Informing targeted HIV self-testing: a protocol for discrete choice experiments in Malawi, Zambia and Zimbabwe

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ABSTRACT (297/300 words max)

Introduction

HIV self-testing (HIVST) is a new approach to HIV testing where a person collects his or her own specimen, performs an HIV test and interprets the result, either alone or with someone he or she trusts. It is becoming increasingly relevant as a complement to standard-of-care HIV testing and is now recommended by the World Health Organization. Few studies have explored user preferences around HIVST service delivery and optimal models for increasing uptake and linkage to care, particularly among hard-to-reach populations. This paper describes an ongoing study that uses discrete choice experiments (DCE) to identify key HIVST service characteristics that drive people's willingness to self-test for HIV and link to care, measure the relative strength of user preferences, and explore preference heterogeneity in Southern Africa.

Method and Analysis

Two DCEs – one on HIVST delivery and one on linkage to care after a positive self-test – are being administered in Malawi, Zambia and Zimbabwe. The designs in each country were informed by a qualitative study, which identified key HIVST service characteristics that influence user decision-making and refined scenario presentations and illustrations. Following data collection, DCE data will be analysed using a multinomial logit model as well as latent class, nested logit and generalised mixed models to examine heterogeneity in preferences by sociodemographic background, HIV testing experience and sexual behaviour.

Ethics and dissemination

The study has been approved by the College of Medicine Research Ethics Committee in Malawi, the Biomedical Ethics Committee of the University of Zambia, the Medical Research Council of Zimbabwe and the Research Ethics Committee of the London School of Hygiene and Tropical Medicine. Findings from the study will be presented at international conferences and in peer-reviewed journals. The results will help inform the HIVST implementation strategy in Southern Africa, particularly among populations underserved by standard-of-care services, such as men and young women.

STRENGTHS AND LIMITATIONS OF THIS STUDY

- Discrete choice experiments measure preferences in the absence of observable product and service use, and can disentangle preferences for specific components of a service package, such as services to distribute HIV self test kits and link testers to prevention, care and treatment.
- The DCE study design allows for exploration of preference heterogeneity for HIV self-testing (HIVST) across socio-demographic groups and comparison across countries.
- Our findings will inform policy makers on the potential impact of alternative HIVST kit distribution and linkage to care models on service uptake.
- Pictorial representations of service attributes aim to overcome low literacy rates among some rural populations.

- Hypothetical scenarios are presented to participants, some prior to exposure to HIV self-testing, which may make choices less salient.

INTRODUCTION

Expanding access to HIV testing is vital to achieving HIV epidemic control. The HIV burden remains highly concentrated in southern Africa, with an estimated adult prevalence of 9.1% in Malawi, 12.9% in Zambia and 15% in Zimbabwe [1]. There has been remarkable progress in reaching the UNAIDS 90-90-90 targets, in 2015, an estimated 62% of people living with HIV in southern and eastern Africa were aware of their sero-status [2]. Despite these gains, HIV testing rates remain disproportionately lower among men and young women [3]. Achieving higher and more equitable coverage of HIV testing requires alternative, targeted modalities beyond standard HIV testing and counselling.

HIV self-testing (HIVST) has great potential to improve early HIV detection. Oral rapid tests packaged for self-use have demonstrated high sensitivity and specificity when carried out by lay users [4-6]. HIVST has also proven to be acceptable across a range of populations and contexts in southern Africa [7-10]. Appeal related to privacy and confidentiality has led to notable uptake among people currently not reached by facility-based or community-based HIV testing and counselling (HTC) services [11-13]. With this growing evidence, national HIV testing policies that include HIVST are being introduced across a range of settings, including Malawi, Zambia and Zimbabwe, where these policies are currently under development [13].

Discrete choice experiments (DCEs) are a valuable way of measuring and quantifying user preferences for goods and services, particularly when there is a dearth of data around observed behaviour [14-16]. As part of the DCE, respondents are asked to select between a set of hypothetical scenarios containing alternating bundles of product or service characteristics, called attributes. Based on the respondent's choice selection, we can analyse key drivers of demand for a good or service and make recommendations on optimal resource allocations [17]. These results can also be integrated into cost-effectiveness analyses to evaluate the potential economic impact of alternative designs [18, 19].

A handful of studies have used DCEs to investigate delivery of HIVST and HTC in sub-Saharan Africa [8, 20-22]. This study, which is taking place in Malawi, Zambia and Zimbabwe, aims to build on this evidence by investigating preferences for distribution of HIVST kits and linkage to confirmatory testing and ART initiation after a positive self-test. Analysis of the DCE will enable us to weigh the relative value for each service attribute and understand preference heterogeneity by including socio-demographic background, HIV testing and sexual behaviour as explanatory variables in the utility function [23].

This research is part of the UNITAID/PSI HIV Self-Testing Africa (STAR) project, which is evaluating strategies for implementing HIVST in Malawi, Zambia and Zimbabwe to inform rapid scale-up within southern Africa and beyond. The DCEs will complement STAR qualitative research on values and preferences for HIVST and cluster randomised trials (CRT) evaluating alternative distribution and linkage strategies.

METHODS AND ANALYSIS

Overview of approach and methods

This study is administering two DCEs in Malawi, Zambia and Zimbabwe to inform HIVST implementation strategies. The first DCE will investigate preferences regarding delivery of HIVST relative to standard-of-care HTC. Since HIVST does not provide a definitive diagnosis and requires a confirmatory test [13], the study will conduct a second DCE to evaluate drivers of demand for linkage to onward HIV testing and care services.

Construction of the DCE involves multiple phases, which are being implemented independently in Zimbabwe and collaboratively in Malawi and Zambia due to similarities in the HIVST intervention designs. The formative phase consists of a literature review on user preferences for HIV testing and care services and individual interviews and focus group discussions (FGD) to identify product or service attributes that are most important or relevant to respondents. Scenario exercises consisting of pictorial illustrations of key attributes and levels are also assessed for user understanding.

Afterwards, the preliminary design is piloted, with the collected data used to generate a D-efficient design [24]. The DCE questionnaires are then nested within household surveys under the CRT evaluating community-based distribution of OraQuick ADVANCE HIV I/II Antibody Test packaged for self-use. Finally, the DCE data will be analysed to understand the strength of respondents' preferences for HIVST delivery and linkage to care attributes, such as the collection location for self-test kits or support level following a positive self-test, and to simulate trade-offs of more or less desirable attributes under different scenarios.

The timelines for the study are presented in Figure 1, with the study starting in February 2016 and data collection finishing in all countries by December 2016.

Figure 1 – DCE data collection timelines for Malawi, Zambia and Zimbabwe

<Insert Figure 1 here>

Formative qualitative study – identifying choice tasks, attributes, and levels

A critical part of the DCE development process is the selection of key attributes that influence willingness to self-test for HIV and link to care. To identify these attributes and develop a preliminary DCE design, we reviewed the existing literature on HIV services and conducted qualitative research with community members in rural and urban areas and key informants for product implementation.

Literature review

The literature review aimed to identify key factors affecting utilisation of HIV testing and care services in sub-Saharan Africa. A significant barrier to uptake of HIV testing includes perceived lack of confidentiality by health care workers and fear of HIV-related stigma [7, 25]. Provider-initiated testing and mobile testing have helped to improve service use by enhancing patient privacy and convenience. HIVST has also been seen as a convenient, confidential and highly acceptable testing approach, though some level of guidance or supervision is often needed [4, 7, 26, 27]. In Zambia, a DCE found that counselling, as well as test price, were important drivers of HIVST demand among potential users, whereas the location of test kit collection was perceived as being less important [8].

However, mobile testing has underscored the importance of minimising user costs through accessible service locations [25]. A DCE on HIV testing preferences in Tanzania found that men

preferred testing sites that were close (< 1 km) to home, while women preferred to be tested at home. There was also a strong preference for finger-prick tests over oral swab tests [21]. Community-based distribution of HIVST by lay volunteers and partner-delivered HIVST for home use have additionally shown promising results for increasing HIV testing coverage, including among men and adolescents [28]. These strategies highlight how the type of provider can influence acceptance of HIVST kits.

Similar to HIV testing, key barriers to ART services include distance to health facilities, absence of social networks, and issues around privacy and stigma, especially at overcrowded clinics [9, 29]. One approach for increasing access to HIV treatment includes home-based ART initiation, which in Malawi was found to significantly increase population-level demand for treatment [12]. Additionally, phone calls and text reminders have been used to enhance social support around ART initiation and retention, though these results have been mixed [30-32].

Individual interviews and focus group discussions

Following the literature review, we vetted the compiled list of attributes through individual interviews and FGDs with key informants and community members in each country.

As a first step, we met with local experts to ensure that the DCEs were designed with key policy concerns and questions in mind [33, 34]. Experts included country representatives from Population Services International, our partner implementers under STAR, and the Ministry of Health in Zimbabwe. DCE attributes and levels were then adjusted to include aspects of the HIVST delivery and linkage to care interventions in each country (e.g., use of a free telephone hotline providing HIVST guidance and counselling) as well as future areas of interest.

We then conducted individual interviews and FGDs at the same sites as the STAR CRT. Given that the trials in Malawi and Zambia are similarly evaluating HIVST distribution strategies, the formative qualitative studies were coordinated across both sites. In Zimbabwe, where the trial is evaluating linkage of self-testers to HIV treatment, the DCE underwent a separate design process.

Individual interviews were administered in Malawi with antenatal care (ANC) and voluntary counselling and testing (VCT) clients (n=33) recruited through STAR sub-studies in rural and peri-urban Blantyre. The Malawi results were then applied to the context of rural and urban Zambia, where individual interviews were conducted with men and women between 16 and 50 years old in Kanakantapa villages and peri-urban area of Lusaka (n=10). In Zimbabwe, the qualitative research was done in rural communities in Mazowe district, which had just piloted door-to-door distribution of HIVST kits. Eight FGDs were completed to inform the DCE on HIVST distribution (n=83) and eight FGDs to inform the linkage to care DCE (n=75). Respondents were male and female in equal proportion aged between 16 and 73 years old.

The aim of the qualitative research was to understand which attributes people consider to be the most important and relevant in influencing their decisions to self-test and link to confirmatory testing and treatment. For the interviews and FGDs, respondents were presented with the OraQuick HIV self-test kit to allow for elicitation of meaningful preferences. They were then asked about how they would want HIVST to be implemented in their communities and to rank which HIVST delivery and linkage to care attributes they preferred. Based on the ranking exercise, we narrowed down the

list of attributes and developed pictorial illustrations for each of the levels. To account for low literacy levels among respondents [34, 35], we conducted additional interviews to assess user understanding of the scenarios. Adjustments were then made until we achieved saturation and all concepts and representations were clear to respondents.

Design of the pilot DCE

Analysis of the formative qualitative data led to identification of the key attributes presented in Table 1 for the 3 countries. With a common formative framework for Malawi and Zambia, we selected the same attributes and levels. After discussion with the Zambia's implementer, the only adjustments were the addition of "drugstore" as a distribution channel and we adapted the test price range. Qualitative studies which were conducted separately in Zimbabwe identified slightly different attributes and levels.

Table 1: "HIVST distribution" and "Linkage to care" DCEs design for Malawi, Zambia and Zimbabwe

Malawi and Zambia		Zimbabwe	
"HIVST distribution" DCE			
Attributes	Levels	Attributes	Levels
Location of collection of kits	health facility, mobile clinic, own home, home of the distributor, drugstore[1]	Location of collection of kits	health facility, mobile clinic, home
Type of distributor	counsellor, community-based distributor agent, your partner, drugstore staff[1]	Type of HIVST distribution	deliver tests for whole household, only directly to individuals
Level of pre-test support	instruction leaflet (IL), IL and free hotline, IL, free hotline and in person support, IL and in person support	Level of pre-test support	instruction leaflet, hotline, face to face from distributor
Type of HIV test	blood-based self-test, oral self-test, provider-delivered blood-based test	Time of operation	Monday to Friday 8am-4pm, every day including evenings and weekends
Test price	free, Malawian kwacha (MWK) 50, MWK 150 free, Zambian kwacha (ZMK) 10, ZMK 30, ZMK 50	Test price	free, US dollar (USD) 0.50, USD 1
Level of post-test support	instruction leaflet (IL), IL and free hotline, IL, free hotline and in person support, IL and in person support	Residence of distributor	from the same village, from outside the village
		Age of distributor	below 30 years old, above 30 years old
"Linkage to care" DCE			
Support for linkage	none, SMS reminder, call reminder, in person follow up	Support for linkage	none, SMS reminder, call reminder, in person follow up

Location of confirmatory testing	health facility, mobile clinic, home, home of the HTC counsellor	Proximity of testing facility	less than 30 minutes' walk from home, about 1 hours' walk, more than two hours' walk
User fee for a HIV test	none, MWK 100 none, ZMK 10	User fee for a HIV test	none, USD 1, USD 2
HIV services separation[2]	waiting area with people for all services, separate waiting area for HIV services	Busyness of testing facility	few people, many people
Waiting time to get tested	30 minutes, 1 hour and 30 minutes, 3 hours	Availability to initiate treatment immediately	available, not available
		Operating hours of testing facility	open weekdays 8am-5pm, open weekdays and weekends 8am – 5pm
		Time between distribution of HIV self-test kits and visit by PSI New Start outreach team	within 1 week, from 2-3 weeks, not applicable

[1]Specific to Zambia only

[2]At the health facility and mobile clinic only

Figure 2 is an example of the HIVST distribution DCE in Zambia. Columns 1 and 2 present two HIVST distribution strategies. Column 3 allows respondents to opt-out of choosing either of the two strategies, creating a more realistic scenario that does not overestimate demand for self-testing [36]. For the HIVST distribution DCE, the opt-out option is interpreted as "I would test the way I did before", e.g., standard of care, or "I would still not test for HIV", depending on the individual's HIV testing experience. The opt-out option for the linkage to care DCE is interpreted as "I would not link to confirmatory testing and ART services if linkage 1 and linkage 2 were the only options".

In Zimbabwe, a labelled linkage DCE was chosen because of a better validity to explain real-life choices. This DCE aims to inform preferences between PSI community-based outreach centres and local health facilities for obtaining confirmatory testing and ART initiation. For all other DCEs, unlabelled designs were preferred because the choice of which would be the dominant attribute to use for labels was not evident and the constraint in the numbers of labelled columns for the scenario exercise [37].

Figure 2 – Sample scenario exercises for "HIVST distribution" DCE

<Insert Figure 2 here>

To provide realistic scenarios, we set restrictions on the attributes and levels. For example, in the HIVST distribution DCE scenarios, the option of in-person pre-test support was not available when the kit was received from a partner. For standard-of-care, the provider was an HTC counsellor delivering in-person support. The provider was a pharmacy staff member if the location of collection

was a drugstore. Similarly, in the linkage DCE, a scenario including HIV-specific services only applied if the location of confirmatory testing and ART initiation was at the health facility or at the mobile clinic. As the linkage DCE in Zimbabwe had a labelled design, these constraints were not necessary.

Pilot phase – developing the choice design

We conducted a pilot of the DCE to assess how well the participants understood the questionnaire and gather pilot data to inform the final experimental design. The pilot DCE, using an initial factorial design, was generated in Ngene software [38] and tested with a sample of 200 respondents in Malawi, 50 in Zambia and 50 in Zimbabwe. The DCE was included as part of the piloting of the household survey.

The dataset from the pilot study was analysed using a multinomial logit model (MNL) and the results used to generate a statistically efficient design for the final DCE questionnaire.

The pilot phase also assessed the feasibility of implementing the DCEs on 7 inch tablets. Electronic DCEs are becoming more popular due to improved ease of data management [18, 39, 40]. We decided to use tablets for the DCEs in Malawi and Zambia, but not for Zimbabwe where the team had more experience conducting DCEs using colour-printed paper-based questionnaires.

Data collection phase - administering the DCE

The DCE is nested within the household surveys under the STAR CRT. Other modules include socio-demographic background, experience with HIV testing and care, sexual behaviours, HIV-related stigma and intimate partner violence.

The questionnaire will be administered in rural and peri-urban areas of Blantyre, Machinga, Mwanza and Neno districts in Malawi and rural, peri-urban and urban parts of Choma, Kapiri Mposhi, Lusaka, and Ndola. In Zimbabwe, the distribution DCE will take place in Mazowe district and the linkage DCE in Mberengwa district.

The household surveys and DCE in Malawi and Zambia are being conducted prior to community-based distribution of HIVST kits, while the questionnaires in Zimbabwe will be implemented concurrently with distribution. To elicit more meaningful responses, the surveyors in Malawi and Zambia will present the OraQuick HIVST kit to respondents and demonstrate the self-testing process at the beginning of the interview. Though we ask for preferences around sampling method, we will not show respondents the blood-based HIV self-tests or rapid diagnostic tests (RDT) as we expect most respondents will have experience with HIV testing. Additionally, we believe that people are more familiar with blood-based HIV testing and that verbal explications of these techniques will be enough. However, this may lead to a pro-HIVST bias.

Participants will be encouraged to ask any questions they have on HIVST. The surveyors will be trained on how to demonstrate the self-test and explain the attributes, levels and scenario exercises in line with cross-country standard operating procedures. Twenty surveyors will be recruited in Malawi and Zimbabwe each to administer the questionnaires. In Zambia, between 10 and 20 surveyors will be recruited in each of four districts.

In Malawi and Zambia, the survey and DCE will be programmed using Open Data Kit (ODK) onto electronic tablets (Samsung Galaxy Tab 4 for Malawi and Getac z710 for Zambia). In Zimbabwe, computer tablets will be used for the household questionnaire and paper versions for the DCE, with unique IDs linking both forms. The household survey will take approximately one hour, with the DCE module taking 10 minutes to complete.

Sampling criteria and sample size

Eligibility in all countries includes respondents from randomly selected households who are 16 years or above and provide consent. For Malawi and Zambia, the tablet will then generate a random number allocating eligible respondents to the extended household survey modules and either the distribution or linkage DCE. All respondents reporting a positive HIV status will be allocated to the linkage DCE. Supposing we have a representative sample in our survey, we can expect our HIV-positive sample size between 45 to 65 individuals based on the HIV prevalence in each country and estimated sample size of 500 people [1]. To ensure a sufficient sample size, we will also randomly assign 40% of participants who report an HIV negative status or do not know their status to the linkage DCE. The rest of this sample will be given the distribution DCE estimated to be between 450 and 550 respondents.

In Zimbabwe, the distribution DCE will be conducted separately and the first 500 participants in the household survey will receive the linkage DCE. All DCE participants, except in Zambia, will be given financial compensation (USD 1.4 in Malawi and USD 5 in Zimbabwe) for their time.

There is a lack of consensus regarding the minimum sample size required for stated choice data [41]. We employed the commonly-used rule of thumb by Johnson and Orme to ensure that we were able to estimate parameters for the full sample as well as analyse preference heterogeneity between sub-groups [42]. This method suggests a minimum sample size of 170 for both distribution and linkage DCE for Malawi, 210 and 170 for Zambia, 90 and 110 for Zimbabwe. Our sample size being between 300 and 500, we will be able to analyse main effects and preference heterogeneity among socio-economic groups.

Data analysis

The results from this study will provide recommendations on the implementation strategy of HIVST in Malawi, Zambia and Zimbabwe and interventions for optimising uptake among the general population and hard-to-reach sub-groups. Our analysis of the DCE data will examine main effects and relative preferences for HIVST delivery and linkage to care attributes.

The most basic approach to the DCE analysis is a simple multinomial logit (MNL) model. [36] The MNL model assumes irrelevance of independent alternatives (IIA), meaning that the probability of choosing an alternative over another in a choice set is not affected by the presence of the other alternative and that preferences are the same across similar individuals. However, the IIA is often not respected in DCE. Our analysis will therefore include other choice models, such as the mixed multinomial logit, the latent class model and generalized multinomial logit model, that do not have the IIA restriction and allow for exploration in heterogeneity in the data [36].

Sociodemographic characteristics (e.g., age, sex, education and wealth), HIV-related indicators (e.g., use of HIV testing, HIV status, and stigma around HIV), sexual behaviour, and risk aversion and

subjective well-being will be explored to understand how they may influence respondents' preferences. Interaction effects between the services attributes and socio-demographics will allow us to estimate preference heterogeneity across observable individual characteristics. Parameter estimates will allow us to provide quantitative values on preferences, allowing for recommendations on optimal HIVST strategies.

ETHICS AND DISSEMINATION

Ethical considerations

The research project has been approved by the College of Medicine Research Ethics Committee in Malawi, the Biomedical Ethics Committee of the University of Zambia, the Medical Research Council of Zimbabwe and the Research Ethics Committee of the London School of Hygiene and Tropical Medicine.

Informed consent will be taken for participation in this study. In cases where the participant is illiterate, they will be asked to give verbal consent plus a witnessed thumb print. Finally, parental consent will be required if participants are 16 or 17 years old. The surveyors will answer any questions raised by the participant and allow them sufficient time to respond during the questionnaire.

Dissemination

The findings will be used to inform the programmatic strategy by the STAR consortium. Results will be disseminated regionally to District and Council Health Offices, nationally to the Ministries of Health in Malawian, Zambian and Zimbabwean governments and internationally in peer-reviewed journals, conferences and to UNITAID.

Contributors – FTP and MDE were responsible for the conceptual design of the study. MDE, PI, LM, ES, GM, MK, AC, LC and FTP were involved with the experimental design of the DCE. MDE drafted the manuscript; all authors revised and approved the final manuscript.

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We have read and understood BMJ policy on declaration of interests and declare that we have no competing interests.

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Figure 1 – Study design for Malawi, Zambia and Zimbabwe

Stage 1 – Formative phase	
Activities	Timelines
1. Literature review: identify key drivers for HIV testing and self-testing 2. Qualitative phase: refine list of attributes, identify levels and develop pictorial illustrations. Ensure participant understanding of attributes, levels and pictorial representations 3. Pilot study: to generate efficient design and adjust DCE exercise	Malawi: February – May 2016 Zambia: May – June 2016 Zimbabwe: February – April 2016 and July 2016

Stage 2 – Data collection	
Activities	Timelines
4. Conduct DCE survey within the STAR household survey	Malawi: June – August 2016 Zambia: October – December 2016 Zimbabwe: June 2016 – October 2016

Stage 3 – Data analysis and publication	
Activities	Timelines
5. Analysis: choice of model, socio-demographic characteristics for heterogeneity in preferences 6. Publication and dissemination of results	Malawi: September 2016 – March 2017 Zambia: February 2017 – August 2017 Zimbabwe: September 2016 – March 2017

Figure 2 - Sample scenario exercises for “HIVST distribution” DCE