GUIDELINES ON HIV SELF-TESTING AND PARTNER NOTIFICATION

SUPPLEMENT TO CONSOLIDATED GUIDELINES ON HIV TESTING SERVICES

Annex 16: Methodology for guideline development on HIV self-testing and HIV partner notification services

DECEMBER 2016
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16.1 Overview

These guidelines were developed in response to countries’ requests to update the World Health Organization (WHO) Consolidated guidelines on HIV testing services with further guidance on HIVST and assisted HIV partner notification services. Thus, these guidelines focus specifically on these two HIV testing services (HTS) approaches and implementation considerations across diverse populations, settings and contexts.

The WHO HIV Department led the development of these guidelines in accordance with procedures and reporting standards laid out in the WHO handbook for guideline development.

16.2 Establishing the Groups to Develop the Guidelines

The WHO HIV Department set up four groups to perform specific guideline development functions. Members of the groups were selected so as to ensure a range of expertise and experience, including appropriate geographical, gender and community representation.

1. WHO Guideline Steering Group. The WHO HIV Department, Key Population and Innovative Prevention Unit, led this group. Participants included WHO staff from other units in the HIV Department, the Department of Essential Medicines and Health Products, the Department of Reproductive Health and Research, the Global Hepatitis Programme and the Global Tuberculosis (TB) Programme. This group included WHO technical staff from all WHO regional offices: the African Region, the Region of the Americas, the South-East Asia Region, the European Region, the Eastern Mediterranean Region and the Western Pacific Region. There were also additional contributors from United Nations’ (UN) agencies and partner organizations.

2. Guideline Development Group (GDG). This group consisted of 20 members, with a balance of geographical representation, gender and backgrounds, including academia and research, programme implementation and policy, and people from community organizations and networks. This group was responsible for the formulation of the new WHO recommendations, implementation and service delivery considerations and review and approval of the final content of the guidelines document.

3. HIV self-testing (HIVST) Technical Working Group (TWG). This group consisted of external experts in in vitro diagnostics (IVDs), with a balance of geographical representation, gender and backgrounds, including academia and research, programme implementation and policy, and people from community organizations and networks. This group was co-convened with the WHO Prequalification of IVDs Programme to inform the development of criteria and standards for assessing the suitability, usability and performance (sensitivity and specificity) of HIV RDTs used for self-testing and the development of post-marketing surveillance and monitoring and reporting systems for HIVST.

4. External Review Group. This group was selected in consultation with the WHO Steering Group and GDG to assure geographical and gender balance. In addition to review and inputs by other groups above, there were external peer reviewers from academia, policy and research, implementing programmes and community organizations and networks, including key population networks, reviewed the guidelines. In general, reviewers made suggestions to improve the clarity of the document and provided additions and corrections to the narrative.

16.2.1 Involvement of key stakeholders

An important element of this work was engaging with a diverse set of stakeholders to update and synthesize key messages across existing WHO guidance on HTS. These stakeholders included countries (ministries of health and laboratory services), researchers, international and national implementing agencies, WHO regional and country offices
and UN agencies community networks and implementers, including key populations and people living with HIV, and additional experts in the field.

16.2.2 Declarations of interest

All members of the GDG and HIVST TWG submitted curriculum vitae (CVs), declarations of interest and confidentiality statements to the WHO secretariat. All members of the External Review Group also submitted declarations of interest and confidentiality statements to the WHO secretariat. Across all groups, all non-WHO staff participating in meetings or guideline development in any capacity also submitted declarations of interest and confidentiality statements to the WHO secretariat.

Two reviewers in the WHO secretariat independently reviewed all declarations of interest forms. The reviewers considered all possible conflicts of interest based on the latest guidance from the WHO Guideline Review Committee (GRC), focusing on possible financial or personal conflicts, relationships with diagnostics companies or a major role in completed, ongoing or planned trials of a particular HIV test. Each reviewer also conducted Internet-based searches on each prospective member. Following this procedure, biographical statements for all members of the GDG were posted on the WHO website for public comment in February 2016 at http://www.who.int/hiv/mediacentre/news/hiv-gdg2016-hts/en/.

After careful review, the WHO Secretariat was satisfied that the declarations of interest had been transparent and that no case necessitated exclusion from the deliberations. They also noted the broad range of constituencies represented by the GDG and that the majority of members had no declared interests. Therefore, all individuals who submitted declarations of interest participated in the meetings of the Steering Group, the GDG and the HIVST TWG.

A summary of all declarations of interest are available in Annex 1 of the Consolidated Guidelines on HIV testing services.

16.3 Defining the scope of the guidelines

To develop these guidelines, the WHO Guideline Steering Group used mapping conducted for the Consolidated guidelines on HIV testing services (2).

Two of the critical gaps identified were the need for normative guidance on (1) HIVST and (2) assisted HIV partner notification services. Due to the availability of new evidence on both of these topics, WHO undertook an update focused on these two approaches.

Other guidelines under development

The HIV Department and other WHO departments currently are developing or updating a number of guidelines relevant to HTS in 2016/2017. These include:

- Guideline on hepatitis B and C testing
- Guidance on the treatment of specific sexually transmitted infections (STIs) and syphilis screening and treatment of pregnant women
- Prequalification of IVDs programme sample dossier for HIV rapid diagnostic tests (RDTs) used for HIVST
- Prequalification of IVDs programme approval pathway for HIV RDTs used for HIVST
- Pre-exposure prophylaxis (PrEP) implementation guidance tool.

16.4 Review of the evidence

Development of the two new recommendations began with systematic reviews of the evidence and values and preference on HIVST and on assisted HIV partner notification services. The GDG recommended that WHO also
commission additional values and preferences, qualitative studies, a review of country policies and a systematic review on the performance of HIV RDTs for self-testing to further assess the feasibility of implementing these approaches.

Because HIVST does not provide a definitive HIV-positive diagnosis, a methodology adapted from standard diagnostic accuracy reviews was developed in consultation with the WHO GRC Secretariat, the WHO Prequalification of IVDs Programme, the GDG and HIVST TWG. Ultimately, the review sought to assess if there were differences in the performance of HIV RDTs in the hands of self-testers compared to trained testers. In addition to this, the review also collected information on the sensitivity, specificity, rates of invalid results and user errors.

These results are summarized in various sections in Chapters 3 and 4 of the Supplement Guidelines on HIV self-testing and partner notification.

Additional details on the systematic review on the performance of HIV RDTs used for self-testing are available in Annex 19 of the Supplement Guidelines on HIV self-testing and partner notification.

16.5 Development of recommendations

As noted, the scoping exercise identified a need for evidence-based recommendations concerning HIVST and assisted HIV partner notification services. The WHO Steering Group drafted a single population, intervention, comparator, outcome (PICO) question for each of these areas. The members of the GDG reviewed and finalized the PICO questions and the outcomes and stratifications for each systematic review. Using an electronic survey, the GDG then ranked the importance of each systematic review on the Grading of Recommendations, Assessment, Development and Evaluation (GRADE) rating scale of 1 – 9 (0-3 NOT IMPORTANT, 4-6 IMPORTANT, 7-9 CRITICAL) (3).

Once the PICO questions were completed and agreed, external researchers Caitlin Kennedy of the Johns Hopkins Bloomberg School of Public Health, and Virginia Fonner of the Medical University of South Carolina used them to develop search protocols and perform a systematic review of the available scientific evidence, as described below. Both protocols and reviews were assessed and reviewed by Nandi Siegfried, the appointed independent methodologist.

See Annexes 17 and 18 of the Supplement Guidelines on HIV self-testing and partner notification, for tables on the relative importance of each outcome and complete details on each systematic review.

16.5.1. Systematic review of HIVST

The WHO Steering Group and GDG formed the following PICO question to inform the development of guidance on HIVST:

Should HIVST be offered as an additional approach to deliver HTS?

P: Populations receiving any form of HTS
I: HTS that included HIVST
C: HTS that do not include HIVST or no testing intervention
O: Listed below

The primary outcomes assessed in this review were:

1. Uptake of HIV testing
2. Frequency of HIV testing
3. Social harm/adverse events (e.g., device-related issues, coercion, violence [including intimate-partner violence, violence from family members or community members], psycho-social harm, self-harm, suicide, stigma, discrimination, frequency of sexually transmitted infections (STI) screening)
The secondary outcomes assessed in this review were:

1. Proportion of people diagnosed HIV-positive
2. Linkage to further testing, clinical assessment or anti-retroviral therapy (ART)
3. Measurement of CD4 or viral load
4. Linkage to an HIV prevention service
5. Sexual risk behaviour (e.g., condom use/condomless sex, STI, point-of-sex testing and number of sexual partners)

**Inclusion criteria**

- a study design that compares people who were offered HIVST with people who were only offered standard HTS (facility-based or community-based) or no intervention (no HIV testing)
- measured one or more of the primary or secondary outcomes listed above
- published in a peer-reviewed journal or accepted as a conference abstract prior to 1 June 2016.

The search was not restricted on the location of the intervention or the language of publication. Articles in languages other than English were translated as necessary.

**Search strategy**

The reviewers searched a total of 10 electronic databases covering the period up to 1 June 2016, including: PubMed, CINAHL, Sociological Abstracts, PsycINFO, EMBASE, clinicaltrials.gov, the WHO International Clinical Trials Registry Platform, the Pan African Clinical Trials Registry and two conference databases including abstracts from the International AIDS Conference (IAC), the Conference on HIV Pathogenesis, Treatment, and Prevention (IAS) and the Conference on Retroviruses and Opportunistic Infections (CROI). The IAC and IAS conference abstracts were searched for all available years (2001-2015). A search of abstracts accepted for IAC 2016 was also conducted. For CROI, only the most recent conferences (2014, 2015 and 2016) were searched; the abstracts of earlier conferences were inaccessible.

Experts in the field were also contacted to identify additional articles and abstracts – including from conferences like the IAC 2016 – which had been accepted but were not publicly available at the time of the review.

Secondary reference searching was conducted on all studies included in the review as well as on previously published review articles on related topics.

**Search terms**

The reviewers adapted the following search strategy for entry into all computer databases for both the main systematic review (PICO question) and for the values and preferences review:

\[(HIV\ [tiab] \ OR \ “human\ immunodeficiency\ virus”\ [tiab])\ AND\ (self-test\ [tiab] \ OR \ ”self-testing”\ [tiab] \ OR \ “home-based\ test”\ [tiab] \ OR \ “home-based\ testing”\ [tiab] \ OR \ “home\ test”\ [tiab] \ OR \ “home\ testing”\ [tiab])\].

Only terms for self-testing were used to search conference abstracts because all conferences searched were HIV-related and search functions were limited.

**Screening abstracts**

Titles, abstracts, citation information, and descriptor terms of citations identified through the search strategy were screened independently by two reviewers (CK and VF). Full text articles were obtained for all selected abstracts and both
Guidelines on HIV self-testing and partner notification: supplement to consolidated guidelines on HIV testing services

reviewers independently assessed all full-text articles for eligibility to determine final study selection. Differences were resolved through discussion and consensus.

Articles not meeting the inclusion criteria for the review but presenting values and preferences or complementary background information, such as review articles, were included in an annotated bibliography.

**Data extraction and management**

Titles, abstracts, citation information, and descriptor terms of citations identified through the search strategy were screened independently by two reviewers (CK and VF). Full text articles were obtained for all selected abstracts and both reviewers independently assessed all full-text articles for eligibility to determine final study selection. Differences were resolved through discussion and consensus.

The same two reviewers independently extracted data using standardized data extraction forms. When necessary, they resolved differences in data extraction through consensus and referral to a senior team member from WHO or the methodologist (Nandi Siegfried). They contacted study authors when additional information or data were needed.

The following information was gathered from each included study:

- **study identification**: author(s); type of citation; year of publication;
- **study description**: study objectives; location; population characteristics; description of the intervention; study design; sample size; follow-up periods and loss to follow-up;
- **outcomes**: analytic approach; outcome measures; comparison groups; effect sizes; confidence intervals; significance levels; conclusions; limitations.

Where possible, outcomes were also stratified and analysed by the following categories:

- General populations (all adults)
- Adolescents and young people (ages 10-14, 15-24)
- Sex (males and females)
- Key populations
- Directly assisted (defined as when a person receives direct in-person support, demonstration or explanation on how to perform a self-test and interpret the results)
- Unassisted (defined as when a person self-tests using an HIVST kit using the manufacturer-provided instructions for use without in-person demonstration or assistance)
- Past HIV testing frequency (particularly for the outcome of frequency of HIV testing)
- Partner type (for example, social harm from primary versus non-primary partners, test distribution to different types of partners, etc.).

For randomized controlled trials, reviewers assessed the risk of bias using the Cochrane Collaboration’s tool for assessing risk of bias (4). This tool assesses random sequence generation (selection bias), allocation concealment (selection bias), blinding of participants and personnel (performance bias), blinding of outcome assessment (detection bias), incomplete outcome data (attrition bias) and selective reporting (reporting bias). Reviewers assessed and classified methodological components of the studies as being at high, low or uncertain risk of bias.

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1 It was hypothesized that partner type may impact outcomes, particularly those related to social harm or adverse events. This is because risks and benefits may be different for individuals who self-test or promote HIVST with their primary or long-term partner compared with non-primary or short-term partners and other sex partners, such as sex workers and their clients.
**Data analysis**

Where multiple studies reported the same or comparable outcomes, meta-analysis was conducted using random-effects models to combine relative risks for dichotomous data and mean differences for continuous data using REVMAN 5.3.5. Where adjusted estimates or rate ratios were reported we combined these using the generic inverse variance outcome type in REVMAN 5.3.5.

All data was summarized according to the GRADE methodology.

Full details on the systematic review are located in Annex 17 of the Supplement Guidelines on HIV self-testing and partner notification.

### 16.5.2 Systematic review of HIV partner notification

The WHO Steering Committee and GDG formed the following PICO question to inform the development of guidance on HIV partner notification services:

**Should assisted HIV partner notification services be implemented as part of HTS?**

- **P:** Persons receiving HTS who are diagnosed HIV-positive and their partners
- **I:** Any HTS which included an offer of partner notification services using assistance
- **C:** HTS with unassisted referral or no intervention
- **O:** Listed below

The primary outcomes assessed in this review were:

1. Uptake of HTS among partners of people diagnosed with HIV
2. Proportion of partners with an HIV-positive test or newly diagnosed with HIV
3. Social harm/adverse events among people diagnosed with HIV and/or partners of HIV-positive individuals (e.g., violence [including intimate-partner violence, violence from family members or community members], breach of confidentiality, psycho-social harm, self-harm, suicide, stigma, discrimination)

The secondary outcomes assessed in this review were:

1. Measurement of CD4 or viral load among HIV-positive individuals and/or their partners
2. Linkage to clinical assessment or ART among HIV-positive individuals and/or their partners
3. Linkage to an HIV prevention service among HIV-positive individuals and/or their partners after an HIV-negative test result

**Inclusion criteria**

- study design that compared HIV-positive patients who were received assistance with notifying partners (contract, dual or provider referral) with HIV-positive patients who did not receive assistance (passive referral or no partner notification intervention).
- measured one or more of the primary or secondary outcomes listed above
- published in a peer-reviewed journal or conference abstract.

The search was not limited by the location of the intervention or the language of publication. Articles in languages other than English were translated as necessary.
Search strategy

The reviewers searched a total of 11 electronic databases covering the period up to 1 June 2016, including: PubMed, CINAHL, Sociological Abstracts, PsycINFO, EMBASE, clinicaltrials.gov, the WHO International Clinical Trials Registry Platform, the Pan African Clinical Trials Registry and two conference databases including abstracts from the IAC, IAS and CROI. The IAC and IAS conference abstracts were searched for all available years (2001-2015). A search of abstracts accepted for IAC 2016 was also conducted. For CROI, only the most recent conferences (2014, 2015 and 2016) were searched; the abstracts of earlier conferences were inaccessible.

Experts in the field were also contacted to identify additional articles and abstracts — including from conferences like the IAC 2016 – which had been accepted but were not publicly available at the time of the review.

Secondary reference searching was conducted on all studies included in the review as well as on previously published review articles on related topics.

Search terms

The reviewers adapted the following search strategy for entry into all computer databases for both the main systematic review (PICO question) and for the values and preferences review:


Screening abstracts

Two reviewers independently screened titles, abstracts, citation information and descriptor terms of citations identified through the search strategy. They obtained full-text articles for all selected abstracts and both reviewers independently assessed all full-text articles for eligibility for inclusion in the final study. The reviewers resolved differences through discussion and consensus.

Articles not meeting the inclusion criteria for the review but presenting potentially interesting or complementary background information, such as review articles, were included in an annotated bibliography.

Data extraction and management

The same two reviewers independently extracted data using standardized data extraction forms. When necessary, they resolved differences in data extraction through consensus and referral to a senior team member from WHO or the methodologist. They contacted study authors when additional information or data were needed.

The following information was gathered from each included study:

- study identification: author(s); type of citation; year of publication;
- study description: study objectives; location; population characteristics; description of the intervention; study design; sample size; follow-up periods and loss to follow-up;
- outcomes: analytic approach; outcome measures; comparison groups; effect sizes; confidence intervals; significance levels; conclusions; limitations.

Where possible, outcomes were also stratified and analysed by the following categories:

- general populations (all adults)
• adolescents and young people (ages 10–14, 15–19, and 15–24)
• sex (males and females)
• key populations (defined as men who have sex with men, people in prisons or closed settings, people who inject drugs, sex workers and transgender people)
• partner type (for example, social harm from primary versus non-primary partners, test distribution to different types of partners)

For randomized controlled trials, reviewers assessed the risk of bias using the Cochrane Collaboration’s tool for assessing risk of bias (4). This tool assesses random sequence generation (selection bias), allocation concealment (selection bias), blinding of participants and personnel (performance bias), blinding of outcome assessment (detection bias), incomplete outcome data (attrition bias) and selective reporting (reporting bias). Reviewers assessed and classified methodological components of the studies as being at high, low or uncertain risk of bias.

Data analysis

Where multiple studies reported the same or comparable outcomes, meta-analysis was conducted using random-effects models to combine relative risks for dichotomous data and mean differences for continuous data using REVMan 5.3.5. Where adjusted estimates or rate ratios were reported we combined these using the generic inverse variance outcome type in REVMan 5.3.5.

All data was summarized the data in according to the GRADE methodology.

16.5.3. Values and preferences reviews

For the reviews on both HIVST and HIV partner notification services, reviewers used the same search to identify studies presenting information on end-users’ values and preferences related to the PICO question.

HIV self-testing

The values and preferences review for HIVST focused on studies presenting primary data on examining the values and preferences of people who have used or potentially would use self-testing themselves, as well as the values and preferences of providers and other stakeholders, such as policy-makers and health workers. The studies included could be qualitative or quantitative; however, opinion pieces and review articles were excluded.

To further supplement the literature reviews, WHO commissioned focus group discussions among key populations and general population groups in Uganda and among young key populations in India, Indonesia, Pakistan and Thailand.

The results of this review are summarized in Chapter 2 and in Annex 17 of the Supplement Guidelines on HIV self-testing and partner notification.

Assisted HIV partner notification services

The values and preferences review for HIV partner notification services focused on studies presenting primary data examining the values and preferences of people who have used or potentially would use assisted HIV partner

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2 It was hypothesized that partner type may impact outcomes, particularly those related to social harm or adverse events. This is because risks and benefits of HIV partner notification may be different based on the partnerships or contacts, such as primary or long-term partner compared with non-primary or short-term partners and other contacts or sex partners, such as sex workers and their clients or people who use or inject drugs and individuals with whom they share needles or paraphernalia.
notification services themselves, as well as the values and preferences of providers and other stakeholders such as policy-makers and health workers. Studies reporting on values and preferences on unassisted HIV partner notification services were also included. The studies included could be qualitative or quantitative; however, opinion pieces and review articles were excluded.

To further supplement the literature reviews, WHO commissioned focus group discussions among key populations and general population groups in Uganda (5) and among young key populations in India, Indonesia, Pakistan and Thailand (6).

The results of this review are summarized in Chapter 3 and in Annex 18 of the Supplement Guidelines on HIV self-testing and partner notification.

16.5.4. Policy analysis

HIV self-testing

WHO consultants conducted a separate analysis of national HTS policies and of IVD-related regulatory policies to assess the overall feasibility of HIVST. Two reviewers searched and assessed national HIV testing policies from Africa, the Americas, Asia and Europe. From 1 January to 23 June 2016, the reviewers conducted electronic searches for national HIV testing policies using an Internet search engine, governmental and nongovernmental websites and WHO databases. They also reviewed country reports to WHO, UNAIDS and UNICEF through the Global AIDS Response Progress Reporting (GARPR). Two reviewers analysed the most recent national HIV testing policies identified. There were no geographic or language restrictions on this analysis. Policies were translated as necessary. The reviewers addressed and resolved any disagreement through discussion and consensus.

Results of this review are summarized in Chapter 2 of the Supplement Guidelines on HIV self-testing and partner notification.

Assisted HIV partner notification services

WHO consultants conducted an analysis of national HTS policies (and also included ART and PMTCT policies if partner notification was not included in the HTS policy) to assess the feasibility of implementing assisted HIV partner notification services. Two reviewers searched and assessed national HIV testing policies from Africa, the Americas, Asia and Europe. From 25 April to 20 June 2016, the reviewers conducted electronic searches for national HIV testing policies using an Internet search engine, governmental and nongovernmental websites and WHO databases.

The two reviewers analysed the most recent national HTS, ART and PMTCT policies identified. There were no geographic or language restrictions on this analysis. The reviewers resolved any disagreements through discussion and consensus. Results of this review are summarized in Chapter 3 of the Supplement Guidelines on HIV self-testing and partner notification.

16.6 Evidence assessment

Under the WHO guideline development process, the GDG formulates the recommendations guided by the quality of available evidence. Other factors – values and preferences, costs and feasibility – are also taken into consideration when determining the strength of the recommendation.
Interpreting the quality of evidence

The higher the quality of scientific evidence, the more likely that a strong recommendation can be made. The GRADE approach to recommendation development, which WHO has adopted, defines the quality of evidence as the extent to which one can be confident that the reported estimates of desirable or undesirable effects available from the evidence are close to the actual effects of interest (3,7).

The GRADE approach specifies four levels of quality of evidence (Table 16.1A).

Table 16.1A. Interpretation of the four GRADE levels of evidence

<table>
<thead>
<tr>
<th>Quality of evidence</th>
<th>Rationale</th>
</tr>
</thead>
<tbody>
<tr>
<td>High</td>
<td>We are very confident that the true effect lies close to the estimate of effect.</td>
</tr>
<tr>
<td>Moderate</td>
<td>We are moderately confident in the estimate of effect: The true effect is likely to be close to the estimate of effect, but it could be substantially different.</td>
</tr>
<tr>
<td>Low</td>
<td>Our confidence in the estimate of effect is limited: The true effect may be substantially different from the estimate of effect.</td>
</tr>
<tr>
<td>Very low</td>
<td>We have very little confidence in the effect estimate: Any estimate of effect is very uncertain.</td>
</tr>
</tbody>
</table>

Determining the strength of a recommendation

The strength of a recommendation reflects the degree of confidence of the GDG that the desirable effects of the recommendation outweigh the undesirable effects (Table 16.2A). Desirable effects (potential benefits) may include beneficial health outcomes (for example, increased uptake of HTS or earlier linkage to HIV services), reduction of burden on the individual and/or health services and potential cost-savings for the individual, communities, programme and/or health system. Undesirable clinical outcomes, adverse effects and potential harm, such as self-harm, IPV or coercive HIV testing, include those affecting individuals, families, communities or health services. Additional burdens considered include the resource use and cost implications for programmes, care providers or patients of implementing the recommendations.

The strength of a recommendation can be either strong or conditional.

A strong recommendation (for or against) is one for which the GDG has confidence that the desirable effects of adherence to the recommendation clearly outweigh the undesirable effects.

A conditional recommendation (for or against) is one for which the GDG concludes that the desirable effects of adherence to the recommendation probably outweigh the undesirable effects or are closely balanced, but the Group is not confident about these trade-offs in all situations. The Group may formulate conditional recommendations when the quality of evidence is low or may apply only to specific groups or settings. If implemented, a conditional recommendation should be monitored closely and evaluated rigorously. Further research will be required to address the uncertainties and is likely to provide new evidence that may change the calculation of the balance of trade-offs.

The values and preferences of the end users, feasibility and cost as well as consideration of potential benefits and harm contribute to determining the strength of a recommendation.
Table 16.2A. Domains considered when assessing the strength of recommendations

<table>
<thead>
<tr>
<th>Domain</th>
<th>Rationale</th>
</tr>
</thead>
<tbody>
<tr>
<td>Benefits and harm</td>
<td>When a new recommendation is developed, desirable effects (benefits) need to be weighed against undesirable effects (risks or harm), considering any previous recommendation or another alternative. The larger the gap or gradient in favour of the benefits over the risks, the more likely that a strong recommendation will be made.</td>
</tr>
<tr>
<td>Quality of evidence</td>
<td>High quality evidence is likely to lead to a strong recommendation.</td>
</tr>
<tr>
<td>Values and preferences (acceptability)</td>
<td>If the recommendation is likely to be widely accepted or valued highly, it is likely that a strong recommendation will be made. If there is a great deal of variability or strong reasons that the recommended course of action is unlikely to be accepted, it is more likely that a conditional recommendation will be made.</td>
</tr>
<tr>
<td>Cost/financial implications</td>
<td>Lower costs (monetary, infrastructure, equipment or human resources) or greater cost-effectiveness are more likely to contribute to a strong recommendation.</td>
</tr>
<tr>
<td>Feasibility</td>
<td>If an intervention is achievable in a setting where the greatest impact is expected, a strong recommendation is appropriate.</td>
</tr>
<tr>
<td>Equity</td>
<td>If the recommendation is likely to increase access to an intervention for those most in need, a strong recommendation is likely.</td>
</tr>
</tbody>
</table>

16.7 Developing the recommendations

From November 2015 through August 2016 WHO convened one in-person and four virtual guideline development meetings (two parallel morning and afternoon meetings on two separate occasions to allow participation from all time zones), two HIVST TWG meetings (one in person and one virtual) and 15 WHO Steering Group meetings.

During these meetings participants considered the evidence for formulating a new recommendation and reviewed all relevant sections of the consolidated guidelines. Individuals representing a broad range of stakeholders participated in the guideline development meetings as either GDG or expert observers. Participants at these meetings assessed the evidence to answer both the PICO question concerning HIVST and the PICO question concerning assisted HIV partner notification services, along with the risks and benefits, values and preferences of the populations that will be affected by the guidelines and cost-benefits and feasibility associated with each possible intervention, and they made recommendations. The final recommendations and guidance took these considerations into account.

An experienced methodologist, Nandi Siegfried (independent clinical epidemiologist, South Africa), facilitated the discussions. Prior to the guideline meeting the WHO Guideline Steering Group determined that the goal for decision-making would be to reach consensus, defined as agreement of the group. Prior to the start of the guideline meeting the GDG determined that, if consensus could not be reached, a vote of at least 60% would be required to approve the recommendation.

After reviewing the evidence, the GDG resolved disagreements through continued discussion and revision of the recommendation to provide additional clarification or qualifications not included in the PICO question. Ultimately, the group reached consensus and unanimously agreed on the direction and strength of both recommendations.

See the Executive summary and Chapters 3 and 4 of the Supplement Guidelines on HIV self-testing and partner notification, for the final recommendations agreed to by the GDG.
16.8 Producing the guidelines

Following the virtual GDG consultations and the face-to-face meeting, WHO revised the full draft guidelines and circulated them electronically to the GDG, HIVST TWG, WHO Steering Group and the External Review Group for comments and feedback. All responses were considered and addressed in the final draft as appropriate.

16.9 Plans for dissemination

The guidelines will be disseminated as a printed publication and electronically on the WHO website http://www.who.int/hiv/topics/vct/en/ in the six official United Nations languages. The web version will include all annexes. For easy reference a short version will summarize new and existing recommendations. The WHO website will offer a library of all supporting documentation and evidence.

WHO headquarters will work closely with regional and country offices and implementing partners to ensure that the guidelines are disseminated through regional and subregional meetings. WHO will assist Member States to adapt the guidelines to their national context.

16.10 Updating the guidelines

WHO has developed a tool to evaluate how users implement the guidelines. The tool assesses the uptake of the recommendations and barriers to effective implementation. WHO will evaluate uptake of these guidelines using this tool and provide updated guidance accordingly. Currently, the WHO HIV Department plans to develop implementation guidance and tools to accompany this normative guidance in 2017. The Department will review this guidance and consider potential updates in 2018–2019. In the interim, if important new evidence becomes available, the Department may develop technical and programmatic updates.
References