

End Users' Views and Preferences on Prescribing and Taking Postexposure Prophylaxis for Prevention of HIV: Methods to Support World Health Organization Guideline Development

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The 2014 World Health Organization guidelines for human immunodeficiency virus postexposure prophylaxis (PEP) are the first to combine recommendations for all populations and exposures. To inform the development of these guidelines, we gathered views of end users on key aspects of PEP provision. A mixed-methods approach was used to gather views from the populations for whom the guideline will be of relevance. Data gathered from an online survey, focus group discussions, and previously collected data from in-depth interviews with key populations were used to inform the development of recommendations, in particular where there is a paucity of evidence to assess the benefits and harms of an intervention. This was a successful method to gather end users' views and preferences; however, limitations exist in the generalizability and reliability of the evidence. Future guideline development processes should consider methods to include the views of end users to guide the decision-making process.

Keywords. HIV; postexposure prophylaxis; views; preferences; qualitative.

The 2014 World Health Organization (WHO) guidelines for the use of antiretrovirals (ARVs) for the prevention of human immunodeficiency virus (HIV) followed publication of the consolidated guidelines for the use of ARVs in 2013 [1], where it was highlighted that the guidelines for postexposure prophylaxis (PEP) [2] required updating. These new PEP guidelines are the first to combine recommendations for all populations: healthcare workers (HCWs) exposed in occupational settings, and nonoccupational exposures including sexual assault, injection drug use, and consensual sex. The guideline consists of evidence-based recommendations for a public health approach considering both the effectiveness and feasibility of interventions along the care pathway.

In accordance with the requirements of the WHO Guideline Review Committee, the guideline process followed the Grading of Recommendations Assessment, Development and Evaluation (GRADE) [3] approach to develop recommendations. The GRADE approach incorporates a reproducible methodology [4] to assess the quality of evidence of quantitative data in the form of meta-analyses of randomized controlled trials (RCTs) and observational data and grading of the quality of evidence (very low, low, moderate, or high). The WHO guideline process also recognizes the importance of ensuring that the views of end users affected by guidelines are incorporated in the evidence to decision-making process. The balance of benefits and harms of an intervention is formed by judgments by the expert panel [5], and where there is a paucity of evidence or low-grade evidence, the need to take into account the views and preferences of end users is paramount. In addition, the inclusion of end users in guideline development processes facilitates the development of a highly robust product that is relevant and appropriate to the target audience.

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The target audience for the guideline is primarily national HIV/AIDS program managers and policy makers involved in PEP service provision. It is also of interest to HCWs prescribing PEP, particularly in resource-limited settings and organizations working with survivors of sexual assault and key populations.

Assessment and provision of PEP occurs in a variety of settings due to the varied nature of the exposures and is often delivered infrequently by HCWs and received infrequently by patients. Identifying and accessing end users who have views and preferences on the interventions relating to recommendations on preferred drug choices for adults and adolescents, drug choices for children, prescription methods, and adherence support for HIV PEP is therefore challenging.

Within each decision-making table presented to the Guideline Development Group (GDG), the end users' views and preferences provided information on the acceptability of the interventions. Many of the new recommendations were based on low- to moderate-quality evidence, leading to identification of research priorities. The evidence on views and preferences and the variability of those views were important in fully discussing whether the benefits outweighed the harms of the interventions.

In this article, we summarize the methods to gather views and preferences to support the 2014 HIV PEP guideline process and highlight the benefits and the challenges encountered. Recommendations are proposed for future guideline development processes to successfully incorporate the views and preferences of end users in the GRADE approach.

METHODS

A mixed-methods approach (Table 1) was used to gather views from populations with knowledge and experience of taking PEP; men who have sex with men (MSM), people who inject drugs (PWID), female sex workers (FSWs), transgender people, and HCWs; and those with experience of delivering PEP as a clinical intervention in a variety of settings. Data were collected on key aspects of the intended scope of the guideline, including number of ARV drugs; preferred ARV regimen for adults, adolescents, and children; prescribing frequency; and adherence support.

Literature Review

A systematic literature search was conducted in PubMed via Embase and Web of Knowledge until 30 May 2014. The search strategy combined HIV, PEP, and qualitative terminology (Supplementary Appendix). In addition, a hand search of articles reporting on PEP outcomes was performed to identify qualitative findings reported in retrospective and prospective studies. Articles were included if they reported on patients' knowledge and experience of taking PEP using qualitative or mixed methods. A

total of 10 studies were identified exploring MSM knowledge, attitudes, and behavior of PEP [6–15]. No studies were identified that focused on the views of transgender people or specifically explored views and experiences of PWID or FSWs. Twenty-six studies were identified gathering views of HCWs on knowledge of PEP as an intervention and awareness of accessing PEP [16–40] and on delivering PEP services [17, 41–49].

Desk Review

A review of the methods and results used to support publication of the WHO guidelines on the prevention, diagnosis, treatment, and care for key populations [50] was conducted by 2 researchers. This identified the views and preferences of PEP for MSM, PWID, and transgender people previously gathered by in-depth interviews.

Focus Group Discussions

Focus group discussions were conducted in Ghana by FHI 360. Information related to FSW PEP preferences from a report prepared by the Human Rights and Advocacy Centre was used in conjunction with a topic guide (Supplementary Appendix) to facilitate a focus group discussion with 20 FSWs associated with local nongovernmental organization partners (West Africa Program to Combat AIDS and Sexually Transmitted Infections and Pro-Link). Information was collected on attitudes, knowledge, and behavior in relation to the use of drugs for PEP following possible HIV exposure including drug regimens, HIV testing, follow-up, and adherence to treatment.

Online Survey

An online cross-sectional survey was piloted and translated into 3 United Nations languages (Supplementary Appendix). Dissemination of the survey to HCWs delivering PEP in all exposure settings was conducted through communication with authors of published papers on PEP ($n = 97$), regional WHO offices, and key organizations related to the topic ($n = 14$). The survey was open for 4 weeks, May–June 2014. All responses ($n = 306$) were translated into English prior to analysis. Completion rates were calculated per question. Caution was taken in interpreting questions with response rates $<50\%$. A subsurvey of HCWs (Supplementary Appendix) with experience of taking PEP was conducted following consent from individuals self-selected by the initial survey.

RESULTS

The following provides an overview of the views and preferences that were gathered and presented to the GDG to ascertain the benefits and harms of the interventions.

- PEP ARV regimens for adults and adolescents (*low- to moderate-quality evidence for 2-drug regimen [backbone]; very low-quality evidence for third drug choice*)

Table 1. Methods for Primary and Secondary Qualitative Data Collection

Source of Data	Population	Date	Sample Size	Countries	Recruitment
Secondary data collection					
Review of primary data to support WHO guidelines on prevention, diagnosis, treatment, and care for key populations ^{a,b,c}	MSM	Dec 2013– Jan 2014	11	Australia, England, Indonesia, Lebanon, Liberia, Mexico, Paraguay, United States, and Zambia	Individual email invitations
	People who inject drugs	2013 ^d	25	Country-level data not reported	Identification through networks
	Transgender people (online survey and in-depth interviews)	2013 ^d	14	Brazil, El Salvador, Fiji, France, India, Indonesia, Philippines, Russia, Singapore, South Africa, Thailand, and United States	Convenience snowball
Primary data collection					
Focus group discussions	Female sex workers	May–June 2014	20	Ghana	Convenience sampling: links to NGOs
Online cross-sectional survey	HCWs delivering PEP	May–June 2014	306	Multiple: South Africa (90), United States (51), Lesotho (16), Armenia (16), Kenya (15)	Invitation to authors of published peer review articles, networks
Online cross-sectional survey	HCWs accessing PEP	June 2014	15	Lesotho, Malawi, Papua New Guinea, South Africa, Switzerland, Zambia	Self-selected substudy of online survey

Abbreviations: HCW, healthcare worker; MSM, men who have sex with men; NGO, nongovernmental organization; PEP, postexposure prophylaxis; WHO, World Health Organization.

^a Arreola S, Makofane K, Ayala G. Values and preferences of MSM: the use of antiretroviral therapy as prevention. Commissioned by the World Health Organization, 2014. Available at: http://apps.who.int/iris/bitstream/10665/128117/1/WHO_HIV_2014.19_eng.pdf?ua=1&ua=1. Accessed 11 August 2014.

^b Henderson M. Values and preferences of people who inject drugs, and views of experts, activists and service providers: HIV prevention, harm reduction and related issues. World Health Organization, 2014. Available at: http://apps.who.int/iris/bitstream/10665/128118/1/WHO_HIV_2014.20_eng.pdf?ua=1&ua=1. Accessed 11 August 2014.

^c Schneiders M. Values and preferences of transgender people: a qualitative study. World Health Organization, 2014. Available at: http://apps.who.int/iris/bitstream/10665/128119/1/WHO_HIV_2014.21_eng.pdf?ua=1&ua=1. Accessed 11 August 2014.

^d Data not available in published report.

HCWs views on preference for prescribing and use of drug combinations was presented by regions. There was a tendency for HCWs to prefer prescribing 3 drugs for PEP. Views on the perceived effectiveness, tolerability, cost, availability, and overall use of each regimen aided the decision making and identified that HCWs had little discrimination between overall preference for the third drug choice. There was, however, a degree of uncertainty of perceived effectiveness of 2 vs 3 ARV drugs for use as a PEP regimen.

- PEP ARV regimen choice in children (*low-quality evidence*)

Limited responses were received in the online survey from HCWs with experience of prescribing PEP for children, and caution was taken in using the results to guide the decision-making process. Among the participants, there was a demonstrated trend toward ritonavir-boosted lopinavir as the third drug option, and in children aged 3–10 years there was a preference for efavirenz as the third drug option.

- Prescription methods of PEP (*very low-quality evidence*)

There was agreement from the HCWs for full 28-day dosing

to be prescribed by any HCWs (n = 84 [49.7%]). A total of 65.5% disagreed that 28-day prescribing should only be prescribed by HIV specialists (n = 110). HCWs expressed views on the relevance of starter packs in emergency settings (n = 146 [86.4%]) and agreed that they could allow non-HIV specialists to start PEP safely (n = 126 [74.1%]).

A total of 73.3% of HCWs taking PEP (n = 11) demonstrated a preference to receive a 28-day course at the first appointment. The in-depth interviews of key populations showed that access to care is a barrier to completion of PEP. FSWs also expressed a willingness to return to clinic services if necessary but described barriers to accessibility (ie, cost or transport). These views were useful in considering potential equity issues of prescription methods.

- Enhanced adherence counseling (*moderate-quality evidence*)

HCWs expressed support for adherence counseling as a key part of a minimum package of care for patients receiving PEP. Various methods to deliver adherence support seemed to be acceptable to populations and providers (including

counseling on possible side effects of PEP, adherence, and reduction of future risk). There were perceptions from providers that counseling (n = 149 [92.5%]) would support adherence to HIV PEP. FSWs described the need for more support to prevent defaulting and ensuring adherence to treatment; however, consideration was given to the sensitivity required to ensure that additional counseling is not an added barrier to accessing PEP.

DISCUSSION

A mixed-methods approach guided by a literature review provided valuable information on end users' views and preferences to support the WHO HIV PEP guideline development process; this information supported the deliberations by the GDG on the benefits and harms of interventions under consideration.

Both existing data in the form of published qualitative literature and data collected by other guideline processes can be combined, and new data can be gathered using appropriate qualitative methods. For PEP, where evidence in the form of RCTs and observational studies on the interventions guiding recommendations is minimal, these views and preferences were crucial in the decision-making process and allowing the GDG to make judgments guided by evidence. The online survey was also beneficial in sharing information with the wider healthcare community on the process and intended output of the guideline.

As PEP is delivered in a variety of settings to a variety of populations, it is difficult to ensure that all populations are equally represented when assessing views and preferences. Results from many of the methods will not be generalizable to other populations or different settings. The online survey responses were successful in identifying HCWs preferences, but the small numbers of HCWs prescribing multiple episodes of PEP and PEP to children mean that the results may not be replicable for these issues.

For future guideline development, we recommend identifying the guideline questions that include assessment of qualitative data in the views and preferences of end users. Existing data should be identified from published and unpublished data supporting other guideline processes and contributing to the qualitative literature. In particular, for the development of recommendations when the evidence is likely to be low or the intervention may have strong preferences for end users, further evidence should be collected using appropriate methods. This would benefit from input from communities to identify the most efficient ways to interact with the intended guideline audience. Although limitations exist, it is important that this information be used to support the development of evidence-based recommendations that are feasible and acceptable to the intended audience.

Supplementary Data

Supplementary materials are available at *Clinical Infectious Diseases* online (<http://cid.oxfordjournals.org>). Supplementary materials consist of data provided by the author that are published to benefit the reader. The posted materials are not copyedited. The contents of all supplementary data are the sole responsibility of the authors. Questions or messages regarding errors should be addressed to the author.

Notes

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