Optimisation of Instructions for the Use of COVID-19 Self-Test Kits in Abuja, Nigeria: Enhancing Usability with References from Malawi and Zimbabwe

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Abstract

Background: Self-test kits have emerged as promising tools for enhancing testing accessibility and convenience. We optimised the instructions for the use of self-test kits for Corona Virus Disease (COVID-19) testing in Nigeria, drawing from adaptations made by Malawi and Zimbabwe to ensure accurate self-testing outcomes and promote effective self-testing practices.

Methods: We conducted a qualitative study employing the health literacy framework, a cognitive interview of three rounds of iterations among participants selected purposively across primary health care, patent medicine stores, and community pharmacy settings. We observed while they performed COVID-19 self-testing using modified Instruction For Use (IFU). A structured guide, which outlined the process of testing in the IFU, was used to guide the optimization process. Qualitative data were analysed using a thematic approach and proportions.

Results: Twelve participants were recruited over three rounds of iterative cognitive interviews. Seventy-five percent were females, and over half had a primary and secondary education. Overall, all participants (100%) recorded usability in conducting the steps in the testing process, with a few records of misinterpretation of the images, symbols, and instructions in the IFU among participants during the self-testing process. However, all the participants interpreted their test results correctly after the first round of IFU revision.

Conclusion: Despite cultural differences, the adapted optimised IFUs required only minor modifications in Nigeria to support accurate self-testing. Our results show the value of rapid evaluation of manufacturer's IFUs using cognitive interviewing.

Keywords: COVID-19, Self-test kits, Instructions for use, Kit optimisation, Abuja

Introduction

The COVID-19 pandemic, initially reported in 2019, spread across numerous countries, including Nigeria, causing high rates of morbidity and mortality.[1,2] Following the identification of the index case in Nigeria by the Nigeria Centre for Disease Control (NCDC) in February 2020, daily records of confirmed cases were consistently reported, indicating evidence of community transmission.[1-3]

The Federal Ministry of Health, in collaboration with the NCDC, has prioritized testing as a key strategy in responding to COVID-19 in Nigeria.[4] Testing services are critical for effectively identifying cases, linking these cases to care, and preventing disease transmission during and in the post-pandemic phases of the COVID-19 outbreak in Nigeria.[5] The self-testing approach has shown encouraging promise in bolstering the diagnostic capacity for various infectious diseases, including COVID-19, and improving community access to testing, particularly in low- and middle-income countries.[6-9]

The successful implementation of self-testing for diseases such as COVID-19 relies on untrained users' ability to independently conduct the test accurately and interpret the results correctly.[9] Clear and culturally adapted instructions for the use of COVID-19 self-test kits provided by manufacturers are crucial to this achievement.[10,11] More importantly, the development of culturally adaptable IFUs for COVID-19 self-testing is pivotal for the government's planned rollout of the COVID-19 self-testing strategy in Nigeria.[10,11]
We investigated the cross-cultural compatibility in Nigeria using IFUs adapted in Malawi and Zimbabwe for the STANDARD Q COVID-19 Ag self-test through cognitive interviews. Cognitive interviewing, commonly used to identify potential sources of response errors in survey questionnaires, was employed. [12-17] Cognitive interviewing has been extensively documented in the iterative development and enhancement of research tools and end-user materials, especially in examining the comprehension of survey questions by research participants and the need for substantial contextual adaptation in this regard.[13-15]

By employing verbal probing to elicit 'thinking out loud', this method evaluates people's comprehension of specific words and phrases, assessing their relevance and acceptability within a particular context. [12-18] The objective was to assess the usefulness of cognitive interviewing in optimising the local comprehension of manufacturers' IFUs to ensure accurate COVID-19 self-testing, as intended by the manufacturers, and to ensure contextual adaptation to the Nigerian setting.

To achieve this goal, we adapted cognitive interviewing techniques to encompass not only verbal comprehension but also in-depth qualitative interviews and the observation of individuals' ability to follow instructions. We adapted the STANDARD Q COVID-19 Ag self-test IFUs from Malawi and Zimbabwe, which had undergone cognitive interviewing, for the optimisation of IFUs in Nigeria.

Methodology

Research design, participant recruitment and cognitive interviewing

This study was part of the Self-Testing Africa (STAR) consortium study which aimed at a large-scale evaluation of COVID-19 self-test in low- and middle-income countries. The study was conducted in the Federal Capital Territory (FCT), Abuja, Nigeria. A health literacy approach informed the study's design. Participants were purposively selected from Primary Health Care centres (PHCs), Patent Medicine Stores (PMs), and Community Pharmacies (CPs) to represent the intended users of the COVID-19 self-test kit in Nigeria. In the study, individuals at different levels of literacy were included. The inclusion criteria included having COVID-19 symptoms, being aged > =18 years, possessing the ability to read a page of an English-language newsletter, and a voluntary willingness to participate in the study.

Based on the results of 287 cognitive interviews conducted in Malawi and Zimbabwe, which involved iterations of IFU changes to achieve data saturation and usability thresholds (i.e., correct execution of all critical self-testing instructions),

we conducted three iterative rounds of cognitive interviews with four participants each to attain data saturation. During these interviews, participants were observed while attempting to complete the COVID-19 self-testing steps, utilizing a structured interview guide that presented the steps outlined in the adapted IFUs from Malawi and Zimbabwe.

Trained research assistants, overseen by a social scientist, were responsible for recruiting participants. A structured interview guide, mirroring the steps depicted in the IFUs (Fig 4), informed the interviews. Subsequently, all participants were provided with a Standard™ Q COVID-19 Ag Home test kit (SD Biosensor®, Republic of Korea), featuring a modified IFU adapted from the Malawi and Zimbabwe study, highlighting key differences from the manufacturer's original IFU. The IFU comprised four procedural steps outlining preparation, sample collection, test procedure, and result interpretation, accompanied by eleven key instructions aimed at guiding participants through the test independently. Participants were instructed to
(1) read the instructions,
(2) analyse the pictorial and written instructions and explain them to the social scientist,
(3) perform the depicted actions, and
(4) consider how easy or difficult other members of their community might find the written and pictorial instructions.

The interview guide included scripted probes to ensure comprehension at each step of the self-testing process, and research assistants were trained to use spontaneous probes while an observation checklist was likewise completed during the assessment process. Participants responded in both English and vernacular, which is a commonly used means of communication for individuals with low literacy levels in Nigeria.

Data regarding adherence to instructions, alongside an evaluation of the accuracy of testing and interpretation of results by each participant, were reported. The themes from the cognitive interviews were patterned after the HIV self-testing studies in Zambia, Malawi, and Zimbabwe [12] and the final themes for the study agreed upon by the authors for the thematic analysis of the transcripts.

Results

Based on the findings from 287 cognitive interviews conducted in Malawi and Zimbabwe as part of the COVID-19 self-test kit optimisation exercise, our study engaged 12 participants across three rounds of iterative cognitive interviews. Three-quarters (75%) were females aged less than 40 years, while more than half (58%) had completed primary and secondary education (Table 1).

The observation assessment results indicated a notable improvement in participant performance throughout the cognitive interview rounds. Specifically, the proportion of participants accurately identifying the various components of the test kits increased from 83% (10 out of 12) in rounds 1 and 2 to 100% (12 out of 12) in round 3, as illustrated in Figure 1. Similarly, the percentage of participants who correctly interpreted test results within 30 minutes of testing increased from 92% (11 out of 12) in rounds 1 and 2 to 100% (12 out of 12) in round 3, as presented in Figures 2 and 3.

Outcome of Cognitive Interviews

This report presents the outcomes of the thematic analysis, highlighting key findings and participant perspectives on the current IFU for COVID-19 self-testing in Nigeria. Through thematic analysis of cognitive interview data, key themes emerged, shedding light on IFU strengths and weaknesses, including clarity of instructions, understanding of terminology, language considerations, clarity of images, interpretation of test results, and guidance on waste management. Throughout the optimisation process and cognitive interviews, participants demonstrated increasing proficiency and understanding of self-test kit instructions, reflecting the iterative nature of usability improvement efforts. Notably, improvements were observed in rounds two and three of the cognitive interviews, addressing challenges identified in round one after IFU revisions based on participants' suggestions.

Understanding and clarity of instructions
Participants generally found the instructions clear, particularly with the aid of diagrams/images. They emphasised that understanding could be achieved solely through visual aid, highlighting the importance of clear visual imagery. Participants further elucidated that the instructions guided them through the process of preparing for the test, emphasising the clarity and understanding of the steps.

"The instructions are clear with the diagram. If a person looks at the pictures (images) and reads the instructions, they can easily understand the instructions"
[Cognitive Interview-Round 1, Female, 28 years] *"Without the instructions per say, if you look at the diagram, you can carry out the test easily."*
[Cognitive Interview-Round 1, Female, 28 years] *"In my own understanding, the diagram is telling me to first of all wash my hands or sanitise my hands making sure my hands are properly neat and clean before I can start the test."* **[Cognitive Interview-Round 1, Female, 25 years]**

Language and literacy
Concerns were raised regarding the language used, with some participants expressing their difficulty with some complicated language used in the IFU, and they felt that uneducated individuals might struggle with certain instructions. Other participants highlighted the need for the instructions to be in local dialects, emphasising accessibility for those less proficient in English and other rural end users

"A layman or an uneducated person might not understand a few languages used in the IFU except that somebody who is very educated explain to them" **[Cognitive Interview-Round 1, Female, 28 years].** *".... they also say open the pouch, I don't even understand the English; so can you break it down for me"* **[Cognitive Interview-Round 1, Female, 22 years]** *"So, I think it will be a good idea, if they can put the whole instructions perhaps in the local dialect apart from the normal official language; English…. if the instructions can still be translated in major dialect, perhaps maybe in Yoruba, Igbo and Hausa language…"*
[Cognitive Interview-Round 1, Female, 22 years]

Unfamiliar and confusing images and symbols
Participants found some images and symbols in the instructions unclear or poorly labelled and struggled with identifying kit components due to inadequate labelling. They also noted inconsistencies between images and instructions, suggesting improvements such as labelling and using familiar symbols such as clocks for better clarity.

"Which one is it? Which one is cassette? I cannot understand the instructions and diagrams because the diagrams and pictures are not well labelled in the IFU"
[Cognitive Interview-Round 1, Female, 31 years]"*Okay, identifying the test kit components is difficult to me because not all of the kit components are well labelled in the test kit manual (IFU). What I can see here are test device, solution tube and nozzle cap, sterile swab, waste bag, instructions for use and quick reference instructions can be found here. For other kit components, I don't know what they are, as I am not health personnel."* **[Cognitive Interview-Round 1, Female, 31 years]**

"The image provided under instruction six conflicts with the accompanying instruction and not very clear to me because in this image, it is showing we should hold the swab stick at the tip, but the instruction is saying we should not touch the tip of the swab stick. Maybe you should clearly indicate or label what you are referring to as the tip of the swab stick in the IFU for the purpose of clarity?"
[Cognitive Interview-Round 1, Female, 25 years]

"The image under instruction eleven is not very clear to me, and I think the same for other users, as it does not depict a time clock to the layman. Many people are familiar with the picture of the common wall clock at home or with the wristwatch. So, I will suggest you use the image of the common wall clock or wristwatch that everyone is familiar with for better clarity then indicate the time in the instruction on it…. You can use a good and bad symbol to indicate the correct time and wrong time

for reading the test results on the images under instruction eleven in the IFU" **[Cognitive Interview-Round 1, Female, 25 years].**

Ability to interpret test results

Participants demonstrated an understanding of interpreting test results, citing specific criteria for determining the test result outcome.

"...to my understanding, they said I should read it 15-30 minutes so that the result to be accurate then after 30 minutes then I should not read the test results."

[Cognitive Interview-Round 1, Female, 22 years] *"...For negative results, a coloured band will appear only on the control line, so my test result is negative."*

[Cognitive Interview-Round 1, Female, 25 years]*".... I suggest for the "Invalid result" there should be an instruction or a statement for the scenario where there is no test line appearing neither in the Control area or test area in the kit cassette for better result interpretation...."*

[Cognitive Interview-Round 2, Male, 72 years]

Instruction for waste management

Concerns were raised about the lack of instructions for waste disposal. Participants in round 1 of the cognitive interview noted the absence of guidance on using the plastic bag for waste disposal, suggesting the addition of clear instructions and images for proper disposal steps.

"I observed the instructions and images for disposal of the test kit used were omitted from the IFU. I notice there is a plastic bag among the test kit components but no instruction on what to use it for which I guess is for waste disposal, so the instruction for waste disposal can be added with clear images showing step by step to us how to properly dispose of the used test kit and other items"

[Cognitive Interview-Round 2, Male, 45 years].

Overall, participants highlighted the importance of clear language, visual imagery, and inclusive instructions for better usability of COVID-19 self-test kits, particularly emphasizing the needs of diverse users in Nigeria.

Tables and figures

Table 1: Sociodemographic characteristics of the respondents

Variable	Frequency n=12 n (%)
Age (in years)	
≤30	6 (50.0)
31-40	3 (25.0)
> 40	3(25.0)
Gender	
Male	3 (25.0)
Female	9 (75.0)
Education level	
Primary	3 (25.0)
Secondary	5 (43.0)
Tertiary	4 (32.0)

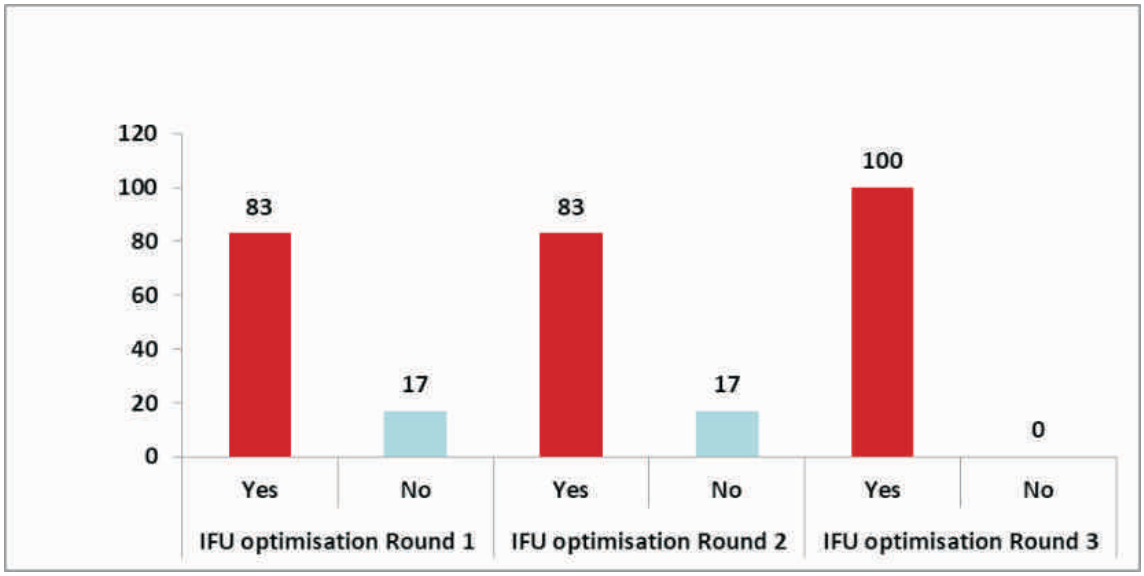

Figure 1: Participants who were able to identify test kit components

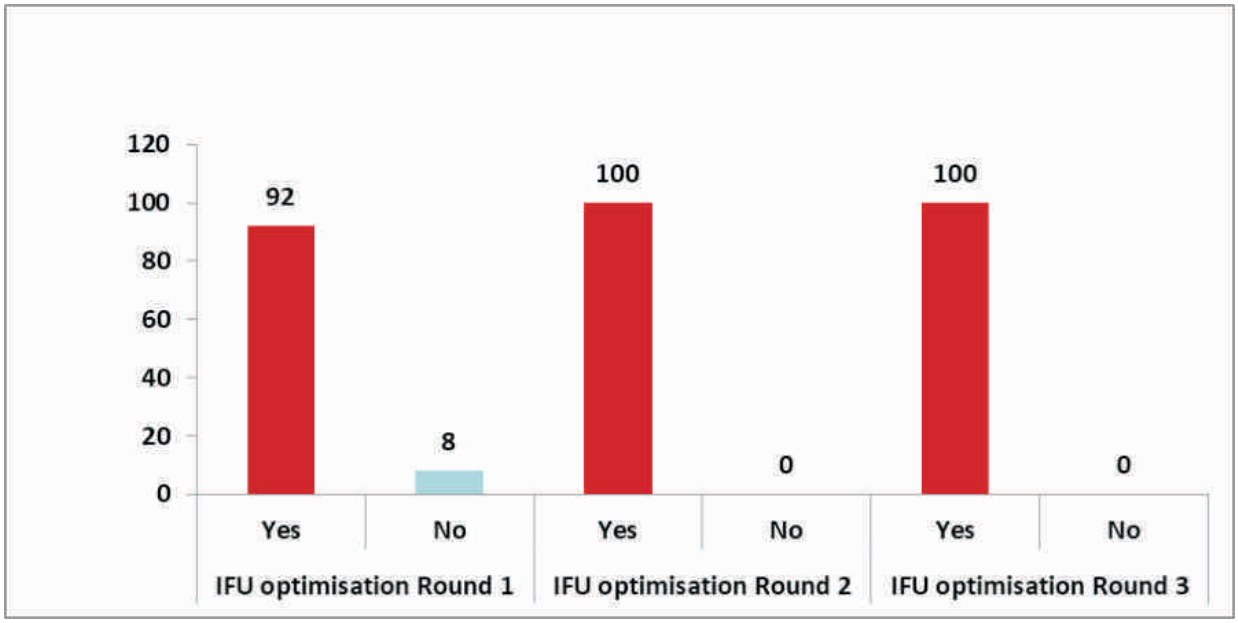

Figure 2: Participants who interpreted test results within 15-30 minutes

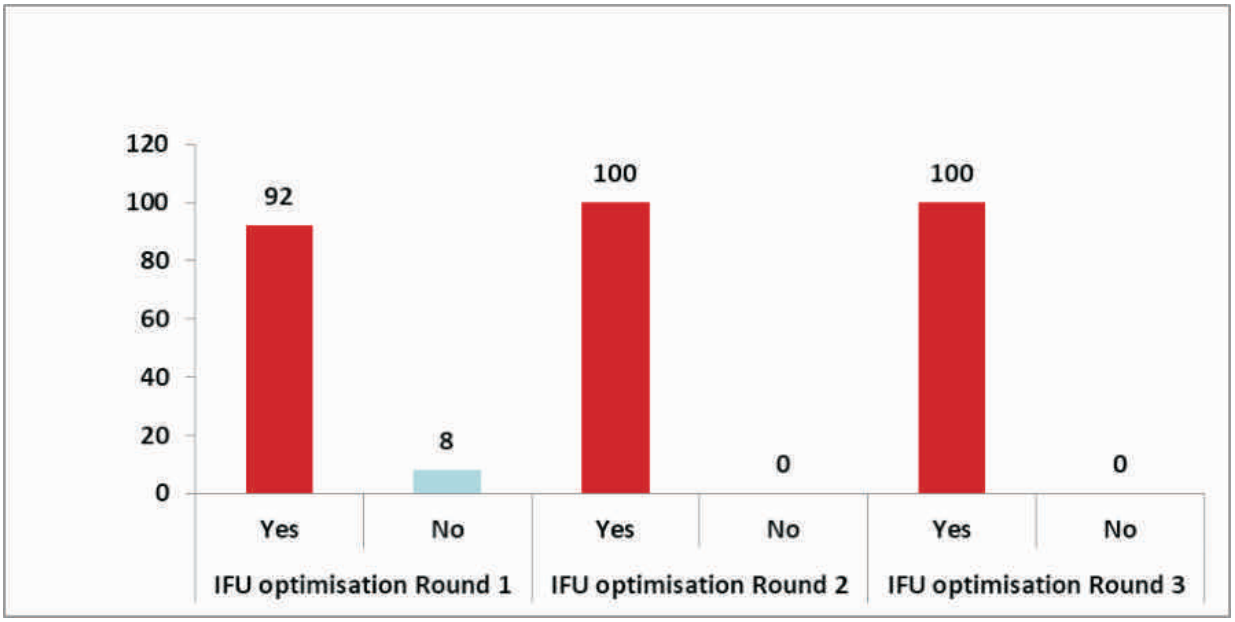

Figure 3: Correct COVID-19 Ag-RDT self-test outcome result interpretation by participants

IFU before optimisation

Changes made to optimised IFU

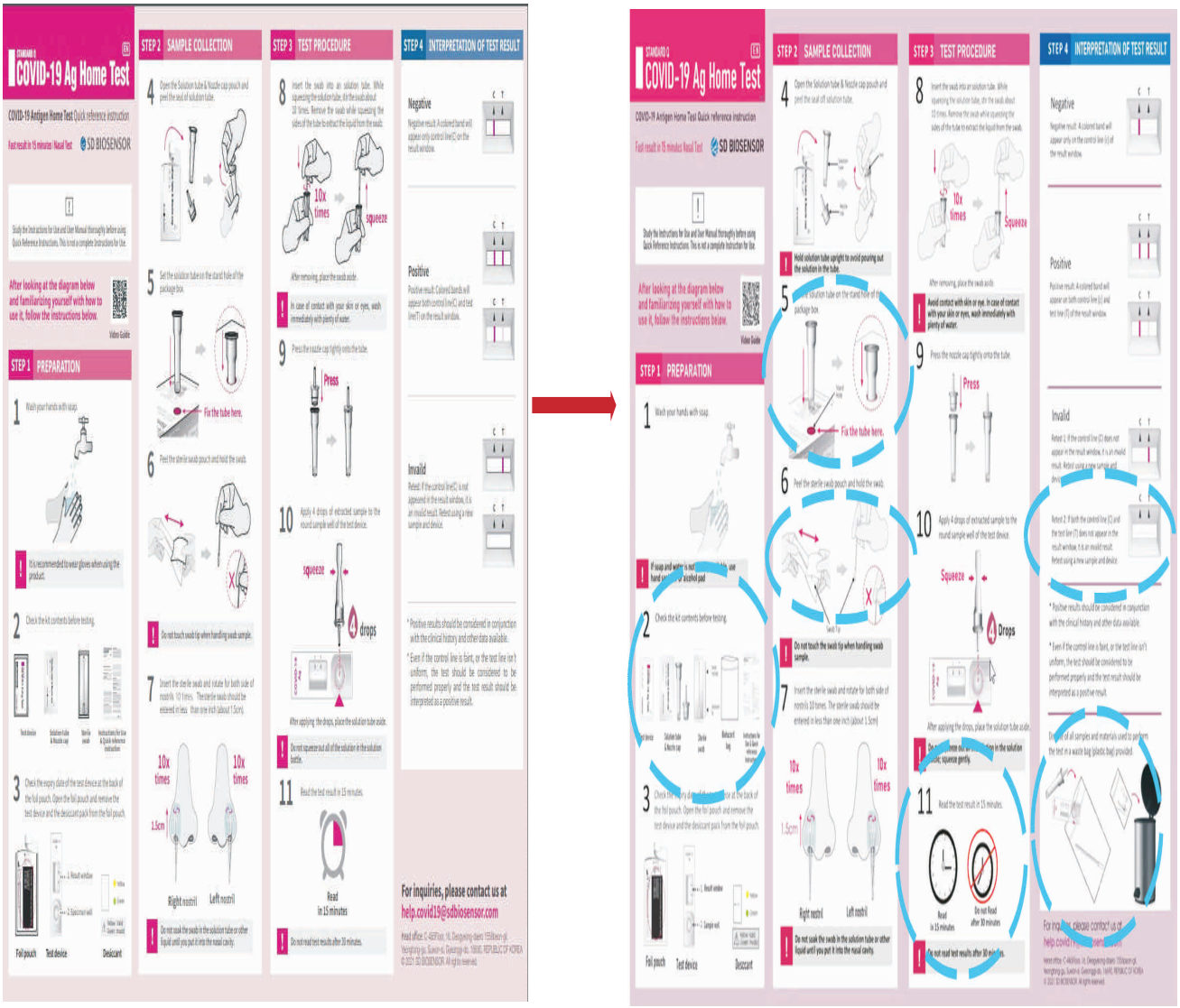

Figure 4: Preoptimized IFU vs. Optimised IFU; highlighting key revisions

Discussion

Findings from our study provided valuable insights into the usability of self-test kits for COVID-19 testing to enhance large-scale rollout in Nigeria. We found that despite several steps and procedures involved in COVID-19 Ag-RDT self-testing, participants were able to understand and follow instructions for use and self-tested correctly. Engaging 12 participants across three rounds of iterative cognitive interviews using adapted IFU previously optimised in Malawi and Zimbabwe allowed for a comprehensive understanding of user experiences and perspectives in their ability to self-test independently and unassisted in Nigeria. Furthermore, more than half of the participants had completed primary/secondary education, reflecting a range of educational backgrounds that are crucial in Nigeria.

The results of the cognitive interviews demonstrated a noticeable improvement in participants' performance throughout the iterative process. Specifically, the proportion of participants who accurately identified test kit components and interpreted test results within 30 minutes increased substantially across the three rounds of interviews. This improvement suggests the effectiveness of iterative refinement in enhancing user understanding and proficiency with the use of self-test kits.[9,12]

Thematic analysis of the cognitive interview data revealed several key themes related to the usability of the IFU included with the self-test kits. Participants generally found the instructions clear, particularly when accompanied by clear and self-explanatory images. Notably, language and literacy emerged as significant factors influencing participants' ability to understand IFU. Some participants expressed difficulty with complex language and suggested the use of simpler, more accessible language throughout the instructions. This finding is expected, given the low literacy level among the Nigerian population vis-à-vis health service utilisation in the country.[19-21] Additionally, concerns were raised about the lack of instructions in local dialects, highlighting the importance of linguistic diversity in ensuring inclusivity, especially in culturally diverse settings like Nigeria, with several languages.

The above findings are in keeping with other studies undertaken by previous authors on HIV self-testing and COVID-19 self-testing in other African countries with low literacy levels.[9, 12, 22] In 2019, a study on optimising HIV self-test kit IFU in Malawi, Zimbabwe, and Zambia.[9] linked lower literacy levels, along with the use of unfamiliar images and symbols and complex terminologies in the IFU, as key barriers to participants' comprehension and ability to perform the HIV self-test as intended by the manufacturer. In a similar vein, another study highlighted a significant challenge regarding the diagnostic accuracy of COVID-19 self-testing among untrained lay users in their study conducted in countries with very low literacy levels.[11] Consequently, our study participants advocated for well-translated and culturally relevant IFUs to facilitate the large-scale implementation of self-testing for COVID-19 in Nigeria.

Furthermore, a few unfamiliar or confusing images and symbols were identified as barriers to understanding the IFU, with participants struggling to identify kit components and interpret instructions accurately. Suggestions for improvement included clearer labelling and the use of familiar symbols for better clarity and comprehension.

Despite these identified barriers, our study participants were able to navigate through the steps in the IFU using pictorial images, as most participants were familiar with other self-care and self-testing health-related procedures common in the Nigerian context, such as the pregnancy home test and HIV self-test.[23-26]

Participants demonstrated an understanding of interpreting test results, citing specific criteria for determining outcomes. However, suggestions were made for enhancing clarity, particularly regarding invalid results. Concerns about the lack of instructions for waste disposal were also highlighted, indicating a need for clear guidance on proper disposal steps to meet globally accepted safety measures.

Despite the valuable insights gained from this study, several limitations should be considered. First, the study focused on cognitive interviews conducted in the African regions of Malawi and Zimbabwe, which may limit the generalizability of the findings to other regions or populations. Additionally, the sample size of participants in each round of cognitive interviews was relatively small, which may affect the robustness of the results. Though efforts were made to address language barriers by adapting IFUs, challenges in language comprehension may persist among certain other user groups.

Conclusion

Our study highlights the importance of iterative cognitive interviewing in optimising IFUs for COVID-19 self-testing and adapting the IFU to the Nigerian context. Using a modified COVID-19 Ag-RDT self-test kit IFU adapted from Malawi and Zimbabwe, we conducted 12 cognitive interviews and made three iterations of changes to the IFU. We observed significant improvements in participant performance and comprehension. The findings indicated that the iterative approach led to enhanced proficiency in identifying test kit components and interpreting test results accurately within the specified time frame. Additionally, thematic analysis revealed key insights into IFU strengths and weaknesses, particularly regarding the clarity and understanding of instructions, language considerations, clarity of images, interpretation of test results, and guidance on waste management. Overall, the study underscores the significance of clear language, visual imagery, and inclusive instructions in ensuring the usability of COVID-19 self-test kits for catering to the diverse user population in Nigeria.

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Conflicts of interest

None declared.

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