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Assessing stakeholder perceptions of the acceptability and feasibility of national scale-up for a dual HIV/syphilis rapid diagnostic test in Malawi

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ABSTRACT

Objectives The WHO recommends pregnant women receive both HIV and syphilis testing at their first antenatal care visit, as untreated maternal infections can lead to severe, adverse pregnancy outcomes. One strategy for increasing testing for both HIV and syphilis is the use of point-of-care (rapid) diagnostic tests that are simple, proven effective and inexpensive. In Malawi, pregnant women routinely receive HIV testing, but only 10% are tested for syphilis at their first antenatal care visit. This evaluation explores stakeholder perceptions of a novel, dual HIV/syphilis rapid diagnostic test and potential barriers to national scale-up of the dual test in Malawi.

Methods During June and July 2015, we conducted 15 semistructured interviews with 25 healthcare workers, laboratorians, Ministry of Health leaders and partner agency representatives working in prevention of mother-to-child transmission in Malawi. We asked stakeholders about the importance of a dual rapid diagnostic test, concerns using and procuring the dual test and recommendations for national expansion.

Results Stakeholders viewed the test favourably, citing the importance of a dual rapid test in preventing missed opportunities for syphilis diagnosis and treatment, improving infant outcomes and increasing syphilis testing coverage. Primary technical concerns were about the additional procedural steps needed to perform the test, the possibility that testers may not adhere to required waiting times before interpreting results and difficulty reading and interpreting test results. Stakeholders thought national scale-up would require demonstration of cost-savings, uniform coordination, revisions to testing guidelines and algorithms, training of testers and a reliable supply chain.

Conclusions Stakeholders largely support implementation of a dual HIV/syphilis rapid diagnostic test as a feasible alternative to current antenatal testing. Scale-up will require addressing perceived barriers; negotiating changes to existing algorithms and guidelines; and Ministry of Health approval and funding to support training of staff and procurement of supplies.

BACKGROUND

Globally, over 1.4 million pregnant women are infected with syphilis. Untreated syphilis in pregnancy contributes to more than 520 000 adverse perinatal outcomes, including stillbirth, early fetal loss, neonatal death, low birth weight and congenital syphilis.[1] The WHO has developed a strategic plan for global elimination of mother-to-child transmission (MTCT) of syphilis and recommends that all pregnant women receive on-site syphilis testing at their first antenatal care (ANC) visit.[2–4]

In Malawi, an estimated 90%–95% of women attend ANC at least once during pregnancy.[5 6] Although HIV testing to reduce perinatal HIV transmission is well integrated into ANC programmes, maternal syphilis infection is less well recognised despite its higher transmission rate during pregnancy and strong association with perinatal mortality.[7] Among ANC first-time attendees, the estimated prevalence of syphilis and HIV was 2% and 6%, respectively, in 2016.[8] Malawian national ANC guidelines stipulate that all pregnant women should be tested for syphilis at their first visit, free of charge. However, only 10% of pregnant women were tested for syphilis at their first ANC visit in 2013 and only 55% of pregnant women attending ANC were tested for syphilis at any visit in 2016, compared with 94% who were tested for HIV at their first visit in 2016.[9 10]

The high utilisation of ANC in many countries makes it an ideal setting to introduce point-of-care (rapid) diagnostic tests (RDT)—a strategy for increasing testing for syphilis and HIV infections when laboratory capacity is limited. Dual RDTs afford infected pregnant women the opportunity to be tested and treated for syphilis and HIV at the same ANC visit, thereby integrating screening and ensuring prompt treatment for both infections while avoiding delays in returning test results and reducing missed opportunities for treatment.[11 12]

Public health investigators from the US Centers for Disease Control and Prevention (CDC) have worked with the Malawi Ministry of Health (MoH) and the Machinga District Health Office for many years on antenatal interventions aimed at improving maternal and perinatal health outcomes (eg, safe water, malaria). In 2014, a collaborative team conducted an evaluation of a novel, dual HIV/syphilis RDT, the Chembio Dual Path Platform HIV-Syphilis Assay (Chembio DPP®, USA). The field evaluation, implemented in an ANC clinic at Machinga District Hospital, assessed the performance characteristics of the dual RDT in a rural, low-resource setting.[13 14] MoH and community health workers already conducting HIV rapid testing received a 3-day, hands-on training on use of the dual test, importance of fidelity to test procedures and results interpretation for the investigational

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Table 1 Comparison of dual RDT and single-pathogen HIV and syphilis test characteristics and procedures*

Characteristics/procedures	HIV/syphilis rapid test Chembio Dual Path Platform HIV-Syphilis Assay (Chembio DPP®, USA) (Investigational RDT)	HIV rapid test Alere Determine™ HIV-1/2, Ireland ('First-line' RDT)	Syphilis rapid test Alere Determine™ Syphilis TP, Ireland ('First-line' RDT)
Test device	Cartridge	Single strip	Single strip
Sample type	Whole blood	Whole blood	Whole blood
Sample collection and volume	10 µL Loop	50 µL Capillary tube	50 µL Capillary tube
Number of buffers/diluents	2† SampleTainer (black-top bottle) Running buffer (green-top bottle)	1 Chase buffer	1 Chase buffer
Buffer/diluent volume	2 drops (SampleTainer), well 1 4 drops (running buffer), well 2	1 drop chase buffer	1 drop chase buffer
Run time	Well 1: 5 min Well 2: 10 min	15 min	15 min
Valid reading time frame	10–25 min	15–60 min	15 min–24 hours
Storage conditions	2°C–30°C (36°F–86°F)	2°C–30°C (36°F–86°F)	2°C–30°C (36°F–86°F)
Shelf life	24 months	14 months	18 months
Package contents	Product insert 20 test units 20 blood collection loops 20 sample collection bottles (1 mL) 1 buffer bottle (6 mL)	Product insert 20 or 100 test units (buffer and capillary tubes not included)	Product insert 30 or 100 test units (buffer and capillary tubes not included)

*The RDT for HIV and syphilis used in Malawi, at the time of this study, consist of single-pathogen RDTs (Alere Determine™ HIV-1/2 and Alere Determine™ Syphilis TP, Ireland) and HIV confirmatory testing is conducted using Uni-Gold™ Recombigen® HIV (Trinity Biotech, Ireland); confirmatory tests are not conducted for syphilis.
†The running buffer and sample diluent system requires application of two separate reagents at two separate locations, each collected blood is initially dispensed into a small SampleTainer bottle (black top) as a 'resting spot' for the sample itself allowing homogenous dispersion of the blood solution applied on the test cartridge (well 1).
RDT, rapid diagnostic test.

Table 2 Characteristics of stakeholders interviewed

Characteristic	Number of stakeholders interviewed (n=25)	Number of interviews conducted (n=15)*
District level		
Healthcare worker (testers/field evaluation coordinator)	3	3
Laboratorian	3	1
Management/decision-maker	4	3
National level		
Management/decision-maker	8	3
Donor/technical assistance partner	7	5
Sex		
Male	14	8
Female	11	11
Trained to use investigational RDT†		
Yes	6	4
No	19	11

*Some interview sessions were conducted jointly with up to four stakeholders during one session.
†Extensive 3-day training on how to use the RDT was conducted at Machinga District Hospital and only nurses and laboratory technicians involved in the field evaluation were eligible to participate. Staff at the Ministry of Health's National Reference Laboratory also received an introduction to the RDT, but it only included minimal exposure to the new rapid test.
RDT, rapid diagnostic test.

RDT. The dual test was not under field evaluation or use in any other district. The evaluation of the dual RDT demonstrated that the product's syphilis performance is comparable to that of the Malawi-approved single test for syphilis. The HIV specificity of the dual test was lower than the Malawi-approved single test for HIV, but the HIV sensitivity of the dual test was higher. Given that the dual test would be a substitute for Malawi's 'first-line' single HIV test in the rapid HIV algorithm, the favourable sensitivity of the dual RDT is essential. Table 1 describes the main characteristics of each RDT.

As a qualitative component of the field evaluation, we interviewed stakeholders to explore acceptability of the dual RDT and feasibility of national scale-up.

METHODS

Participant selection and consent

In consultation with CDC-Malawi, we used purposive sampling to identify stakeholders (ie, key informants) from various government and non-government organisations with a role in preventing MTCT of HIV and syphilis and/or awareness of the dual RDT. To elicit varied perspectives, we then invited stakeholders for interview in terms of their level of implementation (eg, local health district, partner/donor agencies) and role in testing (eg, healthcare worker, decision-maker) (table 2).[15] Eligibility was limited to those with programmatic experience in preventing HIV or syphilis in pregnancy and those who make decisions—or were likely to provide input to the MoH—about RDTs in Malawi. All stakeholders provided verbal informed consent. Sampling continued in consideration of 'snowball' referrals and logistical limitations (eg, translation, scheduling), with attention to saturation of stakeholder perspectives. No incentives were provided for interview participation. This study was approved by the Malawi Institutional Review Board from the National Health Sciences Research Committee.

Interview materials and methods

In-person interviews were conducted over a 2-week period during June and July 2015, by a lead researcher and a local research

assistant, using a semistructured interview guide. Key concepts covered perceived importance of the dual test; perceived or real complexity of performing the dual test and interpreting results; sustainability of dual RDT use; and recommendations for national scale-up of the dual test. Excluding one phone interview, interviews were conducted in a private space at the stakeholders' respective workplaces. Interviews were conducted in English, with the exception of two interviews conducted in the local language, Chichewa, due to stakeholder preference and interviewer availability. Some interviews were conducted jointly, with up to four stakeholders of similar perspectives at one time (eg, decision-makers).[16] A job aide graphic (online supplementary file 1) outlining procedural steps of the HIV and syphilis RDTs used in-country and a sample dual test kit used during field training were shown to stakeholders during the interview process.

Thirteen of 15 interviews were audio-recorded. For all interviews, handwritten interview notes as well as field notes of interviewer observations and reflections were transcribed into Microsoft Word. For interviews conducted in English, the primary researcher used recordings to revise and expand her original interview notes.[15 17] A second team member not involved in the original interviews also listened to the audio recordings and developed a second set of interview notes; both sets of notes were merged into one set of expanded interview notes. For interviews that were not audio-recorded, notes were expanded immediately following the interview. Interviews conducted in Chichewa were translated into English interview notes by the local research assistant and verified using audio recordings by a second Chichewa-speaking team member not involved in the original interviews. All interview notes reflected a summary of each interview, addressing the evaluation objectives. Expanded interview notes with salient verbatim quotes were uploaded into NVivo V.10 (QSR International, 2012).

Data analysis

We used an exploratory (ie, content-driven) inductive analysis approach, a common approach to qualitative data analysis, particularly when seeking to understand perceptions and attitudes without a predetermined hypothesis.[18] Prior to data collection, the research team designated a priori codes related to the domains of the evaluation and interview guide.[19] Two team members conducted a basic review of the interview notes and supplemented the a priori codes with emergent codes. Codes were entered into a codebook, and both team members coded three sets of interview notes in NVivo independently.[20]

Once intercoder agreement from the first three independently coded interviews exceeded 90%, the remaining interview notes were dual-coded. The codes were reviewed to generate key themes and subthemes within each code by all stakeholder types and for patterns or key differences between stakeholder types. We also searched for outliers and researcher effects. We then summarised and synthesised information across stakeholder perspectives (eg, among all healthcare workers at the district level).[17] Throughout analysis, preliminary findings were checked for relevance with the evaluation team.

RESULTS

We conducted 15 interviews, 5 jointly, with 25 stakeholders. We categorised our findings into four main topics: acceptability, feasibility, sustainability/scale-up and recommendations for improving the dual RDT.

Acceptability

Importance of dual test

Overall, stakeholders viewed the dual RDT favourably and were likely to support its implementation, if found to have strong test performance characteristics as a result of the field evaluation. Importance of the dual test was related to the perceived ability of the dual test to improve efficiency, prevent missed opportunities for syphilis diagnosis and treatment, prevent MTCT of HIV and syphilis, improve infant outcomes and increase syphilis screening. The test's ability to provide simultaneous results for syphilis and HIV was viewed as paramount.

> Knowledge of both syphilis and HIV results at once helps women to be treated for the two diseases at once. —Healthcare worker, district level

> Chembio would be the best option, as it detects HIV and syphilis. —Laboratorian, district level

A few stakeholders also believed a dual test could improve the perceived value of the syphilis test within the healthcare sector, given its integration with the more routine and well-funded HIV test; a dual test would help level the playing field.

> By using Chembio, it means that syphilis testing will not suffer. It will be carried on together with HIV. It will be of value just like HIV testing. —Management, district level

Feasibility

Test setting and capacity

Stakeholders viewed the dual RDT as a feasible alternative to the standard tests for use in the ANC setting. Those trained to use the dual test felt confident in their ability to conduct the test correctly and believed the training they received was sufficient. Some stakeholders indicated there was existing capacity in-country regarding laboratory techniques and clinical decision-making to support test implementation. However, keeping trained testers on staff, due to limited human resources and infrastructure in some clinics, would pose a challenge.

> It would not be difficult to learn. The problem is that people will be trained, then afterwards and later they may have changed systems, and you'll have to repeat the training, which would be very expensive. —Laboratorian, district level

Chembio dual test concerns

Stakeholders expressed concerns regarding technical aspects specific to the Chembio dual test. Stakeholders were concerned about the additional procedural steps in comparison to the standard tests (4 vs 3), and additional wells and buffer/sample diluent (2 vs 1) needed to perform the dual test.

> I think Chembio ticks most of the [same] boxes as the current standard, but the two levels of using two different buffers has an added level of technicality. —Partner/donor, national level

They believed these steps would intensify the training required and leave room for errors, especially during busy clinic days or among lay workers whom they perceived as less educated (ie, voluntary testing and counselling testers in rural areas compared with ANC staff in hospitals).

Stakeholders were concerned that testers may not adhere to the test running period (5 min) or required waiting time (10 min) before interpreting results, because they often use a patient 'conveyor belt' system, where ANC attendees are tested in groups; clinic staff may not have stopwatches or timers available; and nurses often demand testers see patients quickly.

> Adherence to incubation periods is a challenge; many sites don't have timers and improvise. [The current standard test] has a long incubation period and the result appears within 2–3 min, which is a real issue. —Decision-maker, national level

> Putting blood in the bottle before the device is challenging when there are a lot of people waiting at the clinic and only one tester. —Healthcare worker, district level

Some stakeholders viewed the etching on the dual test cartridge as too hard to read, the window size as too small, the result lines as too faint, and they wanted to better understand the stability of the result read-out, as this could be a concern if the results fade before testers were able to read them (eg, during busy clinic days). Others wondered whether having three result lines (syphilis, HIV and control) versus two (syphilis *or* HIV and control) might pose problems with interpreting test results.

Dual test funding

Although a few stakeholders felt the MoH may lack the ability to sustain funding, most believed the Malawian government and/or donors would identify funding for the test. Cost-savings for switching from a single-pathogen to a dual-pathogen RDT was perceived as an essential factor to funding the dual test.

> [Determining] cost would be an important next step. If comparable, [the] dual test would be preferred; if higher cost of the dual test then it would be difficult to incorporate into the algorithm. There needs to be some cost savings, not just be equal to buying two singles [separate tests for HIV and syphilis]. —Management/decision-maker, national level

Given that health services are free of charge, asking women to pay for dual testing was viewed as an unreasonable option to supplement funding for the test. While a few stakeholders viewed urban women, working women and those with experience using fee-based services at partner/mission clinics as being more likely to pay, the majority believed some women would choose not to test if they had to pay for it.

> [HIV and syphilis] testing will be for the rich, as it is hard for most women to find money; [hence] they will not be willing to test. Some women will be reluctant to pay just to be taken their own blood for testing. —Healthcare worker, district level

Test kit stock-outs

The prevailing thought among stakeholders was that HIV tests are viewed as a '*protected commodity*' and the national prioritisation given to HIV would likely ensure the dual test remains in stock. They suggested that if the dual test was under a similar procurement and supply chain as HIV tests, then stock-outs would be unlikely. Perceived reasons for syphilis test kit stock-outs included a low baseline supply of tests given limited funding, expired test kits or staff unwillingness to conduct the tests because they have not received training.

> Syphilis test kits were stocked out because they were expired and people wanted to be trained to use the test kits. —Decision-maker, national level

Sustainability/national scale-up

Essential components for national scale-up

Stakeholders overwhelmingly believed the country was poised to scale up dual testing, pending field evaluation findings. Stakeholders identified the essential components for scale-up as uniform coordination and clear communication, revisions to national guidelines and testing algorithms, MoH and partner funding and technical assistance, intensive and refresher training of staff on the use of the test and a reliable supply chain. Decision-makers at the national level and partners/donors were more vocal about scale-up and the need for a coordinated approach and strategic planning with all districts.

> It would need coordination across the ministry level…Therefore, it requires further collaboration and agreement with the diagnostics, clinical, and reproductive health arms [of MoH]. —Partner/donor, national level

Healthcare workers and management-level stakeholders indicated that refresher trainings, and in some cases, intensive training, would be necessary to address tester confidence in interpreting results, adherence to time requirements and understanding the benefits of the dual test. Stakeholders consistently stated that modifications to existing guidelines would be needed to support successful implementation of the dual test.

> [The] HIV testing algorithm changes if Chembio comes in. It will all depend on the results. Changing the algorithm [must be] part of the scale-up. —Healthcare worker, district level

All stakeholders identified the procurement of supplies and the consideration of phase-out projections for single-pathogen tests as necessary for ensuring adequate stock in the course of national scale-up of the dual tests, and most believed it was the MoH's responsibility to do so.

> As for procurement of supplies, the Ministry of Health would have to make phase-out projections of the old test to coincide with procurement of the new test. —Management/decision-maker, national level

> Another issue is that sometimes we are running out of reagents, so sometimes we stop testing. [The MoH would] need to ensure the reagents are in stock. —Laboratorian, district level

Most stakeholders believed that the existing HIV supply chain—which has in recent years come under more robust supply chain monitoring—should be used to avoid issues with stock-outs.

> […] have to ensure a logistic supply system that is robust for these tests; HIV is good at supply chain. —Partner/donor, national level

Improvements to the Chembio dual test

Management/decision-makers at the national level offered the majority of suggested improvements to the dual test kit to make it more user-friendly, based chiefly on their perceptions as they had not used the test. These recommendations included: having additional buffer bottles per package to ensure it does not run out, incorporating a built-in timer to prevent results from being read too early, improving result line stability, reordering result window labelling so that HIV results are read first and using different colours to designate the disease-specific result.

Some stakeholders felt the order of test results as they appear in the results window should reflect the test name (ie, 'HIV-Syphilis Assay'). They recommended changing the order of read-out lines from 'syphilis-HIV-control' to 'HIV-syphilis-control' to avoid confusion with reading test results, given that 'HIV-Syphilis' is the name of the dual test and that testing is commonly referred to as 'HIV-syphilis' testing. Given that testers are not accustomed to using multiple buffers/diluents and wells with the standard tests, the use of a running buffer and sample diluent

(often referred to by stakeholders as 'two buffers') was the sole issue identified by healthcare workers.

> The buffers, maybe if they were made in a different way, […]it would be easier for the people who will be using it. —Healthcare worker, district level

DISCUSSION

Although our study is among the first to assess stakeholder perceptions of a dual HIV/syphilis rapid test in a low-resource ANC setting, our findings are consistent with previous research focused on acceptability, feasibility and scale-up of point-of-care tests.[21–29] Our assessment demonstrated that stakeholders viewed the introduction and potential scale-up of the dual RDT favourably, believed implementation was feasible and were willing to support national scale-up. Previous studies have shown that rapid syphilis tests can improve syphilis screening in the ANC setting and integration of these services may address missed opportunities to reduce adverse pregnancy outcomes.[11 21–24] However, prior to introducing a new, dual HIV/syphilis test, it is important to gain the acceptance of key stakeholders who would play a role in its implementation and use.

Studies from 2010 to 2012 introducing rapid syphilis testing in low-level ANC facilities in Kenya and Zambia found that the tests were feasible for health providers and patients and greatly improved coverage of syphilis testing (18%–70% and 79%–95%, respectively) without impacting HIV testing.[22 24] Rapid syphilis tests were also found to be a suitable addition to existing services among healthcare workers in a pilot and implementation study in Zambia.[26] A 2013 survey in Peru found high satisfaction among ANC providers towards another dual HIV/syphilis test's (SD Bioline) ability to obtain two results with one blood sample on a single test cartridge.[25] Additional aspects of rapid syphilis and HIV testing, such as same-day testing and treatment, perceived increases in screening and ease of learning test procedures are also similar to our findings.[22 26 28]

Stakeholder concerns and recommendations for scale-up regarding coordination, funding and technical support, negotiating revisions to existing guidelines and algorithms, intensive and refresher training of testers, tester adherence to proper procedures, human resources and supply chain logistics echo those of various stakeholders described in related point-of-care test studies.[21–24 26–28] Dual rapid tests could potentially address issues around stockouts, reduce provider burden and ease tracking systems needed to ensure women are tested for both diseases as part of WHO recommendations.

The identified difficulties related to test features and processes are similar to those in the 2013 dual test survey,[25] such as the packaging, and colour of cartridge numbers and letters; however, stakeholders in our study also suggested reordering of the test result lines to mirror common terminology and implementation of a built-in timer.

Various point-of-care studies highlight the importance of simple processes and readers,[26 28] although the required use of a running buffer and sample diluent (ie, 'two buffers') was identified as an area of concern for stakeholders, this system is actually one of the strengths of the dual test. The lower blood volume required with this method and the even distribution of sample on the test cartridge may reduce errors seen with single-pathogen tests. It is possible that the stakeholders' references to the sample diluent as a 'buffer' could be related to their lack of understanding of this procedural step or simply their comfort with 'buffer' as a default technical term. Still, the fact that both test users and non-users repeatedly identified the 'two-buffer' system as a potential problem highlights an important need for educating stakeholders (including policymakers, public health leaders and clinicians) about the intricacies of the dual test. Stakeholders also noted concern regarding testers using an 'assembly line' approach to test multiple ANC attendees at one time—although this has already been identified as an issue for rapid HIV testing alone. This 'assembly line' approach was not described in other point-of-care testing literature, but one could conceive that introducing a single device covering two infections would be less likely to lead to 'assembly line' approaches. It is important to highlight that only healthcare workers at the district level had hands-on experience using the test; most of the stakeholders had not performed the test and therefore, their beliefs concerning test 'complexity' were solely based on perception, not experience. Most components of this dual test are in line with testing preferences prioritised by pregnant women described in a study assessing attributes of dual testing for HIV and syphilis (eg, free, one blood draw, fingerprick and 20 min to results).[22 29]

Potential changes to the testing algorithm and guidelines prompt consideration as to how the dual test will be incorporated into clinical practices across the country. Of note, WHO has published interim guidance on treatment based on rapid, HIV/syphilis dual test results.[30] A future consideration will be whether or how the country chooses to adopt the interim guidance for dual HIV/syphilis testing during pregnancy.

Our study is subject to limitations. As stakeholders were purposively selected, it is possible that the results do not reflect perspectives of other stakeholders with important interactions or a role in preventing MTCT and funding of those efforts in-country. Additionally, experience 'using' the product (for non-healthcare workers) was often limited to a 5–10 min demonstration and did not allow for real-world concerns to be tested. Furthermore, preliminary, not final, field evaluation results of dual RDT performance characteristics were shared with stakeholders, which may have limited the extent to which stakeholders expressed their perceptions of the test. However, stakeholders noted that sharing lessons learnt from the study and application of the test in a real-world setting will help assess its true feasibility and address provider concerns.

Future studies should evaluate testers' adherence to dual test procedures and dual test use outside of research settings. While this assessment and stakeholder perceptions are unique to Malawi, these findings and the methods employed to engage stakeholders and document their perspectives may be transferable to other low-resource settings considering implementation of a dual HIV/syphilis RDT.

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Key messages

- Dual HIV/syphilis rapid tests are perceived by stakeholders as important for preventing missed opportunities for diagnosis and treatment, improving infant health outcomes and increasing syphilis testing coverage.
- Stakeholders view targeted provision of dual HIV/syphilis rapid tests in antenatal care settings as feasible and acceptable relative to the current standard, single-pathogen tests.
- Scale-up of dual HIV/syphilis rapid tests will require addressing perceived barriers, ensuring uniform coordination and securing funds to support training and procure supplies.

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Competing interests None declared.

Ethics approval This study received ethical approval from the Malawi Ministry of Health and non-research determination from the U.S. Centers for Disease Control and Prevention. Ethical review was conducted and approved by the Malawi Institutional Review Board from the National Health Sciences Research Committee (NHSRC), protocol no. 1251.

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