obvious. The most explicit adjectives were chosen (e.g. cheap, easy to use, reliable). When aiming for insights about interaction qualities or personal values, this kind of words have to be taken out of the questionnaire (therefore, the feeling cards were added later on).
- The list of adjectives might have biased the participants in the second questionnaire, wherein the three scenarios had to be rated on adjectives that were already presented in the first list. They had already been asked to think about their perspective on important aspects. It is not sure whether the tool has influenced the other (and whether this is negative or positive), but use of similar elements in different methods has to be considered in advance of a (follow-up) research.

14.2.15 Questionnaire

After explanation of the Excelscope, a questionnaire was presented for comparison of the three scenarios. A list of seven adjective-paris had to be rated for each of the diagnostic possibilities. Similar to the list of adjectives, this tool was used for gaining deeper insights about the participants' perspective on the options in a qualitative way. Some remarks:

- Some adjectives were ambiguous or unclear. For example, the meaning of 'secure' was not understood or interpreted differently by many participants. Therefore, further questions about participants' answers was essential in order to generate useful results.
- The rating system was difficult to understand. Although some clarity (adding +++ and ---) was added, the questionnaire still had to be explained to most of the participants. In some interviews, it had to be translated into Yoruba language.
- Use of this kind of questionnaires might be common in the field of Industrial Design Engineering (in Delft), but has to be reconsidered and adjusted to other contexts.
- Although an attempt for quantitative analysis has been done, this turned out to be impossible. Due to different interpretations of the adjectives and scenarios, the limited amount of participants, the results were used for qualitative comparison. Yet, the tool was useful as a conversation starter.

14.2.16 Feelings

As described before, the adjective-questionnaires mainly gave insights in the stakeholders' perspective on the device, but little results were gained about their values and needs in handling a diagnostic device. Therefore, another tool was added; seven images of feelings that were assumed to be relevant. The tool was useful to get some insights about values (e.g. lab scientists that wanted to feel relieved), but might also have guided participants into just saying something about the words that were presented to them.

The cards were made based on personal standards, which can be culture-based. The culture difference was not taken into account when designing this tool, but perception of feelings and emotions (and images) might be different in another country. Since all answers were discussed, the interpretation of the images were explained. This reduced misinterpretation of the results. However, it is important to be aware of cultural differences when doing research in another context.

14.2.17 Participants

- Only 1-on-1 interviews were held, which gave a lot of different views on malaria diagnostics and the device. It would be interesting to conduct a focus group with different stakeholders, in order to respond to each other's ideas and potentially find consensus on e.g. the kind of information that is needed for a proper diagnosis.
- All interviews were held with professionals within Ibadan. Opportunities and advantages for use of this device within the city have been found, but it would be interesting to do more research in rural areas.
- As mentioned before, the sample of participants was too small to draw conclusions per group of stakeholders. However, it was interesting to see that the differences within the defined target groups were already significant. It might be obvious that people have different opinions and knowledge, but it is easy to generalize when defining a target group and analyzing results.
- Six stakeholders have been defined, but other professionals were interviewed too (e.g. salesman, government employee). No specific results from these interviews were gained, but their insights helped shaping the picture and context analysis.

14.2.18 User scenario design

As a result of the field study, the user scenario was improved for each defined stakeholder group. Although some choices were made on diagnostic scenario, tasks and mHealth applications, the storyboards were not much different from the initial presented scenarios.

Staining was still included, although a strong recommendation is to eliminate this from the procedure. The user scenarios did not yet meet the final conclusions, since the analysis of the results was being done parallel to the user scenario design. However, these scenarios were mainly being used for another evaluation study, therefore not being explained into much detail. It is recommended to develop a detailed user scenario (including all tasks and related to context) in further development of the Excelscope.

14.2.19 Evaluation study through Whatsapp

A short study was done to evaluate the new scenarios and discuss the defined mHealth applications. Most of the interviews were done through Whatsapp, since this medium is widely used throughout Nigeria and makes it a low-threshold way of communicating. This approach was new and had to be explored. Some limitations and advantages of this method have been identified:

Advantages
- Whatsapp enables transferring images
- It is possible to start direct discussions, which is more difficult by interviews through e-mail
- Communication through Whatsapp is informal and direct. Since Nigerians are quite direct in their communication too, the interviews resulted in honest and critical answers on the user scenarios.

Limitations
- The results are dependent on the responsiveness of participant and researcher. It is not always possible to send an answer immediately, which causes a long stretched interview.
- It can be hard to explain questions through text messages. Thereby, messages can be interpreted differently (from both sides), which is harder to verify than in a discussion in real life.

In the end, the evaluation study did not bring a lot of new insights or answers on the proposed research questions, but brought awareness for the different opinions from stakeholders and the actual need for mHealth applications. Interviews through Whatsapp is a useful method to discuss ideas with stakeholders/experts in remote areas and get immediate feedback.

14.3 RECOMMENDATIONS

FOR IMPLEMENTATION, FURTHER RESEARCH, DEVELOPMENT

The study into use and acceptance of the Excelscope leads to recommendations on different levels. The recommendations are related to research and development on the technology of the Excelscope, as well as social aspects and business strategies. Next to that, recommendations for development of smart medical devices in general can be derived from the findings and discussion of this project.

14.3.1 Technology

- Based on findings of this study, it is recommended to aim for eliminating the time-consuming and resourceful tasks that are related to conventional microscopy. However, the device has to be robust and affordable too, which brings challenges for the technological development of the Excelscope.
- A study into similar devices (used in the local context) can be done in order to fit form language and usecues to the user's expectation and familiarity. This can be done on the level of hardware and interface design.
- Further development of a working (prototype of an) application is recommended to study usability and understanding of the procedure.
- A usability study on the device and application needs to be done in each stage of the process to adapt and iterate according to usability on new developments.

14.3.2 Context

- Based on the findings from the context analysis, it is recommended to do the implementation process top down: start implemenation in urban advanced settings and work towards coverage on (rural) primary settings.
- Finally, expansion to community pharmacies and medicine shops would increase coverage and access to diagnostics signifciantly.
- More research on the private healthcare sector is recommended, since this sector has not extensively been studied yet. The private sector might be interesting for implementation, since it covers a large part of the Nigerian primary health care sector.
- Since this study focused on urban healthcare settings, little is known about rural facilities and access to healthcare in these areas. To anticipate on future use in rural areas (where malaria is more endemic than in urban areas) a study into that areas is highly recommended.

14.3.3 User

- This study recommends to develop the Excelscope for use by doctors in the first place, after which use can be extended to lower-level medical professionals. Yet, this suggestion has to be discussed further with stakeholders on different levels.
- It is recommended to do more research on the abilities of nurses and their acceptance towards the device. Can they be trained to support the doctor or use the device independently? Are they allowed to provide a diagnosis and prescription?
- Involvement of nongovernmental organizations in the development of the Excelscope can be interesting, but will bring new research questions: how do NGOs organize healthcare facilities, where are they situated, who (which level of medical education) provides healthcare, what are there values with regard to a smart device?
- Moreover, a more extensive research on needs and concerns of a specific target group is recommended. Since this research has been explorative, a small group of participants was included. Focus on one target group and a bigger sample size will generate more insights on the acutal needs and provides the possibility to combine qualitative and quantitative results.
- Understanding of a clinical test result and interventions done by the (chosen) healthcare provider need to be tested. Attention has to be placed on interpretation of positive and negative test results.

14.3.4 Patients

- Until now, research was limited to the user (medical professionals). However, effectiveness of the Excelscope is dependent on the patient as well. A study can investigate patient awareness for diagnostics, willingness and ability to pay and adherence to test results.
- Access to the different healthcare facilities can further be studied. This includes geographical and financial access, but also habits with regard to seeking care and view on (the capabilities of) healthcare providers.
- Insights on the patients' perspective on a smart device might give new insights and suggestions for the development of the Excelscope (e.g. on place of use, smartness and mHealth applications).

14.3.5 Awareness

- In the process of implementation of the Excelscope, attention needs to be placed on creating awareness for the existence and benefits of the device amongst both caregivers and patients.
- Awareness can be created through for example promotion via (social) media, drama plays and/or banners. Several stakeholders can be involved, such as the (local) government, a healthcare facility or company. A study into awareness and involvement of community members and caregivers adds to this study by expanding knowledge on context and user.

14.3.6 Impact

The current stage of the Excelscope cannot bring accurate estimations, but it is recommended to do research on the expected or intended impact on malaria management in (urban) Nigeria, Africa or on global level. What is the aim of the device in use and scale, and which new questions will derive from that? For example, a cross-cultural analysis might be needed when targeting different countries from the start, but the device can also be fully developed for the Nigerian healthcare sector before expanding it to other countries.

When estimating the impact on malaria management in Nigeria, a wide range of aspects need to be taken into account (coverage, compliance, awareness, treatment, prevention, etc).

14.3.7 Regulations

It is allowed to buy antimalaria drugs without prescription (PMVs are allowed to sell the drugs). In order to reduce overtreatment and misdiagnosis based on clinical decisions, prescription based on a valid test result should be obligatory. Although changing regulations is out of reach of this project, there can be aimed for use of the Excelscope by PMVs. Whenever the government allows PMVs to provide diagnoses, it is a step closer to eliminate over-the-counter antimalarials.

More research on policy and regulations is needed in order to define possible interventions for development for specific target groups.

14.3.8 Business strategy

A business strategy specifically made for a target group is necessary in order to gain constant revenues and be beneficial for supplier, caregiver and patient. Since developing sustainable business models was out of scope of this project, the proposed ideas have not further been elaborated on. It is recommended to more research on business strategies and include factors such as private/public sector, treatment availability at the point-of-care and type of patients that visit the specific healthcare centre.

14.3.9 Smart diagnostic devices

The results from this study on the Excelscope bring insights on the development and implementation of smart devices in general. When designing (smart diagnostic devices) for healthcare in developing countries, the following aspects need to be taken into consideration:

- Study the different intencives for use of a smart device (e.g. maintaining health or making profit)
- Study the habit, knowledge and perspective from the local community towards diagnostics on that specific disease. When people are not aware of the need to diagnose, adherence to a new method might be harder to achieve from both patient and healthcare providers' side.
- Take differences in perception of research methods and definitions into account when designing research tools.
- Combine findings from context and user research with (future) technological developments in order to create an overview of the possibilities for the specific innovation.

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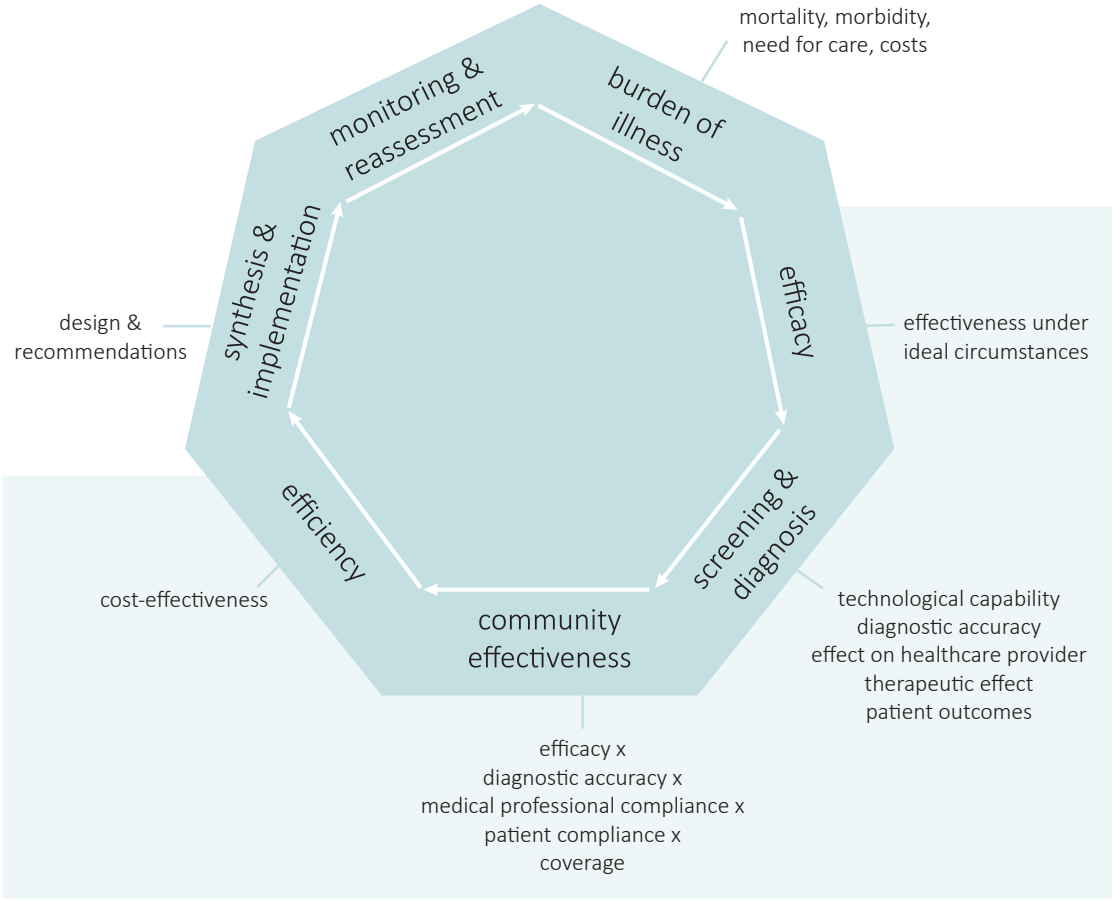
APPENDICES

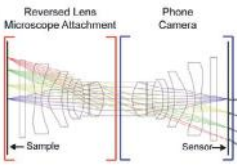
APPENDIX 1 'TAIL' ASSESSMENT TOOL

The Technology Assessment Iterative Loop, developed by Tugwell et al. [5] shows the influence of different factors related to context, user and technology on the effectiveness of an innovation in healthcare. The figure below shows the loop and its elements. The tool- or a similar evaluation method- is useful for anticipation on potential influencing factors and defining elements to study. In a later stage, the innovation can be assessed by use of a certain method.



APPENDIX 2 SMART MALARIA DIAGNOSTIC DEVICES

This overview gives a more extensive explanation of the selected devices that have been compared to the Excelscope in chapter 3.2.

Overview of similar technologies for malaria diagnostics		Comparison
	**Autoscope malaria diagnostics** The Autoscope states to be able to read a Giemsa stained slide in 20 minutes and analyse the smear through artificial intelligence. The algorithms detect parasite presence, species, stage and parasitaemia. Therefore, the aim of the device is similar to the Excelscope. However, the Autoscope requires electricity and costs 1500-4000 dollars, which makes it unaffordable for the places where it is needed the most.	**x automated** measure parasite load smartphone based low-cost **x blood sample preparation**
	**Sight diagnostics Ltd** Sight Diagnostics Ltd (before: Parasight) has developed a computer vision platform for (malaria) parasite detection. Sample preparation can be done by using compatible low-cost cartridges, that can be placed in the device. The machine processes the slides automatically and takes images of a large amount of fields. Currently, Sight Diagnostics is piloting the technology [1,4].	**X automated** measure parasite load smartphone based **?** low-cost blood sample preparation
	**Cellscope** Switz et al. (2014) described the use of a reversed mobile phone camera lens to make magnified images. Red and white blood cells were identified on images taken by this set up [13]. The first concept of the Excelscope was based on this idea and proved to magnify images up to 200x [12]. However, as far as known the concept 'Cellscope' has not further been developed [1].	**automated** measure parasite load **X** smartphone based **X** low-cost **X** blood sample preparation
	**MOMALA malaria diagnostics** MOMALA is a smartphone application that is able to detect Malaria parasites in a microscopic image of a blood smear. The phone will be attached to a microscope and automatically take pictures of a tick blood smear. Automatic analysis (a deep-learning convolutional neural network) will identify white blood cells and four different plasmodium parasites. The application is meant for speeding up the diagnostic process in laboratories and clinics, but a microscope and lab technician are still required. The app is not on the market yet: a clinical study will be done by the end of 2017 in Kenya [5].	**x automated** **x measure parasite load** **x smartphone based** low-cost **x blood sample preparation**
	**xRapid-Malaria** xRapid-Malaria is relatively similar to MOMALA. The UK/USA-based company develops an iPhone application for (the five species of) malaria detection, which can be connected to a microscope. The company sells the whole kit (including microscope and iPhone) or an adapter which can be used to connect the phone to an existing microscope. The app is currently available for iPhones in the app store. Each test will be charged a maximum of one dollar [6].	**x automated** **x measure parasite load** **x smartphone based** low-cost **x blood sample preparation**

>> Overview of similar technologies for malaria diagnostics

Comparison

MOPID malaria diagnostics
The MOPID is a polarized microscope platform that uses the smartphone's abilities and an extra plastic lens module to capture images of a blood slide. The system only captures digital images, but does not run automatic analysis of the images. The design has potential to become a low-cost and simple device [8].

automated
measure parasite load
x **smartphone based**
x **low-cost**
x **blood sample preparation**

QuantuMDx
The QuantMDx provides a qualitative result for the five species of malaria parasites. Therefore, it goes beyond the abilities of normal rapid diagnostic tests. Sample preparation is not required and the company develops a way to detect drug resistance through DNA sequencing. The mobile device provides the possibility to store data and connect to the intenet. The launch of the product is scheduled in 2017 [9].

x **automated**
measure parasite load
smartphone based
? low-cost
blood sample preparation

Magneto Optical Device (MOD)
The technology utilizes hemozoin, a waste product from malaria parasites. When hemozoin is exposed to a magnetic field, they align in a specific way that affects the opacity of the blood sample. The parasite concentration can be measured by sending a laser beam through the solution and a result is presented within one minute. The device can withstand temperatures up to 50 degrees Celsius. At this moment, no further development is being made on this R&D project [1,10].

x **automated**
measure parasite load
smartphone based
x **low-cost**
blood sample preparation

Fionet automated RDT reader
This device reads rapid diagnostic tests (RDT) that detect antigens, after which the results can be uploaded to a central data system immediately, aiming for managing disease outbreaks. The Fionet device is based on smartphone software. It has been tested for Ebola as well as for Malaria parasites. Next to data storage and analysis, a step-by-step manual is provided to guide the user through the use and analysis of the RDT [11].

x **automated**
measure parasite load
smartphone based
x **low-cost**
blood sample preparation

APPENDIX 3 INTERVIEW GUIDE

This is the first version of the interview guide, which was used as a tool for the semi-structured interviews. The questions were addressed during the interviews, but let room for other topics or change in order of questions. The interview guide has been developed during the month of field research.

Interview guide

Hello, my name is Julia. I am a student from the Netherlands and are working on a malaria diagnostic project. We have developed a smart device to diagnose malaria, but we need to know more about healthcare and malaria in Nigeria. Therefore, I would like to ask you some questions first, and discuss the device with you afterwards. Thank you for your participation.

I have a consent form, which asks for your permission to record the interview on audio and camera.

Do you have any questions before we start?

1. First of all, I would like to more about this/your health centre and your job as a medical professional. Can you tell me something about your tasks and responsibilities?
2. Which other people work at this HC?

3. How many clients do you attend to per day?
4. What kind of clients do you have?
    a. where do they come from? Do you know how they travel to the health centre?
5. What are the major challenges you have to overcome in your HC / job?

6. Are there many people who come here with suspected malaria?

7. How do you diagnose or test malaria? Who is in charge?
8. Which resources do you need to perform the test?
    a. tools/instruments
    b. do you register patient data
    c. how is a blood sample taken?
9. How much time does it take to provide a diagnosis?

10. Microscopy: how many field of views do you analyse?

11. What do you do when a malaria test (RDT/microscopy) gives a negative result?
12. Do you base you decision on the test result, or do you take clinical symptoms into account?
13. Are there other diseases you test on?

14. What are the major challenges in malaria diagnostics?
    a. resources, skills, staff
15. What is the most difficult task in the procedure?
16. What is the easiest task?

APPENDIX 4 LIST OF ADJECTIVES

The list of adjectives has been presented to the participants in advance of an explanation about the Excelscope.

Assessment questionnaire

participant #:

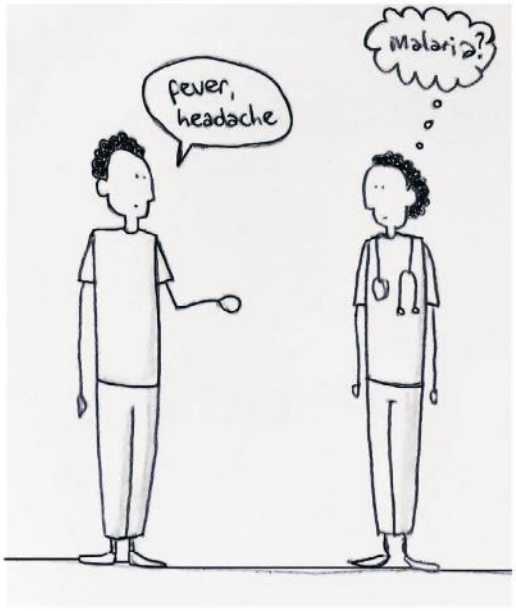
We would like to know what you think is important when doing malaria diagnostics. Please go through the words and consider the most important qualities of a malaria diagnostic device.

1. <u>Pick three words</u> that are most important for you when thinking of a diagnostic device

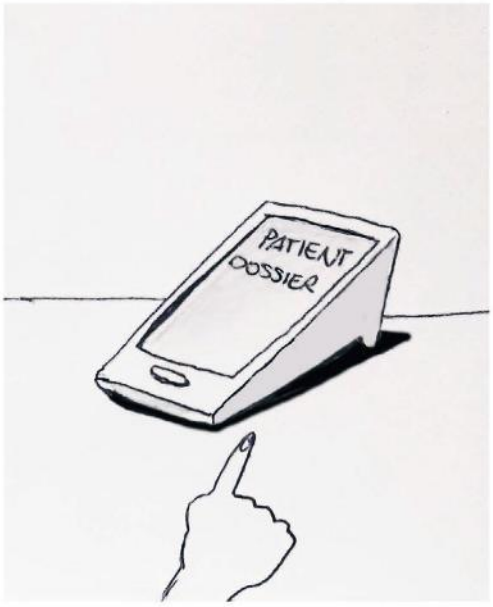
Practical	Satisfying	Professional	Ordinary
Easy	Time-saving	Efficient	Inviting
Comprehensive	Transparent	Consistent	Controllable
Empowering	Reliable	Cheap	Quick
Technical	Secure	Accessible	High quality
High-tech	Pleasant	Supportive	Advanced
Controllable	Easy to use	Trustworthy	Motivating
Human	Familiar	Straight forward	Clear

APPENDIX 5 STORYBOARDS

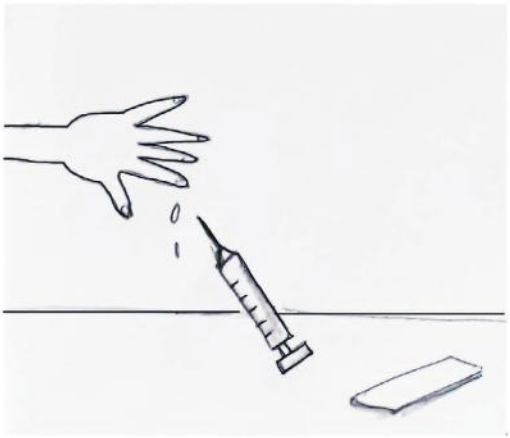
Storyboards were created to explain the working principle of the Excelscope and the different scenarios for diagnostic analysis.



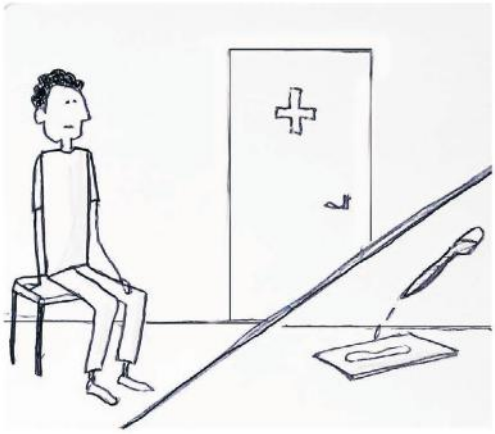
1. A patient visits the health centre with symptoms.



2. Malaria is suspected, a patient dossier is made in the Excelscope.



3. A sample of blood is taken from the patient.



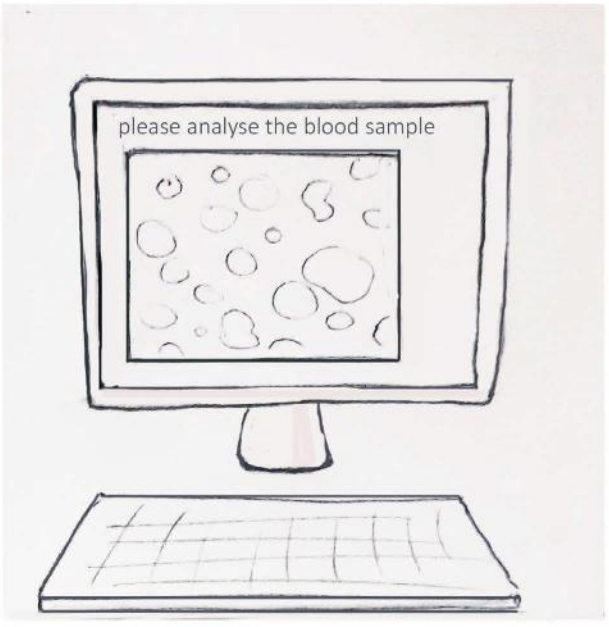
4. While the patient waits, the blood sample is stained.

5. The prepared sample is placed in the Excelscope.

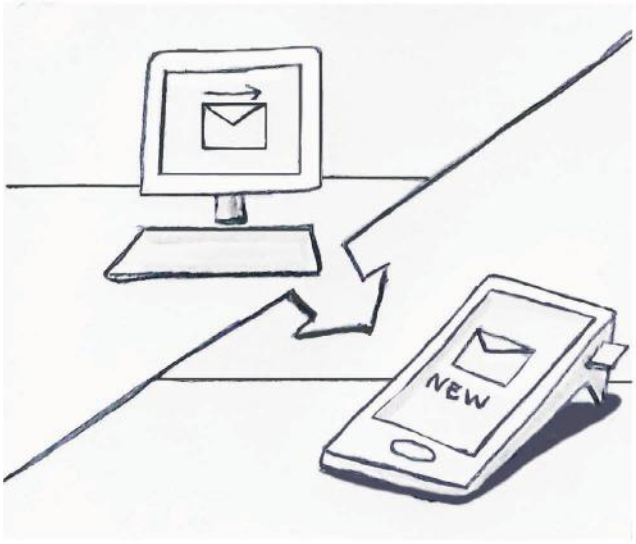
6. The sample is captured in pictures for all needed field of views.

Scenario 1

7. The images are sent to a malaria expert on another location .



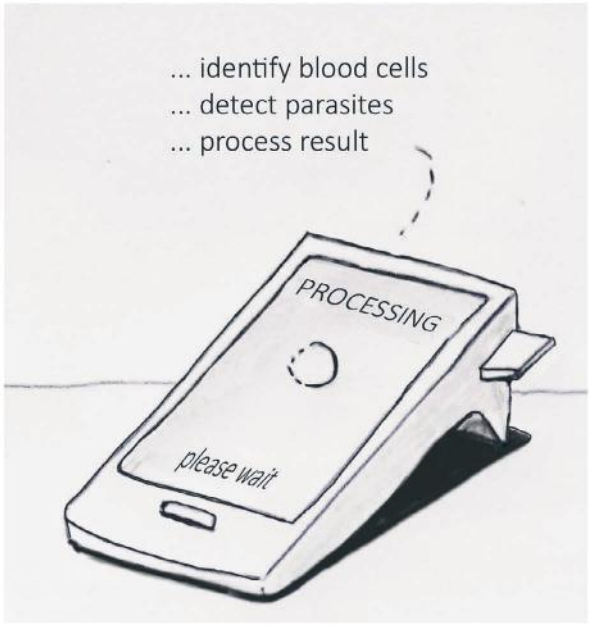
8. The expert analyses the blood sample in order to detect parasites.



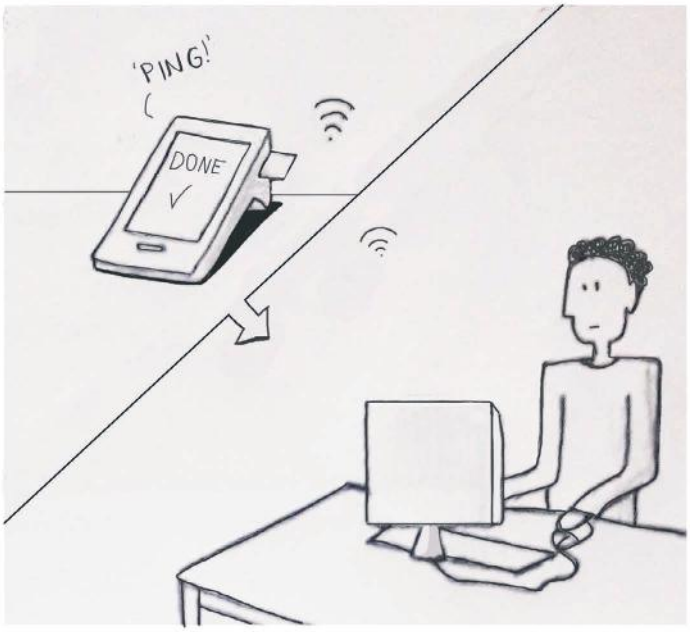
9. The expert sends the diagnosis back to the Excelscope at the health centre.

10. The health care provider communicates the diagnosis to the patient.

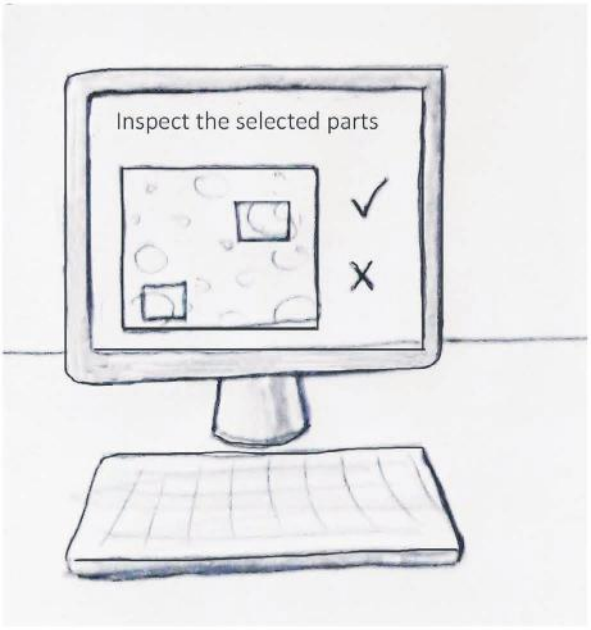
SCENARIO 2



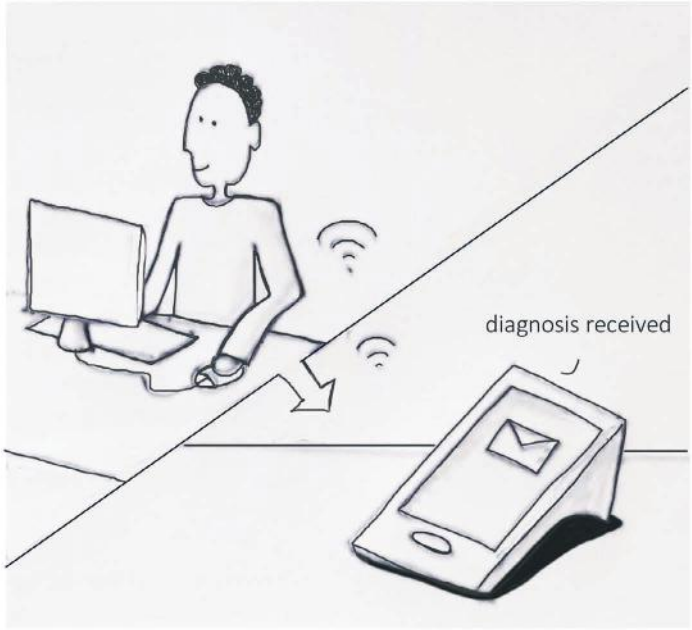
7. When the image is captured, the device starts an analysis to detect parasites.



8. The result of the analysis is sent to an expert in order to inspect the report.

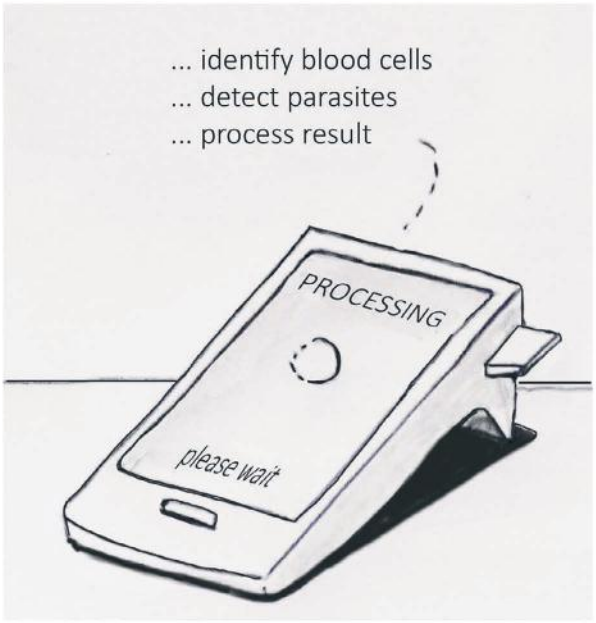


9. Only a **selection of the image** needs to be inspected, wherein parasites are found by the analysis of the device.



10. The expert verifies the diagnosis and sends it back to the health centre, where it can be communicated to the patient.

SCENARIO 3



7. When the image is captured, the device starts an analysis to detect parasites.

8. The result is shown on the Excelscope and does not have to be inspected by an expert.

9. The diagnosis can be communicated to the patient at the point of care.

APPENDIX 6 ADJECTIVE QUESTIONNAIRE

This questionnaire has been used to get more understanding of the participants' preference for one of the three scenarios. The answers were used to ask questions (why do you rate ... better than ...?) and gain qualitative data about the participants' values and concerns.

With help of the word pairs please enter what you consider the most appropriate description for each of the following statements with regard to use of the Excelscope.

1. An (external) malaria expert is in charge of the analysis of the blood sample

	+++	++	+	+/-	-	--	---	
Reliable	◯	◯	◯	◯	◯	◯	◯	Unreliable
Time-saving	◯	◯	◯	◯	◯	◯	◯	Time-consuming
Transparent	◯	◯	◯	◯	◯	◯	◯	Ambiguous
Practical	◯	◯	◯	◯	◯	◯	◯	Impractical
In control	◯	◯	◯	◯	◯	◯	◯	Out of control
Supportive	◯	◯	◯	◯	◯	◯	◯	Unsupportive
Secure	◯	◯	◯	◯	◯	◯	◯	Insecure

2. The diagnosis is based on analysis of both computer and human expert

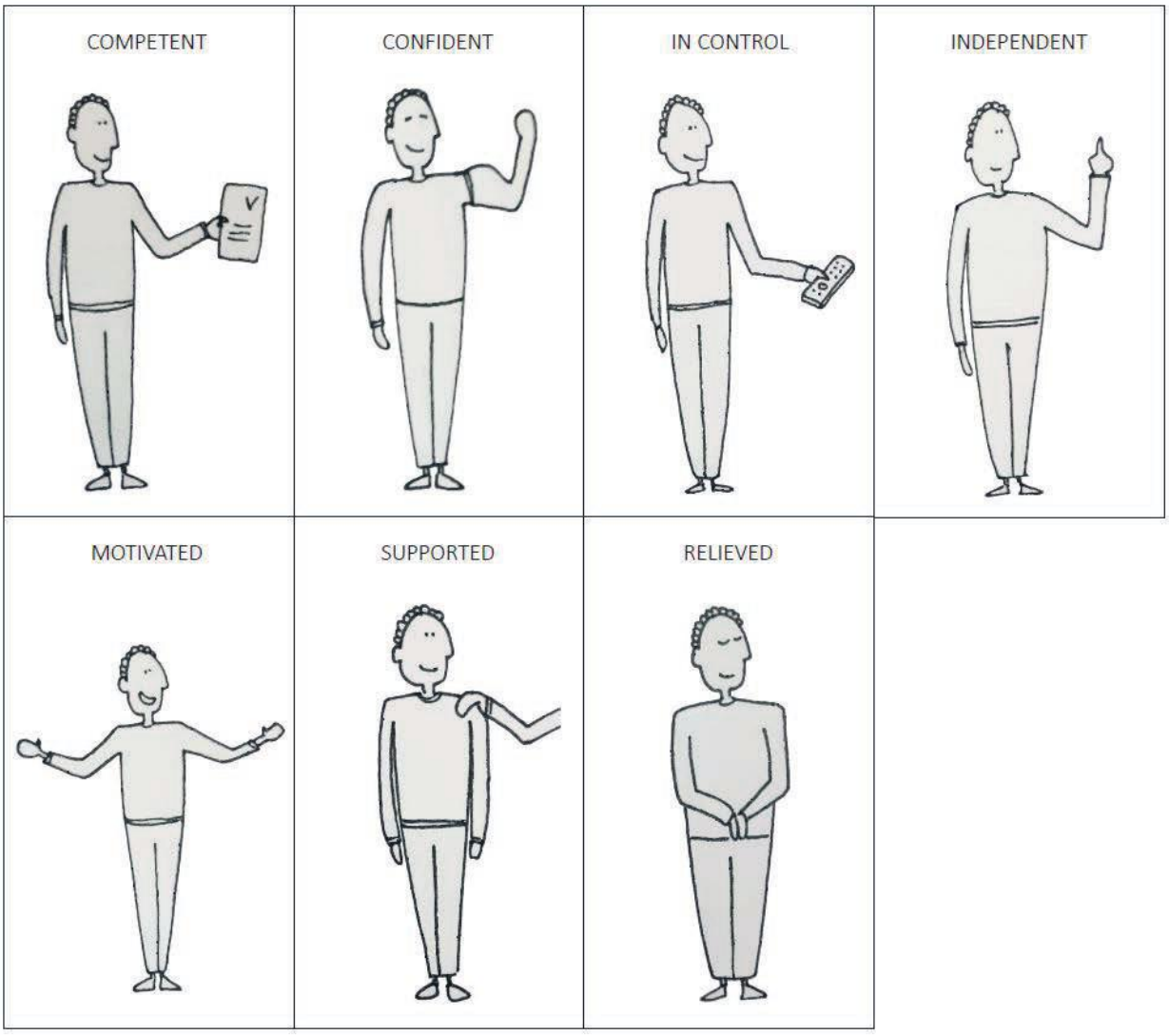
	+++	++	+	+/-	-	--	---	
Reliable	◯	◯	◯	◯	◯	◯	◯	Unreliable
Time-saving	◯	◯	◯	◯	◯	◯	◯	Time-consuming
Transparent	◯	◯	◯	◯	◯	◯	◯	Ambiguous
Practical	◯	◯	◯	◯	◯	◯	◯	Impractical
In control	◯	◯	◯	◯	◯	◯	◯	Out of control
Supportive	◯	◯	◯	◯	◯	◯	◯	Unsupportive
Secure	◯	◯	◯	◯	◯	◯	◯	Insecure

3. The diagnosis is based on the automatic analysis of the smart device alone

	+++	++	+	+/-	-	--	---	
Reliable	◯	◯	◯	◯	◯	◯	◯	Unreliable
Time-saving	◯	◯	◯	◯	◯	◯	◯	Time-consuming
Transparent	◯	◯	◯	◯	◯	◯	◯	Ambiguous
Practical	◯	◯	◯	◯	◯	◯	◯	Impractical
In control	◯	◯	◯	◯	◯	◯	◯	Out of control
Supportive	◯	◯	◯	◯	◯	◯	◯	Unsupportive
Secure	◯	◯	◯	◯	◯	◯	◯	Insecure

APPENDIX 7 FEELING CARD SORT

Participants were asked to choose 1-3 feelings on importance or desire when conducting diagnostic tests. The cards were used as a trigger to get more detailed information.

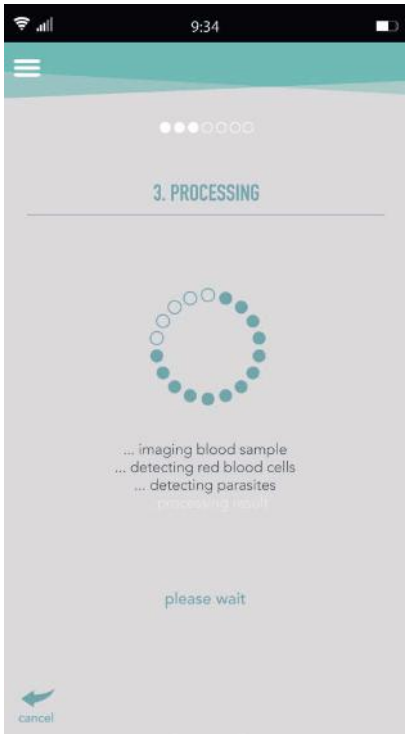


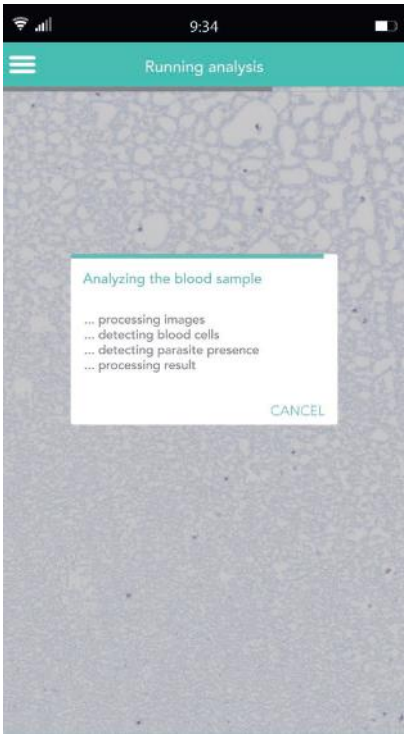
APPENDIX 8 INTERFACE DESIGNS

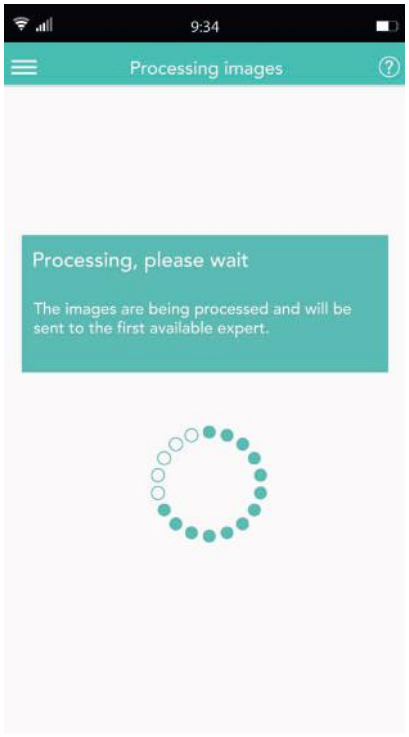
The following design iterations have been made on different interfaces. The interfaces were used to dicuss necessary information on the display and improve understandability. This study did not aim for desiging a complete application. Therefore, the interfaces have not further been developed or dicussed. Future design projects can use the interfaces as a source of information and inspiration.

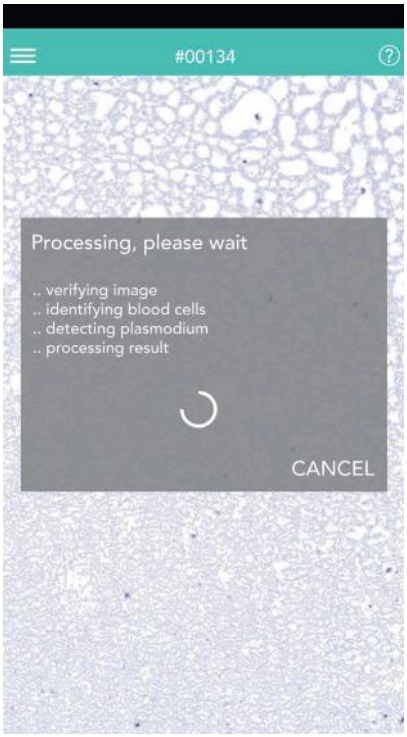
Processing result

Considerations: visual, simple, advanced information: understandability & transparency.



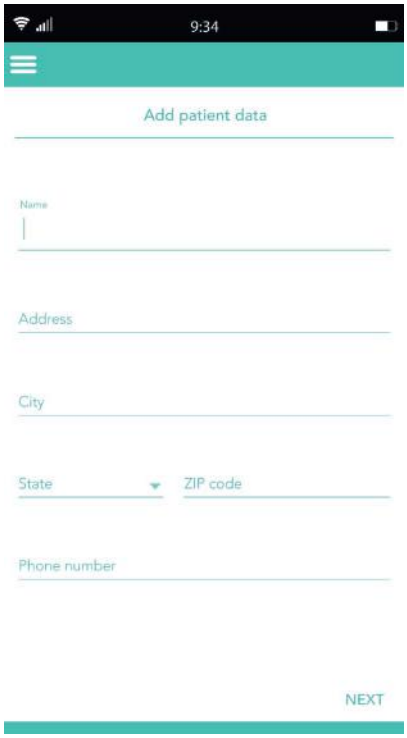


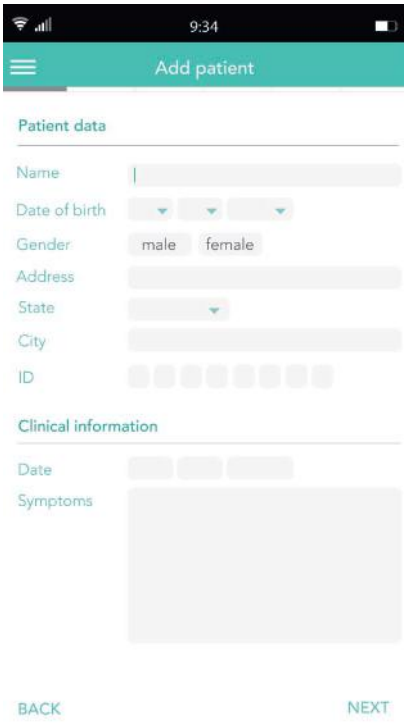


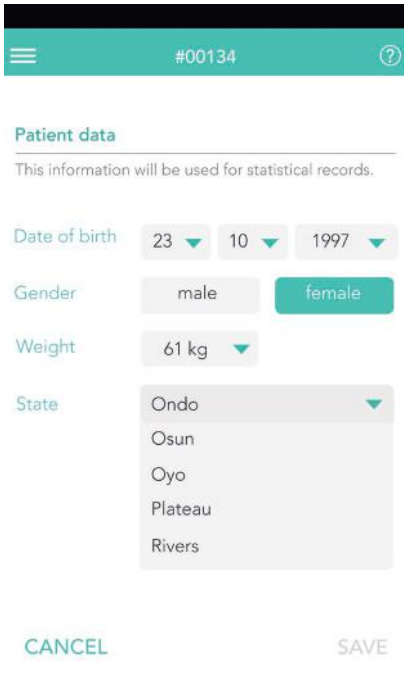


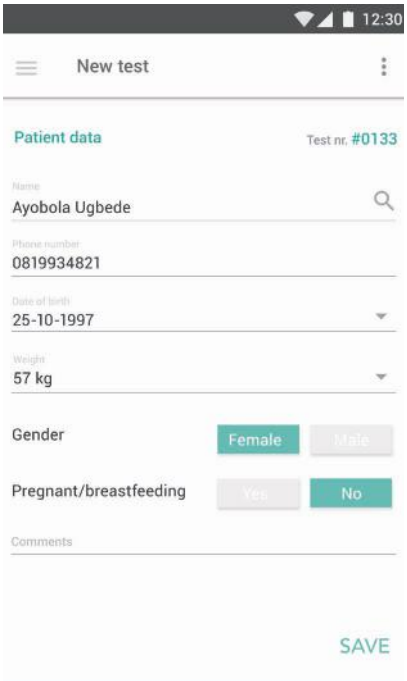
Processing result

Considerations: use data for health monitoring, keep the procedure as quick as possible, safety of data.



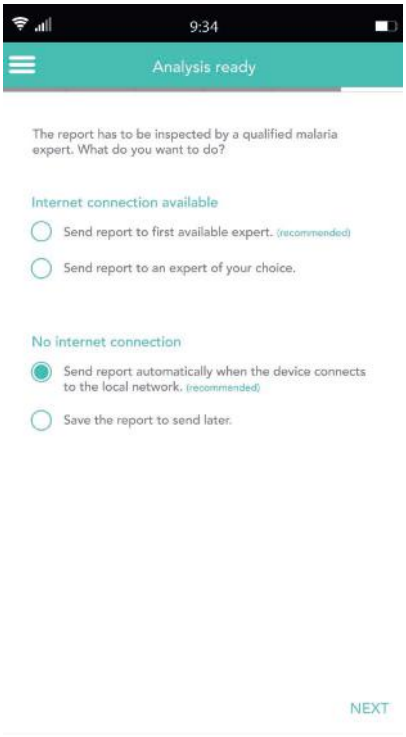






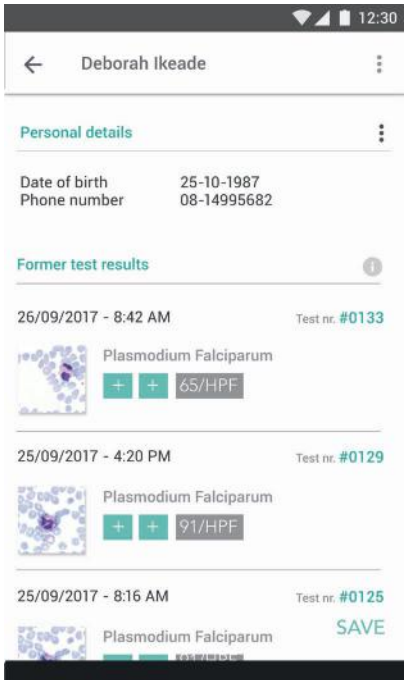
Remote diagnostics: send to expert

Considerations: send to familiar or first available expert: transparency / in control / quick procedure.



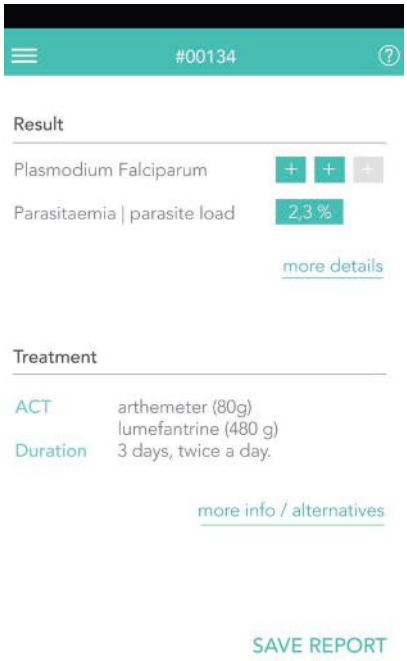
Patient health monitoring

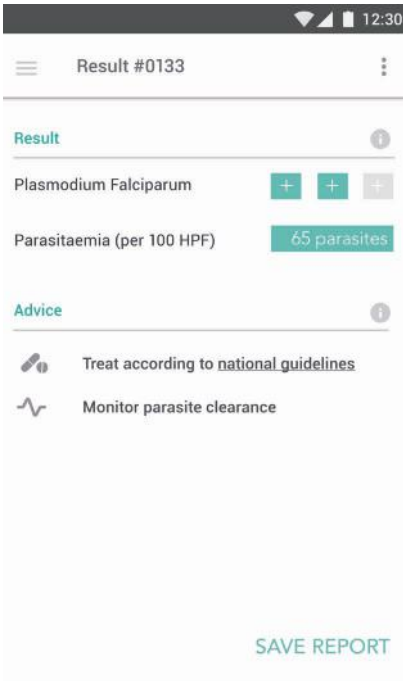
Considerations: amount of information (personal details or test nr), safety of data, desirability.

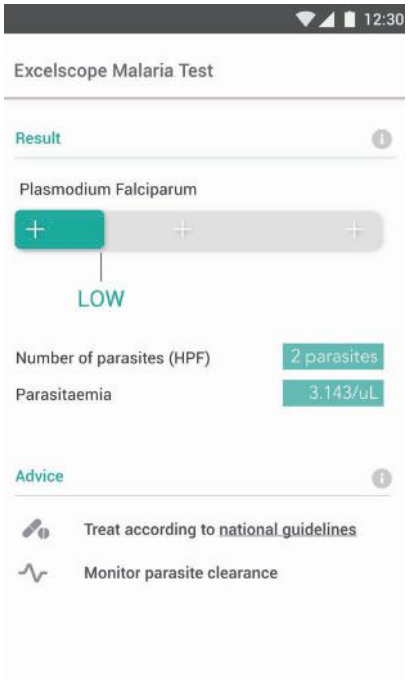


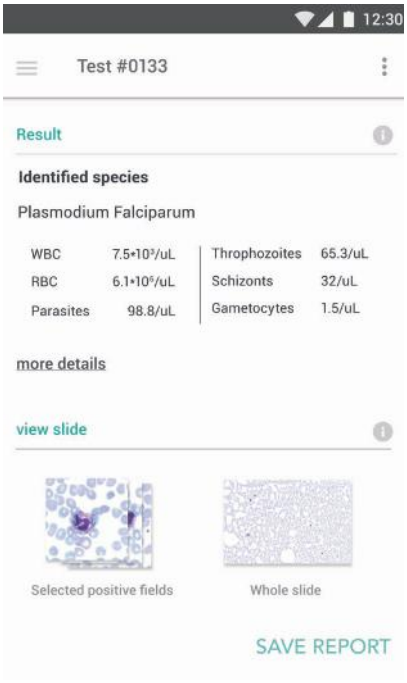
Result visualization

Considerations: amount of information per stakeholder, visual/technical information, trustworthiness, understandability









APPENDIX 9 RESULTS

The following quantitative results weer gained from the two questionnaires. Although the methods aimed for generating qualitative data, the results can give an indication of the general answers.

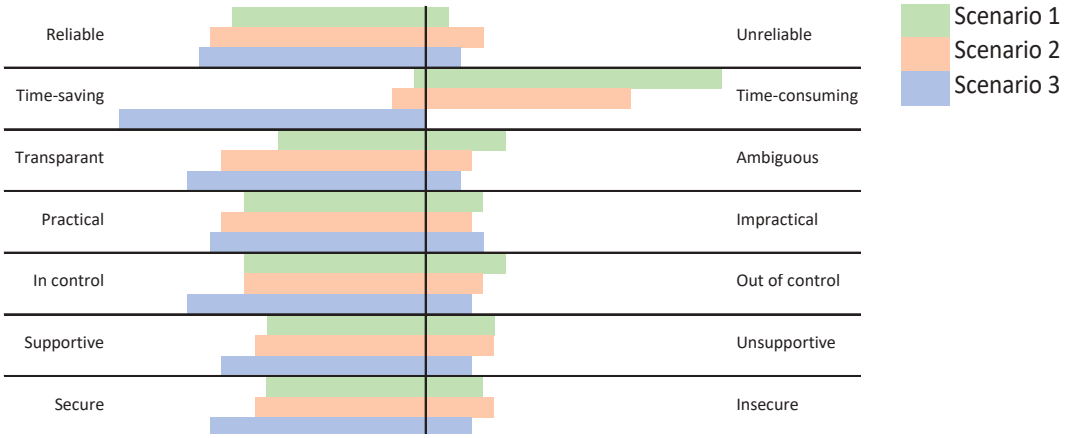
Chosen words from the list of adjectives

. The list shows the amount of choices for each of the presented words.

Easy to use	10	Consistent	1
Reliable / trustworthy	9	Straight forward	1
Cheap	7	Advanced	1
Time-saving / quick	7	Comprehensive	0
High quality	5	Technical	0
Efficient	4	Human	0
Controllable	4	Satisfying	0
Practical	3	Secure	0
Transparent	2	Pleasant	0
Professional	2	Familiar	0
Accessible	1	Ordinary	0
High-tech	1	Inviting	0
Supportive	1	Motivating	0
Empowering	1	Clear	0

Overview of results from the adjective questionnaire

. A visualization of the questionnaire results, wherein participants were asked to rate each of the three scenarios on seven different qualities. Although the data cannot be used for statistical analysis, the overview gives an idea of people's opinion towards the scenarios.



APPENDIX 10 SUS QUESTIONNAIRE

For the user scenario evaluation study (chapter 12), a short questionnaire was designed based on the System Usability Scale (SUS questionnaire). The set up of this questionnaire was used as a guidance in creating relevant statements about the scenarios. Participants were asked to state whether they (party) agreed on the staement, instead of rating them, in order to design the tool according to the digital platform Whatsapp.

System Usability Scale

	Strongly disagree				Strongly agree
1. I think that I would like to use this system frequently	1	2	3	4	5
2. I found the system unnecessarily complex	1	2	3	4	5
3. I thought the system was easy to use	1	2	3	4	5
4. I think that I would need the support of a technical person to be able to use this system	1	2	3	4	5
5. I found the various functions in this system were well integrated	1	2	3	4	5
6. I thought there was too much inconsistency in this system	1	2	3	4	5
7. I would imagine that most people would learn to use this system very quickly	1	2	3	4	5
8. I found the system very cumbersome to use	1	2	3	4	5
9. I felt very confident using the system	1	2	3	4	5
10. I needed to learn a lot of things before I could get going with this system	1	2	3	4	5