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Citation (APA)
Bengtson, M. L., Onasanya, A. A., Oyibo, P. O., Meulah, B., Samenjo, K. T., Braakman, I. G., Andi, W. O., & Diehl, J. C. (2022). A usability study of an innovative optical device for the diagnosis of schistosomiasis in Nigeria. In *2022 IEEE Global Humanitarian Technology Conference, GHTC 2022* (pp. 17-22). (2022 IEEE Global Humanitarian Technology Conference, GHTC 2022). IEEE. https://doi.org/10.1109/GHTC55712.2022.9911019

Important note
To cite this publication, please use the final published version (if applicable).
Please check the document version above.

A usability study of an innovative optical device for the diagnosis of schistosomiasis in Nigeria

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

Keywords— *digital optical device, schistosomiasis, usability, mixed-model questionnaire, resource-limited settings*

I. Introduction

A. Epidemiology of Schistosomiasis

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

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

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

Although conventional microscopy is highly specific and quantitative, it has several limitations. Egg excretions are variable. Therefore, eggs are often missed in low-intensity infections or due to inter- and intra-variation in egg distribution, collectively resulting in reduced sensitivity [1]. Although the limitation of uneven egg distribution is not

unique to microscopy, even highly trained microscopists can miss eggs and report inconsistent results. Microscopy is time-consuming and highly operator-dependent and therefore error-prone, particularly as user-fatigue develops after many hours of analyzing samples (field observations). It is also difficult to standardize microscopy as a readout. The use of conventional microscopy in (remote) endemic regions is further hindered by logistic constraints [4]. The availability of microscopes is limited by high costs, lack of both spare parts and required skills for repairs and maintenance, and erratic power supplies [4]. The use of alternative diagnostic tests, e.g. that detect adult worm-associated circulating antigens [3], is currently not feasible for routine use due to logistic and financial constraints.

C. Proposed diagnostic solution: digital optical devices

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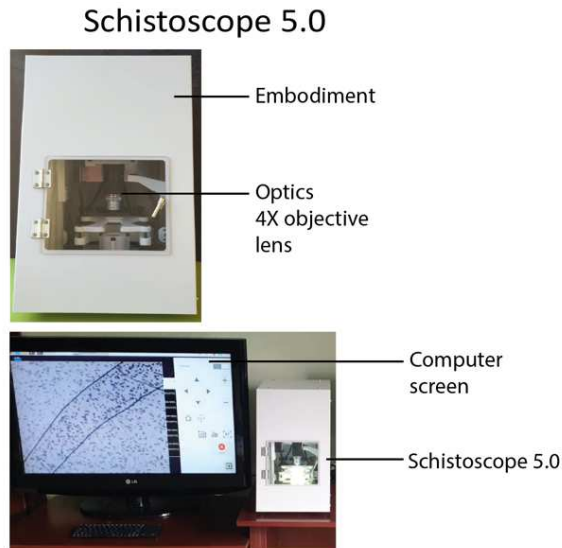

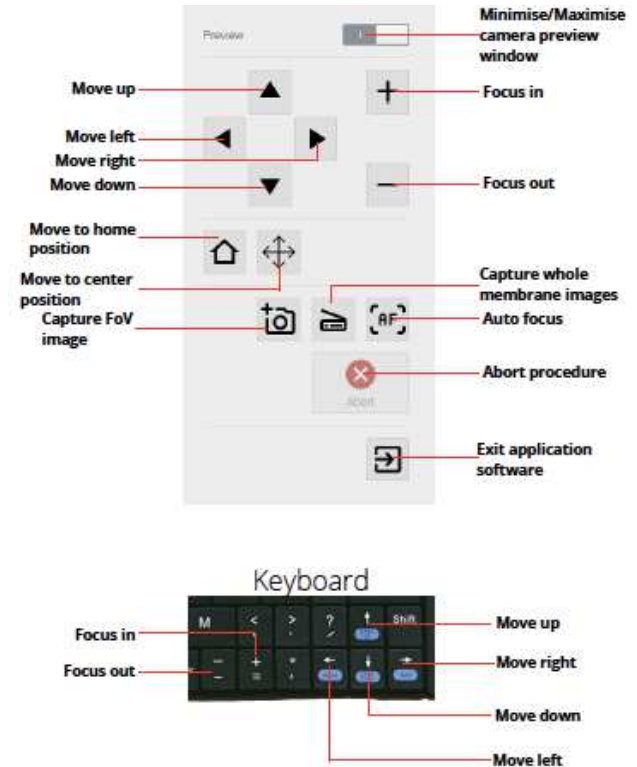Fig. 1. Schistoscope 5.0 (top) connected to a computer screen (bottom).

Fig. 2. The graphical user interface of the Schistoscope 5.0

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

User-centered design (UCD) is an iterative design process in which designers focus on the users and their needs in each phase of the design process, from product conception to the final product [7]. A UCD approach involves four distinct phases: contextual inquiry, user specification, prototyping, and user experience [7]. Co-creation is the foundation of UCD during the research and development phase, and it facilitates researchers to elucidate product specifications [8]. While designing the Schistoscope, we understood the context of the users [8] and opportunities for this device [9]. We also identified and specified the user's requirements by developing a target product profile [10]. We are currently evaluating the diagnostic performance of the device, and assessing how the product fits into the end-user's work environment in SSA by conducting a usability and acceptability study. This close user involvement will enhance the probability of meeting their expectations, and consequently increase uptake of the device in their daily practice [8]. The usability and user-acceptance study of the Schistoscope (version 5.0) was conducted in the Federal Capital Territory (FTC), Abuja, Nigeria, by health workers and medical students who are likely to use the device in their daily work activities. The aim of this paper is to describe the findings of the usability study.

II. METHODS

A. Study design and setting

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

B. Ethical considerations

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

C. Eligibility criteria and sample size

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

TABLE I.   TABLE 1: CHARACTERISTICS OF STUDY PARTICIPANTS (N=NUMBER OF PARTICIPANTS THAT PROVIDED INFORMATION).

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

*presented as a percentage

D. Procedure

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

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

- Schistoscope 5.0
- Filter membrane containing *S. haematobium* eggs on a glass slide
- Investigators provide a brief introduction to the Schistosope 5.0
- Participant reading the user manual (appendix A)
- An impression of user interactions: microscopists and university students

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

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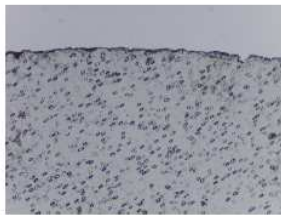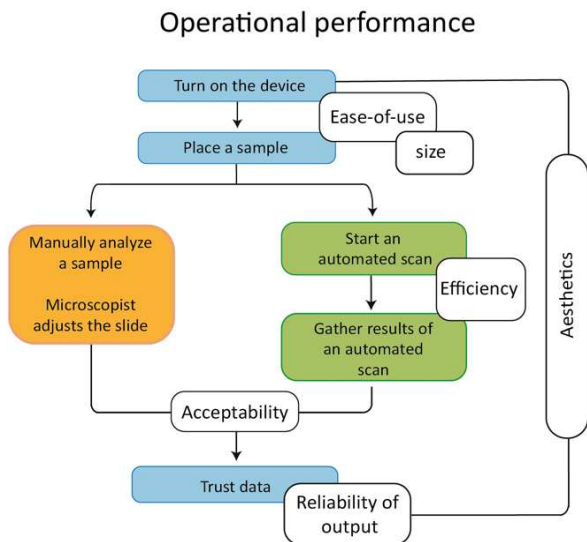

Fig. 4. Sample page of the user manual.

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

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

Statement	Likert scale					Average ± std dev
	disagree		agree			
	-2	-1	0	1	2	
Turn on the device						
Executing this task was difficult	14	3	-	-	-	-1.8 ± 0.4
The task is easier on the Schistoscope than on a standard microscope	14	3	-	-	-	-1.8 ± 0.4
I spend more time on this task than I expected	10	1	-	2	4	-0.6 ± 1.8
With standard microscopy, this task is different	2	2	3	3	7	0.6 ± 1.5
Place a sample						
Executing this task was difficult	12	5	-	-	-	-1.7 ± 0.5
The task is easier on the Schistoscope than on a standard microscope	12	3	1	-	1	-1.5 ± 1
I spend more time on this task than I expected	2	6	3	2	4	0 ± 1.5
With standard microscopy, this task is different	0	3	5	3	6	0.7 ± 1
Manually analyze a sample						
Executing this task was difficult	9	8	-	-	-	-1.5 ± 0.5
The task is easier on the Schistoscope than on a standard microscope	9	7	-	1	-	-1.4 ± 0.8
I spend more time on this task than I expected	2	3	4	2	6	0.4 ± 1.5
With standard microscopy, this task is different	-	1	1	6	9	1.4 ± 0.9
Start an automated scan						
Executing this task was difficult	10	6	1	-	-	-1.5 ± 0.6
I spend more time on this task than I expected (n=16)	2	3	2	1	8	0.6 ± 1.6
Gather results of the automated scan						
Executing this task was difficult	7	6	2	1	1	-1 ± 1.1
I spend more time on this task than I expected	2	2	2	3	8	0.8 ± 1.5
Trust (n=16)	-	-	-	6	10	1.6 ± 0.5

Key to the 5-Point Likert scale

-2	Strongly disagree with the statement
-1	Disagree with the statement
0	Neutral
1	Agree with the statement
2	Strongly agree with the statement

E. Data Analysis

Confidentiality of information retrieved and anonymity of results was ensured by assigning unique codes to the questionnaires before data analysis. The data were digitized by two investigators. Thereafter all data were analyzed descriptively using Microsoft Excel software by one investigator. Ranked responses were analyzed quantitatively (Mann-Whitney statistics; Prism 9), and open-questions were used to support the ranked responses in a descriptive manner. A conventional qualitative content analysis approach was used to code the data [12]. User impressions were considered as 'codes', which were then grouped into meaningful categories based on the relationship between the codes. Categories were generated until all the data were considered, and then grouped into a central usability theme (operational performance). The co-authors discussed the codes that emerged from the descriptive analysis. No discrepancies occurred (Figure 5).

III. Results and Discussion

The aim of this study was to elucidate the perceptions of end-users as they document their experiences with the device. The following codes were identified: ease of use; size; efficiency (time); acceptability compared to microscopy (workflow in daily routine); reliability of outcomes, and general aesthetic impressions (Figure 5). Participants were also asked 8 open questions to document their overall experience when using the Schistoscope compared to conventional microscopy. Their responses were stratified into the codes, and the average score in response to each statement are discussed here:

A. Ease of Use

The participants agreed that it was easy to start the device (average score -1.8), and that this task was not time consuming (-0.6). They perceived this task as different compared to microscopy (0.6). The participants agreed that it was easy to place a sample into the Schistoscope (-1.7), however, placing a sample in a conventional microscope was considered to be easier (-1.5). Although participants reported a neutral response to the time taken to place a sample in the device (0), this task was perceived as different compared to microscopy (0.7). These responses to starting a new device and placing a sample in the device are inherently perceived as different. In the open questions, all the participants reported that the Schistoscope was easy to use from sample placement to capturing a digital image. The use of a computer screen (Figure 1) was well-perceived, and multiple participants stated that it was impressive to see the parasitic eggs projected clearly on the screen.

"I was impressed that I could see the eggs projected on the screen with ease" –microscopist with 10 years' work experience

Other comments included the added value of the digital display on the screen which circumvented the need to look directly into the eyepiece for a magnified view of the slide, as would be required when using a conventional microscope. Interestingly, a student reported that the Schistoscope was easy to use without formal training, which is in line with the WHO recommendation of one-day training for diagnostic devices [4]. The use of the Schistoscope as both a manual and automated device was positively reported. In addition to one participant that stated that the manual operation of the device was easy, multiple participants noted that the automatic focus and scanning features of the Schistoscope were value added features.

"The simplicity of the device in focusing samples was amazing, the auto-focus button was one of the best features, it saves time and energy" –microscopist with 3 years' work experience

Although the Schistoscope prototype tested in this study had an auto-focus feature, the analysis of the sample was performed manually, meaning that the end-user (microscopists and students) manually counted the number of *S. haematobium* eggs identified, analogous to conventional microscopy. Numerous participants noted that automatic analysis would be an added value feature, where AI software could quantify the number of eggs. Such 'sample-in-answer-out' capabilities were noted as desirable features by the participants. Other display features that were suggested include a digital indication of which part of the slide is scanned during the auto-scan process as the field of view is changed in real-time, and the magnification status.

B. Suitability in the workflow and acceptability

The participants agreed that it was easy to manually analyze a sample (-1.5), however, this task was considered to be easier and less time consuming when using a conventional microscope (-1.4 and 0.4, respectively). Manually analyzing a sample on the Schistoscope was perceived as different compared to microscopy, as expected (1.4). To enhance the suitability and desirability of the device in the workflow in the field, an integrated sample storage unit was noted as an additional feature to store samples safely. Conventional microscopes contain 4 objective lenses (4X; 10X; 40X; and 100X). The Schistoscope 5.0 prototype had a single 4X objective lens which was sufficient to identify *Schistosoma* eggs, however, one participant noted that it would be advantageous to incorporate additional objective lenses. Another suggestion included the possibility to detect other pathogens, however, the scope of this particular prototype was focused on the detection of *Schistosoma* eggs. Finally, large data storage capabilities were noted by participants as desirable.

C. Efficiency

The participants agreed that it was easy to start an automated scan (-1.5), and to save the results of the scan (-1). They noted that it did not take more time than expected to start an automated scan or save results (0.6 and 0.8, respectively). Although participants were encouraged to provide their insights to each open question, this was not a requirement. Only two participants provided elaborate responses related to efficiency of use. In terms of the amount of time that it takes the end-user to scan a slide when using the auto-scan function, one participant reported that there should be a time limit on the device for this function. This participant noted that the use of the Schistoscope takes more time to perform a scan compared

to a microscopist using a conventional microscope (~15 minutes for the Schistoscope, and less than 10 minutes for a conventional microscope; personal observations in the field). In agreement with this observation, another participant also noted that the auto-scan time should ideally take less than 10 minutes. It is well acknowledged that scan time and accuracy is a common trade-off i.e. a faster scan time could reduce accuracy, however, further improvements in scan-time can be explored in the next design iteration.

D. Reliability of data generated by the Schistoscope

Given that captured images are displayed on a screen, the majority of the participants noted that the data generated would be considered reliable. Interestingly, one participant noted that digital microscopy, like conventional microscopy, is only reliable provided that the microscopist can identify the eggs, and this relies on the expertise of the microscopist. However, a challenge remains when dealing with a negative sample.

"Yes, it is reliable if I can see a positive result, but not reliable if negative. Quality control is needed" – microscopist with 10 years' experience

E. Aesthetics

Responses related to the size of the device demonstrate that it was generally perceived as too big. Suggestions were to reduce the size of the device to increase portability; and also reduce the amount of space that would be occupied on a laboratory bench or a table in the field. However, a device that is too small can also be easily misplaced. Other responses included the size of the door handle used to place a sample in the device was too small, undesirability of visible wires, and added value of a small screen fitted to the device to enhance portability by replacing the computer screen.

For each step in the process, no statistically significant differences in responses were identified between microscopists and students, indicating the ease-of-use for both groups.

IV. CONCLUSION

The aim of this study was to elucidate the perception(s) of end-users related to the use of the Schistoscope in a representative context. The mixed-model questionnaire consisted of several ranked and open questions to assess the usability of the device compared to conventional microscopy, and user-acceptance in terms of overall experience (interaction with the device), reliability of data generated, and aesthetics (size and general appearance). One user was excluded from the study due to contradicting responses. Therefore, negatively-worded questions are a limitation of the questionnaire design and can be rephrased as positively-worded (agreeable statements) in future usability studies.

The Schistoscope is a digital microscope, designed to support the daily work of a microscopist, that can be used manually, analogous to a conventional microscope except with a digital interface, or automated. Sample preparation is the same for both detection methods, so use of Schistoscope does not disrupt the workflow of the microscopist or other technicians in the laboratory or at field sites. It is therefore not surprising that the Schistoscope was perceived as easy to use by both students and trained microscopists with very little training or explanation for operation. Summing up, it is expected that the use of this device can be implemented with minimal capacity building.

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