

Community and service provider views to inform the 2013 WHO consolidated antiretroviral guidelines: key findings and lessons learnt

Amy C. Hsieh^a, Gitau Mburu^b, Adam B.J. Garner^a, Anja Teltschik, Mala Ram^b, Christoforos Mallouris^{c,d}, Martina Penazzato^e, Nathan Shaffer^e, Philippa J. Easterbrook^e and Andrew Ball^e

Objective: The objective was to evaluate community and healthcare worker (HCW) values and preferences on key topics to inform the development of the 2013 WHO consolidated guidelines for antiretroviral therapy in low and middle income countries.

Design: Cross-sectional e-survey and e-forum discussion; focus group discussions (FGDs)

Methods: Data were collected on community perspectives regarding a range of potential clinical and operational recommendations in the 2013 guidelines between November 2012 and January 2013 through an e-survey ($n = 1088$) and e-forum ($n = 955$). Additional FGDs were held with people living with HIV (PLHIV) in Malawi and Uganda ($n = 88$) on antiretroviral therapy (ART) use among pregnant women. Two surveys were also undertaken on similar topics covered in the e-survey for health care workers caring for adults ($n = 98$) and children ($n = 348$).

Results: There were 1088 e-survey respondents from 117 countries: of whom 37.7% (298/791) were females, 49.9% (431/864) PLHIV, and 20.9% (174/831) from low-income countries. The proportion of e-survey respondents who supported raising the CD4⁺ T-cell threshold for ART initiation in adults from 350 to 500 cells/ μ l was 51.0% (355/696), and regardless of CD4⁺ T-cell count for all pregnant females 89.8% (607/676), HIV serodiscordant partners 71.9% (486/676), and all children on diagnosis of infection 47.4% (212/447). E-survey respondents strongly supported discontinuing use of stavudine (72.7%, 416/572), task-shifting/sharing from doctors to nurses (75.2%, 275/365) and from nurses to community health workers (71.1%, 261/367) as strategies to expand access to HIV testing, care, and treatment. Focus group discussion respondents identified service capacity, and social and legal concerns as key considerations influencing the decisions of women living with HIV to continue ART after the risk of vertical transmission has passed. Key lessons learnt in these consultations included the need for piloting and validation of questions; sufficient time to adequately disseminate the survey; and consideration of using FGDs and mobile phone technology to improve participation of people with limited internet access.

Conclusion: Community participation in guideline development processes is important to ensure that their perspectives are considered in the resulting recommendations.

^aGlobal Network of People Living with HIV, Amsterdam, The Netherlands, ^bThe International HIV/AIDS Alliance, Hove, United Kingdom, ^cSocial Justice 4 All, Amsterdam, The Netherlands, ^dUNAIDS, Geneva, Switzerland, and ^eHIV department, World Health Organization, Geneva, Switzerland.

Correspondence to Amy C. Hsieh, Eerste Helmersstraat 17 B3, 1054 CX Amsterdam, The Netherlands.

E-mail: ahsieh@gnpplus.net

DOI:10.1097/QAD.0000000000000251

Communities should be actively involved in the adaptation, implementation, and accountability processes related to the guidelines.

© 2014 Wolters Kluwer Health | Lippincott Williams & Wilkins

AIDS 2014, **28** (Suppl 2):S205–S216

Keywords: acceptability, antiretroviral therapy, community, guidelines, healthcare workers, Option B+, survey

Introduction

Antiretroviral therapy (ART) is a therapeutic and preventive cornerstone of comprehensive efforts to reduce HIV morbidity, mortality, and transmission. Its scale up over the past decade has been possible through the ownership, involvement, and action of people living with HIV (PLHIV) and their communities [1,2].

In HIV program implementation, community participatory approaches are important to ensure that policies and interventions respond to the needs and circumstances of people most at risk of or living with HIV [3]. Participatory methodologies, like community consultations, provide a platform for community voices to be heard and ensure that new recommendations and interventions are acceptable, safe, and accessible, particularly to the most marginalized communities [4,5]. Involving affected communities has the potential to create a sense of ownership of new interventions and programs [6,7].

This is also applicable to the development of new HIV prevention, treatment, and care guidelines, whose recommendations affect communities living with or affected by HIV. The practice of engaging affected communities in the development of HIV-related policies and guidelines was employed to inform the WHO's 2010 guidelines on ART for adults and adolescents, and the use of antiretrovirals (ARVs) for preventing vertical transmission [8,9]. More recently, WHO convened consultations in Harare and Bangkok that aimed to collect views from community representatives on the strategic use of ARVs [10,11].

The approach to developing WHO guidelines

WHO uses the Grading of Recommendations, Assessment, Development and Evaluation (GRADE) system during the guidelines development process [12]. This approach emphasizes a structured, explicit, and transparent process of rating the quality of evidence and strength of recommendations. It also involves a critical review of the evidence, usually comprising systematic reviews, randomized clinical trials, and observational studies, as appropriate.

As part of the GRADE process used to develop recommendations for the 2013 consolidated guidelines

on the use of antiretroviral drugs for treating and preventing HIV infection (2013 Guidelines), the guidelines development groups also considered the values and preferences of communities and healthcare workers (HCWs); potential implications on equity and human rights; cost and cost-effectiveness; feasibility and barriers; and overall benefits and harms of potential recommendations [13]. To ascertain the perspectives of affected communities regarding priority clinical, operational, and programmatic issues, WHO commissioned the International HIV/AIDS Alliance (Alliance) and the Global Network of People Living with HIV (GNP+) to conduct a series of community consultations. WHO also conducted an assessment of HCW values and preferences [14,15].

This article highlights the key findings and lessons learnt from these consultation processes. It also discusses the implications of the findings in relation to the adaptation and implementation of the 2013 Guidelines at the country level, and suggests how to optimize community engagement to inform future guidelines.

Methods

These community consultations employed the following participatory methodologies: e-survey, e-forum discussions, and thematic focus group discussions (FGDs). These data were also evaluated with the findings from the HCW surveys conducted by WHO.

E-survey

The e-survey consisted of 70 questions, delivered using Survey Monkey (www.surveymonkey.com) in six languages (English, French, Arabic, Chinese, Russian, and Spanish). The questionnaire explored community preferences regarding possible clinical recommendations (e.g., which ARVs to use and when to initiate ART for adults, adolescents, pregnant and breastfeeding women, and children), as well as operational and programmatic considerations of ART delivery. Questions were developed based on key topics to be addressed in the 2013 Guidelines, together with existing guidance on the topic and potential scenarios for new recommendations, provided by the WHO Secretariat. Each e-survey

section contained a summary of the current WHO guidance on the topic, if any, and possible new recommendations. The questions were revised and validated with input from a Community Consultation Working Group that consisted of representatives from communities of PLHIV, key populations, and service providers (see Acknowledgements). All questions were optional, excluding consent to participate and age. For 28 questions, respondents were able to choose multiple responses from the options presented. For 20 questions, respondents rated the importance of, or their agreement with, particular options provided to the question on a Likert scale from 'not important/strongly disagree' to 'very important/strongly agree'. For eight questions, respondents ranked the options provided in numerical order, from most important to least important. Responses were obtained over a 6-week period between November and December 2012.

E-forum

The e-forum discussion, conducted in five languages (Arabic, English, French, Russian, and Spanish), explored selected topics and early draft recommendations by probing for further discussion on aspects that could not be covered comprehensively by the e-survey questions. A one week period was allocated to each of the four main topics between December 2012 and January 2013. E-forum facilitators were responsible for posting the questions, rephrasing ambiguous questions to stimulate discussion, and posting a thematic summary of the main points at the end of each week. The facilitators summarized all discussions after all e-forum topics were discussed.

Focus group discussions

FGDs conducted by GNP+ and the International Community of Women Living with HIV (ICW) in Malawi, using Chichewa (with simultaneous translation into English), and in Uganda, using English (with translation into Luganda as needed), explored the perspectives and experiences of women and their partners living with or affected by HIV regarding the offer of lifelong ART to pregnant or breast-feeding women (Option B+) to prevent vertical transmission of HIV. FGDs were held over two weeks in November 2012.

Healthcare worker surveys on pediatric and adult care

Two cross-sectional e-surveys, conducted in English, were developed by WHO for HCWs providing pediatric or adult ART to elicit their perspectives on potential policy changes. Responses were collected over three weeks in November 2012.

Participant recruitment

Invitations to communities and civil society to participate in the e-survey and e-forum were disseminated through

the GNP+ website, GNP+ Facebook page, national and regional networks of PLHIV, and other key populations, and the Alliance website, intranet, and network of local organizations, with a request to further disseminate widely to nongovernmental organizations (NGOs), community-based organizations (CBOs), and community-level contacts. WHO's HIV/AIDS department also circulated an announcement through its website and partner networks. Further messages were posted on global, regional, and national list servers used by PLHIV communities, NGOs and CBOs concerned with HIV care and treatment (e.g., AIDSPortal website, GHDonline forum, E-drug online forum, *British Medical Journal* blog pages, among others). FGD participants were recruited by national networks of women living with HIV in Malawi and Uganda. The HCW surveys were distributed through major ART provider agencies and networks: African Network for AIDS Physicians (ANEPA), International Centre for AIDS Care and Treatment Programs (ICAP), International Epidemiologic Databases to Evaluate AIDS (IeDEA), and Médecins Sans Frontières (MSF) for the adult HCW survey; and African Network for Care of Children Affected by HIV/AIDS (ANECCA), Clinton Health Access Initiative (CHAI), and Paediatric European Network for Treatment of AIDS (PENTA-ID) for the pediatrics HCW survey. All e-survey, e-forum, and FGD participants provided voluntary written consent.

Analysis

E-survey responses were analyzed using SPSS (version 21; IBM). Descriptive analysis was performed of self-identified gender, HIV status, key population membership, and income status of respondents' country of origin. For questions that required selecting a degree of importance/agreement to options, numerical values were assigned to responses (-2 for very unimportant/strongly disagree; 0 for neither agree nor disagree/important nor unimportant; +2 for very important/strongly agree). For questions that required respondents to rank the importance of options, numerical values were assigned from 1 for the least important up to the highest number of options available to be selected. Using these numerical values, the arithmetic means for each option were calculated and resulted in the comparative ratings of options for these questions. In addition, Pearson's χ^2 test and Welch's *t*-test were performed to investigate differences between subgroups. E-forum content was analyzed by identifying common themes and areas of consensus in each discussion [16]. FGDs were moderated by a facilitator, who asked open-ended questions and used probes, recorded, transcribed, and thematically analyzed [16]. For the HCW surveys, quantitative data were analyzed using Microsoft Excel 2010, and a thematic analysis was undertaken for free text responses [16].

Results

Characteristics of respondents

Table 1 summarizes the key demographic characteristics of the e-survey, e-forum, and FGD respondents.

E-survey

Overall, 1088 people from 117 countries responded to the e-survey, including 37.7% (298/791) women, 49.9% (431/864) PLHIV, 20.9% (174/831) from low-income

countries, and 58.9% (458/831) from middle-income countries, based on self-identification.

E-forum

There were 955 subscribers who posted 155 responses. No demographic information was obtained from e-forum participants.

Focus group discussions

Of the 88 participants, there were 76 women living with HIV and 11 male partners. In Lilongwe, Malawi,

Table 1. E-survey, e-forum, and focus group discussion respondent demographics.

Variable	E-survey respondents (n = 1088)		E-forum subscribers (n = 955)		FGD respondents (n = 88)	
	n	(%)	n	(%)	n	(%)
Sex	791	(72.7)	n/a		86	(97.7)
Women	484	(61.2)			75	(87.2)
Men	298	(37.7)			11	(12.8)
Transgender	9	(1.1)			0	(0.0)
HIV status	864	(79.2)	n/a		86	(97.7)
PLHIV	431	(49.9)			81	(94.2)
HIV-negative	406	(47.0)			5	(5.8)
Do not know	27	(3.1)			0	(0.0)
Key populations	489	(44.9)	n/a		n/a	
Pregnant women ^a	80	(16.4)				
Young people (20–24 years old)	61	(12.5)				
Adolescents (10–19 years old)	14	(2.8)				
MSM	220	(45)				
Transgender	14	(2.8)				
People who inject drugs	28	(5.8)				
Sex workers	30	(6.1)				
Refugees/migrants	42	(8.6)				
Age	880	(80.9)	n/a		n/a	
10–19 years old	10	(1.1)				
20–24 years old	53	(6.1)				
25–34 years old	264	(30)				
35–44 years old	280	(31.8)				
45–54 years old	189	(21.5)				
55–64 years old	67	(7.6)				
65+ years old	17	(1.9)				
Country income status ^b	831	(76.4)	n/a		88	(100.0)
Low	174	(20.9)			88	(100.0)
Middle+	489	(58.9)				
High	168	(20.2)				
Language	1088	(100.0)	955	(100.0)	n/a	
English	658	(60.5)	546	(57.2)		
French	88	(8.1)	99	(9.1)		
Spanish	65	(6.0)	74	(7.7)		
Russian	75	(6.9)	68	(7.1)		
Arabic	9	(0.1)	168	(17.6)		
Chinese	193	(17.7)	n/a			

Low-income countries included Kenya ($n = 35$), Zimbabwe ($n = 26$), countries with n between 6–15 (Democratic Republic of the Congo, Ethiopia, Malawi, Myanmar, Nepal, Rwanda, Tanzania, Uganda), and countries with $n \leq 5$ (Bangladesh, Benin, Burkina Faso, Burundi, Cambodia, The Gambia, Guinea, Guinea-Bissau, Haiti, Kyrgyz Republic, Liberia, Mali, Mozambique, Niger, Sierra Leone, Togo). **Middle-income countries** included China ($n = 146$), India ($n = 23$), Moldova ($n = 16$), Nigeria ($n = 62$), South Africa ($n = 29$), Ukraine ($n = 28$), Zambia ($n = 18$), countries with n between 6–15 (Argentina, Cameroon, Mexico, Morocco, Namibia, Philippines, Russian Federation, Senegal, Swaziland, Thailand), and countries with $n \leq 5$ (Armenia, Algeria, Anguilla, Belize, Bhutan, Bolivia, Bosnia and Herzegovina, Botswana, Brazil, Chile, Colombia, Republic of the Congo, Costa Rica, Côte d'Ivoire, Cuba, Djibouti, Dominican Republic, Ecuador, Fiji, Georgia, Ghana, Indonesia, Iran, Jamaica, Kazakhstan, Lebanon, Lithuania, Malaysia, Mauritius, Pakistan, Paraguay, Peru, Romania, Samoa, Serbia, Seychelles, Sri Lanka, St. Kitts and Nevis, Sudan, Suriname, Syrian Arab Republic, Uruguay, Uzbekistan, Venezuela, Vietnam). **High-income countries** included United Kingdom ($n = 35$) and United States ($n = 74$), countries with n between 6–15 (Australia, Canada, Netherlands, Switzerland), and countries with $n \leq 5$ (Austria, Barbados, Belgium, Bermuda, Brunei, Czech Republic, Denmark, France, Germany, Greece, Hungary, Ireland, Israel, Netherlands Antilles, Norway, Poland, Singapore, Spain, Sweden, Taiwan, Trinidad and Tobago).

^aA woman who is pregnant or has been pregnant in the last 2 years, or who is planning to have a child in the next 2 years.

^bWorld Bank Country Income Status definitions were used.

43 participants were allocated to one of four group sessions that included women living with HIV from rural settings ($n = 10$), those from urban settings ($n = 11$), those who are Muslim ($n = 9$), or who had leadership experience ($n = 13$). In Kampala, Uganda, 45 participants were allocated to one of four group sessions that included women living with HIV under 30 years of age ($n = 11$), women living with HIV from rural settings ($n = 12$), women living with HIV with leadership experience ($n = 12$), and male partners of women living with HIV ($n = 10$). Participants were grouped by these characteristics to understand the different experiences of those involved in decision-making or policy-making, those from a religious minority, and male partners.

Healthcare worker surveys

The pediatric HCW survey had 348 respondents. The majority (44.5%, 155/341) were from southern Africa, east Africa (22.0%, 75/341), west or central Africa (16.4%, 56/341), and south-east Asia (7.0%, 24/341). Most respondents were pediatricians (37.9%, 128/338), general physicians (29.3%, 99/338), or clinical officers (9.5%, 32/338), providing care to children older than 2 years (87.7%, 292/333). The adult HCW survey had 98 respondents. The majority (46%) were from southern or east Africa (32%).

Key findings

Table 2 summarizes the key areas covered in the e-survey and e-forum. The relevant e-survey questions can be found in the Web Appendix, <http://links.lww.com/QAD/A498>.

When to start antiretroviral therapy?

Figure 1 shows e-survey respondent preferences regarding when to start ART. Overall, 51.0% (355/696) of all e-survey respondents supported starting adults and adolescents on ART at a CD4⁺ T-cell count between 350 and 500 cells/ μ l or less. Only 9% of the adult HCW

survey respondents stated that earlier initiation should not be considered before full coverage was reached at 350 cells/ μ l.

What antiretroviral therapy regimen to use for adults?

With earlier initiation, e-survey respondents were keen to see increased access to simpler, more tolerable, and effective ARVs, preferably as 'once-daily' dosing with a single pill (77.9%, 493/633). The majority of the adult HCW survey respondents agreed that once-daily regimens were either critical (54%) or important (35%).

E-survey respondents who reported current use of stavudine preferred not continuing with this medication (72.7%, 416/572). However, the adult HCW survey respondents held mixed views regarding the priority for phasing out stavudine: users with side-effects (42%) were the priority, followed by all users (27%).

Who should be offered antiretroviral therapy regardless of CD4⁺ T-cell count?

Figure 2 shows e-survey responses to the question, 'which people or populations living with HIV should be offered ART regardless of CD4⁺ T-cell count? Support for ART initiation in specific populations regardless of CD4⁺ T-cell count among e-survey respondents was greatest for PLHIV in serodiscordant couples (63.3%, 286/452), with other groups, including PLHIV who are sex workers, MSM, and people who inject drugs, ranging between 52.9 and 23.0%. The offer of lifelong ART to pregnant women is addressed below. A third of e-survey respondents (33.0%, 149/452) supported offering ART to anyone living with HIV, regardless of CD4⁺ T-cell count. There were no statistical differences according to HIV or country income status. The adult HCW survey respondents also supported offering ART to partners in serodiscordant relationships (47%). E-forum contributors reaffirmed that early ART could benefit individuals in serodiscordant relationships or who also live with hepatitis

Table 2. E-survey and e-forum topics covered.

E-survey topics	E-forum topics
Use of ARVs for treatment and prevention in adults and adolescents	Use of ARVs for treatment and prevention in adults and adolescents
When to start	When to start – changing the ART initiation threshold from 350 to 500 CD4 ⁺ cells/ μ l
What treatment	Which ARVs – what form of ARV (e.g., once-daily, co-blistering, etc.)
How to deliver	TasP/PrEP – what opportunities does TasP/PrEP offer to the HIV response
Use of ARVs in pregnant women	Use of ARVs in children
When to start	When to start – changing the ART initiation threshold
What treatment	Which ARVs – preferred regimen
How to deliver	How to deliver – challenges of pediatric ART enrolment
Use of ARVs in children	Use of ARVs in pregnant women
When to start	Which ARV regimen to prevent vertical transmission
What treatment	Programmatic issues
How to deliver	How to deliver – how to link with broader care for women; how to scale up access
Operational and service delivery issues	Human rights in the guidelines on ARVs for treatment and prevention
Programmatic decision-making issues	Community involvement in country-level decision-making
	How to make the decision-making process more inclusive, fair and transparent

ART, antiretroviral therapy; ARV, antiretroviral.

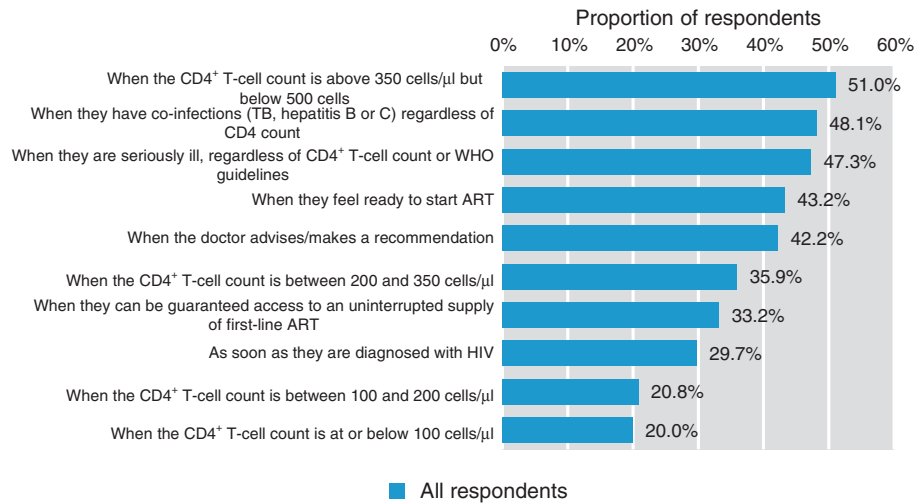


Fig. 1. When should people living with HIV be offered antiretroviral therapy? (n = 696).

B, and should be offered to key populations, such as injecting drug users or men who have sex with men.

Potential challenges to offering antiretrovirals for prevention, and essential actions to overcome them

E-survey respondents highlighted important challenges to offering ARVs for prevention, including the difficulty of adhering to ART while feeling healthy (1.17 on a scale of -2 to +2 from strongly disagree to strongly agree); sustainability of ART access (1.13); and criminalization of key populations (1.19). PLHIV e-survey respondents were particularly concerned that some public services may use ARVs for prevention to ‘test and treat’ people without respect for individual rights and choices (0.89).

To overcome these challenges, e-survey respondents considered it important to use ARVs for prevention in combination with, rather than substituting, behavioral

and community interventions (1.69 on a scale of -2 to 2 from least important to most important); to acknowledge that the primary benefit of treatment is for the individual and the secondary benefit is for prevention (1.67); and to ensure that literacy related to use of ARVs for prevention is strengthened (1.60). E-survey respondents frequently called for ARVs for treatment and prevention programs to use a human rights approach (1.47).

Preferences for lifelong antiretroviral therapy in pregnant women

A majority of e-survey respondents agreed that pregnant women should be offered ART regardless of CD4⁺ T-cell count (89.8%, 607/676) and strongly preferred Option B+ (described as ‘triple ARV treatment for all pregnant women living with HIV regardless of CD4⁺ T-cell count as soon as HIV diagnosis is confirmed and ART is continued for life; provides infants with daily nevirapine

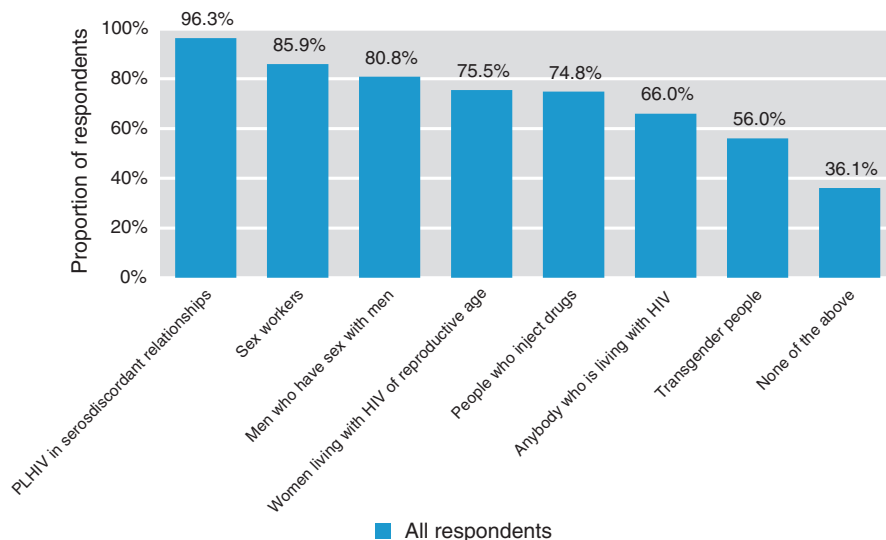


Fig. 2. Who should be offered antiretroviral therapy regardless of CD4⁺ T-cell count? (n = 452).

or zidovudine from birth through age 4–6 weeks regardless of infant feeding method') (66.1%, 290/439; versus 13.2% for Option A, 17.5% for Option B, and 3.2% for none of the above), which correlates with e-forum and FGD findings. A majority of the adult HCW survey respondents (79%) agreed.

One e-forum respondent stated, 'all countries should move to Option B+ if the resources are available ... However, cost, the burden of care, long-term adherence, and toxicities are problem[s]. As a result, pregnant women would choose the option themselves. All pregnant women should be referred to an HIV physician who could explain all options to the women.'

While recognizing many benefits associated with Option B+, FGD participants also identified concerns, such as the expectation that women must start ART as soon as they received a diagnosis of infection, without sufficient psychosocial and counseling support, and time to think through the implications or prepare for disclosure to partners. One female FGD respondent from Malawi remarked, 'Women have challenges because if they go out of the hospital with medication, they can't think of ways to inform their husbands so they take [the medications] behind their husband's back. Some of them don't take their medication.'

Considerations of whether to continue When the risk of vertical transmission had passed, e-survey respondents identified uninterrupted access to first-line ARVs (1.79) and ease of accessing ARVs (1.76) as among the most important considerations in determining whether or not women living with HIV should continue on ART. Women living with HIV from the e-survey also considered their CD4⁺ T-cell counts as an important consideration (1.55). One female Ugandan FGD respondent said, 'After giving birth, I'll stop that drug because you know I was started on the drugs with pressure just to protect my child,' indicating that personal readiness to continue lifelong treatment, as well as messaging, is also critical.

Service capacity issues E-survey respondents identified the following as important for the successful implementation of Option B+: ensuring that quality of care is not compromised (1.89); linkage between sexual and reproductive health services and HIV services (including ART) (1.82); retention in postnatal ART care for mothers (1.82); capacity of health facility-based services (1.81); retention in postnatal ART care for children (1.81); and the capacity of community-led services (1.71).

Social and legal considerations One Muslim Malawi FGD participant cited an example of discrimination due to her religion when seeking antenatal care: '[They said], 'The way that you dress [as a Muslim woman], how could

you get infected?' ... It was a public hospital, so my husband took me to a private hospital.' Similarly, e-survey respondents identified the following as important challenges to overcome for the successful implementation of Option B+: stigma and discrimination from healthcare providers (1.68), family members (1.65), and within the community (1.64); inequity (1.57); gender-based violence (1.49); male involvement (1.48); HIV criminalization (1.25); and forced sterilization (0.84).

Involvement of women living with HIV In addition to verifying the e-survey results, FGD participants highlighted that communities should have an ongoing role in decision-making, monitoring, and supporting the implementation of Option B+. One female Ugandan FGD respondent with leadership experience stated, 'No women living with HIV of childbearing age were consult[ed]...' FGD respondents remarked that community participation improves understanding and support in the community; builds active partnerships between community, health ministry, and service providers; and provides ongoing feedback to address issues and strengthen programs. To achieve this, FGD respondents felt that women living with HIV require support and access to capacity-building opportunities. One female Ugandan FGD respondent suggested, 'If we involve [young women living with HIV] in such trainings, forums, workshops, especially in their clinics or train their counsellors ... by the time they get pregnant, they know what to expect.' (A fuller discussion of these considerations and recommendations can be found at: <http://www.gnpplus.net/option-b-understanding-the-perspectives-experiences-of-women-living-with-hiv-in-uganda-and-malawi/>.)

When should children be offered antiretroviral therapy?

Figure 3 shows e-survey preferences for what age children should be offered ART regardless of their CD4⁺ T-cell count. Nearly half of e-survey respondents (47.4%, 212/447) agreed that children should initiate ART immediately after a diagnosis of infection, although it was unclear whether they preferred an age-specific cut-off (e.g., children ≤5 years old). There were no statistical differences by country income status ($P > 0.05$) or gender ($P > 0.05$). Meanwhile, 64.2% (194/303) of the pediatric HCW survey respondents thought that immediate ART should be recommended beyond infancy, and the majority (67.7%, 153/226) indicated 5 years old or younger as the preferred option.

What antiretroviral therapy regimen to use for children?

For children younger than 3 years, 51.4% (223/434) of e-survey respondents preferred regimens with greater effectiveness, such as syrup containing lopinavir/ritonavir, despite known storage and administration difficulties.

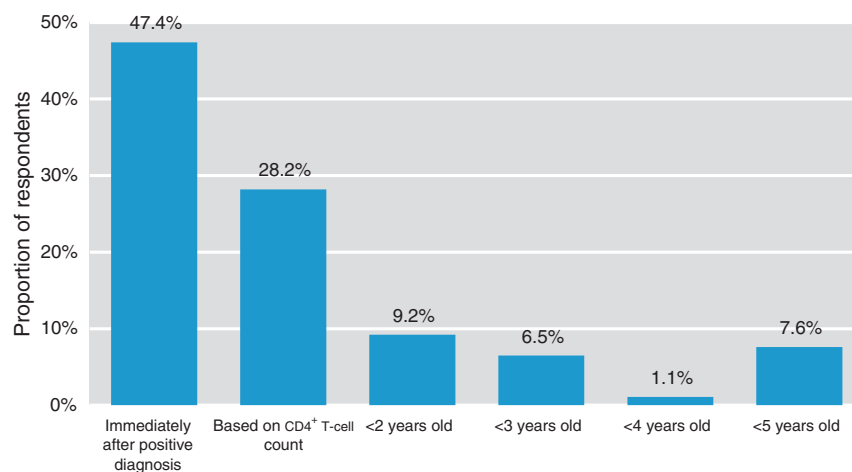


Fig. 3. When should children be offered antiretroviral therapy? ($n = 447$).

These findings were consistent with those from the pediatric HCW survey, who viewed lopinavir/ritonavir very favorably (31.1%, 87/279) or somewhat favorably (21.1%, 59/279) [14]. For children older than 3 years, 36.6% of e-survey respondents (155/424) preferred tenofovir/lamivudine/efavirenz as a first-line regimen. Although 30.8% of the pediatric HCW survey respondents (80/260) preferred the same regimen, more pediatric HCW survey respondents (36.9%, 96/260) preferred a zidovudine-based regimen [14]. The need for toxicity monitoring was their main rationale for deprioritizing tenofovir.

On a scale of -2 to $+2$ from least to most important, e-survey respondents noted that the need for toxicity monitoring of tenofovir (1.70), official approval of proposed medication (e.g., tenofovir) for use in young children (1.40), once-daily dosing (1.58), and ease of storage without refrigeration (1.55) are important considerations for parents or caregivers, and can affect children's adherence to ART. As stigmatizing attitudes or lack of support can prevent children from accessing treatment, an e-forum participant suggested 'building the capacity of health workers in pediatric HIV and offering treatment literacy education to parents' as means of mitigating this.

Operational and service delivery

Improving access, retention in care, and adherence Figure 4 demonstrates the barriers that must be addressed to improve retention in HIV care. On a scale of 1–6 from least to most important, e-survey respondents identified access to ARVs (4.6 among PLHIV) and HIV testing (4.2 among PLHIV) as among the most challenging barriers that must be addressed to improve retention. There were some statistical differences ($P < 0.05$) according to HIV status. For example, PLHIV identified healthcare provider attitudes (4.1 among PLHIV, 3.5 among non-PLHIV) and age of

consent for adolescents (3.8 among PLHIV, 2.3 among non-PLHIV) as more challenging barriers, whereas those not living with HIV regarded access to HIV testing (4.8), linkage to care (4.2), and availability of ARVs in antenatal clinics (4.4) as more important. Low-income country respondents assigned greater importance to HIV testing access, whereas middle-income country respondents assigned lesser importance to the cost of childcare during clinic visits ($P < 0.05$). This disparity provides another reminder that the barriers actually identified by PLHIV themselves should be prioritized to improve their retention in care. 'People who are still relatively well . . . might not put adherence in its proper perspective. [A] lot more rigorous patient education on adherence' would be required.'

Task-shifting/sharing and decentralization E-survey respondents supported task-shifting/sharing from doctors to nurses (75.0%) and from nurses to community health workers (71.0%). However, they noted that nurses and community health workers need to receive adequate training, regular supervision and updating, and should be allowed to provide HIV care and treatment services to PLHIV who are stable and do not require a doctor's consultation. As this question referred only to the care of PLHIV, respondents most likely answered this question to mean care for adults, not children.

Role of communities

E-forum respondents discussed the importance of community systems linkages with health systems, and support for ART adherence, stigma reduction, and advocacy. They identified community mobilization, empowerment, and sensitization as requirements for successfully supporting access to services for PLHIV and other key populations, and addressing human rights issues. Across e-forum discussions, communities were seen as critical partners for civil society and government

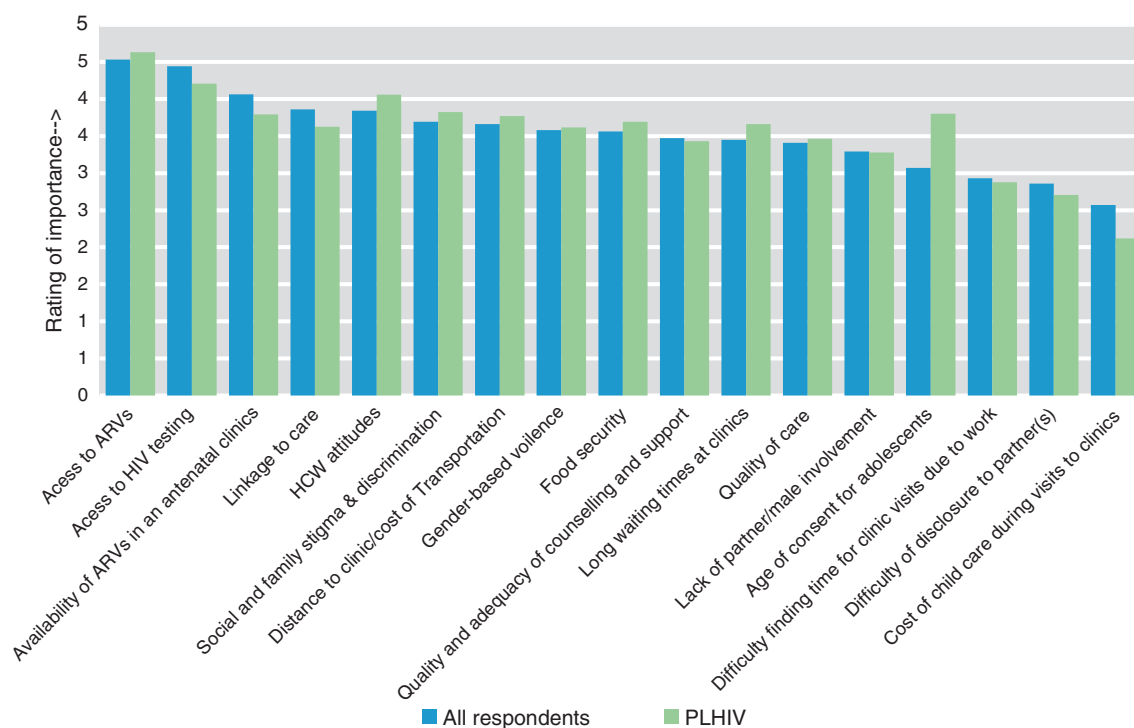


Fig. 4. Barriers that must be addressed to improve retention in HIV care (people living with HIV, PLHIV = 431; non-PLHIV = 406).

in advocating for the elimination of stigma and discrimination; demanding and supporting inclusive, fair, and transparent ART programs; holding leaders to account; and supporting adherence to treatment. E-forum respondents also emphasized the importance of involving communities at all stages of developing and implementing the 2013 guidelines. Echoing the results of the Harare and Bangkok community consultations, community respondents in these consultations highlighted the many roles communities are uniquely positioned to play in service delivery, scale up of interventions, operational research and evaluation, and advocacy at local, national, and regional levels to increase the effectiveness of efforts to provide access to HIV care and ART for all who need it [17,18].

Discussion

This consultation, based on different methodologies, was one of the largest and most comprehensive global community consultations on ARV use undertaken to date to inform a guidelines development process. As one of the decision-making components of the GRADE method for developing guideline recommendations, the consultation findings informed some key recommendations in the 2013 guidelines. Preliminary findings were presented to the adult and adolescent, maternal and child health, and programmatic guidelines development

groups. Key community values and preferences considered by the Guidelines Development Groups included the earlier offer of ART to all PLHIV; the immediate offer of ART to certain groups (e.g., pregnant women using Option B+ and serodiscordant couples); the expansion of the immediate start of pediatric treatment; the phase out of stavudine; and task-shifting/sharing of HIV-related services with nurses and community health workers. Additionally, participants expressed the view that successful implementation of the 2013 guidelines requires an enabling environment in which the human rights of PLHIV and key populations are protected and promoted; stigma and discrimination are eliminated; gender inequalities, poverty, and food insecurity are mitigated; and integration and decentralization are prioritized through appropriate task-shifting/sharing strategies. These data were incorporated into the GRADE decision-making process and contributed to the final recommendations.

Challenges and lessons learnt

The challenges experienced during this community consultation process yielded valuable lessons that can help optimize the role of communities in future consultations for developing guidelines.

The need for internet access to participate in the e-survey and e-forum limited the representativeness and generalizability of the findings. Conducting consultations on the ground (e.g., using FGDs or mobile phone technology), particularly with underrepresented communities to

optimize stakeholder representation, could compensate for the limitations of online consultations and regional consultation meetings, and improve applicability and relevance of the guidelines.

The e-forum responses during December 2012 were also limited, possibly due to proximity to the December holiday period. Ensuring appropriate timing for community consultations could prevent this problem.

The e-survey question structure presented some challenges and limitations to the interpretation of responses. The length of the e-survey and the technical nature of some questions caused many respondents to skip questions, which may introduce bias. This could be addressed by shortening and simplifying the e-survey, or by separating the sections into separate surveys and sharing them with relevant communities to increase accessibility by a wide and relevant range of respondents. Increasing investment in consultations on the ground could also improve relevance of the outcomes.

The e-survey questions using a Likert scale (i.e., strongly agree/strongly disagree; most important/least important) were subject to known limitations of rating scales and the tendency for responses to support the statement. For instance, the discriminatory value of a Likert scale is dependent on a variety of factors, such as internal structure of the questionnaire [19] and local context [20]. Likert scales are commonly associated with acquiescence bias, which is a tendency to agree with statements, independent of their content [21]. Additionally, there is no consensus on the optimal number of response alternatives in rating scales more generally [19]. In the e-survey, weightings needed to be assigned by the analyst rather than allowing respondents to rank the importance or limit the number of options deemed 'important'.

Additionally, the wording of some questions resulted in ambiguous answers that are difficult to interpret with certainty. No data or analysis, is, therefore offered for these questions in this report.

The structure of e-survey questions differed in terms of the range of options and possible selections. The ratings calculated for one question are not comparable to the ratings of another question if the question structures are not the same. Working with consultation groups to assist in refining and revising the questions could help to sharpen the questionnaire. Further limiting the number of options for selection by respondents could also prevent these shortcomings.

The e-survey dataset also presented some challenges and limitations. Respondents were permitted to skip questions, and only small numbers of respondents answered some of the questions (for reference, the total number of respondents is noted for each question

throughout the report). Future surveys could be more rigid, with no option to skip questions, in order to prevent unequally sized datasets.

Incorrect data entry by some respondents invalidated some answers (e.g., respondent identifying as both 'male' and 'pregnant woman'). Designing the survey with more question flows (e.g., gender-specific options for answers) and a built-in validation check could minimize this.

Few respondents self-identified as members of specific population groups (e.g., adolescents, over 65-year-olds, transgender people), yielding results that did not have sufficient sample sizes for reliable and accurate statistical interpretation (for reference, the total number of respondents self-identifying with specific populations is noted for each question throughout the report). As noted in the respondent demographics, some groups (e.g., transgender people) were underrepresented, whereas others (e.g. MSMs) were overrepresented in the e-survey, which may hinder generalizability of the findings. However, FGDs engaging specific populations (e.g., pregnant and breastfeeding women) proved very useful for focusing on specific issues and could be expanded to other specific populations in the future. Directing the survey to community key population networks and groups could increase sample size and equitable representation. Using a mixture of methods and triangulation of data from different data sources (qualitative and quantitative) could also supplement this data gap. Additionally, future consultations employing multiple methodologies could improve their comparative value by collecting the same demographics data for all participants.

Because of the above limitations, community responses regarding key populations, such as sex workers or injecting drug users, do not necessarily reflect the views of key populations themselves. For some e-survey questions regarding services provided to key populations, answers may have been biased by respondents' opinion of the service rather than their opinion about a key population. Alternatively, for some questions regarding barriers to services, answers may have been biased by respondents' opinion about a key population rather than access issues. This could be addressed by designing question flows so that the opinion of HCWs can be differentiated from that of community members. Respondents could also be asked directly if answers are based on personal experience.

Overall, sufficient time is needed to enable pilot testing of the e-survey before its full launch to increase the clarity and relevance of the questions. Moreover, a good communication strategy, both during and after the guidelines development process, is needed to ensure that findings are clearly communicated and influence the recommendations.

Although community values and preferences from this consultation were generally considered in the guidelines development process, the nature of such evidence was not fully amenable to the GRADE methodology. Therefore, to better inform operational and programmatic recommendations of future guidelines, a more systematic approach to gathering evidence of community perspectives is needed, as well as a standardized way of assessing the quality of this information. Communities should also be involved early in the process. Ample time should be provided to allow for substantive and nuanced e-forums and FGDs, as well as increased community mobilization for participation. Enabling the collection of high-quality community data increases their credibility and usefulness in the guidelines development process.

Implications

Ongoing communication and consultation with communities and civil society members remains important in the dissemination and implementation of the 2013 Guidelines, and national decision-making. The 2013 guidelines recommend a transparent and inclusive process involving all stakeholders, including communities and civil society, as a guiding principle of decision-making at the national level [13]. Community and civil society groups could assess how well their national HIV programs are meeting the recommendations in the 2013 Guidelines, and use their analysis in discussions with government and other key stakeholders to understand the gaps, how to prioritize these areas, and how to work effectively to improve ART access and retention in care. Further work is needed to understand how to operationalize the recommendation to increase task-shifting/sharing, such as through consultation with community health workers [13]. Finally, CBOs, NGOs, and networks have an important role to play in incorporating some of the new recommendations into their own programs to better complement public healthcare services.

There is also a need for activities to enhance understanding of the new guidelines and treatment literacy more broadly at the community level. For example, the Community Guide on the Use of ART for Treatment and Prevention, developed by GNP+, STOP AIDS NOW! and the Alliance, provides practical support for communities to engage in the national guidelines' adaptation processes [22]. Similarly, the International AIDS Society is developing a code of good practice for clinicians and HCWs [personal Communication between Edwin Bernard (International AIDS Society, Consultant) and Amy Hsieh on 24 October 2013] and the Community Engagement Workgroup of the Interagency Task Team on Prevention and Treatment of HIV Infection in Pregnant Women, Mothers, and Children is developing 'A Treatment Literacy Guide for Pregnant Women Living with HIV, Mothers, and Infant Caregivers' to provide individual-level guidance to those offered lifelong treatment through Option B+ [personal Communication

between Jessica Rodrigues (Interagency Task Team on Prevention and Treatment of HIV Infection in Pregnant Women, Mothers, and Children, Knowledge Management) and Amy Hsieh on 19 November 2013]. It is possible that many initiatives are being started to prepare communities and HCWs to implement the guidelines.

Conclusion

The findings of these community consultations have reinforced the importance of community representation, involvement, and participation in normative guidelines development. For the effective scale up of ART programs, it is critical to have a nuanced appreciation for the different ways in which people interact with certain services, and the role of communities and civil society in service delivery.

The implications of the 2013 Guidelines for the community of PLHIV, other key populations, and community service providers are far reaching. The 2013 Guidelines provide guidance beyond clinical recommendations, including recommendations on how treatment can best be delivered in different contexts to support access, adherence, and retention in care, most of which resonated with the findings from community consultations. In particular, the 2013 Guidelines call for a greater community role in decision-making and implementation of national ART programs. The emphasis on human rights, equity, and ethics [5] also provides an opportunity for communities and civil society to shape the way the guidelines are implemented. Effective participation of communities to increase demand and support for the delivery of community-based HIV services requires investments to strengthen the capacity of community groups and systems to ensure that they are properly informed and fully engaged [18].

Acknowledgements

The authors acknowledge the contributions of Moono Nyambe, ICW Global (Sonia Haerizadeh, Beri Hull), ICW Eastern Africa (Lillian Mworeko, Dorothy Namutamba), ICW Malawi (Joyce Kamwana), and Coalition for Women Living with HIV/AIDS in Malawi (Annie Banda) for hosting and the FGDs in Uganda and Malawi, and Rebekah Webb Consulting (Rebekah Webb and Marta Monteso) for analyzing the data. The authors also thank WHO headquarters staff and consultants (April Baller, Meg Doherty, Shaffiq Essajee, Cadi Irvine, Lulu Muhe, Eyerusalem Negussie, Amitabh Suthar and Marco Vitoria) for commenting on the e-survey instruments used for the consultation. This community consultation was made possible through the support of WHO.

The authors appreciate the support of the members of the Community Consultation Working Group who contributed their time and expertise to shaping the community consultation: David Barr (Pangaea Global AIDS Foundation), Polly Clayden (HIV I-Base), Yvette Fleming (Stop AIDS Now!), Lee Hertel (INPUD), Joanne Keatley (MSMGF), Anton Kerr (the Alliance), Anupam Khungur Pathni (IPPF), Christoforus Mallouris (WHO), Evgenia Maron (Astra Foundation), Babalwa Mbono (mothers2mothers), Othman Mellouk (ITPC MENA), Noah Metheny (MSMGF), Ruth Morgan (NSWP), Lillian Mworeko (ICW Eastern Africa), Luis Adrián Quiroz (DVVIMSS+, RedLA+), Asia Russell (HealthGap), Anastacia Ryan (NSWP), Gisela Schneider (German Institute for Medical Mission), Kenly Sikwese (AFROCAB), Bui Tung (Youth Voices Count) and Anna Zakowicz (EATG, GNP+, AIDS Healthcare Foundation). Many of the members of this working group also serve on the civil society reference group on HIV convened by WHO.

A.H., G.M., A.G., A.T., and C.M. contributed primary research and writing to the article. M.R. analyzed the community consultation data and prepared the figures included in the article. M.P. coordinated the WHO pediatric HCW survey and provided the data in this article. P.E., N.S., and A.B. coordinated the consultation and provided comments on the article.

Conflicts of interest

There are no conflicts of interest.

References

- World Bank. *Investing in communities achieves results: findings from an evaluation of community responses to HIV and AIDS*. Washington, D.C.: January 2013. http://elibrary.worldbank.org/doi/abs/10.1596/9780821397411_CH05. [Accessed 26 January 2014]
- World Health Organization. *Global HIV/AIDS response: epidemic update and health sector progress towards universal access – Progress Report 2011*. Geneva: World Health Organization, 2011. http://whqlibdoc.who.int/publications/2011/9789241502986_eng.pdf. [Accessed 26 January 2014]
- Cornish F, Priego-Hernández J, Campbell C, Mburu G, McLean S. **The impact of community mobilisation on HIV prevention in middle and low income countries: a systematic review and critique**. *AIDS Behav* 2013 In Press.
- Tynan A, Hill PS, Kelly A, Kupul M, Aeno H, Naketrumb R, et al. **Listening to diverse community voices: the tensions of responding to community expectations in developing a male circumcision program for HIV prevention in Papua New Guinea**. *BMC Public Health* 2013; **13**:749.
- Vaughan C. **'When the road is full of potholes, I wonder why they are bringing condoms?' Social spaces for understanding young Papua New Guineans' health-related knowledge and health-promoting action**. *AIDS Care* 2010; **22** (Suppl 2):1644–1651.
- Campbell C. *'Letting them die': why HIV/AIDS prevention programs fail*. Oxford: The International African Institute; 2003.
- Campbell C, Nair Y, Maimane S. **Building contexts that support effective community responses to HIV/AIDS: a South African case study**. *Am J Community Psychol* 2007; **39**:347–363.
- World Health Organization. *Antiretroviral therapy for HIV infection in adults and adolescents: recommendations for a public health approach [2010 revision]*. Geneva: World Health Organization; 2010. http://whqlibdoc.who.int/publications/2010/9789241599764_eng.pdf. [Accessed 26 January 2014]
- World Health Organization. *Antiretroviral drugs for treating pregnant women and preventing HIV infection in infants: recommendations for a public health approach – [2010 version]*. Geneva: World Health Organization; 2010. http://whqlibdoc.who.int/publications/2010/9789241599818_eng.pdf. [Accessed 26 January 2014]
- World Health Organization. *The strategic use of antiretrovirals for treatment and prevention of HIV infection. Report of a WHO Technical Consultation*. Geneva, 14–16 November 2011. http://extranet.who.int/iris/restricted/bitstream/10665/70912/5/9789241503808_eng.pdf. [Accessed 1 November 2013]
- World Health Organization. *The strategic use of antiretrovirals for treatment and prevention of HIV infection: 2nd expert panel meeting*. Geneva, 2–4 May 2012. http://whqlibdoc.who.int/hq/2012/WHO_HIV_2012.13_eng.pdf. [Accessed 1 November 2013]
- World Health Organization. *Handbook for Guideline Development*. Geneva: World Health Organization; 2012.
- World Health Organization. *Consolidated guidelines on the use of antiretroviral drugs for treating and preventing HIV infection*. Geneva: World Health Organization; 2013. www.who.int/hiv/pub/guidelines/arv2013. [Accessed 26 January 2014]
- Penazzato M, Nelson L, Ellis J, Essajee S, Nardone A, Baller A, et al. **Paediatric antiretroviral treatment (ART): healthcare workers perspectives contributing to the WHO 2013 Consolidated Guidelines Development**. International AIDS Society. 30 June to 1 July 2013. <http://pag.ias2013.org/EPPosterHandler.axd?aid=1576>. [Accessed 1 November 2013]
- World Health Organization. *Adult antiretroviral therapy (ART): healthcare workers' perspectives contributing to developing the WHO 2013 consolidated guidelines*. Geneva: World Health Organization, 2013. http://apps.who.int/iris/bitstream/10665/91044/1/WHO_HIV_2013.62_eng.pdf. [Accessed 26 January 2014]
- Silverman D. *Interpreting qualitative data: methods for analysing talk, text and interaction*. London, United Kingdom: Sage; 2001.
- World Health Organization and the Pangaea Global AIDS Foundation. *Draft meeting report on optimizing HIV treatment access and retention in care: linking community-level interventions with healthcare delivery systems in Sub-Saharan Africa. 26–28 March 2012*. <http://hivtreatmentoptimization.org/events/optimizing-hiv-treatment-access-and-retention-care-linking-community-level-interventions-0>. [Accessed 11 June 2013]
- Asian Pacific Network of People Living with HIV/AIDS and the Pangaea Global AIDS Foundation in Partnership with WHO and UNAIDS. *Optimising HIV treatment access and retention in care: linking community level interventions with healthcare delivery systems. A Treatment 2.0 initiative*. 18–20 September 2012, Bangkok, Thailand. <http://hivtreatmentoptimization.org/events/optimizing-hiv-treatment-access-retention-care-bangkok-thailand-15>. [Accessed 11 June 2013]
- Maydeu-Olivares A, Kramp U, García-Forero C, Gallardo-Pujol D, Coffman D. **The effect of varying the number of response alternatives in rating scales: experimental evidence from intra-individual effects**. *Behav Res Methods* 2009; **41**:295–308doi: 10.3758/BRM.41.2.295.
- Lee JW, Jones PS, Mineyama Y, Zhang XE. **Cultural differences in responses to a Likert scale**. *Res Nurs Health* 2002; **25**:295–306.
- Schuman H, Presser S. *Questions and answers in attitude surveys*. New York: Academic Press; 1981.
- GNP+, International HIV/AIDS Alliance, STOP AIDS NOW! *Briefing Paper: summary of the new 2013 guidelines recommendations and key issues from a community and civil society perspective. 18 September 2013*. http://www.gnpplus.net/images/stories/Community_ART_briefing_paper_FINAL.pdf. [Accessed 1 November 2013]