Thematic Window 2
HIV Oral Self-Testing
Phase 2 Request for Proposals

Issue date: 21 May 2014
Deadline for questions: 23:59 GMT, 3 June 2014
Application submission deadline: 23:59 GMT, 7 July 2014

1. Overview

The International Initiative for Impact Evaluation (3ie) is issuing an open request for proposals (RFP) to implement pilot interventions to use HIV oral self-tests in the Republic of Kenya and conduct impact evaluations of those pilot interventions in order to produce robust and actionable evidence of how to safely and effectively promote HIV oral self-testing as an additional HIV testing option in the Republic of Kenya.

Questions regarding this RFP should be submitted by 3 June 2014. A document with the questions and the answers (Q&A) will be published on the 3ie website by 10 June 2014.

Applicants are responsible for knowing all the information provided in this RFP as well as in the public Q&A document.

2. Background

HIV prevention continues to be a critical element in the fight against the HIV and AIDS epidemic. Among HIV prevention interventions, HIV testing plays a significant role. While HIV testing and counselling (HTC) uptake has increased recently, the majority of HIV-positive people in Africa are still unaware of their status. Knowledge of HIV status can help prompt desired behaviours, such as seeking treatment and reducing risky sexual behaviour. HTC programmes are a gateway to knowing one’s HIV status and making informed decisions about HIV prevention, as well as accessing care and treatment for people living with HIV (PLHIV).

In Kenya, like much of Sub-Saharan Africa, HTC coverage has increased over the last five years. The 2012 Kenya AIDS Indicator Survey reported that the percentage of people aged 15-64 who have ever been tested for HIV has increased from 34 per cent in 2007 to 72 per cent (80 per cent for women and 63 per cent for men) in 2012. Although different

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1 Staveteig S., 2013. Demographic patterns of HIV testing uptake in sub-Saharan Africa. ICF International, Calverton, MD.
approaches including voluntary counselling and testing, provider-initiated counselling and testing, mobile testing, and home-based testing have helped increase the uptake of HIV testing, coverage is still below the 80 per cent goal. Many HIV-positive individuals (53 per cent) are still unaware of their HIV status (up from 16 per cent in 2007). Numerous barriers limit individuals’ ability to access HTC services through current mechanisms, including, stigma and discrimination, lack of privacy, transportation costs and long waiting times. There is a need for additional approaches to HTC that circumvent these barriers that could then potentially increase uptake.

HIV self-testing is a possible approach for overcoming some of the barriers faced by individuals accessing other testing approaches. If implemented appropriately, HIV self-testing, as a complement to other testing strategies, could dramatically increase knowledge of status and repeat testing rates.

3ie’s Thematic Window 2 (TW2) programme, Promoting the Beneficial Use of HIV Self-tests in Kenya: Evidence-Based Programme Design, is designed to provide the Kenyan government the evidence they want and need to best incorporate HIV self-tests into their national HIV and AIDS programme. By working closely with the Kenyan government, and using a transparent and competitive process, 3ie first commissioned formative research studies that help describe and define the local environment surrounding self-testing. These formative studies were conducted under phase 1 of the grants window. This RFP is part of phase 2 of the grants window. 3ie will select a small number of promising pilot programmes (two to three) and fund both the implementation and the rigorous impact evaluation of those programmes.

3ie and Kenya’s National AIDS and STI Control Programme (NASCOP) collaborated to select questions for the phase 1 studies to assess accuracy, identify potential users and messaging to reach users, identify potential distribution outlets, assess packaging and labelling of self-test kits, investigate how best to promote linkage to care, and assess potential social harms and how to avoid them. The formative research studies in Kenya have the following findings:

1. There is nearly universal interest in self-testing. While there was some concern about access to counselling and linkage to care, over 90 per cent of study participants, in five out of six studies, were interested in self-testing. Female sex workers and men who have sex with men (MSM) were generally also highly interested.

2. Communication around sensitisation and awareness was desired both before and during the roll-out of HIV oral self-tests. Study participants listed the following as information they would like to hear: where to find the tests, how to perform the tests, and what to do if testing HIV positive, the need for and locations of confirmatory testing, ways to access counselling and support as well as care and treatment, and the ethical and appropriate use of tests (including the illegality of coercion). Concerns regarding reactions to testing positive (access to support services) were also mentioned among the concerns to be addressed.

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3. Without supervision or demonstration of how to perform the test (but with slightly modified package inserts), the test kits used showed 90 per cent sensitivity (percentage of people who were HIV positive who tested positive) and 99 per cent\(^3\) specificity (percentage of people who were HIV negative who tested negative), but 15 per cent of tests were invalid. One study suggested that improved instructions in the packaging may help, but in person demonstration of usage may be necessary.

4. Results from multiple studies suggested that linkage to care is going to be a challenge but no particular approach was identified as being most recommended.

5. Many people would like to be able to get HIV oral self-tests from public health facilities, but other people also expect to find them in pharmacies, private health facilities, shops, and through the local government administration.

The results of the formative research indicate that there still many unanswered questions regarding how HIV oral self-tests can best be used to increase overall testing rates and promote more frequent testing among specific populations.

The purpose of this grant window is to fund pilot interventions of innovative programmes to introduce the use of HIV oral self-tests to increase testing rates or testing frequency among the general public and/or specific sub-populations, and fund the rigorous impact evaluations of those programmes in order to produce robust and actionable evidence of what works or what is most effective and cost-effective among those interventions.

3. Scope of the grant programme

3ie expects to fund two to three grants of about US$300,000. Each grant will fund one project, and each project will combine both the implementation of the pilot intervention and the conduct of the impact evaluation. While grant money can be used to fund the implementation, it is expected that most of the intervention will be funded using other resources, with 3ie grant funding used for the impact evaluation and for adjustments or additions to current programming to facilitate the impact evaluation. A team applying for a grant may include multiple organisations (for example, one organisation that will implement the pilot programme and one organization that will conduct the impact evaluation) but a single organisation must apply for the grant as the prime grantee and then issue sub-awards to other team members. It is not required, however, that teams include multiple organisations. A single organization may apply to implement both the programme and the impact evaluation, but will need to describe the steps taken for maintaining independence in their proposal.

The pilot programmes must be interventions meant to use HIV oral self-tests to increase testing rates generally or testing rate and/or frequency of testing among targeted populations. The programmes proposed should be well-motivated by a theory of change that is supported by past experience or by research or both. As suggested by formative research, each pilot should include:

\(^3\) 89.7% sensitivity; 98.0% specificity by ELISA, 99.4% by staff finger stick.
1. A plan for communication before and during the implementation of the pilot programme for using HIV oral self-tests.
2. A mechanism to estimate or measure linkage to care after a positive HIV test.

The impact evaluation designs must meet 3ie’s definition of impact evaluation. They should measure net impact against a counterfactual, which may be constructed experimentally or quasi-experimentally. The impact evaluation designs should also incorporate mixed methods data collection and analysis to enable the research to address the evaluation questions about how and why the intervention worked or did not work in using or offering HIV oral self-tests, and to assess unintended consequences. Read 3ie’s principles for impact evaluation.

3ie expects that the primary outcome measured will relate to the theory of change that underpins the pilot programme. The projects should be completed within nine months after all ethical approvals, where necessary, have been granted but by no later than 31 December 2015.

The projects may be implemented anywhere in Kenya. The programmes and rapid impact evaluations should be designed with a view to producing evidence that is externally valid, that is, can be applied to other countries. As HIV oral self-testing within the lay population (as opposed to health care workers) is relatively new, the results from Kenya’s pilot programmes will be of interest to many other countries who are contemplating if and how HIV oral self-testing can be integrated into their national HIV and AIDS programmes.

4. Eligibility

The call is open to organisations implementing HIV and AIDS programmes in Kenya. The applicant organisation must be able to sign the 3ie grant agreement, which is available from 3ie upon request.

For-profit organisations are eligible to apply, but are restricted to the same indirect cost limits as non-profit organisations and may not charge a fee.

Each proposal must be submitted by a single organisation that may include others as sub-grantees or sub-contractors (subject to 3ie’s direct and indirect cost policies).

Organisations may submit more than one proposal and may be included on more than one proposal. They should, however, have the capacity to implement any and all grants awarded to them under the window.

5. Timeline

Grant applications are due by 7 July 2014. 3ie hopes to announce prospective awards by 8 August 2014. After grants are awarded 3ie will host a post-award workshop to share plans among awardees and for awardees to receive feedback on the proposals from both 3ie and from other awardees. At least one principal investigator (PI) from the study team must be able to attend the post-award workshop if awarded the grant. The post-award workshop is planned for the week of 8 September 2014. Grant signing is expected to be
completed in the three to five weeks following award announcement. This timing will depend on whether revisions are requested to the proposed research designs.

**All draft final reports are due no later than 31 December 2015.**

6. **Instructions for applicants**

Each proposal shall consist of a cover page and four documents:

1) A technical proposal not to exceed 25 pages (including any attachments, tables, figures, etc. but excluding the cover page and CVs) submitted as a single Microsoft Word file with font size no smaller than 11 point.

2) The curriculum vitae of all proposed PIs, not to exceed five pages per person and compiled in a single Microsoft Word file with font size no smaller than 11 point.

3) A cost proposal submitted as a Microsoft Excel file in the 3ie budget template with all formulas visible; and

4) A budget narrative submitted as a Microsoft Word file.

**The application deadline is 23:59 GMT, 7 July 2014.** All applications must be submitted in a single email message with no more than four attachments (five if the cover letter is a separate scanned document) to tw2@3ieimpact.org.

The cover letter must include the following information:
• Complete legal name of applicant organisation
• Legal form of applicant organisation
• Country in which applicant organisation is legally registered
• Full postal address of applicant organisation
• Website address of applicant organization (if applicable)
• Name, title, phone number, and email address of a single contact person for this application
• Name, title, phone number, and email address of individual authorised to sign the grant agreement documents

The cover letter must also include the following text as certification:

*By submitting this proposal under 3ie’s Thematic Window 2, we certify that we are legally eligible to receive grants from organisations in other countries. We also certify that the individual authorised to sign the grant agreement documents has reviewed 3ie’s TW2 grant agreement template available on 3ie’s website and confirmed that the applicant organisation can agree to the terms of the agreement.*
7. Technical proposal requirements

The technical proposal should be structured in two parts: the first part should include a technical proposal for the implementation of the pilot programme to use HIV oral self-testing to increase overall HIV testing rates in Kenya, and among targeted populations that currently lag behind in HTC coverage or test less frequently than recommended, the second part should include a technical proposal for the implementation of the rapid impact evaluation. The proposal should include the following sections for each part (presented in the same order as indicated below):

I. Programme implementation

a. **Overview of the pilot programme.** This section should present a one to two paragraph description of the pilot programme that is appropriate for non-specialist readers.

   Note: If the proposal is accepted for award, the text in this section may be used by 3ie in publications and on our website.

b. **Intervention description and justification.** This section should include a detailed description of the intervention, the theory of change (or programme theory) for the intervention, and the evidence that was used to inform the design of the intervention. This section should describe the available HIV testing services and rationale for HIV oral self-testing in the area or sub-population. Applicants should also discuss the potential policy impact of the evidence produced from the pilot programme in this section. That is, why do the applicants believe that, if shown to be effective, this intervention will be adopted and scaled up? Applicants should also discuss the expected cost-effectiveness of the proposed intervention at scale.

c. **Programme implementation and work plan.** This section should describe the activities that will be undertaken in order to implement the intervention (i.e. how the intervention will be carried out) and should include a month-by-month work plan for the implementation of the intervention. This section should also describe the coordination necessary with any stakeholders, including the government, in order to implement the intervention, and discuss how this coordination has been or will be achieved.

d. **Staffing plan.** This section should present the names and credentials of all key personnel for the implementation of the intervention. CVs (no more than four pages each) may be included in an annex, but any relevant qualifications should be summarised in the text of the technical proposal.

e. **Organisational qualifications.** This section should include three performance references for past or current projects implemented by the organisation primarily responsible for implementing the intervention. These references should be for projects related to the work of implementing the intervention proposed. The performance references should include a description of the past or current project and must include the contact name and information for the client or funder of each project. In addition,
this section should describe any other past, current, or potential activities around HIV self-testing.

f. **Management plan.** The management plan should describe the overall management for the project, including the implementation and impact evaluation. The plan should identify a single PI for the project as a whole. This PI must have the authority to speak for the prime grant-holding institution. This PI will be the primary point of contact for 3ie, but the identification of this PI does not preclude multiple PIs for the impact evaluation. The plan should also document what policies and procedures are in place or will be put in place to ensure the independence of the research.

Note: The placement of the management plan in the first part of the technical proposal is not meant to indicate that if there are two partners, it should be the team implementing the intervention that provides overall project management. It could also be that the research team provides the overall project management. In either case, the management plan should be presented here in the proposal.

II. Impact evaluation

a. **Overview of impact evaluation design.** This section should introduce the evaluation questions and briefly describe the main characteristics of the impact evaluation design as an introduction to the following sections.

   Note: If the proposal is accepted for award, the text in this section may be used by 3ie in publications and on our website.

b. **Identification strategy (internal validity).** This section should present the details of the identification strategy of the impact evaluation design. That is, how will the counterfactual be measured? How will issues such as confounding factors, selection bias, spillover effects, contamination of control groups, impact heterogeneity and other threats to internal validity be addressed? The description of the methodologies to be used for data analysis should be included here, including a description of the primary outcome of interest and how it will be measured.

c. **Data collection methods (including sampling strategy) and power calculations.** This section should describe how the data will be collected and also present the power calculations to support the primary outcome measurement as well as any other outcomes to be measured for each relevant sub-group in support of the theory of change. The power calculation description should include any assumptions and a rationale for the proposed desired detectable effect size. This section should include a description of the mixed methods analysis to be conducted and how that analysis will answer evaluation questions related to the theory of change.

d. **Policy impact.** This section should describe how the impact evaluation will achieve policy impact. This section should also discuss the external validity of the impact evaluation design as well as a presentation of the communication activities to be conducted by the project team in order to make the evidence available to the relevant policymakers and programme managers.

   Note: The impact evaluation should also have policy impact if the findings are null or
negative for the intervention piloted. That is, policymakers and programme managers should also receive evidence of what does not work or works poorly.

e. **Work plan.** This section should describe the activities that will be undertaken in order to conduct the impact evaluation and disseminate the findings in a month-by-month work plan. The work plan should include a detailed description of the ethical approvals necessary for the project and the projected timeline for requesting and receiving those ethical approvals. Applicants are encouraged to check with local institutional review boards to see whether their project may qualify for an exemption.

f. **Staffing plan.** This section should present the names and credentials of the PIs and any other key personnel for the conduct of the impact evaluation. CVs (no more than four pages each) may be included in an annex, but any relevant qualifications should be summarised in the text of the technical proposal.

g. **Organisational qualifications.** This section should include three performance references for past or current projects implemented by the organisation primarily responsible for conducting the impact evaluation. These references should be for projects related to the work of conducting the impact evaluation proposed. The performance references should include a description of the past or current project and must include the contact name and information for the client or funder of each project. If a single organization is both implementing the intervention and conducting the impact evaluation, the proposal should still include six different past performance references—three related to implementation and three related to impact evaluation.

### III. Cost proposal

The cost proposal must include the following elements in the required formats:

a. Proposed line-item budget in the [3ie budget template](#) and conforming to the [3ie direct cost policies](#)

b. Budget narrative submitted as a Word file according to the instructions in the budget workbook template.

### 8. Submission and review process

Any questions regarding this RFP should be submitted to TW2@3ieimpact.org no later than 23:59 GMT, 3 June 2014. All submitted questions and the answers will be published on the 3ie website by 10 June 2014.

All applications must be sent via four attachments in a single email message to TW2@3ieimpact.org. The cover email message must include a certification that the applicant has read and is willing and able to sign the 3ie grant agreement. **Applications must be received by 23:59 GMT, 7 July 2014.**

Applications will be scored according to the following selection criteria and points by at least two internal and one external reviewer.
<table>
<thead>
<tr>
<th><strong>Programme Implementation</strong></th>
<th><strong>Description</strong></th>
<th><strong>Weight</strong></th>
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</thead>
<tbody>
<tr>
<td>Justification for intervention</td>
<td>The intervention is well justified and well designed. It is likely to have policy impact and can be scaled up in a cost-effective manner.</td>
<td>40%</td>
</tr>
<tr>
<td>Feasibility and effectiveness of implementation</td>
<td>The proposed programme is feasible and will be implemented in an effective way during the timeframe set forth by the RFP.</td>
<td>20%</td>
</tr>
<tr>
<td>Credentials of key personnel</td>
<td>The key personnel are qualified to implement the programme.</td>
<td>15%</td>
</tr>
<tr>
<td>Qualifications of organisation</td>
<td>The organisation is qualified to implement the program.</td>
<td>10%</td>
</tr>
<tr>
<td>Quality of management plan</td>
<td>The management plan ensures that the full project will be carried out efficiently and effectively. The impact evaluation will maintain independence in the analysis of, interpretation of, and reporting of results.</td>
<td>15%</td>
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<table>
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<tr>
<th><strong>Impact Evaluation</strong></th>
<th><strong>Description</strong></th>
<th><strong>Weight</strong></th>
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<tr>
<td>Internal validity</td>
<td>The impact evaluation design presents a valid identification strategy and appropriately handles threats to identification in order to achieve high internal validity.</td>
<td>25%</td>
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<tr>
<td>Sufficiency of data and statistical power</td>
<td>Data collection methods and measurement methods are appropriate to the evaluation questions and analytical methods proposed. There is adequate statistical power to measure effects for the key outcome variables.</td>
<td>25%</td>
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<tr>
<td>Policy impact</td>
<td>The evaluation questions addressed, design of the evaluation, and the communication activities all will help ensure that the findings of the impact evaluation will have policy impact in the pilot and in other countries.</td>
<td>20%</td>
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<tr>
<td>Feasibility of the work plan</td>
<td>The work plan is feasible within the timeframe set forth by the RFP.</td>
<td>5%</td>
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<tr>
<td>Credentials of key personnel</td>
<td>The key personnel (especially PIs) are qualified to conduct the impact evaluation.</td>
<td>15%</td>
</tr>
<tr>
<td>Qualifications of organisation</td>
<td>The organisation is qualified to</td>
<td>10%</td>
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Grants will be awarded on a best value basis. Therefore, cost proposals will not be scored, but the final selection will take into account cost-reasonableness of individual applications and relative prices across applications as well as total funding available.