CONSOLIDATED GUIDELINES ON HIV PREVENTION, DIAGNOSIS, TREATMENT AND CARE FOR KEY POPULATIONS

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GUIDELINES

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Annex 1: Pre-exposure prophylaxis for men who have sex with men:
A systematic review

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Systematic review write up

Background
An estimated 35.3 million people globally are living with HIV (UNAIDS, 2013). A number of prevention methods are available, from condoms to male circumcision, prevention of mother-to-child transmission to clean needles, but to date these have not been sufficient to stop the epidemic. In 2012 alone, an estimated 2.3 million people became newly infected (UNAIDS, 2013). Additional safe and effective approaches to HIV prevention are urgently needed.

Men who have sex with men (MSM) have a disproportionate burden of HIV in most countries in the world, even in many countries with generalized HIV epidemics. Worldwide, for MSM, the odds of being infected with HIV are 19.3 times higher than for men in the general population (Baral et al., 2007). Although there are a variety of existing efficacious HIV prevention interventions for MSM, they face political and structural barriers to accessing services in many settings due to their stigmatized and marginalized status. The disproportionate burden of HIV faced by MSM suggests that existing methods of HIV prevention are not sufficient and additional prevention modalities would be helpful.

Pre-exposure prophylaxis (PrEP) is the use of an antiretroviral drug to block the acquisition of HIV infection by uninfected people. Proof of concept has long been established in the laboratory by animal studies and in real world application by the prevention of mother-to-child transmission and post-exposure prophylaxis. The safety of the drugs being considered for PrEP, tenofovir and emtricitabine, has been established through their use for treatment and in safety trials in uninfected people (Peterson et al., 2007). Five trials of effectiveness (Phase IIb and Phase III) have been conducted in the last decade. These focus on effectiveness of PrEP among people who inject drugs, serodiscordant couples, heterosexual women and high risk MSM.

The first trial to produce results was the iPrEx trial (Grant et al., 2010). This Phase III clinical trial tested whether a daily combination of tenofovir and emtricitabine could safely and effectively prevent HIV infection among MSM. Of the five effectiveness trials, this trial conducted in six countries on four continents was the only one to examine efficacy in MSM.

The iPrEx study demonstrated a 44% reduction in HIV transmission on the modified intention-to-treat analysis. Adherence to the recommended regimen was lower than expected, though it varied by country. For those men who reported taking the pills on 90% or more days, however, the efficacy of PrEP was 73%. Resistance was only found in two participants who had an existing acute HIV infection undetected at baseline and who were randomized to active drug. Few concerns about safety were detected. A marked trend toward risk reduction, specifically increased condom use and decreased number of partners, was reported in both arms and all sites.

In 2012, WHO developed guidelines for PrEP for serodiscordant couples, MSM, and transgender people (TG) at high risk of HIV (WHO, 2012). This systematic review updates the review of PrEP for MSM that was completed for those guidelines. This systematic review examined the following PICO question: Should oral PrEP (containing tenofovir (TDF)) be used for HIV prevention among men who have sex with men? A few minor changes were made to the PICO question from the earlier guidelines. First, the
new PICO question includes only MSM, not transgender people. Second, the new PICO question covers all oral PrEP containing tenofovir, as opposed to the previous PICO question which focused specifically on the combination of emtricitabine (FTC 200mg) and tenofovir (TDF 300 mg) used in the iPrEx study.

In addition, in 2011, a review of values and preferences of MSM about PrEP was conducted through a review of published literature. However, most of the studies available at that time were based on data collected before the iPrEx trial results were available. Values and preferences may have changed now that MSM are aware of the partial effectiveness of PrEP. This values and preferences literature review was also updated to capture literature through the end of 2013, with a focus on studies that collected data after iPrEx study results were released.

Methods

**PICO question**

**PICO 1:** Should oral PrEP (containing tenofovir (TDF)) be used for HIV prevention among men who have sex with men?

**P:** Men who have sex with men

**I:** Oral PrEP (containing tenofovir (TDF))

**C:** Placebo

**O:** (1) HIV infection, (2) any adverse event, (3) any stage 3 or 4 adverse event, (4) condom use, and (5) number of sexual partners

**Inclusion criteria**

To be included in the review, an article had to meet the following criteria:

1) Randomized controlled trial evaluating the use of oral PrEP (containing tenofovir (TDF)) to prevent HIV infection among MSM participants.

2) Measured one or more of the following key outcomes: (1) HIV infection, (2) any adverse event, (3) any stage 3 or 4 adverse event, (4) condom use, and (5) number of sexual partners.

3) Published in a peer-reviewed journal, or presented as an abstract at a scientific conference, between January 1, 1990 and January 1, 2014.

No restrictions were placed based on location of the intervention. No language restrictions were used on the search. Articles in languages other than English were translated where necessary.

Following the GRADE approach, if direct evidence from MSM populations was limited for one or more of the key outcomes, indirect evidence from other populations (e.g., heterosexual men) would have been instead, but downgraded for indirectness. If evidence from other populations was limited, evidence from non-randomized but controlled studies would have been used instead, but also downgraded for directness.
Search strategy
The following electronic databases were searched using the date ranges January 1, 1990 to January 1, 2014: PubMed, CINAHL (Cumulative Index to Nursing and Allied Health Literature), and EMBASE. Secondary reference searching was conducted on all studies included in the review. Further, selected experts in the field were contacted to identify additional articles not identified through other search methods.

Abstracts from the following conferences were searched from January 1, 1990 to January 1, 2014: International AIDS Conference (IAC) and IAS Conference on HIV Pathogenesis, Treatment, and Prevention (IAS). We had planned to search the Conference on Retroviruses and Opportunistic Infections (CROI) as well, but abstracts from this conference were no longer available online to the public at the time the search was conducted.

Search terms
The following terms were entered into all computer databases:

("men who have sex with men" or MSM or transgender or TG or “gay men”) AND (“pre-exposure prophylaxis” or PrEP or emtricitabine or tenofovir or Truvada or FTC or TDF) AND (HIV OR AIDS)

The search for abstracts was more difficult given the search engines available on conference websites. For each conference, a search was first conducted for all abstracts including the word “PrEP”. These search results were then further searched for keywords regarding MSM.

Screening abstracts
Titles, abstracts, citation information, and descriptor terms of citations identified through the search strategy were screened by two reviewers. 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 consensus.

Articles not meeting the inclusion criteria for the review, but presenting potentially interesting background information relevant to PrEP among MSM, including review articles, qualitative studies, cost or cost-effectiveness analyses, or descriptions of interventions without an evaluation component, were included in an annotated bibliography of additional articles.

Data extraction and management
Data were extracted independently by two reviewers using standardized data extraction forms. Differences in data extraction were resolved through consensus and referral to a senior team member from WHO when necessary. Study authors were contacted 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
Annex 1

- Outcomes: Analytic approach; outcome measures; comparison groups; effect sizes; confidence intervals; significance levels; conclusions; limitations

Risk of bias was assessed using the Cochrane Collaboration’s tool for assessing risk of bias (Cochrane Handbook, chapter 8.5 – Higgins & Green, 2011). 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). Methodological components of the studies were assessed and classified as high, low, or uncertain risk of bias.

Data analysis
Data were analyzed according to coding categories and outcomes. If multiple studies reported the same outcome, meta-analysis would have been conducted using random-effects models to combine effect sizes with the program Comprehensive Meta-Analysis (CMA). Data were summarized in GRADE tables, summary of finding tables, and risk/benefit tables.

Results
Combining search results from both the 2011 and 2014 searches, initial database searching yielded 764 citations and 139 conference abstracts; one additional study was identified through other means, such as searching through the reference lists of relevant articles (Figure 1). Once all duplicates were removed, 609 records were reviewed and 348 article citations and 119 abstracts were excluded for being unrelated to the study topic. After thoroughly reviewing the remaining 142 articles and abstracts, 3 were excluded for being unrelated to the study topic, 4 did not meet the study design criteria, and 128 were coded as background or values and preferences; an additional 3 conference abstracts presented preliminary data and were used in the 2011 review, although all 3 were later published as peer-reviewed articles and thus were duplicative of other included articles. Ultimately, 4 studies reported in 5 articles were deemed eligible for inclusion in our review. Of these, one was a Phase III efficacy trial, while three were smaller pilot feasibility/acceptability or extended safety studies. Given the discrepancies in the study purposes, drug regimens/dosing schedule, and size/statistical power (and thus imprecision and quality according to the GRADE framework), we generally present results from the primary Phase III efficacy trial below and in GRADE tables, and present additional findings from the smaller studies in the results below along with the efficacy trial. However, for the HIV infection outcome, we were able to merge the results from two studies with the same drug regimen.

The primary Phase III efficacy trial meeting all inclusion criteria was the iPrEx trial (Grant et al., 2010). This study was a randomized controlled trial to evaluate the safety and efficacy of once-daily oral FTC-TDF as compared with placebo for the prevention of HIV acquisition among MSM. The trial was conducted among 2499 participants in 6 countries: Peru, Ecuador, South Africa, Brazil, Thailand, and the United States. All study participants were born male, although 29 (1%) reported their current gender identity as female. Participants’ ages ranged from 18 to 67 years. Using the Cochrane Risk of Bias tool, the study was judged to have low risk of bias across all of the following categories: 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). The study measured all five key outcomes for this review: 1)
HIV infection, 2) Any adverse event, 3) Any stage 3 or 4 adverse event, 4) Condom use, and 5) Number of sexual partners.

The smaller safety study was the US CDC Safety Study, a phase II, randomized, double-blind, placebo-controlled, extended safety trial of TDF in MSM in the United States (Grohskopf et al., 2013; Liu et al., 2013). The trial was conducted among 400 MSM aged 18-60 in 3 US cities: Atlanta, Boston, and San Francisco. Participants were randomized in equal numbers to one of 4 study arms: (1) daily TDF beginning at enrollment, (2) daily placebo beginning at enrollment, (3) daily TDF beginning 9 months after enrollment, and (4) daily placebo beginning 9 months after enrollment.

The smaller pilot feasibility and acceptability study was Project PrEPare, a study to examine the feasibility of a combination prevention intervention, including PrEP, for young MSM in the United States (Hosek et al., 2013). The study was conducted among 58 young MSM aged 18-22 in Chicago. Participants were randomized to one of 3 study arms: (1) a behavioral HIV prevention intervention called Many Men, Many Voices (3 MV) alone, (2) 3 MV combined with PrEP (FTC-TDF), and (3) 3 MV combined with placebo.

Finally, one small study examined safety and adherence to intermittent or daily oral FTC-TDF among Kenyan MSM and female sex workers (Mutua et al., 2012). This study randomized 67 MSM and 5 female sex workers to daily FTC-TDF or placebo, or intermittent FTC-TDF or placebo in a 2:1:2:1 ratio.

**HIV infection**

In the iPrEx study, incident HIV infection was significantly reduced among participants in the FTC-TDF study arm as compared to the control arm using both an intention-to-treat analysis and a modified intention-to-treat excluding participants who had HIV RNA detected at baseline (Grant et al., 2010). In the intention-to-treat analysis, there were 38 incident cases of HIV infection out of 1251 participants in the FTC-TDF study arm and 72 incident HIV infections out of 1248 participants in the control group, resulting in a hazard ratio of 0.53 (95% CI 0.36-0.78, p=0.001). In the modified intention-to-treat analysis, there were 36 incident cases of HIV in the FTC-TDF group (N=1251) and 64 incident cases of HIV in the control group (N=1248). For this analysis, the hazard ratio of HIV infection comparing those in the FTC-TDF group to the control was 0.56 (95% CI 0.37-0.85, p=0.005), thus showing a 44% reduction in the relative risk of HIV infection.

The CDC safety study had 7 seroconversions among 400 participants (Grohskopf et al., 2013). None occurred among participants taking TDF (n=201), 3 occurred among participants taking placebo (n=99), and 3 occurred among delayed arm participants who had not yet started drug (n=100). One occurred in a participant assigned to placebo who was HIV-1 antibody negative at screening and enrollment and then was seropositive at the 1-month visit.

Project PrEPare had zero seroconversions among 58 study participants (Hosek et al., 2013). The Kenya intermittent PrEP study had one incident infection in the placebo arm (Mutua et al., 2012).

**Any adverse event**

In the iPrEx study, there was no statistically significant difference in reported adverse events between the two study arms (Grant et al., 2010). In the FTC-TDF arm, 867 out of 1251 patients (69%) reported having
any adverse event compared to 877 out of 1248 patients (70%) in the control group. The relative risk of having any adverse event comparing the intervention to control group was 0.99 (95% CI 0.94-1.04), which was not statistically significant.

The CDC safety study also found that there was no statistically significant difference in reported adverse events between the two study arms; overall, 2428 adverse events occurred among 334 (90%) participants, with most of mild or moderate severity (Grohskopf et al., 2013).

Project PrEPare reported 6 adverse events total, 5 of which were possibly or probably related to the study drug, all in the FTC-TDF arm.

The study on intermittent PrEP in Kenya found that both dose regimens had similar rates of adverse events (Mutua et al., 2012).

**Any stage 3 or 4 adverse event**

In the iPrEx study, both study arms also reported similar rates of grade 3 and 4 adverse events (Grant et al., 2010). In the FTC-TDF study arm, 151 out of 1251 patients (12%) reported having a grade 3 or 4 adverse event compared to 164 out of 1248 patients (13%) in the control arm. The relative risk of having any grade 3 of 4 adverse event was 0.92 (95% CI 0.75-1.13) comparing the intervention to control arm, thus showing no statistical difference between the two groups.

The CDC safety study also found that there was no statistically significant difference in grade 3 and 4 adverse events between the two study arms (TDF: 36 events, 13.2 per 100 person-years (py); Placebo: 26 events, 9.9 per 100 py, rate ratio: 1.13 (95% CI: 0.61, 2.11, p=0.703) (Grohskopf et al., 2013). This finding remained consistent in multivariable analyses dichotomized by adherence levels.

Project PrEPare reported three grade 3 adverse events which were possibly or probably related to the study drug, all in the FTC-TDF arm (Hosek et al., 2013).

The study on intermittent PrEP in Kenya found no study-related serious adverse events (Mutua et al., 2012).

**Condom use**

The iPrEx study found that both groups reported increased condom use (defined as the percent of partners using condoms during receptive intercourse) over the course of the intervention, but that differences in condom use rates between the FTC-TDF arm (N=1251 at baseline) and control arm (N=1248) did not differ significantly (p=0.36) (Grant et al., 2010). To examine this relationship, a linear mixed regression model was fitted with a random intercept and fixed effects for treatment visit and treatment by visit interaction. The p-value is from a Wald test of the treatment by visit interaction which corresponds to whether or not there is a difference during the study period between the FTC-TDF and control groups. The description of the analysis conducted was received as correspondence from the study authors and was not included in the original publication.

The CDC safety study found that overall, the proportion of MSM reporting unprotected anal sex (UAS) in the past 3 months decreased significantly, from 57% at baseline to 48% during months 3-9 and 52% during months 12-24 (p<0.001) (Liu et al., 2013). The change in proportion of men reporting UAS from
baseline to months 3-9 was similar between the immediate vs. delayed arms (p=0.15). The proportion of men reporting UAS did not change significantly after initiation of study drug in the delayed arm (p=0.41) or with continuation of drug in the immediate arm (incident rate ratio (IRR)=1.17, 95% CI: 0.98 to 1.39, p=0.09).

Project PrEPare found no statistically significant differences in the distribution of male-to-male UAS acts among the 3 treatment groups across study visits (Hosek et al., 2013). Percentages of participants reporting UAS in the past month at baseline and week 24 were 42% and 42% for the PrEP arm, 40% and 10% for the placebo arm, and 31% and 23% for the no pill arm. There was a non-significant trend of decreasing UAS across all treatment arms from baseline to week 24.

**Number of sexual partners**

In the iPrEx study, in both study arms, the number of receptive sexual intercourse partners declined from baseline to follow-up over the course of the study; however, there was no significant difference between the number of partners reported in each study group at each time point (p=0.97) (Grant et al., 2010). Results were calculated by fitting a linear mixed regression model with a random intercept and fixed effects for treatment visit and treatment by visit interaction. The p-value is from a Wald test of the treatment by visit interaction which corresponds to whether or not there is a difference during the study period between the arms in the number of sexual partners (total male partners at over a 12 week recall period with whom the participant had oral or anal sex). These results and a description of the analysis conducted were received as correspondence from the study authors and were not included in the original publication.

The CDC safety study found that overall, mean number of sex partners in the past 3 months decreased significantly from 7.25 at baseline to 6.02 during months 3-9 and 5.71 during months 12-24 (p<0.001) (Liu et al., 2013). These declines were similar between the immediate and delayed study arms during months 3-9 (p=0.67), and the mean number of partners did not differ in months 12-24 vs. months 3-9 with initiation of study drug in the delayed arm (IRR=0.93, p=0.22) or continuation of drug in the immediate arm (IRR=0.96, p=0.56).

The Kenya intermittent PrEP study reported slight changes in number of sexual partners over time but did not assess statistical significance.
Figure 1: Disposition of citations during the search and screening process

Records identified through database searching (N=764)

Conference abstracts identified (N=139)

Additional records identified through other sources (N=2)

Records after duplicates removed (N=610)

Records screened (N=610)

Full-text articles assessed for eligibility (N=143)

Studies included in the review (N=4) (primary data presented in 5 articles)

Records excluded after first review (N=348)

Abstracts excluded after first review

Full-text articles excluded (N=138) because:
- Not related to PrEP (N=3)
- Does not meet study design criteria (N=4)
- Coded as background or values and preferences (N=128)
- Preliminary overlapping data in abstracts (N=3)
### Table 1: Risk-benefit table

<table>
<thead>
<tr>
<th>Factor</th>
<th>Explanation / Evidence</th>
</tr>
</thead>
<tbody>
<tr>
<td>Quality of Evidence</td>
<td>One multi-country RCT without serious limitations. All study outcomes rated as “high quality” in GRADE. Additional data from 3 smaller studies.</td>
</tr>
<tr>
<td>Balance of Benefits vs. Harms</td>
<td><strong>HIV infection</strong></td>
</tr>
<tr>
<td></td>
<td>In iPrEx, oral PrEP was associated with reduced risk of HIV in both intention-to-treat analysis (HR: 0.53, 95% CI 0.36-0.78, p=0.001) and modified intention-to-treat analysis (HR: 0.56, 95% CI 0.37-0.85, p=0.005). Other studies were not powered for this outcome, but the CDC safety study found 7 incident infections (0 PrEP, 3 placebo, 3 delayed, 1 placebo who was HIV+ at 1-month visit). Project PrEPare had 0 incident infections, and the Kenya intermittent PrEP study had 1 incident infection in the placebo group.</td>
</tr>
<tr>
<td></td>
<td><strong>Adverse events</strong></td>
</tr>
<tr>
<td></td>
<td>In iPrEx, there was no significant difference in reported adverse events between the FTC-TDF and control arms for either any adverse event (RR: 0.99, 95% CI 0.94-1.04) or grade 3 and 4 adverse events (RR: 0.92, 95% CI 0.75-1.13). Analyses from additional studies show no major differences in adverse events or grade 3 or 4 adverse events across treatment and control groups.</td>
</tr>
<tr>
<td></td>
<td><strong>Condom use</strong></td>
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<tr>
<td></td>
<td>In iPrEx, both the FTC-TDF and control study arms reported increased condom use from baseline to follow-up over the course of the study; there was no significant difference in condom use rates between study arms over time (p=0.36). Both the CDC safety study and Project PrEPare found decreased unprotected sex over time, and no significant differences across study arms.</td>
</tr>
<tr>
<td></td>
<td><strong>Number of sexual partners</strong></td>
</tr>
<tr>
<td></td>
<td>In iPrEx, both the FTC-TDF and control study arms reported reduced number of receptive sexual intercourse partners from baseline to follow-up over the course of the study; there was no significant difference in the reported number of sexual partners between study arms over time (p=0.97). The CDC safety study found decreased numbers of sexual partners over time, and no significant differences across study arms.</td>
</tr>
<tr>
<td>Values and Preferences</td>
<td>Despite a proliferation of relevant literature, reported values and preferences of PrEP use among MSM have remained relatively consistent when compared with results from a previous systematic review conducted in 2011 (see page 13). Awareness of PrEP among MSM continues to be limited globally, although several studies suggest awareness has increased since the release of the iPrEx results. Willingness to use PrEP varies widely across studies, with some reporting high interest, others reporting low acceptance, and the majority of studies reporting willingness to use PrEP between 40-70%. Main barriers and facilitators to PrEP use include effectiveness, side-effects, and cost. Concerns about accessibility, mistrust of healthcare providers, stigma, and risk compensation were also mentioned. Few studies reported on preferred PrEP dosing, administration, and dispensing sites. All studies measuring potential risk compensation found evidence that at least some participants anticipated changing their sexual behavior as a result of PrEP. Providers generally expressed awareness and support of PrEP, although fewer had...</td>
</tr>
</tbody>
</table>
prescribed it. Providers’ concerns included drug resistance, risk compensation, availability of ART (in Peru), poor adherence, lack of local guidelines, and concern that PrEP doesn’t fit well in current (US) models of care that do not include frequent, regular clinic visits.

| Resource Use | Cost-effectiveness studies of PrEP among MSM were located mostly in the US, but also Australia and Peru. Cost-effectiveness estimates varied widely depending on model parameter estimates, including efficacy of PrEP, cost of PrEP, HIV incidence and age of the target population, the impact of PrEP on risk compensation and community-level outcomes, and program prioritization and roll-out.  

In the US and Australia, results range from multiple estimates of PrEP being cost-saving to multiple estimates of PrEP costing over US$300,000 per QALY saved. In Peru, PrEP could be a cost-effective addition to current MSM prevention programs at US$1,702-$2755 per DALY saved, below the WHO recommended threshold for cost-effective interventions for the region.  

In concentrated epidemics in the US, authors of post-iPrEX studies agreed that PrEP use among MSM could have a significant impact on the domestic HIV epidemic. |
| Feasibility | Oral PrEP for MSM has proven feasible in various trial settings and acceptability studies (including among young MSM). Issues of criminalization, stigma and discrimination, and violence should be considered during implementation, especially where MSM behavior is illegal. |
Values and preferences review of the literature

Description of studies

Since 2011 the number of studies describing values and preferences of PrEP use among men who have sex with men (MSM) has increased dramatically. Our systematic review identified 36 peer-reviewed articles and 17 conference abstracts/presentations that reported on values and preferences of PrEP use among MSM, plus an additional 6 articles and 1 conference abstract that reported on perceptions of health care providers.

For values and preferences among MSM, study locations included the United States, China, Thailand, Peru, France, United Kingdom, Australia, Kenya, Canada, and Germany. Two studies were conducted regionally, one in North America and the other in Latin America (including Spain and Portugal), and three studies were conducted across multiple settings globally.

Across studies the majority of participants were MSM with HIV-negative or unknown serostatus. Several studies also included HIV-positive MSM, MSM in serodiscordant relationships, and a minority of non-MSM groups. Nine studies specified the inclusion of transgender individuals in addition to MSM. Other studies included key populations in addition to MSM, including female sex workers, injection drug users, and serodiscordant couples. In most studies, participants were PrEP naïve, but some included participants from the iPrEx trial, other PrEP trials based in Kenya and the US, and an HIV vaccine trial. One study focused on young MSM aged 16-20 years.

PrEP awareness

Knowledge of PrEP has increased since the release of the iPrEx study results but remains limited. Studies from the US that surveyed MSM both pre- and post-release of iPrEx results found increases in PrEP knowledge from 21% to 28% in Denver, 11% to 19% in Boston, and 12.7% to 18.6% in a nationally-based survey.

In one global survey of over 5,000 MSM, 60% reported no knowledge of PrEP. An Internet-based survey conducted in Latin America, Spain, and Portugal found 11% awareness of PrEP among 36,477 MSM surveyed. A global study of 2197 MSM found less awareness but more PrEP acceptability in the Global South as compared to the Global North. PrEP awareness was higher among certain populations. For example, in a sample of 593 HIV-positive MSM in France, 41.8% reported awareness of PrEP and 29.5% had had discussions about PrEP. Among a sample of serodiscordant couples in the United States, 62% reported having heard of PrEP, but a quarter of participants confused PrEP with PEP.
Willingness to use PrEP
Reported willingness to use PrEP was generally high but measurement of PrEP acceptance and/or willingness varied greatly across studies, thus making comparison difficult. The highest rate of willingness to use PrEP was found in a US-based study of MSM in serodiscordant relationships with 94% reporting willingness to use PrEP if available. However, qualitative results from another study among serodiscordant couples found ambivalence and low support for PrEP.14 A study among 650 MSM in China reported 91.9% of participants would accept PrEP if it was safe, effective, and free.28 More commonly, studies reported a range of willingness to use, acceptance of, or interest in PrEP among 40-70% of those surveyed across a variety of settings.1, 2, 10, 21, 29, 30, 38, 41, 47, 50, 51 Willingness to use PrEP was low in several studies. One study from Australia found the majority of participants were unwilling to use PrEP,44 and another study from Thailand found only a third of MSM surveyed were interested in PrEP after being read a statement explaining results from the iPrEx study.32

Among studies comparing acceptability of PrEP before and after the release of the iPrEx results, willingness to use PrEP did not change significantly following the release of results. For example, one study from the US found 66% willingness to use PrEP, assuming no side effects, before the release of iPrEx results and 62% after the release.1 Another study found high interest in PrEP both before (75%) and after (79%) the release of iPrEx results.19 A nationally-based survey from the US found that 78.4% and 76.9% of MSM reported being likely to use PrEP before and after the release of iPrEx results, respectively.22

Barriers and facilitators to PrEP
Commonly mentioned factors affecting willingness to use PrEP included effectiveness, side-effects, and cost. One study found that PrEP acceptability declined as hypothetical effectiveness decreased and potential side-effects increased.1 Another study found that willingness to use daily PrEP fell once monthly HIV testing and a $60 co-pay per visit to receive PrEP were added as stipulations.23 Among young MSM surveyed in Chicago, interest in PrEP was higher if dosing and side-effects were not inconvenient and perceived benefits were high.12 A qualitative study among a sample of female sex workers, MSM, and transgender individuals in Peru found that cost and side-effects were the largest factors in PrEP acceptability.36 Among a sample of 40 MSM who reported using club drugs in the US, 80% reported that their willingness to use and adhere to PrEP would decrease if the cost of PrEP limited their ability to afford their current lifestyle, including substance use and going out to meet men.21 Among MSM in Thailand, factors of PrEP acceptability included having private insurance, a lifetime history of sexually transmitted infections, previous HIV testing, regularly planned sex, and infrequent sex.35

Other barriers to PrEP use included long-term effects on health, limited accessibility, stigma associated with taking HIV-related medicine, medical monitoring, burden of daily regimen, site of PrEP dispensing, risk compensation, and response of peers.3, 20 Among a study of MSM and transgender individuals in California, lack of community awareness and confusion about PrEP
were also mentioned as barriers. PrEP associated stigma, discrimination, and mistrust of healthcare providers were cited as barriers to PrEP in a study including MSM, transgender individuals, and female sex workers in Peru. One study among high-risk substance-using MSM in Boston found that concerns about using PrEP differed with type of sexual partner. Primary partners were seen as sources of support for PrEP whereas discussing PrEP with casual partners was seen as unnecessary, in part due to HIV-related stigma and substance use. One US-based study found that reasons for interest in PrEP differed between white and black participants, suggesting a need for targeted PrEP messaging.

Regarding adherence, participants reported client-centered counseling, receiving daily reminders, and individualized routines as important factors. Among studies with iPrEx trial participants in the US and Thailand, participants reported factors facilitating adherence were receiving quality health care as part of the trial, including non-judgmental medical staff and counseling. Barriers to adherence included changes in routine, side-effects, and stress among US participants, and for Thai participants contextual factors surrounding PrEP, such as social life, conflicts with partners, being mistakenly identified as HIV-positive, and unintentional disclosure of sexual identity negatively affected adherence. Among a US-based sample of PrEP naïve and PrEP experienced MSM, barriers to adherence included mental health issues, stigma, and relationships with healthcare providers.

**PrEP dosing, route of administration, and dispensing site**

Several studies reported on participants’ preference for the dosing and administration of PrEP. In one study among MSM in Boston, 90% of participants preferred daily PrEP over intermittent options. In the UK, 80.2% of respondents reported they would prefer daily PrEP while 19.8% preferred coital dosing. In Thailand, daily oral PrEP or a long-lasting injection were the preferred routes. However, female sex workers and MSM involved in a PrEP trial in Kenya favored intermittent dosing, but noted challenges with intermittent use, particularly with post-coital dosing. A study from Germany found that 55.6% of participants would use PrEP only as-needed while 19.5% would use it daily.

Three studies based in Peru, Kenya, and the US reporting on PrEP dispensing sites found that participants preferred obtaining PrEP from health care providers. In the US-based study, 40.9% of participants preferred obtaining PrEP from primary healthcare providers, followed by other healthcare settings and the internet. In Peru participants preferred health centers as opposed to pharmacies, and in Kenya participants preferred obtaining PrEP from existing health centers followed by HIV/family planning centers. A multi-site study found that the PrEP dispensing site was an important attribute of PrEP for MSM in South Africa.

**Risk compensation**

All studies measuring potential risk compensation found varying degrees of hypothetical behavior changes related to PrEP use. A US-based Internet survey of 1155 MSM found that 75%
anticipated no change to their condom use while on PrEP, even though 21% perceived themselves at less risk of HIV infection from unprotected insertive anal sex and 39% from receptive anal sex while on PrEP.\textsuperscript{26} Another US-based study found that over 80% of respondents said their condom use would not decline during anal sex while taking PrEP both before and after the release of the iPrEx results.\textsuperscript{22} A study involving 121 MSM in the UK found that 67.2% would not change condom use while on PrEP and 87.3% would not have more sexual partners.\textsuperscript{42} Other studies reported participants would significantly reduce condom use as a result of using PrEP. For example, a US-based study among 180 MSM in New York City found that 35% would decrease condom use while on PrEP.\textsuperscript{9} A study from China also found that 35% of respondents were less likely to use condoms while taking PrEP.\textsuperscript{31} In a study among MSM in serodiscordant relationships, 26% said they were more likely to have unprotected sex with an HIV-infected partner while taking PrEP, and 27% said it would be difficult to take daily PrEP and consistently use condoms.\textsuperscript{16} A study of 329 MSM from Germany found that 44.7% would neglect condom use while on PrEP but that quality of life on PrEP was expected to increase among 83.6% of participants.\textsuperscript{48}

**Health care provider perspectives**

Six additional peer-reviewed articles and one conference abstract examined health care provider perspectives on PrEP for MSM. Most studies were conducted in the US and Canada, though one was conducted in Peru and one was conducted in Kenya.

In the US and Canada, several surveys have shown that most providers have heard of PrEP (69%-90%) and support PrEP, but fewer (9-19%) had actually prescribed it.\textsuperscript{54-56} PrEP prescribing practices were variable and clinicians reported many barriers to its real-world provision.\textsuperscript{55} Greatest concerns about prescribing PrEP included antiretroviral resistance (32%), risk compensation (22%) and poor adherence (21%).\textsuperscript{54} In qualitative interviews conducted in 2011, US providers believed that current models of care (which do not involve routine, frequent office visits) were not well suited for prescribing PrEP, highlighted the need to build capacity, and were concerned about monitoring side effects and adherence.\textsuperscript{57} Finally, one study found that US medical students' racial stereotypes about sexual risk compensation impacted willingness to prescribe PrEP to Black vs. White MSM.\textsuperscript{58}

In Peru, a survey of 186 health care providers found that 57.5% were aware of PrEP while 44.6% said they would be likely to prescribe it now.\textsuperscript{59} Lack of local guidelines, concern about risk compensation, antiretroviral drug resistance, and limited availability of antiretroviral treatment (ART) for HIV-infected individuals were the most common barriers to prescribing PrEP. Likelihood of prescribing was higher if PrEP were supported by local guidelines (70.3%), if more trials supported its effectiveness (68.5%), and if intermittent use were effective (62.2%).\textsuperscript{59} In Kenya, a qualitative study of 16 providers identified training needs for dealing with MSM clients around topics like PrEP.\textsuperscript{60}
Conclusion
Despite a proliferation of relevant literature, reported values and preferences of PrEP use among MSM have remained relatively consistent when compared with results from a previous systematic review conducted in 2011. Awareness of PrEP among MSM populations continues to be limited globally, although several studies suggest awareness has increased since the release of the iPrEx results. Willingness to use PrEP varies widely across studies, with some reporting high interest, others reporting low acceptance, and the majority of studies reporting willingness to use PrEP between 40-70%. Main barriers and facilitators to PrEP use include effectiveness, side-effects, and cost. Concerns about accessibility, mistrust of healthcare providers, stigma, and risk compensation were also mentioned. Few studies reported on preferred PrEP dosing, administration, and dispensing sites. All studies measuring potential risk compensation found evidence that at least some participants anticipated changing their sexual behavior as a result of PrEP. Providers generally expressed awareness and support of PrEP, although fewer had prescribed it. Providers’ concerns included drug resistance, risk compensation, availability of ART (in Peru), poor adherence, lack of local guidelines, and concern that PrEP doesn’t fit well in current (US) models of care that do not include frequent, regular clinic visits.
Annexes

Annex 1: GRADE table

Author(s): Caitlin Kennedy, Virginia Tedrow  
Date: 2014-04-06  
Question: Should oral PrEP (containing tenofovir (TDF)) be used in men who have sex with men (MSM)?  
Settings: Lima and Iquitos, Peru; Guayaquil, Ecuador; Cape Town, South Africa; Rio de Janiero and Sao Paulo, Brazil; Chiang Mai, Thailand; Boston and San Francisco, USA


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<th>Quality</th>
<th>Importance</th>
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### Condom use (percent of receptive anal partners with which condoms were used) (follow-up median 1.2 years)

1. Grant et al. 2010 – iPrEx study
2. Hosek et al., 2012 – Project PrEPare
3. Hazard Ratio from Grant et al. 2010
4. Total baseline sample size
5. This was a comparison between the two study arms of the percent of partners using condoms during receptive anal intercourse. The results were calculated by fitting a linear mixed regression model with a random intercept and fixed effects for treatment visit and treatment by visit interaction. The p-value is from a Wald test of the treatment by visit interaction which corresponds to whether or not there is a difference during the study period between the arms in the percent of partners using condoms during receptive anal intercourse.
6. This was a comparison between the two study arms of the total number of sexual partners reported. Results were calculated by fitting a linear mixed regression model with a random intercept and fixed effects for treatment visit and treatment by visit interaction. The p-value is from a Wald test of the treatment by visit interaction which corresponds to whether or not there is a difference during the study period between the arms in the number of sexual partners (total male partners at over a 12 week recall period with whom the participant had oral or anal sex).
Annex 2. Annotated bibliography

New Primary Studies - Efficacy (n= 2 studies, 3 articles)


OBJECTIVES: To evaluate the clinical safety of daily tenofovir disoproxil fumarate (TDF) among HIV-negative men who have sex with men. DESIGN: Randomized, double-blind, placebo-controlled trial. Participants were randomized 1:1:1:1 to immediate or delayed study drug (TDF, 300 mg orally per day, or placebo). METHODS: Four hundred healthy HIV-uninfected men who have sex with men reporting anal sex with another man within the previous 12 months enrolled in Atlanta, Boston, and San Francisco. HIV serostatus, clinical and laboratory adverse events (AEs), adherence (pill count, Medication Event Monitoring System, and self-report), and sexual and other sociobehavioral data were assessed at 3-month intervals for 24 months. Primary outcomes were clinical safety, assessed by incidence of AEs and laboratory abnormalities. RESULTS: Study drug was initiated by 373 (93%) participants (186 TDF and 187 placebo), of whom 325 (87%) completed the final study visit. Of 2428 AEs reported among 334 (90%) participants, 2366 (97%) were mild or moderate in severity. Frequencies of commonly reported AEs did not differ significantly between TDF and placebo arms. In multivariable analyses, back pain was more likely among TDF recipients (P = 0.04); these reports were not associated with documented fractures or other objective findings. There were no grade >/=3 creatinine elevations; grades 1 and 2 creatinine increases were not associated with TDF receipt. Estimated percentage of study drug doses taken was 92% by pill count and 77% by Medication Event Monitoring System. Seven seroconversions occurred: 4 on placebo and 3 among delayed arm participants not yet on study drug. CONCLUSIONS: Daily oral TDF was well tolerated, with reasonable adherence. No significant renal concerns were identified.


OBJECTIVE: To evaluate for changes in sexual behaviors associated with daily pill use among men who have sex with men (MSM) participating in a preexposure prophylaxis trial. DESIGN: Randomized, double-blind, placebo-controlled trial. Participants were randomized 1:1:1:1 to receive tenofovir disoproxil fumarate or placebo at enrollment or after a 9-month delay and followed for 24 months. METHODS: Four hundred HIV-negative MSM reporting anal sex with a man in the past 12 months and meeting other eligibility criteria enrolled in San Francisco, Atlanta, and Boston. Sexual risk was assessed at baseline and quarterly visits using Audio Computer-Assisted Self-Interview. The association of pill taking with sexual behavior was evaluated using logistic and negative-binomial regressions for repeated measures. RESULTS: Overall indices of behavioral risk declined or remained stable during follow-up. Mean number of partners and proportion reporting unprotected anal sex declined during follow-up (P < 0.05), and
mean unprotected anal sex episodes remained stable. During the initial 9 months, changes in risk practices were similar in the group that began pills immediately vs. those in the delayed arm. These indices of risk did not differ significantly after initiation of pill use in the delayed arm or continuation of study medication in the immediate arm. Use of poppers, amphetamines, and sexual performance-enhancing drugs were independently associated with one or more indices of sexual risk. CONCLUSIONS: There was no evidence of risk compensation among HIV-uninfected MSM in this clinical trial. Monitoring for risk compensation should continue now that preexposure prophylaxis has been shown to be efficacious in MSM and other populations and will be provided in open-label trials and other contexts.


BACKGROUND: This study examined the feasibility of a combination prevention intervention for young men who have sex with men (YMSM), an anticipated target population for HIV pre-exposure prophylaxis (PrEP). METHODS: Project PrEPare, a pilot study using a randomized 3-arm design, compared an efficacious behavioral HIV-prevention intervention (3MV) alone, 3MV combined with PrEP (tenofovir/emtricitabine), and 3MV combined with placebo. Eligible participants were 18-22 year old HIV-uninfected men who reported unprotected anal intercourse (UAI) in the past year. Participants were screened for preliminary eligibility at youth venues and community organizations, and were also referred through social networks. Laboratory screening determined final eligibility. Behavioral and biomedical data were collected at baseline and every 4 weeks thereafter for 24 weeks. RESULTS: Sixty-eight youth (mean age = 19.97 years; 53% African-American, 40% Latino were enrolled; 58 were randomized. Self-reported medication adherence averaged 62% (range 43-83%) while rates of detectable tenofovir in plasma of participants in the FTC/TDF arm ranged from 63.2% (week 4) to 20% (week 24). There were 5 (greater-than or equal to) Grade 2 adverse events possibly/probably related to the study medication. Sexual risk behavior declined from baseline to week 24 in all study arms. CONCLUSIONS: The feasibility of enrolling at risk youth, particularly YMSM of color, into Project PrEPare has been demonstrated. The acceptability of the group intervention along with counseling and testing was high. Self-reported medication adherence and corresponding plasma drug concentrations were low indicating the need for enhanced adherence counseling. Exploration of PrEP use among youth in non-randomized, open label trials is warranted.

**OBJECTIVE:** To assess current and intended future use of pre-exposure prophylaxis (PrEP) among men who have sex with men (MSM) and characterise those attending sexual health clinics, the anticipated PrEP delivery setting. **DESIGN:** Cross-sectional study. **METHODS:** Self-administered survey of 842 HIV negative MSM recruited from social venues in London in 2011. **RESULTS:** One in 10 (10.2%, 83/814, 95% CI 8.2% to 12.5%) and one in 50 (2.1%, 17/809, 95% CI 1.2% to 3.3%) reported having ever used post-exposure prophylaxis (PEP) and PrEP respectively. Half reported they would be likely to use PrEP if it became available as a daily pill (50.3%, 386/786, 95% CI 46.7% to 53.9%). MSM were more likely to consider future PrEP use if they were <35 years (adjusted OR (AOR) 1.57, 95% CI 1.16 to 2.14), had unprotected anal intercourse with casual partners (AOR 1.70, 95% CI 1.13 to 2.56), and had previously used PEP (AOR 1.94, 95% CI 1.17 to 3.24). Over half of MSM (54.8% 457/834 95% CI 51.3 to 58.2) attended a sexual health clinic the previous year. Independent factors associated with attendance were age <35 (AOR 2.29, 95% CI 1.68 to 3.13), and >/= 10 anal sex partners in the last year (AOR 2.49, 95% CI 1.77 to 3.52). **CONCLUSIONS:** The concept of PrEP for HIV prevention in the form of a daily pill is acceptable to half of sexually active MSM in London. MSM reporting higher risk behaviours attend sexual health clinics suggesting this is a suitable setting for PrEP delivery.


As part of the National HIV Behavioral Surveillance System among men who have sex with men (MSM) in Denver, Colorado, we assessed knowledge of pre-exposure prophylaxis (PrEP); willingness to use PrEP; and potential changes in risk behaviors among HIV-negative participants reporting sexual activity with a male partner in the preceding 12 months. We examined knowledge of PrEP before (2008) and after (2011) results of the iPrEx trial were available. Of the 425 participants in the 2008 sample, 91 (21 %) were aware of PrEP compared to 131 (28 %) of the 461 participants in the 2011 sample (adjusted prevalence ratio: 1.43, 95 % confidence interval: 1.18, 1.72). Despite the increase in 2011, few MSM in Denver were aware of PrEP. Educating high-risk MSM about the potential utility of PrEP as an adjunct to other effective prevention methods is needed when considering the addition of PrEP to the HIV prevention arsenal.


We surveyed a convenience sample of 215 HIV-negative men who have sex with men (MSM) recruited at a Gay Pride event and in an STD clinic about their willingness to use
pre-exposure prophylaxis (PrEP). Overall, 44% reported that they would take PrEP every day if it helped prevent HIV. There was no association between sexual risk behavior and interest in taking PrEP.


The objective of this mixed methods study was to examine current sexual risk behaviors, acceptability and potential adoption of pre-exposure prophylaxis (PrEP) for HIV prevention, and sexual behavior intentions with PrEP adoption among HIV-negative gay and bisexual men (GBM) in HIV serodiscordant relationships. A multiracial/ethnic sample of 25 HIV-negative GBM in serodiscordant relationships completed a qualitative interview and a brief interviewer-administered survey. A modified grounded theory approach was used to identify key themes relating to acceptability and future adoption of PrEP. Participants reported engaging in sexual risk behaviors that place them at risk for HIV infection. Participants also reported a high level of acceptability for PrEP and willingness to adopt PrEP for HIV prevention. Qualitative themes explaining future PrEP adoption included: (1) the opportunity to engage in sex using a noncondom HIV prevention method, (2) protection from HIV infection, and (3) less anxiety when engaging in sex with an HIV-positive partner. Associated with the future adoption of PrEP, a majority (64%) of participants indicated the likelihood for an increase in sexual risk behaviors and a majority (60%) of participants also indicated the likelihood for a decrease or abandonment of condom use, both of which are in contrast to the findings from the large iPrEx study. These findings suggest that the use of PrEP by HIV-negative GBM in serodiscordant relationships carries with it the potential for risk compensation. The findings suggest that PrEP only be offered as part of a comprehensive HIV prevention strategy that includes ongoing risk reduction counseling in the delivery of PrEP to help moderate risk compensation.


The purpose of this study was to identify factors that may facilitate or impede future adoption of preexposure prophylaxis (PrEP) for HIV prevention among gay and bisexual men in HIV-serodiscordant relationships. This qualitative study utilized semistructured interviews conducted with a multiracial/ethnic sample of 25 gay and bisexual HIV-serodiscordant male couples (n=50 individuals) recruited from community settings in Los Angeles, CA. A modified grounded theory approach was employed to identify major themes relating to future adoption of PrEP for HIV prevention. Motivators for adoption included protection against HIV infection, less concern and fear regarding HIV transmission, the opportunity to engage in unprotected sex, and endorsements of PrEP's
effectiveness. Concerns and barriers to adoption included the cost of PrEP, short- and long-term side effects, adverse effects of intermittent use or discontinuing PrEP, and accessibility of PrEP. The findings suggest the need for a carefully planned implementation program along with educational and counseling interventions in the dissemination of an effective PrEP agent. (copyright) 2011 Taylor & Francis.


BACKGROUND: The use of antiviral medications by HIV negative people to prevent acquisition of HIV or pre-exposure prophylaxis (PrEP) has shown promising results in recent trials. To understand the potential impact of PrEP for HIV prevention, in addition to efficacy data, we need to understand both the acceptability of PrEP among members of potential user groups and the factors likely to determine uptake. METHODS AND FINDINGS: Surveys of willingness to use PrEP products were conducted with 1,790 members of potential user groups (FSWs, MSM, IDUs, SDCs and young women) in seven countries: Peru, Ukraine, India, Kenya, Botswana, Uganda and South Africa. Analyses of variance were used to assess levels of acceptance across different user groups and countries. Conjoint analysis was used to examine the attitudes and preferences towards hypothetical and known attributes of PrEP programs and medications. Overall, members of potential user groups were willing to consider taking PrEP (61% reported that they would definitely use PrEP). Current results demonstrate that key user groups in different countries perceived PrEP as giving them new possibilities in their lives and would consider using it as soon as it becomes available. These results were maintained when subjects were reminded of potential side effects, the need to combine condom use with PrEP, and for regular HIV testing. Across populations, route of administration was considered the most important attribute of the presented alternatives. CONCLUSIONS: Despite multiple conceivable barriers, there was a general willingness to adopt PrEP in key populations, which suggests that if efficacious and affordable, it could be a useful tool in HIV prevention. There would be a willingness to experience inconvenience and expense at the levels included in the survey. The results suggest that delivery in a long lasting injection would be a good target in drug development.


In November 2010, the iPrEx study reported that preexposure prophylaxis (PrEP) with daily tenofovir disoproxil fumarate/emtricitabine reduced HIV infections by 44% among men who have sex with men and subsequent trials corroborated efficacy among heterosexual men and women. During regularly scheduled follow-up visits from January to March 2011, participants in an ongoing phase 2b vaccine efficacy trial completed an anonymous Web survey about PrEP. Among 376 respondents, 17% reported they were
very likely to use PrEP in the next year. Nonwhite participants were more likely to use PrEP. Among those with some level of interest, intent to use PrEP was greatest if the drug were available through the clinical trial or health insurance. Most (91%) believed taking PrEP would not change their willingness to stay in the vaccine trial and few thought it would affect recruitment. As key stakeholders, currently enrolled trial participants can offer vital input about emerging prevention technologies that may affect the design of future HIV vaccine and nonvaccine prevention trials.


This study examined pre-exposure prophylaxis (PrEP) acceptability among female sex workers, male-to-female transgendered persons and men who have sex with men in Lima, Peru. Focus groups explored social issues associated with PrEP acceptability and conjoint analysis assessed preferences among eight hypothetical PrEP scenarios with varying attribute profiles and their relative impact on acceptability. Conjoint analysis revealed that PrEP acceptability ranged from 19.8 to 82.5 out of a possible score of 100 across the eight hypothetical PrEP scenarios. Out-of-pocket cost had the greatest impact on PrEP acceptability (25.2, P < 0.001), followed by efficacy (21.4, P < 0.001) and potential side-effects (14.7, P < 0.001). Focus group data supported these findings, and also revealed that potential sexual risk disinhibition, stigma and discrimination associated with PrEP use, and mistrust of health-care professionals were also concerns. These issues will require careful attention when planning for PrEP roll-out.


BACKGROUND: An international randomized clinical trial (RCT) on pre-exposure prophylaxis (PrEP) as an human immunodeficiency virus (HIV)-prevention intervention found that taken on a daily basis, PrEP was safe and effective among men who have sex with men (MSM) and male-to-female transgender women. Within the context of the HIV epidemic in the United States (US), MSM and transgender women are the most appropriate groups to target for PrEP implementation at the population level; however, their perspectives on evidenced-based biomedical research and the results of this large trial remain virtually unknown. In this study, we examined the acceptability of individual daily use of PrEP and assessed potential barriers to community uptake. METHODS: We conducted semi-structured interviews with an ethnoracially diverse sample of thirty HIV-negative and unknown status MSM (n = 24) and transgender women (n = 6) in three California metropolitan areas. Given the burden of disease among ethnoracial minorities in the US, we purposefully oversampled for these groups. Thematic coding and analysis of data was conducted utilizing an approach rooted in grounded theory. RESULTS: While participants expressed general interest in PrEP availability, results demonstrate: a lack of community awareness and confusion about PrEP; reservations about PrEP
utilization, even when informed of efficacious RCT results; and concerns regarding equity and the manner in which a PrEP intervention could be packaged and marketed in their communities. CONCLUSIONS: In order to effectively reduce HIV health disparities at the population level, PrEP implementation must take into account the uptake concerns of those groups who would actually access and use this biomedical intervention as a prevention strategy. Recommendations addressing these concerns are provided.


In 2010, the iPrEx study demonstrated efficacy of daily emtricitabine/tenofovir disoproxil fumarate (FTC/TDF) pre-exposure prophylaxis (PrEP) in reducing HIV acquisition among men who have sex with men. Adherence to study product was critical for PrEP efficacy, and varied considerably, with FTC/TDF detection rates highest in the United States. We conducted a qualitative study to gain insights into the experiences of iPrEx participants in San Francisco (SF) where there was high confirmed adherence, to understand individual and contextual factors influencing study product use in this community. In 2009 and 2011, we conducted focus groups and in-depth interviews in 36 and 16 SF iPrEx participants, respectively. Qualitative analyses indicate that participants joined the study out of altruism. They had a clear understanding of study product use, and pill taking was facilitated by establishing or building on an existing routine. Participants valued healthcare provided by the study and relationships with staff, whom they perceived as nonjudgmental, and found client-centered counseling to be an important part of the PrEP package. This facilitated pill taking and accurate reporting of missed doses. Adherence barriers included changes in routine, side effects/intercurrent illnesses, and stress. Future PrEP adherence interventions should leverage existing routines and establish client-centered relationships/ environments to support pill taking and promote accurate reporting.


Background: Pre-exposure prophylaxis (PrEP) has the potential to become a powerful HIV prevention tool; however, many questions remain about its acceptability and impact on behavior among men who have sex with men (MSM). Brief surveys have been conducted to assess willingness to take PrEP, but almost no studies have examined psychosocial predictors of both PrEP acceptability and its potential influence on sexual risk-taking. Methods: Data were collected from 3 populations critical to the success of PrEP as a prevention strategy: a) lesbian, gay, bisexual, and transgender (LGBT) youth (aged 16-24 years) in the Ballroom scene in New York City (n = 85); b) blackidentified MSM never tested for HIV (n = 45); and c) highly sexually active MSM (median of 20
partners in the past 90 days; n = 80). Participants completed self-report surveys about PrEP knowledge, acceptability, and risk compensation. All data were collected between March and December 2011 (ie, after the release of the iPrEx results.) Results: Among youth, the most important predictor of PrEP acceptability was a desire to escape constant worry about HIV infection. On the other hand, youth expressed concern about the association of daily antiretroviral (ARV) medication use with nullbeing sick.null Among Black MSM, HIV conspiracy beliefs- especially negative beliefs about HIV medications- were the strongest predictor of resistance to PrEP. Among highly sexually active MSM, 34% reported that taking PrEP would increase their risk behavior. Risk compensation was strongest among MSM who a) make decisions about condom use based on situational risk perception (p < .001) and b) prefer unprotected sex because they consider it transgressive (p < .001). Conclusions: Findings from all 3 studies underscore the importance of social-behavioral data in the development of PrEP polices and interventions. The creation of effective PrEP messaging must acknowledge an existing sociopolitical context around HIV prevention formany MSM, which may influence the way messages are interpreted and internalized. Behavioral interventions to support PrEP use are critical, and must recognize the role of risk perception and affect in sexual decision making.


This study examined potential facilitators and barriers to pre-exposure prophylaxis (PrEP) use and their association with PrEP acceptability and motivations for adherence among 184 MSM and transgender women living in New York City. Participants were presented with educational information about PrEP and completed a computerized survey. Overall, 55.4% of participants reported willingness to take PrEP. The most highly endorsed barriers to PrEP use were health concerns, including both long-term impacts and short-term side effects, questions about PrEP's impact on future drug resistance, and concerns that PrEP does not provide complete protection against HIV. The most highly endorsed facilitator was free access to PrEP, followed by access to support services such as regular HIV testing, sexual health care/monitoring, and access to one-on-one counseling. Participants of color rated both barriers and facilitators as more important than their White counterparts. In multivariate models, barrier and facilitator scores significantly predicted not only PrEP acceptability, but also motivation for PrEP adherence among those who were likely to use PrEP. PrEP implementation programs should consider addressing these barriers and facilitators in protocol and policy development. Findings underscore the importance of support services, such as sexual health counseling, to the success of PrEP as a prevention strategy.

We assessed attitudes to medicines, HIV treatments and antiretroviral-based prevention in a national, online survey of 1,041 Australian gay men (88.3% HIV-negative and 11.7% HIV-positive). Multivariate analysis of variance was used to identify the effect of HIV status on attitudes. HIV-negative men disagreed with the idea that HIV drugs should be restricted to HIV-positive people. HIV-positive men agreed and HIV-negative men disagreed that taking HIV treatments was straightforward and HIV-negative men were more sceptical about whether HIV treatment or an undetectable viral load prevented HIV transmission. HIV-negative and HIV-positive men had similar attitudes to pre-exposure prophylaxis but divergent views about 'treatment as prevention'.


Objectives: To investigate willingness to use HIV preexposure prophylaxis (PrEP) and the likelihood of decreased condom use among Australian gay and bisexual men.

Methods: A national, online cross-sectional survey was conducted in April to May 2011. Bivariate relationships were assessed with x2 or Fisher’s exact test. Multivariate logistic regression analysis was performed to assess independent relationships with primary outcome variables. Results: Responses from 1161 HIV-negative and untested men were analysed. Prior use of antiretroviral drugs as PrEP was rare (n=6). Just over a quarter of the sample (n=327; 28.2%) was classified as willing to use PrEP. Willingness to use PrEP was independently associated with younger age, having anal intercourse with casual partners (protected or unprotected), having fewer concerns about PrEP and perceiving oneself to be at risk of HIV. Among men who were willing to use PrEP (n=327), only 26 men (8.0%) indicated that they would be less likely to use condoms if using PrEP. The likelihood of decreased condom use was independently associated with older age, unprotected anal intercourse with casual partners (UAIC) and perceiving oneself to be at increased risk of HIV. Conclusions: The Australian gay and bisexual men the authors surveyed were cautiously optimistic about PrEP. The minority of men who expressed willingness to use PrEP appear to be appropriate candidates, given that they are likely to report UAIC and to perceive themselves to be at risk of HIV.


This study was designed to identify predictors of lower versus higher willingness to use pre-exposure prophylaxis (PrEP) to reduce HIV among men who have sex with men (MSM) in China. Participants were 570 MSM who completed self-report measures of willingness to use HIV PrEP, beliefs about HIV, psychosocial factors, sexual experiences and sociodemographic characteristics. Results of a hierarchical binary logistic regression analysis indicated that membership in a higher willingness group was predicted by previous consultation about HIV, more reported barriers to using condoms, and
elevations in depressive symptoms. Independent of these factors, higher willingness to use HIV PrEP was predicted by beliefs that the intervention was low in stigma and high in potential benefits. In sum, the study highlighted the utility of broad-based assessment of demographic, behavioral, personality, and cognitive factors in identifying Chinese MSM who express willingness to use a promising biologically-based intervention to lower HIV risk.


BACKGROUND: In 2010, the iPrEx trial demonstrated that oral antiretroviral pre-exposure prophylaxis (PrEP) reduced the risk of HIV acquisition among high-risk men who have sex with men (MSM). The impact of iPrEx on PrEP knowledge and actual use among at-risk MSM is unknown. Online surveys were conducted to assess PrEP awareness, interest and experience among at-risk MSM before and after iPrEx, and to determine demographic and behavioral factors associated with these measures.

METHODS AND FINDINGS: Cross-sectional, national, internet-based surveys were administered to U.S. based members of the most popular American MSM social networking site 2 months before (n = 398) and 1 month after (n = 4,558) publication of iPrEx results. Comparisons were made between these samples with regards to PrEP knowledge, interest, and experience. Data were collected on demographics, sexual risk, and experience with post-exposure prophylaxis (PEP). Regression analyses were performed to identify factors associated with PrEP awareness, interest, and experience post-iPrEx. Most participants were white, educated, and indicated high-risk sexual behaviors. Awareness of PrEP was limited pre- and post-iPrEx (13% vs. 19%), whereas interest levels after being provided with a description of PrEP remained high (76% vs. 79%). PrEP use remained uncommon (0.7% vs. 0.9%). PrEP use was associated with PEP awareness (OR 7.46; CI 1.52-36.6) and PEP experience (OR 34.2; CI 13.3-88.4). PrEP interest was associated with older age (OR 1.01; CI 1.00-1.02), unprotected anal intercourse with >/=1 male partner in the prior 3 months (OR 1.40; CI 1.10-1.77), and perceiving oneself at increased risk for HIV acquisition (OR 1.20; CI 1.13-1.27).

CONCLUSIONS: Among MSM engaged in online networking, awareness of PrEP was limited 1 month after the iPrEx data were released. Utilization was low, although some MSM who reported high-risk behaviors were interested in using PrEP. Studies are needed to understand barriers to PrEP utilization by at-risk MSM.


Pre-exposure prophylaxis (PrEP) is a promising strategy whereby HIV-uninfected people could take antiretroviral (ARV) medications to reduce their risk of HIV acquisition. Reports suggest that unsupervised PrEP use has been occurring in gay communities of USA cities before human safety and efficacy data became available. We administered a
20-item questionnaire to men undergoing HIV testing at Hassle Free Clinic, a sexual health clinic in the gay village of Toronto. Questionnaire items enquired about demographics, sexual partners, substance use and awareness of, usage of and willingness to use PrEP. Logistic regression was used to identify characteristics associated with PrEP-related outcomes. Of 256 participants, 11.7% were aware of PrEP, with more men who have sex with men (MSM) aware (14.1%) than non-MSM (4.9%). No participants reported PrEP usage. Willingness to consider PrEP use was high and associated with high-risk activities, suggesting opportunities for PrEP use in the future.


Although predictors of willingness to take daily, self-administered pre-exposure HIV prophylaxis (PrEP) for men who have sex with men (MSM) have been studied in the context of several PrEP trials internationally, little is known about MSM interested in participating in a trial on the use of PrEP on an "on-demand" basis, i.e., taking a first dose of combined tenofovir/emtricitabine a few hours before possible HIV sexual exposure and a second dose a few hours afterwards. A double-blind placebo randomized PrEP trial will soon begin in France to evaluate the effectiveness of PrEP in terms of reducing HIV infection rates, among MSM self-administering "on-demand" PrEP. To assess potential participants' characteristics associated with willingness to participate in the trial and identify barriers and facilitators to implementation, MSM completed a self-administered questionnaire, distributed via gay venues and community websites. Among the 443 respondents who reported being HIV-negative, 40% reported being interested in participating. Factors independently associated with interest included: reporting lower educational level, more than 20 male sexual partners in the previous year, reporting unprotected anal sex with casual partners and preferring PrEP follow-up visits in a devoted area within a hospital. There is great interest in participating in a future "on-demand" PrEP trial among HIV-negative MSM and particularly in those at potentially high risk of HIV exposure. Providing confidentiality and tailored counseling during PrEP follow-up are important issues.


Background: We examined knowledge, attitudes, and practices toward use of daily PrEP among MSM and factors associated with their willingness to take PrEP if available and offered for free or covered by health insurance. Methods: Between August-December 2011, MSM in two U.S. metropolitan areas heavily impacted by HIV (Miami, Florida and Washington, D.C.) were recruited and interviewed through venue based sampling for the CDC National HIV Behavioral Surveillance study. Multivariable logistic regression analysis assessed demographic, socioeconomic, drug use and sexual risk correlates of being very willing to take PrEP for each city. Results: The samples included 321 in
Miami (median age=29;18% black, 10% white, 71% Hispanic, 1% Other) and 323 in Washington D.C. (median age=32, 28% black, 49% white, 13% Hispanic, 10% Other). Fifteen percent of men in Miami and 30% in Washington D.C. had heard information about PrEP, few knew anyone who had taken PrEP (3% in both cities), and none reported having taken it themselves. Almost half (49%) of MSM in Miami and almost two-thirds (61%) in Washington D.C. reported they would be willing to take PrEP. In Miami, only non-injection drug use in the past year was associated with decreased willingness to use PrEP (OR=.59, 95% CI (.36, .96). In Washington, D.C., >33 years of age (OR=.45, 95% CI (.33, .74) and having fewer sexual partners (OR=.57, 95% CI (.33, .98) were associated with decreased willingness to use PrEP; non-injection drug use (OR=1.67, 95% CI (1.02, 2.73) was associated with increased willingness to use PrEP. Conclusion: Awareness and use of PrEP in these two US HIV epicenters is low; innovative strategies are needed to inform and educate MSM about this new prevention strategy. Willingness to use PrEP may be impacted by drug use and sexual risk behaviors. Future studies are needed to understand how non-injection drug use may impact PrEP use.


Men who have sex with men (MSM) remain at great risk of HIV in the United States, representing 65% of incident HIV infections. One factor contributing to the high rate of HIV infection among MSM is use of "recreational" drugs that are highly associated with unprotected anal sex. Pre-exposure chemoprophylaxis (PrEP) is a novel biomedical HIV prevention strategy that has the potential to reduce HIV transmission in MSM. Main and casual sex partners play a role in HIV prevention efforts for MSM. The study aimed to qualitatively explore the perceived influences of sexual relationships on promoting and inhibiting PrEP use among high-risk MSM who report regular drug use. Semi-structured qualitative interviews were conducted with 40 participants recruited in Boston, Massachusetts. Data were analyzed using descriptive qualitative analysis. Casual partners presented a distinct set of concerns from primary partnerships. MSM generally viewed main partners as a potential source of support for taking PrEP. Given their informal and often temporary nature, PrEP disclosure to casual partners was considered unnecessary. HIV-related stigma and substance use were also perceived as barriers to discussing PrEP use with casual partners. MSM articulated a high degree of personal agency regarding their ability to take PrEP. Findings suggest that behavioral interventions to improve PrEP utilization and adherence for high-risk MSM should be tailored to sex partner type and the parameters established between sex partners. Approaches to PrEP disclosure and partner engagement should be informed by the relative benefits and limitations characterized by these different types of relationships.

Background: Pre-exposure prophylaxis (PrEP) has been shown to decrease HIV transmission in high-risk men who have sex with men (MSM), but to be effective, adherence must be optimized. MSM who use drugs (eg, crystal meth/GHB/cocaine/ecstasy/poppers) to enhance sexual activity are at increased risk for HIV acquisition and may be a particularly important group to consider when designing PrEP intervention and uptake protocols. Methods: We are collecting 40 semistructured qualitative interviews with HIV-uninfected MSM who meet DSM-IV criteria for substance abuse/dependence and report unprotected anal sex with a casual or serodiscordant male partner while using drugs in the past 3 months. The interview guide addresses: substance use, sexual-risk, social-support, healthcare, employment/housing, knowledge of PrEP, and logistical considerations for PrEP utilization. Interviews were recorded, transcribed, and examined using thematic analysis. Results: Twenty participants have completed the interviews thus far. The mean age was 36 years (SD = 12.0), 33% were black and Latino, and their mean number of partners in the last 3 months was 7 (SD = 5.8). Seventy-two percent had heard of PrEP, and 86% were unlikely to use it. The most salient theme regarding perceived PrEP adherence was the preference for daily PrEP rather than PrEP before sex. Although benefits of intermittent use (eg, mitigating side effects, cost) were discussed, subthemes to contextualize preferences for daily use included 1) ease of integrating PrEP with other medications/into daily routines; 2) concerns about missing doses of intermittent PrEP due to drug/alcohol use; 3) ambivalence of using PrEP around casual partners due to privacy concerns; 4) reluctance to carry pills away from their residence; and 5) inability to plan ahead about sex. Conclusions: Among substance using, high-risk MSM, daily dosing of PrEP may enhance acceptability/adherence to this HIV prevention strategy. Further data elucidating facilitators and barriers to PrEP will inform intervention development to improve access and utilization of biomedical prevention among this population.


OBJECTIVE: Oral preexposure prophylaxis (PrEP) with antiretrovirals (ARVs) is at the forefront of biomedical HIV prevention research, and ARVs are also being tested for rectal administration to target people practicing unprotected receptive anal intercourse (URAI) and at risk of HIV infection. This study assessed the acceptability of daily oral PrEP and rectal PrEP during URAI among men who have sex with men (MSM) and transgender women (TGW) in Peru. METHODS: During the 2008 HIV sentinel surveillance survey conducted in 3 Peruvian cities (Lima, Iquitos, and Pucallpa), MSM and TGW reported being "versatile," "most of the time receptive," and "exclusively receptive" during anal sex behavior where surveyed on their acceptability of oral and
rectal PrEP. RESULTS: Among 532 individuals, high acceptance of either oral (96.2%) or rectal (91.7%) PrEP products was reported. If both products were efficacious/available, 28.6% would prefer a pill, 57.3% a rectal lubricant, and 14.1% either. A trend toward higher acceptance was observed as receptive anal sex behavior exclusivity rose (P = .013). Being receptive most of the time (adjusted odds ratio [aOR]: 9.1, P = .01) and exclusively receptive (aOR: 7.5, P = .01), compared to being versatile, were independently associated with oral PrEP acceptability. A similar association was found with the acceptability of rectal formulations (aOR: 2.3, P = .07; and aOR: 2.5, P = .02; respectively).

CONCLUSIONS: Oral and rectal PrEP were highly acceptable among Peruvian MSM and TGW, particularly among those at the highest HIV infection risk. These data can guide the implementation of PrEP programs in Peru and similar settings and populations.


Although preliminary studies showed that preexposure prophylaxis (PrEP) lowers the HIV transmission in individuals with HIV, confirmative trials are ongoing and PrEP is not routinely recommended. The aim of this study was to assess whether individuals with HIV share antiretroviral (ARV) drugs for PrEP and to describe awareness and discussion on PrEP in this population. A cross-sectional survey was conducted in France in 23 representative departments of infectious diseases and internal medicine. Physicians administered an anonymous standardized questionnaire to all individuals with HIV receiving ARVs and followed between 24 and 31 October 2011. The questionnaire included items regarding PrEP (awareness; discussion with their close circle, physician or patients' association; experience), personal sociodemographic characteristics, risk behaviors and HIV status of the participants. Five hundred and ninety three participants were recruited: male 74.2% (men who have sex with men 52.4%, heterosexuals 21.6%), member of patient's association 9.8%. Half of them (50.6%) lived with a stable partner and 35.2% with an HIV-negative partner. Almost half (41.8%) were aware and 29.5% had had discussion about PrEP. In logistic regression, awareness and discussion on PrEP were more frequent: (1) among males, in patients' association members (p< 0.001 for both) and in nonheterosexuals (p=0.023 and 0.057, respectively); (2) among women, in those not living with a stable partner (p=0.035 and p=0.03, respectively) or living with an HIV-negative partner (p=0.049 and p=0.083, respectively). One percent of the participants declared having shared ARVs with someone and 8.3% reported PrEP in their close circle. Men reporting PrEP in their close circle shared ARVs more frequently than those who did not (10.3% vs. 0.2%, p < 0.001). Today, individuals with HIV do not seem to widely share personal ARVs for PrEP with seronegative people. A significant number of individuals with HIV are aware of and commonly discuss PrEP. (copyright) 2013 Taylor & Francis.

Understanding prior knowledge and experience with pre-exposure prophylaxis (PrEP) among men who have sex with men (MSM) is critical to its implementation. In fall 2011, NYC MSM were recruited via banner advertisements on six popular dating websites and asked questions about their knowledge and use of PrEP (n = 329). Overall, 123 (38%) respondents reported knowledge of PrEP, of whom two (1.5%) reported PrEP use in the past 6 months. Knowledge of PrEP was associated with high educational attainment, gay identity and recent HIV testing, suggesting an uneven dissemination of information about PrEP and missed opportunities for education. To avoid disparities in use during scale-up, MSM should be provided with additional information about PrEP.


OBJECTIVE: We conducted a mixed-methods study to examine serodiscordant and seroconcordant (HIV-positive/HIV-positive) male couples' PrEP awareness, concerns regarding health care providers offering PrEP to the community, and correlates of PrEP uptake by the HIV-negative member of the couple. DESIGN: Qualitative sub-study included one-on-one interviews to gain a deeper understanding of participants' awareness of and experiences with PrEP and concerns regarding health care providers offering PrEP to men who have sex with men (MSM). Quantitative analyses consisted of a cross-sectional study in which participants were asked about the likelihood of PrEP uptake by the HIV-negative member of the couple and level of agreement with health care providers offering PrEP to anyone requesting it. METHODS: We used multivariable regression to examine associations between PrEP questions and covariates of interest and employed an inductive approach to identify key qualitative themes. RESULTS: Among 328 men (164 couples), 62% had heard about PrEP, but approximately one-quarter were mistaking it with post-exposure prophylaxis. The majority of participants had low endorsement of PrEP uptake and 40% were uncertain if health care providers should offer PrEP to anyone requesting it. Qualitative interviews with 32 men suggest that this uncertainty likely stems from concerns regarding increased risk compensation. Likelihood of future PrEP uptake by the HIV-negative member of the couple was positively associated with unprotected insertive anal intercourse but negatively correlated with unprotected receptive anal intercourse. CONCLUSIONS: Findings suggest that those at greatest risk may not be receptive of PrEP. Those who engage in moderate risk express more interest in PrEP; however, many voice concerns of increased risk behavior in tandem with PrEP use. Results indicate a need for further education of MSM communities and the need to determine appropriate populations in which PrEP can have the highest impact.

Little is known about HIV preexposure prophylaxis (PrEP) acceptability among men who have sex with men (MSM) in Thailand. The authors recruited an online convenience sample of Thai MSM (n = 404) to assess the knowledge of and interest in PrEP. Less than 7% had heard of PrEP; however, 35% indicated interest in PrEP after an explanation of its possible efficacy. Regression modeling demonstrated that HIV knowledge and risk behavior, but not demographics, are significant predictors of PrEP interest. More information and education about PrEP is necessary and more research is needed to examine PrEP acceptability and to inform the message for PrEP uptake.


We elicited attitudes about, and service access preferences for, daily oral antiretroviral pre-exposure prophylaxis (PrEP) from urban, African-American young men and women, ages 18-24 years, at risk for HIV transmission through their sexual and drug-related behaviors participating in eight mixed-gender and two MSM-only focus groups in Atlanta, Georgia. Participants reported substantial interest in PrEP associated with its perceived cost, effectiveness, and ease of accessing services and medication near to their homes or by public transportation. Frequent HIV testing was a perceived benefit. Participants differed about whether risk-reduction behaviors would change, and in which direction; and whether PrEP use would be associated with HIV stigma or would enhance the reputation for PrEP users. This provides the first information about the interests, concerns, and preferences of young adult African Americans that can be used to inform the introduction of PrEP services into HIV prevention efforts for this critical population group.


In 2008, the Pre-exposure Prophylaxis Initiative (iPrEx) study expanded to include men who have sex with men (MSM) in Chiang Mai, Thailand. In full, 114 participants from Chiang Mai joined this international double-blinded trial of daily FTC-TDF (Truvada(R)) or placebo as a pre-exposure prophylaxis (PrEP) HIV prevention strategy. To better understand the characteristics of iPrEx participants specifically from this underserved population in Thailand, and gain insights into their experiences of trying to take a daily tablet as part of this blinded PrEP trial, we conducted a qualitative study. In 2010, 32 MSM iPrEx participants provided in-depth interviews and an additional 14 joined focus group discussions. Results of the qualitative analyzes suggested that participants held generally positive attitudes toward the iPrEx study and study medication and related this
to high rates of adherence to the daily regimen. Participants also reflected on the provision of quality health care as part of participation in the trial, as well as support from clinical research staff, family and friends as helpful in supporting high rates of study medication adherence. Discourse concerning challenges to adherence included medication taking behavior, which was contextualized by lifestyle, living arrangement, social life, social stigma in terms of being mistakenly identified as HIV positive or unintentional disclosure of sexual identity to family and friends, and relationship conflicts with partners. The results provide broader perspectives of participant experiences of the study medication and daily adherence in the larger contexts of the MSM community, close relationships, and the study climate, and can be leveraged in constructing PrEP adherence support approaches within these communities.


Background: Pre-exposure prophylaxis (PrEP) is a promising biomedical approach to primary HIV prevention for men who have sex with men (MSM). Recent clinical trials showed that effectiveness was closely tied to medication adherence. The purpose of the current study was to determine the optimal content for a comprehensive PrEP package that can maximize adherence and minimize risk compensation. Methods: In order to understand barriers and facilitators of PrEP adherence, we conducted 2 focus groups (N = 18) with HIV-uninfected MSM who participated in the iPrEx or CDC PrEP studies at Fenway Health Institute, Boston, Massachusetts, and who were currently taking PrEP. Participants were asked questions about their experiences taking PrEP, perceived barriers and facilitators affecting PrEP adherence, and their suggestions for interventions that could improve PrEP adherence. Focus groups were recorded, transcribed, and examined using thematic analysis. Results: Participants' mean age was 44 (SD = 7.4). Fourteen MSM identified as white, 4 as African American/black, and one as Hispanic/Latino. Participants expressed a high level of motivation to participate in PrEP adherence interventions that could enhance PrEP efficacy. Several descriptive themes to enhance PrEP adherence emerged: 1) providing a better understanding of PrEP effectiveness; 2) addressing substance use and mental health barriers; 3) using novel facilitators (text message reminders, alarm clock/phone); 4) educating about the problems of inconsistent use (drug resistance if acutely infected) and/or long-term use (bone-density loss); 5) addressing potential HIV stigma from friends and partners; and 6) training providers of PrEP in rapport building. Conclusions: These themes were used to inform the development of a PrEP curriculum adherence package, which consists of PrEP psycho-education, solving adherence barriers, promoting individualized facilitators, and managing possible stigma associated with taking PrEP. The next step is to conduct a pilot of this intervention to assess feasibility and enhance participant acceptability.

Background: HIV prevention strategies amongst men who have sex with men (MSM) remain an important area of research. A large multinational, randomised, double blind, placebo controlled, clinical trial (iPrEx) of daily oral antiretrovirals (tenofovir [TDF] and emtricitabine [FTC]) has demonstrated the safety and efficacy of daily TDF/FTC in reducing HIV acquisition in a men who have sex with men (MSM) population exposed to HIV through sexual transmission. We gathered data regarding the acceptability of the treatment and frequency of monitoring, the likelihood of adherence and any possible risk compensation behaviours which may emerge from taking PrEP. Methods: All MSM, aged 18 years or more, who attended the Manchester Centre for Sexual Health between 02/11/2011 and 18/01/2012 and who reported practicing unprotected receptive anal intercourse were eligible to participate in this study. These were identified by the doctor or nurse during the consultation and given a patient information leaflet (PIL) and a questionnaire to complete. Results: There were 3127 new GU attendees during this time of which 12.6% were MSM. 95/112 questionnaires were completed and returned. The mean age of the participants was 28.2 years. 80% were White Caucasian. The most common number of sexual partners in 12 months was 4. 84.2% said that they used condoms at least 50% of the time. Having casual sex with another man of unknown HIV status was the main risk of HIV in 80% of responders. Staying HIV negative was important to 87.4%. 64.2% of MSM practicing receptive anal sex were willing to take PrEP. 20% would only take coital PrEP and 50.5% would take daily PrEP for more than 6 months. 90.5% of MSM taking PrEP would adhere to monitoring and 85.3% would accept the side effects described in the PIL. 66.3% claimed that taking PrEP would not change the frequency of condom use and none said that they would stop condom use altogether. 86.3% would have the same number of partners and 80% would still seek post-exposure prophylaxis after sexual exposure (PEPSE) despite taking PrEP. Conclusion: PrEP has been proven to be an effective prevention strategy for at-risk MSM in a number of clinical trials. Our survey shows that the majority of MSM attending GU services in Manchester would accept an offer of PrEP, and that daily PrEP was the preferred regimen. Individuals on PrEP would not be expected to change their current sexual practice, although this would need to be assessed in larger prospective studies.


OBJECTIVES: Preexposure prophylaxis (PrEP) is a promising strategy to prevent human immunodeficiency virus (HIV) infection, especially among high-risk individuals such as seronegative partners; however, many caveats such as the potential risk of sexual disinhibition and noncompliance need to be considered. We explored the sociodemographic and behavioral factors associated with the adoption of PrEP among HIV seronegative men who have sex with men and heterosexual partners. METHODS: A
A prepiloted self-administered survey was conducted among seronegative partners in a Ryan White HIV/AIDS Clinic in South Carolina from 2010 to 2011. Bivariate and multivariable analyses were used to explore the data. RESULTS: The survey was completed by 89 seronegative partners. The median age was 42 years (interquartile range 32-50) and a majority was men (56%), black (70%), and heterosexual (74%). A majority (94%) was willing to use PrEP if available; however, 26% of subjects suggested that they would be more likely to have unprotected sex with an HIV-positive partner while using PrEP, and 27% suggested that it would be difficult to take a daily dose of PrEP and consistently use condoms. The multivariable results suggest that the belief that a condom is no longer needed while taking PrEP was more likely among those who did not use a condom during their last sexual intercourse (adjusted odds ratio 7.45; 95% confidence interval 1.57-35.45) and among those with a higher HIV knowledge score (adjusted odds ratio 0.43; 95% confidence interval 0.23-0.78). CONCLUSIONS: Overall, these results suggest high acceptability of PrEP among seronegative partners to lower the risk of HIV transmission; however, there is a substantial risk of sexual disinhibition and noncompliance while using PrEP that may be reduced by ongoing education.


The FDA has approved tenofovir-emtricitabine for use as HIV pre-exposure prophylaxis, but it is unknown how approval may affect PrEP acceptability among US men who have sex with men. We conducted 8 focus groups among 38 Rhode Island MSM, including 3 groups among 16 male sex workers and 5 groups among 22 men in the general MSM community. Participants reported wide-ranging beliefs regarding consequences and meanings of FDA approval. Some participants would not use PrEP without approval, while others perceived approval as irrelevant or less significant than other sources of information. Our results suggest that FDA approval sends a signal that directly shapes PrEP acceptability among some MSM, while indirect influences of approval may affect uptake by others. Efforts to educate MSM about PrEP can increase acceptability by incorporating information about FDA approval, and outreach strategies should consider how this information may factor into personal decisions about PrEP use.


This paper used qualitative methods to explore experiences of men who have sex with men and female sex workers in Nairobi and Mtwapa, Kenya, who used oral pre-exposure prophylaxis (PrEP) for HIV prevention as part of a four-month trial of safety, acceptability and adherence. Fifty-one of 72 volunteers who took part in a randomized, placebo-controlled, blinded trial that compared daily and intermittent dosage of PrEP underwent qualitative assessments after completing the trial. Analyses identified three
themes: (i) acceptability of PrEP was high, i.e. side effects were experienced early in the study but diminished over time, however characteristics of pills could improve comfort and use; (ii) social impacts such as stigma, rumors, and relationship difficulties due to being perceived as HIV positive were prevalent; (iii) adherence was challenged by complexities of daily life, in particular post-coital dosing adherence suffered from alcohol use around time of sex, mobile populations, and transactional sex work. These themes resonated across dosing regimens and gender, and while most participants favored the intermittent dosing schedule, those in the intermittent group noted particular challenges in adhering to the post-coital dose. Culturally appropriate and consistent counseling addressing these issues may be critical for PrEP effectiveness.


Existing trials of antiretroviral (ARV) medication as chemoprophylaxis against HIV reveal that the degree of protection is primarily dependent on product adherence. However, there is a lack of data on targets for behavioral interventions to improve adherence to ARV as prevention. Information from individuals who have used ARV as pre-exposure prophylaxis (PrEP) can inform behavioral intervention development. Thirty-nine HIV-uninfected MSM at high risk for HIV acquisition participated in one of four semi-structured focus groups. Two of the focus groups consisted of MSM who had been prescribed and used PrEP in the context of a clinical trial; the other two consisted of high-risk MSM who had not previously used PrEP. An in-depth, within-case/ across-case content analysis resulted in six descriptive themes potentially salient for a PrEP adherence behavioral intervention: (1) motivations to use PrEP, (2) barriers to PrEP use, (3) facilitators to PrEP use, (4) sexual decision-making in the context of PrEP, (5) prospective PrEP education content, and, (6) perceived effective characteristics of PrEP delivery personnel. Addressing these themes in behavioral interventions in the context of prescribing PrEP may result in the optimal "packaging" public health programs that implement PrEP for high-risk MSM.


OBJECTIVE: To study the acceptability of pre-exposure prophylaxis (PrEP) to prevent the transmission of HIV among men who have sex with men (MSM) in Guangxi, China. METHODS: Snow-ball methods were used to recruit 650 MSM in Guangxi. Questionnaires and interview were administrated to these 650 men, using a self-designed questionnaire and face to face interviews to collect information on HIV-related risk behaviors, knowledge and acceptability of PrEP. RESULTS: After an introduction on PrEP by interviewers, followed by the statement-'If PrEP was effective, safe and free of charge', 597 (91.9%) of the 650 MSM claimed that they would accept it, with the main reason as the recognition of 'PrEP can decrease the risk of HIV infection'. For those who
refused to use it, most of them said that were afraid of the side-effect and doubted on the effectiveness of PrEP. Data from logistic regression analysis showed that those who had found partners through friends (OR = 6.21, P = 0.020) and those who would advise his friend to use PrEP (OR = 39.32, P = 0.000) were more likely to accept PrEP. Those who thought they could protect themselves from HIV infection (OR = 0.32, P = 0.010) or not having sex with the ones who refused to use a condom (OR = 0.34, P = 0.010) were less likely to accept PrEP. CONCLUSION: Effectiveness, safety and cost seemed to be the main influential factors related to the acceptability of PrEP. Peer education might improve the acceptability of PrEP.


OBJECTIVE: We aimed to understand the attitudes, preferences and acceptance of oral and parenteral PrEP among men who have sex with men (MSM) in Thailand.

BACKGROUND: Pre-exposure prophylaxis (PrEP), the use of antiretrovirals to prevent HIV acquisition, has shown promising results in recent trials. To assess the potential impact of this new HIV prevention method, in addition to efficacy data, we need to understand which psychosocial factors are likely to determine its uptake among members of potential user groups. METHODS AND FINDINGS: Surveys of willingness to use PrEP products were administered to MSM. Spearman's rank tests were used to uncover associations between questionnaire items. Mann-Whitney tests were performed to ascertain differences between groups. Conjoint analysis was used to examine the attitudes and preferences of MSM towards PrEP attributes. Most participants were willing to consider taking PrEP (39.2% "yes, definitely" and 49.2% "yes, probably") and perceived PrEP as giving them new possibilities in their lives (38.5% "a lot of hope" and 55.8% "some hope"), even after being instructed of potential side effects and costs. HIV testing was considered the most important attribute and a daily pill and longer lasting injection in the arm were the preferred routes of administration. CONCLUSIONS: Despite its multiple challenges, MSM in Thailand would be willing to take PrEP, even if they had to experience inconvenience and expense. If PrEP were to be implemented in Thailand, our findings show that its uptake could be considerable.


BACKGROUND: Northern Thailand has a high burden HIV epidemic among MSM and TG. Oral pre-exposure prophylaxis (PrEP) with tenofovir-emtricitabine has demonstrated efficacy in preventing HIV among MSM and TG in Chiang Mai, Thailand. Determinants of PrEP acceptability are needed to gauge the potential uptake of this prevention strategy. METHODS: From January to February 2012, 238 MSM and TG participants, who self-reported as HIV-uninfected or of unknown status, completed a self-administered survey on hand-held computers. Participants were recruited by venue-day-time sampling and
asked to rate their likelihood of using oral PrEP for HIV prevention with an efficacy of 50%. PrEP acceptability was defined as being "very likely" to use PrEP. Odds ratios and 95% CIs were calculated to identify correlates of acceptability. RESULTS: 131 MSM and 107 TG responded, with mean ages of 23.7 and 21.8, respectively. 24% of MSM engaged primarily in receptive anal sex vs. 74% of TG. 21% of MSM and 44% of TG reported regular medication use. Prior awareness of PrEP was high at 66% among both MSM and TG respondents. 41% of MSM and 37% of TG were "very likely" to use PrEP. Among MSM, factors associated with PrEP acceptability included a prior history of STIs (AOR 4.6; 95%CIs 1.7-12.6), previous HIV testing (AOR 2.4 95%CIs 1.1-5.3), regularly planned sex (AOR 2.8 95%CIs 1.1-7.2), and infrequent sex (AOR 2.9 95%CIs 1.3-6.3). Among TG, factors associated with acceptability included prior awareness of PrEP (AOR 3.3; 95%CIs 1.2-9.0) and having private insurance (AOR 5.0; 95%CIs 1.3-19.0).

CONCLUSION: MSM and TG in Northern Thailand are distinct groups in terms of sexual behaviors, patterns of medication use, and correlates of PrEP acceptability. Efforts to maximize PrEP uptake should include expanded HIV testing services and the provision of financial subsidies to reduce the cost of PrEP.


Pre-exposure prophylaxis (PrEP), as demonstrated in recently published clinical trials, is one promising approach for controlling the emerging epidemic among men who have sex with men (MSM). We evaluated the attitudes towards use of PrEP among MSM in western China. A total of 1402 participants completed a self-administered questionnaire. Overall, 22% of the participants reported that they had heard of PrEP, <1% had ever used medicine to prevent HIV, and 64% reported that they were absolutely willing to use PrEP if it were proven to be safe and effective. The predictors of willingness to use PrEP included lower education, moderate income compared with the lowest income, never or rarely finding sexual partners through the Internet in the past 6 months, sexually transmitted infection (STI) history, more knowledge of AIDS, worrying about HIV as a threat to themselves and their family, having previously heard of PrEP, and believing that PrEP was effective in preventing HIV. This study demonstrates that Chinese MSM have moderate awareness of PrEP and a high interest in using it.


Objective To investigate the attitude on pre-exposure prophylaxis (PrEP) among drug users from high-risk population of AIDS in western China and its influencing factors. Methods A total of 190 drug users were recruited by snowball sampling from high-risk population of AIDS including those involved in men having sex with men (MSM), female sex workers(FSW) and the spouse or sex partner (PAR) of HIV carrier in Chongqing, Sichuan, Guangxi and Xinjiang. Self-ad ministered questionnaire survey was
conducted with the assistance of investigators. Univariate and multivariate logistic regression was employed for statistical analysis. Results MSM, FSW and PAR accounted for 34.74% (66/190), 48.42% (92/190) and 16.84% (32/190) among the 190 drug users, respectively. The positive attitude rate for PrEP among drug users reached 70% in the premise of drug safety and effectiveness, which increased with favorable condition provided. The results of multivariate logistic regression analysis indicated that the factors significantly associated with the positive attitude for PrEP included awareness of AIDS seriousness (OR = 2.66, 95% CI: 1.14-6.25, P = 0.0242), attitudes towards HIV patients (OR = 4.41, 95% CI: 1.68-11.58, P = 0.0026, OR = 2.99, 95% CI: 1.05-8.54, P = 0.0403) and virus detection of AIDS (OR = 1.94, 95% CI: 0.98-3.87, P = 0.0581). Conclusion The attitude for PrEP among drug users from AIDS high-risk population is mainly related to the attitude for AIDS, AIDS-related knowledge and behavior, and preventive measures for AIDS, indicating that PrEP should be implemented and promoted with a sound social background, and education on HIV/AIDS prevention should be reinforced. Positive attitude towards AIDS prevention need to be developed among drug users by various behavioral therapies, so as to improve the attitude for PrEP among drug users with high HIV risks.


OBJECTIVE: We investigated the awareness and acceptability of pre-exposure prophylaxis (PrEP) among men who have sex with men (MSM) and potential predicting factors. METHODS: This study was conducted among MSM in Beijing, China. Study participants, randomly selected from an MSM cohort, completed a structured questionnaire, and provided their blood samples to test for HIV infection and syphilis. Univariate logistic regression analyses were performed to evaluate the factors associated with willingness to accept (WTA) PrEP. Factors independently associated with willingness to accept were identified by entering variables into stepwise logistic regression analysis. RESULTS: A total of 152 MSM completed the survey; 11.2% had ever heard of PrEP and 67.8% were willing to accept it. Univariate analysis showed that age, years of education, consistent condom use in the past 6 months, heterosexual behavior in the past 6 months, having ever heard of PrEP and the side effects of antiretroviral drugs, and worry about antiretroviral drugs cost were significantly associated with willingness to accept PrEP. In the multivariate logistic regression model, only consistent condom use in the past 6 months (odds ratio [OR]: 0.31; 95% confidence interval [CI]: 0.13-0.70) and having ever heard of the side effects of antiretroviral drugs (OR: 0.30; 95% CI: 0.14-0.67) were independently associated with willingness to accept PrEP. CONCLUSIONS: The awareness of PrEP in the MSM population was low. Sexual behavioral characteristics and knowledge about ART drugs may have effects on willingness to accept PrEP. Comprehensive prevention strategies should be recommended in the MSM community.

43. **Background:** MSM increasingly meet sex partners, and get health information, on line. To better understand their response to the first PrEP efficacy data, online surveys of HIV-uninfected American MSM were conducted before and after the iPrEx publication

**Methods:** MSM members of a large sexual/social networking site were invited to complete a survey about PrEP knowledge, interest and experience in September-October, 2010 and January, 2011. Chi squares were use to compare attitudes before and after iPrEx release.

**Results:** Pre-iPrEx, 458 MSM responded to the survey, and afterwards, 4,325 did. Their median age was 40. Most participants were Caucasian (83.6%). Most of the MSM had completed high school (93.6%). Most (73%) reported at least one unprotected anal sex episode in the prior 3 months. MSM surveyed after iPrEx data release were much more likely to have heard about PrEP than those surveyed before (18.6% vs. 12.7%, p< .05). The majority reported they were likely to use PrEP if it were available either time (78.4% vs. 76.9%, NS). Only 0.8% of post-iPrEx men reported having already used PrEP, and only 1.8% had used PEP. More than 80% of the men in either wave indicated they did not think they would decrease condom use during anal sex while taking PrEP. Although most men (82.0%) had a primary care provider, the majority (66.5%) had not discussed having anal sex without condoms with providers. The men's preference's for obtaining PrEP included their primary care providers (40.9%), other healthcare settings (22.7%) or via the internet (28.3%).

**Conclusion:** The majority of these high risk MSM were not familiar with PrEP. Programs designed to educate providers in risk assessment are needed if chemoprophylaxis is to have an impact in arresting the spread of HIV among MSM. The use of sexual/social networking sites to educate at risk MSM about PrEP could facilitate appropriate use.


**Background:** In November 2010, iPrEx results were published demonstrating a 44% reduction in HIV infections in MSM given daily tenofovir/emtricitabine (TDF/FTC). In the trial, behavioral risk declined as participants were given a comprehensive prevention package. However, with known efficacy, risk compensation could undermine benefits.

**Methods:** We administered an online survey to US MSM recruited from Facebook and
Black Gay Chat from 11/30/10-12/14/10. Participants were told about PrEP efficacy and answered questions about risk practices with/out TDF/FTC. We used logistic regression to identify correlates of risk perception and pressure to have unprotected anal sex with/out TDF/FTC.

Results: Overall, 1,155 HIV-negative MSM responded: 73% white, 7% African-American, 12% Hispanic. Mean age was 33 and 38% completed college. Seven percent anticipated less frequent condom use with PrEP, 75% anticipated no change in condom use, 8% anticipated more condom use, and 10% wouldn't use PrEP. However, 21% perceived less risk of HIV infection from unprotected anal insertive sex (UAI) and 39% perceived less risk from unprotected anal receptive sex (UAR) with PrEP versus no PrEP. Likelihood of PrEP use was positively associated with perceptions that PrEP decreases HIV risk of both UAI (AOR=1.63; 95%CI 1.20-2.21) and UAR (AOR=1.88; 95%CI 1.46-2.42). One-third believed they would feel increased pressure from others to have unprotected anal sex were they on PrEP; these individuals were more likely to have completed college (AOR=1.55; 95%CI 1.14-2.10), used a condom during last anal sex (AOR=1.48; 95%CI 1.11-1.98), and not have been HIV-tested in the last 12 months (AOR=1.44; 95%CI 1.08-1.93), controlling for age and race.

Conclusion: PrEP offers promise. Most respondents did not anticipate changing their risk practices on PrEP but there was a substantial minority that might adjust their risk practices, potentially offsetting benefit. It will be important to educate MSM populations on PrEP’s partial efficacy and offer ongoing risk reduction counseling.


Background: The use of PrEP to prevent HIV acquisition among people at high-risk is one of the prevention tools that would be operationally implemented in public-health funded settings. Barriers for implementing PrEP include willingness to use, associated costs, periodic health monitoring among others factors. This study investigates the perception and willingness of using PrEP among MSM with high-risk sexual behaviors in Lima, Peru.

Methods: A counselor-driven structured interview sub-study was included into a HIV Sentinel Surveillance conducted in Lima, Peru in June-October 2011. In this survey, MSM with high-risk sexual behavior who were unaware of their HIV serostatus, participated in this survey for the assessment of HIV and syphilis status, and demographics and sexual behavior patterns. Topics assessed for this sub-study included perceptions and willingness to use daily oral PrEP. Logistic regression was used to study factors associated with willingness to use PrEP as a HIV prevention strategy.

Results: Among the 495 participants enrolled, 323 (65.3%) considered at least probable that they will use PrEP aimed to prevent HIV infection. In a multivariate analysis, having pressure to have unprotected anal sex was associated with 50% reduction in the odds of
willingness to use PrEP (OR=0.51, 95% CI: 0.26-1.13). Similarly, men, who consider that unprotective receptive anal sex increase their levels of pleasure, were 47% less likely to consider using PrEP (OR=0.54, 95% CI: 0.28-0.91). Other factors such as age, and education were not independently associated with willingness to use PrEP.

**Conclusions:** Before considering PrEP as an HIV prevention intervention, it is important to study and understand concerns and fears in the target population.


**Background:** The iPrEx study demonstrated that pre-exposure prophylaxis (PrEP) can reduce HIV incidence among at-risk men who have sex with men (MSM). However, risk compensation (RC) could negate the benefits of PrEP.

**Methods:** After the release of iPrEx results, North American members (n=5035) of an Internet social network for MSM completed an online survey regarding PrEP. Demographics, sexual risk behaviors, PrEP interest, and anticipated RC with PrEP use were assessed through self-report. Multivariable logistic regression procedures adjusted for age, race/ethnicity, and education examined the association between sociodemographic variables, sexual risk behaviors and anticipated RC.

**Results:** The mean age was 39 (SD=12.8), 90% were from the US, 84% were homosexual/gay and 84% were white. Ninety-three percent completed some college, 68% earned ≥$30,000/year, 25% had a history of depression, and 5% had received substance abuse treatment. Sixty-one percent indicated unprotected anal intercourse with ≥1 male partner in the prior 3 months (UAI-3), and 24% reported UAI after ≥5 drinks. On a scale of 1 (no risk) to 10 (high risk), the average self-perceived risk of HIV acquisition was 3.3 (SD=2.3). Seventy-five percent reported interest in using PrEP. While using PrEP, 20% anticipated they would decrease condom use for insertive anal sex, whereas 14% indicated they would for receptive anal sex. Factors associated with increased odds of anticipated RC for insertive anal sex were UAI-3 (aOR=1.58; 95% CI: 1.22-2.04; p=0.0005) and prior substance abuse treatment (aOR=2.04; 95% CI: 1.32-3.16; p=0.002). Factors associated with increased odds of anticipated RC for receptive anal sex were UAI-3 (aOR=1.57; 95% CI:1.16-2.13; p=0.004), UAI after ≥5 drinks (aOR=1.43; 95% CI: 1.09-1.88; p=0.01) and increased self-perceived risk of HIV acquisition (aOR=1.10; 95% CI: 1.05-1.17; p=0.0003).

**Conclusions:** A substantial minority of MSM using an Internet social network anticipate increased unprotected anal sex with PrEP use. Interventions to minimize risk compensation are warranted.

**Background:** Gay men and other men who have sex with men (Gay/MSM) have disproportionately higher risk for HIV infection globally. Although PrEP and HIV treatment hold significant HIV prevention potential for gay/MSM, little is known about barriers and facilitators of access to these interventions.

**Methods:** In April 2012, a convenience sample of 2,197 self-identified gay/MSM (Global South (GS)=67%; Global North (GN)=33%) was recruited to complete a 30-minute global online survey. Survey announcements were circulated online among community-based organizations and regional networks serving gay/MSM worldwide, and web banners posted on regionally popular gay/MSM websites. We used multivariable linear and logistic regression to examine social/structural predictors of PrEP acceptability and access to HIV-related services.

**Results:** Compared to GN, GS respondents reported 1) lower PrEP knowledge (p< .005) but higher PrEP acceptability (p< .005); and 2) less access to HIV-testing (p< .005), HIV treatment (p< .025), condoms (p< .005), and lubricants (p< .005). Among HIV-negative respondents, PrEP acceptability was associated with the following scales (each ranging from 1 to 5): PrEP knowledge (β= -0.137 95%CI: [-0.2; -0.07]), perceived stigma related to PrEP (β=0.516 [-0.57; 0.46]); and being "out" as a gay man/MSM (β=0.201 [-0.27; 0.14]). HIV testing access was associated with: connection to gay community (AOR=1.3 [1.1;1.6]), and comfort with provider (AOR=1.8 [1.5;2.1]). Among HIV-positive men, homophobia was associated with decreased odds of HIV treatment access (AOR=0.5 [0.3;0.8]). Adjusting for facilitators and barriers, compared to high-income countries, respondents in middle-income countries had lower odds of HIV testing access (AOR=0.4 [0.3;0.6]); and respondents in low and middle-income countries had lower odds of access to condoms (AOR=0.6 [0.5;0.9]); and lubricants (AOR=0.4 [0.3;0.6]).

**Conclusions:** Implementation planning for new prevention strategies like PrEP should account for social/structural factors impacting access to HIV prevention and treatment services among gay/MSM, with particular attention to needs of gay/MSM living in the global south, especially low and middle-income countries.


**Background:** Results from a Pre-Exposure Prophylaxis (PrEP) clinical trial revealed that a daily dose of Truvada, a medication typically used to treat HIV infections, was 42% effective in preventing infections among sexually active Men who have Sex with Men
(MSM) and transgender people. AIDS Healthcare Foundation (AHF) implemented a study to better understand the acceptability of PrEP among the aforementioned populations.

**Methods:** AHF developed an online questionnaire to assess the acceptability of PrEP. A third-party marketing research firm was hired to conduct this survey. Participants were screened for eligibility; inclusion criteria required that respondents were over 18 years old, and identified as gay, bisexual, MSM and/or transgender. Participation was voluntary.

**Results:** The survey was completed by 822 male and transgender respondents representing racially diverse backgrounds: 32% White, 30% Hispanic/Latino, 15% Black/African American, and 23% Asian/Pacific Islander or Native American. The majority of respondents, 51%, were between 30 and 54 years old. A total of 665 respondents (81%) reported being sexually active, of these, 24% reported never or rarely using a condom. Overall, 79% of participants said they would be willing to take a pill daily that was > 90% effective at preventing HIV infections. The acceptability reduced to 69% when participants were asked about taking the pill every day and getting monthly HIV/STD tests. Participants were asked about acceptability of paying a $60 co-pay to cover the cost of the medication and labs each month; under this stipulation, only 41% stated that they would be willing to take a pill to prevent HIV.

**Conclusions:** Attitudes towards a pill under 'real life' conditions including co-pays, doctor's visits and labs, decreased acceptability substantially. More in-depth research is necessary to understand the acceptability of PrEP, given that clinical trials have only shown to be 42% effective in preventing HIV infections.


**Background:** Following the publication of the iPrEx study showing partial efficacy of Pre-Exposure Prophylaxis (PrEP), we assessed whether men who have sex with men had heard about PrEP, and what they knew and thought about it.

**Methods:** An ethnically diverse group of 480 men who reported having had sex with other men in the preceding six months participated in a street-intercept survey during New York City's 2011 Gay Pride events.

**Results:** Over a third of all men (38.8%) had heard of PrEP; men who were Black and HIV-positive were most likely to have heard of PrEP. Substantial proportions of men, ranging from 25.0% to 40.9%, answered “Don't know” to attitude and knowledge questions. More than half of the men (58.4%) thought PrEP use should be encouraged, while 32.5% did not know; Latino men were most likely and White men least likely to support encouraging use. Men who did not endorse encouraging PrEP were more likely than those who supported encouragement or did not know to think that if PrEP became
available, gay men would stop using condoms. A substantial proportion of men (50.9%) said it was (very) likely that they would use PrEP if it became easily available while 14.1% did not know. Compared to other ethnic/racial groups, White men were the least likely to say they would use PrEP (38.1%). Men who considered themselves at high risk for HIV infection would be more likely to use it (81.4%) compared to men at low or no risk (46.7% and 46.5%, respectively). Men who thought that PrEP has a lot of side effects were the least likely to say they would use it.

**Conclusions:** While there is interest in PrEP as an HIV prevention strategy, findings indicate a strong need for informational campaigns targeting potential PrEP users.


**Background:** Post-exposure prophylaxis (PEP) and Pre-exposure prophylaxis (PrEP) of antiretroviral medications have decreased the risk of HIV-infection in observational studies and randomized controlled trials. As PEP and PrEP are rolled out, it is imperative to assess awareness and interest for PEP and PrEP among populations disproportionately impacted by HIV, including MSM.

**Methods:** In 2010, we conducted a global online survey (in Chinese, Russian, Spanish, French, and English) among 5,046 MSM and collected data on PrEP and PEP knowledge and interest; access to basic HIV prevention services; perceived levels of external homophobia and self-esteem. We used multivariable logistic regression to evaluate predictors of knowledge and interest for PrEP and PEP, controlling for age and HIV-status, and excluding health providers.

**Results:** “No knowledge” of PEP and PrEP was reported by 53% and 60% of MSM, respectively. “Strong interest” in the use of PEP and PrEP to prevent HIV was reported by 70% and 74% of MSM, respectively. Knowledge of PEP was associated with older age(AOR=1.2[95% CI=1.1-1.3]), region(Asia: AOR=0.3[0.3-0.4]; Central/South America/Caribbean: AOR=0.64[0.4-0.9]), and basic HIV prevention access(AOR=1.5[1.4-1.7]). Knowledge of PrEP was associated with older age(AOR=1.3 [1.1-1.4]), region(Asia: AOR=0.7[0.5-0.9]), and basic HIV prevention access(AOR=1.4 [1.3-1.6]). Strong interest in PEP was associated with younger age(AOR=0.7[0.7-0.8]), region(Asia=AOR 5.0[3.0-8.2]); Central/South America/Caribbean: AOR=3.0[2.2-4.0]), and basic HIV prevention access(AOR=0.7[0.6-0.8]), having sex with men only(AOR=1.6[1.1-2.5]), perceived external homophobia(AOR=1.4[1.2-1.7]), and self-esteem(AOR=1.6[1.2-2.1]). Strong interest in PrEP was associated with younger age(AOR=0.8[0.7-0.9]), region(Asia: AOR=1.9[1.4-2.5]; Central/South America/Caribbean: AOR=3.8[2.2-6.4]) lower access to basic HIV prevention interventions(AOR=0.8[0.6-0.9]), external homophobia(AOR=1.3[1.1-1.5]), and self-
Conclusions: In this sample, there was consistency in the predictors for knowledge and interest across PEP and PrEP. Although knowledge of PEP and PrEP were limited, there is considerable interest in the use of PEP and PrEP to prevent HIV. Efforts to disseminate information about PEP and PrEP are strongly desired and needed by MSM.

51. M. Mimiaga, K. Biello, D. Novak, J. Rosenberger, K. Mayer. MSM in Latin America, Spain and Portugal using an internet social networking site have limited awareness but high interest in pre-exposure prophylaxis to prevent sexual acquisition of HIV. IAS 2013

Background: Antiretroviral pre-exposure prophylaxis (PrEP) has the promise to reduce HIV acquisition for uninfected individuals. Internationally, use, awareness and interest in PrEP are largely unknown. We assessed awareness, prior use, and interest in PrEP among men who have sex with men (MSM) using an online survey across Latin America, Spain and Portugal.

Methods: Active members of a popular MSM internet social networking site in Latin America, Spain and Portugal were invited to participate in a cross-sectional, internet-based survey focused on sexual health. Logistic regression analyses were performed to identify factors associated with PrEP awareness, reported use and interest among 36,477 participants.

Results: Most participants were educated, middle-class and lived in urban areas. Sixty-seven percent had a physical examination with a healthcare provider in the past year and 75% had ever had an HIV test. Fifty-five percent of men reported condom use during most recent intercourse. Awareness of PrEP was limited (11%) and reported prior use was low (< 1%). Interest in participating in a PrEP trial was high (69%). In multivariate models, significant (p < 0.05) predictors of PrEP awareness were: older age, having had a physical exam, ever having HIV test, recent condom use, prior PrEP use, higher perceived PrEP effectiveness and preference for participating in a PrEP trial (vs. HIV vaccine study). Significant multivariate predictors of PrEP use were: awareness of PrEP, higher perceived PrEP effectiveness and preference for participating in a PrEP trial. Significant multivariate predictors of interest in participating in a PrEP trial were: younger age, living in Latin America, higher perceived PrEP effectiveness, preference for participating in a PrEP trial, and willingness to use an HIV home test.

Conclusions: Similar to research in the United States, PrEP use was low and awareness was limited among MSM members of an online networking site. Importantly, interest in PrEP was substantial with MSM who were younger, lived in Latin America and believed that PrEP was very effective being more interested in participating in a PrEP trial. Increasing knowledge of PrEP effectiveness may promote interest in, assist in future delivery of, and increase subsequent utilization of PrEP among high-risk MSM.
Perceptions of HIV pre-exposure prophylaxis use vary among white and black men who have sex with men. IAS 2013.

**Background:** HIV pre-exposure prophylaxis (PrEP) is efficacious at preventing HIV infection among men who have sex with men (MSM), but to realize maximum impact, we must understand patient perceptions of PrEP. Because HIV disproportionately impacts black MSM in the United States, we must also understand whether perceptions vary by race.

**Methods:** InvolvEMENt is a prospective cohort study to explain HIV infection disparities between black and white MSM in Atlanta. Current PrEP use is assessed at each follow-up visit. Knowledge and perceptions were assessed at either baseline or a single follow-up visit.

**Results:** Of 422 MSM enrolled, 1 is using PrEP, 23% (97/422) had heard of PrEP, and 44% (185/422) were interested in using PrEP. Knowledge and interest did not significantly differ by race, but reasons for PrEP interest/disinterest significantly differed (Table 1). White MSM were more likely to report that a provider or counselor recommendation would increase their interest. White MSM were more likely to be disinterested because they thought their partner was HIV negative or they did not want to see a doctor every 3 months. Black MSM were more likely to be disinterested because they were not sexually active. Many MSM who were initially disinterested in PrEP said that more research showing PrEP was more effective and insurance coverage of PrEP would potentially change their interest. White MSM were more likely to report changes in sexual partners as a reason to change their interest. Most participants (58%, 146/422) were willing to pay ≤$25/month for PrEP.

**Conclusions:** Many MSM were interested in using PrEP, but the reasons for interest and disinterest varied between black and white MSM and may require targeted messaging. Many common patient perceptions regarding PrEP are related to personal risk assessment or structural barriers that may be assuaged with improved information and support tools.

**Attitudes towards pre-exposure prophylaxis (PrEP) among MSM in Germany. IAS 2013.**

**Background:** Use of PrEP is being widely discussed with different approaches being taken in various guidelines. We wanted to examine risk behavior, PrEP awareness and use, as well as attitudes towards PrEP among MSM in Germany.

**Methods:** Data were collected from July-Dec. 2012 via an on-line questionnaire. Pamphlets, distributed on Christopher Street Day, through HIV medical centers and NGOs, as well as an interview in a gay magazine were used to inform potential participants of the survey.
Results: 329 MSM (median age 41 yrs.; 22% HIV+, 37% HIV-, 41% unknown HIV-status) participated in the survey. 60.1% reported no risk behavior, while 31.7% reported having 1-5 risk contacts/month, 4.3% 6-10 contacts and 4% >10 contacts. 58.1% had heard of PrEP, 5.5% (n=18) had used it. PrEP awareness was associated with HIV status (53.7% of HIV- vs. 83.1% of HIV+ persons, p< 0.001). PrEP use was associated with number of monthly risk contacts (p< 0.001). Of the 18 persons with a history of PrEP use, 13 indicated medication use as follows: TDF and FTC (n=13) either alone or with DRV/r (n=1), EVF (n=3), NVP (n=1) or RPV (n=2). The extent of PrEP use was evenly distributed between 1-5 times, 6-10 times and >10times. Investigating attitudes towards PrEP in all participants (n=329), one-quarter (24.9%) reported not wanting to use it (37.5% of the HIV+, 42.2% of the HIV-, 2.9% of HIV-unknown population, p< 0.001), 55.6% would use it on an as-needed basis, 19.5% would use it daily. This differed significantly for those persons with a PrEP use history, 61.1% of who would prefer daily use (p< 0.001). With PrEP, 44.7% stated they would omit condom use (55.6% of HIV+ vs. 27.4% of HIV- individuals, p< 0.001) with a subsequent increase in quality of life expected by 83.6%. When asked about PrEP costs, most participants expect them to be either < €200 (35.6%) or > €500 (31.5%).

Conclusions: We found that >50% of MSM were aware of PrEP and >75% would be willing to use it. These findings indicate an urgent need for more information on PrEP.


Background: Recent results of PrEP, Microbicides and vaccine trials have received mixed reactions at community level. Studies have shown successful introduction of health products is often affected by community perceptions and delivery preferences. We documented community preferences for New Prevention Technologies (NPT) in Kenya. Methods: Respondents across 4 regions, 3 groups of key populations, government health officials and trainers were invited to participate in a workshop on NPT throughout 2012. A questionnaire was administered after each workshop and followed by FGDs. Quantitative data was analyzed using Ms Access 2007 and stata version 11. FGD tapes and notes were transcribed and analyzed by two independent researchers who identified key emerging concepts and themes.

Results: 42% of respondents (N=158) were involved in HIV/AIDS for more than 5 years and 20% were involved in NPT research and advocacy for more than 5 years. 62% reported having a fairly good knowledge of the HIV vaccine field and discourse of the recent results against 51% for microbicides and 50% for PrEP. The minimal efficacy level that most respondents would be comfortable to advocate for introduction and use in their community was 74% for vaccines, 71% for microbicides and 76% for PreP. The
majority of respondents preferred microbicide gels (78%), injectable vaccines (69%) and injectable PrEP (67%). However, higher preference for microbicides ring was noted with SW and oral vaccine and oral PrEP with MSM. The highest preference for product regimen was every 5 years for a vaccine (64%), before and after sex for microbicides (61%), and twice a week for PrEP (59%) with varied preferences between key populations. Most preferred service delivery modes for all NPTs were existing health centers followed by family planning /HIV centers. Vaccine was selected as preferred NPT across key populations but was equally ranked with microbicides for heterosexual women. Microbicides were ranked second across most key populations. PrEP was ranked highest for discordant couples, MSM and MSW. Choices were guided by product characteristics, expected cost, accessibility, inclusivity, side-effect, efficacy and associated stigma.

**Conclusion:** Understanding evolving community preferences should be proactive and conducted in sync with socio-behavioral data conducted at trial and demonstration projects.

**Background- Related to Values and Preferences of Providers (n=6 articles and 1 conference abstract)**


BACKGROUND: A recent clinical trial demonstrated that a daily dose tenofovir disoproxil fumarate and emtricitabrine (TDF-FTC) can reduce HIV acquisition among men who have sex with men (MSM) and transgender (TG) women by 44%, and up to 90% if taken daily. We explored how medical and service providers understand research results and plan to develop clinical protocols to prescribe, support and monitor adherence for patients on PrEP in the United States. METHODS: Using referrals from our community collaborators and snowball sampling, we recruited 22 healthcare providers in San Francisco, Oakland, and Los Angeles for in-depth interviews from May-December 2011. The providers included primary care physicians seeing high numbers of MSM and TG women, HIV specialists, community health clinic providers, and public health officials. We analyzed interviews thematically to produce recommendations for setting policy around implementing PrEP. Interview topics included: assessing clinician impressions of PrEP and CDC guidance, considerations of cost, office capacity, dosing schedules, and following patients over time. RESULTS: Little or no demand for PrEP from patients was reported at the time of the interviews. Providers did not agree on the most appropriate patients for PrEP and believed that current models of care, which do not involve routine frequent office visits, were not well suited for prescribing PrEP. Providers detailed the need to build capacity and were concerned about monitoring side effects and adherence. PrEP was seen as potentially having impact on the epidemic but providers also noted that community education campaigns needed to be tailored to effectively reach specific vulnerable populations. CONCLUSIONS: While PrEP may be a novel and
clinically compelling prevention intervention for MSM and TG women, it raises a number of important implementation challenges that would need to be addressed. Nonetheless, most providers expressed optimism that they eventually could prescribe and monitor PrEP in their practice.


Antiretroviral pre-exposure prophylaxis (PrEP) has received increasing recognition as a viable prescription-based intervention for people at risk for HIV acquisition. However, little is known about racial biases affecting healthcare providers’ willingness to prescribe PrEP. This investigation sought to explore medical students’ stereotypes about sexual risk compensation among Black versus White men who have sex with men seeking PrEP, and the impact of such stereotypes on willingness to prescribe PrEP. An online survey presented participants (n = 102) with a clinical vignette of a PrEP-seeking, HIV-negative man with an HIV-positive male partner. Patient race was systematically manipulated. Participants reported predictions about patient sexual risk compensation, willingness to prescribe PrEP, and other clinical judgments. Bootstrapping analyses revealed that the Black patient was rated as more likely than the White patient to engage in increased unprotected sex if prescribed PrEP, which, in turn, was associated with reduced willingness to prescribe PrEP to the patient.


Background. Preexposure prophylaxis (PrEP) with tenofovir disoproxil fumarate and emtricitabine (Truvada) has demonstrated efficacy in placebo-controlled clinical trials involving men who have sex with men, high-risk heterosexuals, serodiscordant couples, and intravenous drug users. To assist in the real-world provision of PrEP, the Centers for Disease Control and Prevention (CDC) has released guidance documents for PrEP use. Methods. Adult infectious disease physicians were surveyed about their opinions and current practices of PrEP through the Emerging Infections Network (EIN). Geographic information systems analysis was used to map out provider responses across the United States. Results. Of 1175 EIN members across the country, 573 (48.8%) responded to the survey. A majority of clinicians supported PrEP but only 9% had actually provided it. Despite CDC guidance, PrEP practices were variable and clinicians reported many barriers to its real-world provision. Conclusions. The majority of adult infectious disease physicians across the United States and Canada support PrEP but have vast differences of opinion and practice, despite the existence of CDC guidance documents. The success of real-world PrEP will likely require multifaceted programs addressing barriers to its provision and will be assisted with the development of comprehensive guidelines for real-world PrEP.

The role of men who have sex with men (MSM) in the African HIV epidemic is gaining recognition yet capacity to address the HIV prevention needs of this group is limited. HIV testing and counselling is not only a critical entry point for biomedical HIV prevention interventions, such as pre-exposure prophylaxis, rectal microbicides and early treatment initiation, but is also an opportunity for focused risk reduction counselling that can support individuals living in difficult circumstances. For prevention efforts to succeed, however, MSM need to access services and they will only do so if these are non-judgmental, informative, focused on their needs, and of clear benefit. This study aimed to understand Kenyan providers’ attitudes towards and experiences with counselling MSM in a research clinic targeting this group for HIV prevention. We used in-depth interviews to explore values, attitudes and cognitive and social constructs of 13 counsellors and 3 clinicians providing services to MSM at this clinic. Service providers felt that despite their growing experience, more targeted training would have been helpful to improve their effectiveness in MSM-specific risk reduction counselling. They wanted greater familiarity with MSM in Kenya to better understand the root causes of MSM risk-taking (e.g., poverty, sex work, substance abuse, misconceptions about transmission, stigma, and sexual desire) and felt frustrated at the perceived intractability of some of their clients’ issues. In addition, they identified training needs on how to question men about specific risk behaviours, improved strategies for negotiating risk reduction with counselling clients, and improved support supervision from senior counsellors. This paper describes the themes arising from these interviews and makes practical recommendations on training and support supervision systems for nascent MSM HIV prevention programmes in Africa.


Oral pre-exposure prophylaxis (PrEP) was the first biomedical intervention to demonstrate efficacy in preventing HIV infection among men who have sex with men (MSM). Healthcare providers attitudes toward PrEP will be critical in translating this finding into effective public health rollout programs. In a convenience sample of 186 healthcare providers in Peru, we assessed knowledge, barriers, and attitudes to prescribe and monitor HIV PrEP for high-risk MSM and transgender women (TGW), the populations with the highest HIV incidence in this setting. 57.5% reported awareness of PrEP, and awareness was independently associated with caring for more than 50 MSM (OR: 3.67, p<.002). Lack of local guidelines, concern about increased high-risk behavior, antiretroviral drug resistance, and limited availability of antiretrovirals for HIV-infected individuals were the most common barriers to prescribing PrEP. 44.6% of all physicians indicated that they would be likely to prescribe oral PrEP now; likelihood to prescribe
was higher if PrEP were supported by local guidelines (70.3%, p<.001), if more trials supported its effectiveness (68.5%, p<.001), and if intermittent use were shown to be effective (62.2%, p=.019). Physicians were more likely to prescribe PrEP now if they care for more than 50 MSM (OR: 6.62, p=.010). Infectious Disease (ID) specialists were less likely to prescribe PrEP (OR: .10, p=.003) than non-specialists. Successful large-scale implementation of PrEP in Peru will require focused educational campaigns to increase awareness and address concerns among healthcare providers.


Antiretroviral medications can be taken by HIV-negative persons to prevent HIV infection, also known as pre-exposure prophylaxis (PrEP). PrEP was first shown to be effective during the iPrEX study. We conducted a survey involving HIV healthcare providers to document their attitudes and prescribing practices about PrEP in response to this study. An online survey was completed by 189 members and credentialed physicians of the American Academy of HIV Medicine between April 2011 and September 2011. Ninety percent of respondents were familiar with the results of the iPrEx study, and most (78%) were familiar with CDC’s interim guidance regarding the use of PrEP in MSM. Only 19% of respondents had prescribed PrEP. The majority of PrEP prescribers were compliant with CDC interim guidance; however, only 61% screened for hepatitis B. Of PrEP prescribers, 78% prescribed to MSM, 31% to MSW, and 28% to WSM. Greatest concerns about prescribing PrEP included development of antiretroviral resistance (32%), potential increase in high-risk behavior, (22%) and poor medication adherence (21%). Fifty-eight percent stated that HIV serodiscordance within a relationship most influenced their decision to prescribe PrEP to the HIV-seronegative partner. This study demonstrates that, despite awareness of the efficacy of PrEP, its use is limited. Survey participants used PrEP most commonly in MSM; however, a significant percentage also prescribed PrEP to women. The best candidate for PrEP is felt to be individuals in an HIV-serodiscordant relationship. Limitations to our study included a low response rate, changes in the evidence base, and the novelty of PrEP.


Background: Recent studies in men who have sex with men (MSM), heterosexual men and women, and serodiscordant couples at high-risk for HIV infection demonstrated efficacy of PrEP in reducing HIV acquisition. PrEP initiation requires monitoring for side effects, regular risk reduction counseling, and HIV testing. Effective and safe use will be limited in clinical practice if healthcare providers are not knowledgeable about risks and benefits of this strategy. Data on providers' attitudes and experience in prescribing antiretrovirals for prevention are limited.

Methods: An anonymous web-based survey was administered to HIV and non-HIV
providers in NYC to assess knowledge about, and willingness to prescribe, PrEP to high-risk populations. HIV and non-HIV providers' responses were compared using Chi square and Fisher's exact tests; variables associated with willingness to prescribe PrEP were assessed using multivariable logistic regression.

**Results:** 47.7% (83/174) were Internal Medicine practitioners; 15% Infectious Disease specialists; 54% identified as both HIV and non-HIV providers; 29.4% practice in non-academic community-based clinics. A high degree of knowledge of post-exposure prophylaxis (PEP) but lower awareness of PrEP was found. 69% of respondents had heard of PrEP; only 9.8% had prescribed it. Of those who had prescribed PrEP, majority (15/17, 88.2%) were physicians who care for over 100 HIV-positive patients and MSM. HIV providers were more likely to be knowledgeable about PrEP (OR=6.04, 95% CI 1.37-26.7) compared to non-HIV providers. The most common concerns about prescribing PrEP were limited clinical trials demonstrating its efficacy, lack of formal Center for Disease Control and Prevention or Department of Health guidelines, and development of antiretroviral resistance.

**Conclusions:** These results highlight the importance of increasing awareness and knowledge of PrEP among providers. Further clinical trial data demonstrating PrEP efficacy as well as formal CDC guidelines may alleviate concerns regarding PrEP use.

**Background- Predictors of PrEP Use (n=3 articles and 2 conference abstracts)**


OBJECTIVES: To understand the factors associated with knowledge of non-occupational post-exposure prophylaxis (nPEP) and pre-exposure prophylaxis (PrEP), bathhouse patrons in New York City (NYC) were surveyed. METHODS: 554 men who have sex with men (MSM) at two NYC bathhouses were given a standardised survey focused on nPEP and PrEP at the time of HIV testing. RESULTS: In the previous 90 days, 63% of respondents reported unprotected sex with a male partner and 7% reported any sex with a known HIV-positive male partner. Less than half reported having a primary provider (primary care practitioner) who was aware of their MSM behaviour. 201 men (36%) were aware of nPEP or PrEP. In univariate analyses, race/ethnicity, previous HIV testing, gay self-identification, higher education level, having a primary provider aware of MSM behaviour, reported interaction with the healthcare system, use of the internet for meeting sex partners, reporting unprotected sex in the previous 90 days, reporting any sex with an HIV-positive male partner in the previous 90 days and having a higher number of sex partners were each significantly associated with being aware of nPEP or PrEP. In multivariate analysis, having a higher number of sex partners was significantly associated (OR 5.10, p=0.02) with post-exposure prophylaxis (PEP)/PrEP knowledge and disclosure to a primary care provider was also associated, although less robustly (OR 2.10, p=0.06). CONCLUSIONS: Knowledge of nPEP or PrEP among sexually active MSM in NYC is low and is associated with having a primary provider aware of their patient's same-sex
behaviours. These findings show the need for improving education about nPEP among high-risk MSM in NYC and the role of providers in these efforts.


BACKGROUND: We aimed to describe the current use of antiretroviral medications (ARVs) before unprotected anal intercourse (UAI) among Australian gay men, which may represent informal HIV pre-exposure prophylaxis (PrEP). METHODS: Using data from Australian Gay Community Periodic Surveys conducted in 2011, we assessed the preventive use of ARVs before UAI and its association with socio-demographic characteristics, and sexual practices and drug use in the preceding six months. Associations were assessed using multivariate logistic regression analysis. RESULTS: Of 3,677 sexually active, non-HIV positive men, 2.5% reported taking ARVs before UAI. The likelihood of ARV use before UAI was significantly higher if any of the following behaviours were also reported: more than one sex partner; UAI with casual partners, irrespective of reporting UAI with regular partners (Adjusted Odds Ratio (AOR)=2.36; 95%CI: 1.24-4.48) or not (AOR=2.71; 95%CI: 1.44-5.07); injecting drugs at least monthly (AOR=2.56; 95%CI: 1.03-6.36); using 'party' drugs, occasionally (AOR=2.23; 95%CI: 1.33-3.73) or regularly (AOR=5.34; 95%CI: 2.99-9.56); and group sex while using party drugs, occasionally (AOR=2.42; 95%CI: 1.29-4.53) or regularly (AOR=5.31; 95%CI: 2.62-10.76). Among non-HIV positive men in regular relationships with HIV positive partners or partners of unknown HIV status, 1.7% and 4.7%, respectively, reported preventive ARV use before UAI. CONCLUSION: Our findings illustrate sporadic use of ARVs before UAI among gay men in Australia, which was associated with high risk casual sex and 'party' drug use. These initial data contribute to a much needed understanding of the informal use of ARVs for HIV prevention.


Background: We aimed to describe the current use of antiretrovirals (ARVs) before unprotected anal intercourse (UAI) among Australian gay men, which may represent informal HIV preexposure prophylaxis (PrEP). Methods: Using data from Australian Gay Community Periodic Surveys conducted in 2011, we assessed the preventive use of ARVs before UAI and its association with sociodemographic characteristics, sexual practices, and drug use in the preceding 6 months. Associations were assessed using multivariate logistic regression analysis. Results: Of 3677 sexually active non-HIV-positive men, 2.5% reported taking ARVs before UAI. The likelihood of ARV use before UAI was significantly higher if any of the following behaviors were also reported: > 1 sex partner; UAI with casual partners, irrespective of reporting UAI with regular partners [adjusted odds ratio (AOR) = 2.36; 95% confidence interval (CI): 1.24 to 4.48] or not (AOR = 2.71; 95% CI: 1.44 to 5.07); injecting drugs at least monthly (AOR = 2.56; 95%
CI: 1.03 to 6.36); using "party" drugs, occasionally (AOR = 2.23; 95% CI: 1.33 to 3.73) or regularly (AOR = 5.34; 95% CI: 2.99 to 9.56); and group sex while using party drugs, occasionally (AOR = 2.42; 95% CI: 1.29 to 4.53) or regularly (AOR = 5.31; 95% CI: 2.62 to 10.76). Among non-HIV positive men in regular relationships with HIV-positive partners or partners of unknown HIV status, 1.7% and 4.7%, respectively, reported preventive ARV use before UAI. Conclusions: Our findings illustrate sporadic use of ARVs before UAI among gay men in Australia, which was associated with high-risk casual sex and party drug use. These initial data contribute to a much needed understanding of the informal use of ARVs for HIV prevention. Copyright (copyright) 2012 by Lippincott Williams and Wilkins.


Background: This cross sectional study examined pre-exposure prophylaxis (PrEP) acceptability among MSM in Shenyang, China. Understanding the demographic and behavioral predictors of intent to use PrEP may prove useful to identify clinical trial participants.

Methods: During 2011, 274 MSM were enrolled at VCT through snowball sampling in gay community in Shenyang, China. After a brief introduction about the results of Truvada clinical trial by trained staffs, interviewer-assisted questionnaire were used to collect demographic, behavioral information and attitude to use Truvada as a daily prevention method. All participants were tested for HIV and syphilis. Data were analyzed by univariate and multivariate logistic regression by SPSS 13.0.

Results: The prevalence of HIV and syphilis was 5.5% and 27.4%. The majority of participants had never heard of PrEP (83.0%). 49.6% of the participants were willing to use PrEP, and 6.6% were very willing to use. Mean age of all participants was 29.0 (SD=8.8), 70.6% were younger than 30. In the past-three-month, 17.5% had female sex partners; 8.2% have sold sex to male clients; 13.8% have used drug. The prevalence of group sex in the past-three-month was 11.3%. Independent associated predictors of willing to use PrEP (each P< 0.05) included family support of the use of PrEP (aOR=4.97); expectation of more sex partners after use of PrEP (aOR=2.01); have heard of PrEP before (aOR=2.09); have sold sex in the past-three-month (aOR=2.47).

Conclusions: PrEP acceptance of Chinese MSM was correlated with awareness and family support. Future PrEP trial participants' enrollment also oral PrEP promotion should focus on medicine orientation propaganda and raising family support of the participants.

**Background:** Young MSM disproportionately contribute to incident and prevalent HIV infections in the United States. Combination HIV Prevention strategies which include biomedical interventions may reduce HIV infections in these groups. Accessing YMSM for epidemiologic study, study recruitment, and HIV prevention interventions has been challenging in the U.S.

**Methods:** GRINDR, a GPS-based social networking application used on smart-phone platforms, was used to recruit a sample of 375 YMSM. Random venue-date-time sampling was used to recruit YMSM local to venues via GRINDR. Participants were administered a CASI-based survey.

**Results:** The sample was 42.4% white, 6.4% African-American, and 33.6% Latino. 359 (95.7%) self-reported HIV-uninfected status and a mean of 3.8 (SD 7.2) anal sex partners in the past month, with approximately 41% reporting inconsistent condom use; 20% of partners were HIV-infected or of unknown serostatus. 274 (76.3%) believed that they were unlikely or very unlikely to become HIV-infected in their lifetime. 42 (11.2%) had previous participated in a research study, and only 54 (14.4%) expressed no interest in an HIV prevention trial; 194 (51.7%) stated they definitely would participate. 13 (3.6%) reported previous use of PEP, and 6 (1.7%) reported previous use of PrEP. In multivariable analysis, prior PEP or PrEP use was associated with meeting a sex partner at work (OR 3.6 [95%CI 1.1-12.2]), an increase in number of sex partners since beginning to use GRINDR (OR 4.7 [1.6-14.3]), methamphetamine use in the past month (OR 5.8 [1.5-21.9]), and non-Latino race (OR 9.3 [1.1-76.9]).

**Conclusions:** Although PrEP has been shown to be efficacious in MSM, demonstration projects for PrEP face challenges in accessing highest-risk populations. YMSM may be targeted by using novel technology-based methods. Uptake of PEP and PrEP is currently limited among YMSM, particularly Latino MSM. Social networking applications such as GRINDR may be useful for recruiting for prevention interventions as well as educational messaging.

**Background- Previous reviews related to PrEP (n=5 articles)**


PURPOSE OF REVIEW: Recent randomized controlled trials have demonstrated that HIV pre-exposure prophylaxis (PrEP) can decrease HIV incidence among several at-risk populations, including men who have sex with men, serodiscordant couples, and heterosexual men and women. As PrEP is a biomedical intervention that requires clinical monitoring and a high level of medication adherence, maximizing the public health effectiveness of PrEP in real-world settings will require the training of a cadre of healthcare providers to prescribe PrEP. Therefore it is critical to understand provider knowledge, practices, and attitudes towards PrEP prescribing, and to develop strategies for engaging and training providers to provide PrEP. RECENT FINDINGS: Limited numbers of studies have focused on PrEP implementation by healthcare providers. These studies suggest that some providers are knowledgeable about PrEP, but many are not, or express misgivings. Although many clinicians report willingness to provide PrEP, few have prescribed PrEP in clinical practice. Provider comfort and skills in HIV risk assessment are suboptimal, which could limit identification of individuals who are most likely to benefit from PrEP use. SUMMARY: Further studies to understand facilitators and barriers to HIV-risk assessment and PrEP prescribing by practicing clinicians are needed. Innovative training strategies and decision-support interventions for providers could optimize PrEP implementation and therefore merit additional research.


BACKGROUND: More than 30 years into the global HIV/AIDS epidemic, infection rates remain alarmingly high, with over 2.7 million people becoming infected every year. There is a need for HIV prevention strategies that are more effective. Oral antiretroviral pre-exposure prophylaxis (PrEP) in high-risk individuals may be a reliable tool in preventing the transmission of HIV. OBJECTIVES: To evaluate the effects of oral antiretroviral chemoprophylaxis in preventing HIV infection in HIV-uninfected high-risk individuals. SEARCH METHODS: We revised the search strategy from the previous version of the review and conducted an updated search of MEDLINE, the Cochrane Central Register of Controlled Trials and EMBASE in April 2012. We also searched the WHO International Clinical Trials Registry Platform and ClinicalTrials.gov for ongoing trials. SELECTION CRITERIA: Randomised controlled trials that evaluated the effects of any antiretroviral agent or combination of antiretroviral agents in preventing HIV infection in high-risk individuals DATA COLLECTION AND ANALYSIS: Data concerning outcomes, details of the interventions, and other study characteristics were extracted by two independent authors using a standardized data extraction form. Relative risk with a 95% confidence interval (CI) was used as the measure of effect. MAIN RESULTS: We identified 12 randomised controlled trials that meet the criteria for the review. Six were ongoing trials, four had been completed and two had been terminated early. Six studies with a total of 9849 participants provided data for this review. The trials
evaluated the following: daily oral tenofovir disoproxil fumarate (TDF) plus emtricitabine (FTC) versus placebo; TDF versus placebo and daily TDF-FTC versus intermittent TDF-FTC. One of the trials had three study arms: TDF, TDF-FTC and placebo arm. The studies were carried out amongst different risk groups, including HIV-uninfected men who have sex with men, serodiscordant couples and other high risk men and women. Overall results from the four trials that compared TDF-FTC versus placebo showed a reduction in the risk of acquiring HIV infection (RR 0.51; 95% CI 0.30 to 0.86; 8918 participants). Similarly, the overall results of the studies that compared TDF only versus placebo showed a significant reduction in the risk of acquiring HIV infection (RR 0.38; 95% CI 0.23 to 0.63, 4027 participants). There were no significant differences in the risk of adverse events across all the studies that reported on adverse events. Also, adherence and sexual behaviours were similar in both the intervention and control groups.

AUTHORS' CONCLUSIONS: Finding from this review suggests that pre-exposure prophylaxis with TDF alone or TDF-FTC reduces the risk of acquiring HIV in high-risk individuals including people in serodiscordant relationships, men who have sex with men and other high risk men and women.


PURPOSE OF REVIEW: The US Food and Drug Administration (FDA) recently approved the use of tenofovir-emtricitabine for pre-exposure prophylaxis (PrEP) for HIV prevention. PrEP is also being investigated in clinical trials as a component of HIV prevention in resource-limited settings. Cost-effectiveness models are useful in identifying health programs with the greatest societal value and projecting long-term program impacts. This review examines six recent studies of the cost-effectiveness of PrEP for preventing HIV transmission in the USA and South Africa. RECENT FINDINGS: Studies used both individual-level and population-level transmission models. PrEP was found to be a cost-effective HIV-prevention intervention in high-risk MSM with HIV incidence at least 2% in the USA (<US$100 000 per quality-adjusted life year) and in young women in South Africa (cost per life year <GDP per capita). Results were sensitive to the cost and efficacy of PrEP and to assumptions about HIV testing and access to treatment in the absence of PrEP. SUMMARY: Future cost effectiveness studies should consider PrEP implementation issues (uptake in high-risk versus low-risk groups, duration on PrEP, adherence), budget impact, and the role of PrEP as part of combination HIV-prevention strategies including expanded testing and treatment access.


AIDS Behav.

Recent research has demonstrated how antiretrovirals (ARVs) could be effective in the prevention of sexually transmitted HIV. We review research on the acceptability of oral
pre-exposure prophylaxis (PrEP) and treatment as prevention (TasP) for HIV prevention amongst potential users. We consider with whom, where and in what context this research has been conducted, how acceptability has been approached, and what research gaps remain. Findings from 33 studies show a lack of TasP research, PrEP studies which have focused largely on men who have sex with men (MSM) in a US context, and varied measures of acceptability. In order to identify when, where and for whom PrEP and TasP would be most appropriate and effective, research is needed in five areas: acceptability of TasP to people living with HIV; motivation for PrEP use and adherence; current perceptions and management of risk; the impact of broader social and structural factors; and consistent definition and operationalisation of acceptability which moves beyond adherence.

Background- Modeling and cost-effectiveness (n=8 articles)


Background: HIV Pre-exposure prophylaxis (PrEP), the use of antiretroviral drugs by those HIV uninfected individuals to prevent HIV infection, recently demonstrated effectiveness in preventing acquisition in a high risk population of men who have sex with men (MSM). There is a need to understand if and how PrEP can be used cost-effectively. This study examines the programmatic implications of the iPrEX study: the only randomised controlled trial of PrEP among men who have sex with men (MSM) published last December in the New England Journal of Medicine. Methods: We developed a mathematical model representing the HIV epidemic among Men who Have Sex with Men (MSM) and transgender people in Lima, Peru as a test-case. It considers differential infectiousness by stage, including the impact of antiretroviral treatment and different sexual practices, such as partnerships type and sexual positioning. The model was used to investigate the population-level impact, cost, and cost-effectiveness of PrEP under a range of implementation scenarios, and to develop possible strategies by which PrEP could be implemented. Results: The epidemiological impact of PrEP is largely driven by Programmecharacteristics-coverage, prioritisation strategy and time to scale up-as well as individual's adherence behaviour. If PrEP is prioritised to key groups, it could be a cost-effective way to avert infection and save lives (up to 8% less new infections with 5% coverage). Across all our scenarios the estimated highest cost perDALY gained (US$2755) is below theWHOrecommended threshold for costeffective interventions for the region (<US$4608/DALY gained) see Abstract LBO-1.2 Figure 1. The impact of PrEP is reduced if those on PrEP decrease condom use, especially if the program has low coverage; but only extreme behaviour changes and a low PrEP efficacy would adversely impact the epidemic overall. However, PrEP will not arrest HIV transmission in isolation, due to its incomplete effectiveness, dependence on adherence, and the high total cost of programmes limiting attainable coverage levels. Conclusions:
This study quantifies the epidemic and financial implications of different programmatic scenarios. While the implementation of a strategic PrEP intervention has potentially important financial implications (a substantial expenditure would likely be required to generate significant reductions in incidence), PrEP among vulnerable populations could be a cost-effective option comparable to currently available interventions for Men who Have Sex with Men (MSM) populations. (Figure presented).


BACKGROUND: Cost-effectiveness studies inform resource allocation, strategy, and policy development. However, due to their complexity, dependence on assumptions made, and inherent uncertainty, synthesising, and generalising the results can be difficult. We assess cost-effectiveness models evaluating expected health gains and costs of HIV pre-exposure prophylaxis (PrEP) interventions. METHODS AND FINDINGS: We conducted a systematic review comparing epidemiological and economic assumptions of cost-effectiveness studies using various modelling approaches. The following databases were searched (until January 2013): PubMed/Medline, ISI Web of Knowledge, Centre for Reviews and Dissemination databases, EconLIT, and region-specific databases. We included modelling studies reporting both cost and expected impact of a PrEP roll-out. We explored five issues: prioritisation strategies, adherence, behaviour change, toxicity, and resistance. Of 961 studies retrieved, 13 were included. Studies modelled populations (heterosexual couples, men who have sex with men, people who inject drugs) in generalised and concentrated epidemics from Southern Africa (including South Africa), Ukraine, USA, and Peru. PrEP was found to have the potential to be a cost-effective addition to HIV prevention programmes in specific settings. The extent of the impact of PrEP depended upon assumptions made concerning cost, epidemic context, programme coverage, prioritisation strategies, and individual-level adherence. Delivery of PrEP to key populations at highest risk of HIV exposure appears the most cost-effective strategy. Limitations of this review include the partial geographical coverage, our inability to perform a meta-analysis, and the paucity of information available exploring trade-offs between early treatment and PrEP. CONCLUSIONS: Our review identifies the main considerations to address in assessing cost-effectiveness analyses of a PrEP intervention—cost, epidemic context, individual adherence level, PrEP programme coverage, and prioritisation strategy. Cost-effectiveness studies indicating where resources can be applied for greatest impact are essential to guide resource allocation decisions; however, the results of such analyses must be considered within the context of the underlying assumptions made.

About 50,000 people are infected with HIV in the US each year and this number has remained virtually the same for the past decade. Yet, in the last few years, evidence from several multinational randomized clinical trials has shown that the provision of antiretroviral drug to uninfected persons (i.e. pre-exposure prophylaxis) reduces the incidence of HIV by about 50%. However, evidence from cost-effectiveness studies conducted in the US yield widely varying estimates of the cost per quality-adjusted life-year (QALY) gained, and this variation reflects the substantial uncertainty surrounding the determinants of HIV transmission (e.g. adherence rates to prophylactic medications, the average number of sexual partners, the number and types of sexual acts, the viral load of infected partners, and the proportion of contacts where condoms are used), as well as different approaches to translating a reduction in HIV cases into an estimate of the increase in the number of QALYs. (copyright) 2013 Springer International Publishing Switzerland (outside the USA).


BACKGROUND: A recent randomized, controlled trial showed that daily oral preexposure chemoprophylaxis (PrEP) was effective for HIV prevention in men who have sex with men (MSM). The Centers for Disease Control and Prevention recently provided interim guidance for PrEP in MSM at high risk for HIV. Previous studies did not reach a consistent estimate of its cost-effectiveness. OBJECTIVE: To estimate the effectiveness and cost-effectiveness of PrEP in MSM in the United States. DESIGN: Dynamic model of HIV transmission and progression combined with a detailed economic analysis. DATA SOURCES: Published literature. TARGET POPULATION: MSM aged 13 to 64 years in the United States. TIME HORIZON: Lifetime. PERSPECTIVE: Societal. INTERVENTION: PrEP was evaluated in both the general MSM population and in high-risk MSM and was assumed to reduce infection risk by 44% on the basis of clinical trial results. OUTCOME MEASURES: New HIV infections, discounted quality-adjusted life-years (QALYs) and costs, and incremental cost-effectiveness ratios.

RESULTS OF BASE-CASE ANALYSIS: Initiating PrEP in 20% of MSM in the United States would reduce new HIV infections by an estimated 13% and result in a gain of 550,166 QALYs over 20 years at a cost of $172,091 per QALY gained. Initiating PrEP in a larger proportion of MSM would prevent more infections but at an increasing cost per QALY gained (up to $216,480 if all MSM receive PrEP). Preexposure chemoprophylaxis in only high-risk MSM can improve cost-effectiveness. For MSM with an average of 5 partners per year, PrEP costs approximately $50,000 per QALY gained. Providing PrEP to all high-risk MSM for 20 years would cost $75 billion more in health care-related costs than the status quo and $600,000 per HIV infection prevented, compared with incremental costs of $95 billion and $2 million per infection prevented for 20% coverage of all MSM. RESULTS OF SENSITIVITY ANALYSIS: PrEP in the general MSM
population would cost less than $100,000 per QALY gained if the daily cost of antiretroviral drugs for PrEP was less than $15 or if PrEP efficacy was greater than 75%.

LIMITATION: When examining PrEP in high-risk MSM, the investigators did not model a mix of low- and high-risk MSM because of lack of data on mixing patterns.

CONCLUSION: PrEP in the general MSM population could prevent a substantial number of HIV infections, but it is expensive. Use in high-risk MSM compares favorably with other interventions that are considered cost-effective but could result in annual PrEP expenditures of more than $4 billion.


Background: In southern India, the identity of men who have sex with men (MSM) is closely related to role taken in anal sex, but little is known about sexual mixing between identity groups. Both role segregation and assortative (within-group) mixing are known to affect HIV epidemic size in other settings. This study aimed to explore how different mixing patterns affect estimated HIV trends and intervention impact for MSM in Bangalore. Methods: Deterministic models describing HIV transmission between three MSM identity groups (mostly insertive panthis/bisexuals (PB), mostly receptive kothis/hijras (KH) and versatile double deckers (DD)), were parameterised with data collected in Bangalore for the evaluation of the Avahan intervention. These models were used to explore four different mixing patterns (table). 300,000 randomly (Table presented) sampled parameter sets were obtained from data ranges and used to find multiple fits to group-specific HIV prevalence data in 2006 and 2009. Model fits were used to compare predicted HIV time trends. To compare the impact of a new intervention scenario, condom use was assumed to decline from high levels in 2010 due to condomintervention fatigue. Oral pre-exposure prophylaxis (PrEP) was introduced in 2015, assuming 42% effectiveness (efficacy x adherence) and 60% coverage, targeted at KH and DD (the groups easiest to reach). Results: Large differences in levels of assortative mixing were seen for fits identified using different mixing patterns (Table 1), but little difference was projected in HIV prevalence trends (A). Different mixing patterns gave somewhat different estimates for group-specific impact of the PrEP intervention (B), but overall impact in the whole MSM population was very similar (< 10% difference in % infections averted). Conclusion: A variety of different mixing patterns are consistent with the data. However, model predictions of future HIV epidemic trends and overall impact of a targeted intervention are robust to the different mixing patterns and intervention scenario explored here.

Background. Antiretroviral therapy (ART) used as pre-exposure prophylaxis (PrEP) by human immunodeficiency virus (HIV)-seronegative individuals reduces the risk of acquiring HIV. However, the population-level impact and cost-effectiveness of using PrEP as a public health intervention remains debated. Methods. We used a stochastic agent-based model of HIV transmission and progression to simulate the clinical and cost outcomes of different strategies of providing PrEP to men who have sex with men (MSM) in New South Wales (NSW), Australia. Model outcomes were reported as incremental cost effectiveness ratios (ICERs) in 2013 Australian dollars per quality-adjusted life year gained ($/QALYG). Results. The use of PrEP in 10-30% of the entire NSW MSM population was projected to cost an additional $316-952 million dollars over the course of 10 years, and cost more than $400,000 per QALYG compared with the status quo. Targeting MSM with sexual partners ranging between more than 10 to more than 50 partners within six months cost an additional $31-331 million dollars, and cost more than $110,000 per QALYG compared with the status quo. We found pre-exposure prophylaxis is most cost-effective when targeted for HIV-negative MSM in a discordant regular partnership. The ICERs ranged between $8,399 and $11,575, for coverage ranging between 15% and 30%, respectively. Conclusion. Targeting HIV-negative MSM in a discordant regular partnership is a cost-effective intervention. However, this highly targeted strategy would not have large population-level impact. Other scenarios are unlikely to be cost-effective.

Background- Other (n=17)


These recommendations have been developed specifically to address the daily use of antiretrovirals in HIV-uninfected people to block the acquisition of HIV infection. This prevention approach is known as pre-exposure prophylaxis. At this stage evidence is available from studies with two groups: men and transgender women who have sex with men; and serodiscordant heterosexual couples. In parallel, WHO also is preparing new recommendations on the use of antiretroviral drugs in people living with HIV to prevent transmission of infection.


In the United States, an estimated 48,100 new human immunodeficiency virus (HIV) infections occurred in 2009. Of these, 27% were in heterosexual men and women who
did not inject drugs, and 64% were in men who have sex with men (MSM), including 3% in MSM who inject drugs. In January 2011, following publication of evidence of safety and efficacy of daily oral tenofovir disoproxil fumarate 300 mg (TDF)/emtricitabine 200 mg (FTC) (Truvada, Gilead Sciences) as antiretroviral preexposure prophylaxis (PrEP) to reduce the risk for HIV acquisition among MSM in the iPrEx trial, CDC issued interim guidance to make available information and important initial cautions on the use of PrEP in this population. Those recommendations remain valid for MSM, including MSM who also have sex with women. Since January 2011, data from studies of PrEP among heterosexual men and women have become available, and on July 16, 2012, the Food and Drug Administration (FDA) approved a label indication for reduction of risk for sexual acquisition of HIV infection among adults, including both heterosexuals and MSM. This interim guidance includes consideration of the new information and addresses pregnancy and safety issues for heterosexually active adults at very high risk for sexual HIV acquisition that were not discussed in the previous interim guidance for the use of PrEP in MSM.


Drug concentrations associated with protection from HIV-1 acquisition have not been determined. We evaluated drug concentrations among men who have sex with men in a substudy of the iPrEx trial (1). In this randomized placebo-controlled trial, daily oral doses of emtricitabine/tenofovir disoproxil fumarate were used as pre-exposure prophylaxis (PrEP) in men who have sex with men. Drug was detected less frequently in blood plasma and in viable cryopreserved peripheral blood mononuclear cells (PBMCs) in HIV-infected cases at the visit when HIV was first discovered compared with controls at the matched time point of the study (8% versus 44%; P < 0.001) and in the 90 days before that visit (11% versus 51%; P < 0.001). An intracellular concentration of the active form of tenofovir, tenofovir-diphosphate (TFV-DP), of 16 fmol per million PBMCs was associated with a 90% reduction in HIV acquisition relative to the placebo arm. Directly observed dosing in a separate study, the STRAND trial, yielded TFV-DP concentrations that, when analyzed according to the iPrEx model, corresponded to an HIV-1 risk reduction of 76% for two doses per week, 96% for four doses per week, and 99% for seven doses per week. Prophylactic benefits were observed over a range of doses and drug concentrations, suggesting ways to optimize PrEP regimens for this population.


Background. The use of oral antiretrovirals to prevent HIV infection among HIV-negative men who have sex with men (MSM) has been shown to be safe and efficacious. A large, randomised, placebo-controlled trial showed a 44% reduction in the incidence of HIV infection among MSM receiving a daily oral fixed-dose combination of tenofovir
disoproxil fumarate and emtricitabine (Truvada) in combination with an HIV prevention package. Improved protection was seen with higher levels of adherence. Aim. The purpose of this guideline is to: (i) explain what pre-exposure prophylaxis (PrEP) is; (ii) outline current indications for its use; (iii) outline steps for appropriate client selection; and (iv) provide guidance for monitoring and maintaining clients on PrEP. Method. PrEP is indicated for HIV-negative MSM who are assessed to be at high risk for HIV acquisition and who are willing and motivated to use PrEP as part of a package of HIV prevention services (including condoms, lubrication, sexually transmitted infection (STI) management and risk reduction counselling). Recommendations. HIV testing, estimation of creatinine clearance and STI and hepatitis B screening are recommended as baseline investigations. Daily oral Truvada, along with adherence support, can then be prescribed for eligible MSM. PrEP should not be given to MSM with abnormal renal function, nor to clients who are unmotivated to use PrEP as part of an HIV prevention package; nor should it be commenced during an acute viral illness. Three-monthly follow-up visits to assess tolerance, renal function, adherence and ongoing eligibility is recommended. Six-monthly STI screens and annual creatinine levels to estimate creatinine clearance are recommended. Hepatitis B vaccination should be provided to susceptible clients. Gastro-intestinal symptoms and weight loss are common side-effects, mostly experienced for the first 4 - 8 weeks after initiating PrEP. There is a risk of the development of antiretroviral resistance among those with undiagnosed acute HIV infection during PrEP initiation and among those with sub-optimal adherence who become HIV infected while on PrEP. Risk compensation (increasing sexual behaviours that can result in exposure to HIV) while on PrEP may become a concern, and clinicians should continue to support MSM clients to continue to use condoms, condom-compatible lubrication and practice safer sex. Research is ongoing to assess optimum dosing regimens, potential long-term effects and alternative PrEP medications. Recommendations for the use of PrEP among other at-risk individuals, and the components of these recommendations, will be informed by future evidence.


PURPOSE OF REVIEW: HIV epidemic spread continues among gay, bisexual, and other MSM globally in 2013. These epidemics are occurring in rapidly shifting contexts among these men, which have important impacts on HIV spread, HIV programs, access to services and human rights. Current HIV prevention strategies are inadequate and are taken to insufficient scale to control HIV spread. RECENT FINDINGS: We reviewed recent reports on epidemiology, HIV prevention advances, human rights, and epidemic disease control among MSM to understand why HIV epidemics among these men remain poorly controlled. Network level factors appear to be critically important for HIV epidemic spread among MSM. The only new prevention technology with evidence for efficacy in this population, daily oral chemoprophylaxis (PrEP), has been little used, particularly in low and middle-income countries. SUMMARY: Much more vigorous prevention efforts are required, including the adaptation and expanded use of PrEP, if we are to reduce new infections among gay, bisexual and other MSM.

With reducing HIV prevalence, India has made gains in containing the epidemic. Yet, unprotected sex and commercial sex work, unprotected anal sex between men and needle sharing among intravenous drug users continue to drive the epidemic. Development of effective, safe and acceptable topical (microbicides) and oral (pre-exposure prophylaxis (PrEP)) chemoprophylaxis could augment the already available tools for HIV prevention. This paper reviews the acceptability of topical microbicides and oral PrEP, in the context of the nature of the HIV epidemic, the sociocultural norms and the acceptability data obtained from studies carried out in India. Overall, men and women have a positive attitude towards the concept and use of microbicide products. Self-perceptions of HIV risk, product attributes, ease and convenience of use during sex, gender norms, the sociocultural context and the potential for undisclosed use were important factors influencing acceptability. A multipurpose product that would simultaneously address women’s contraceptive and disease prevention needs would be devoid of the stigma attached to an anti-HIV product and may be more acceptable. Limited information on the acceptability of oral PrEP amongst high-risk groups merits further research, including carrying out demonstration projects for program introduction.


Professional bodies in the UK (BASHH/BHIVA) do not currently recommended pre-exposure prophylaxis (PREP) to prevent HIV acquisition for men who have sex with men (MSM) [1]. Conversely, although Federal Drug Administration approval is awaited, the Centers for Disease Control (CDC) have issued clinicians in the USA with interim guidance to facilitate PREP prescriptions [2]. Increasingly patients search the internet for information on HIV treatment, but disparate international policy can lead to confusing patient messages. This study was conducted to systematically assess the quality of internet information available to patients in the UK about PREP. More than 90% of internet searches in the UK are performed using ‘Google.co.uk’ and ‘Bing’ [3]. Using pre-specified criteria, we reviewed the first 100 hits retrieved from each search engine when the following searches were performed: [nullHIV pre-exposure prophylaxisnull]; [nullHIV PREPnull]; [nullHIV PREP guidelinesnull]; [nullHIV PREP guidelines UKnull]; [nulltruvada prophylaxis HIVnull]. Of 172 unique websites identified, 124 websites were active at the time of the review (July 2012). 33 websites were links to academic journals including commentaries and clinical trials, not intended to specifically provide patient information; 5 were internet portals directing users to alternative sites and 10 websites contained no information about PREP. Of the remaining 76 websites, 28 were written by medical professionals and 48 were written by journalists, where 7/48 (15%) were individual blogs. 64/76 (84%) contained a definition of PREP; 63/76 (83%) discussed the rationale and 58/76 (76%) reported efficacy data. Advantages and
disadvantages of PREP were presented in 56/76 (74%) and 41/76 (54%) of websites respectively. Only 21/76 (28%) of sites referenced existing national guidelines (CDC/BASHH). A minority of sites described the current clinical practice in the UK (7/76, 9%) with an even smaller number presenting the contrast in clinical stance between the CDC and BASHH/BHIVA (3/76, 4%). The use of PREP is evolving, and the internet is an important patient resource. However, current clinical practice in the UK is seldom described in accessible websites. Avoiding ad hoc and unsupervised use of PREP is crucial to prevent future drug resistance and risky sexual behaviour. More should be done to engage at-risk groups and ensure patients in the UK have access to comprehensive information including the current UK PREP professional guidance.


The impending implementation of pre-exposure prophylaxis (PrEP) has prompted complicated bioethical and public health ethics concerns regarding the moral distribution of antiretroviral medications (ARVs) to ostensibly healthy populations as a form of HIV prevention when millions of HIV-positive people still lack access to ARVs globally. This manuscript argues that these questions are, in part, concerns over the ethics of the knowledge production practices of epidemiology. Questions of distribution, and their attendant cost-benefit calculations, will rely on a number of presupposed, and therefore, normatively cultural assumptions within the science of epidemiology specifically regarding the ability of epidemiologic surveillance to produce accurate maps of HIV throughout national populations. Specifically, ethical questions around PrEP will focus on who should receive ARVs given the fact that global demand will far exceed supply. Given that sexual transmission is one of the main modes of HIV transmission, these questions of ‘who’ are inextricably linked to knowledge about sexual personhood. As a result, the ethics of epidemiology, and how the epidemiology of HIV in particular conceives, classifies and constructs sexual populations will become a critical point of reflection and contestation for bioethicists, health activists, physicians, nurses, and researchers in the multi-disciplinary field of global health. This paper examines how cultural conundrums within the fields of bioethics and public health ethics are directly implicated within the ethics of PrEP, by analyzing the problems of population inaugurated by the construction of the men who have sex with men (MSM) epidemiologic category in the specific national context of South Africa.


On the heels of several trials demonstrating the efficacy of pre-exposure prophylaxis (PrEP) and the recent approval by the FDA of the supplemental indication for Truvada as PrEP, researchers, advocates, and community providers are calling for the investigation of implementation strategies that combine behavioral interventions with biomedical
prevention. This paper describes the modification and integration of an evidence-based group-level intervention into a small PrEP pilot trial with young men who have sex with men (YMSM). The behavioral intervention as well as ongoing risk reduction counseling sessions were found to be highly acceptable among a sample of racially diverse YMSM.


Introduction: Pre-exposure prophylaxis (PrEP) is a rapidly emerging HIV prevention strategy. Following release of iPrEx results, several demonstration projects are being planned to evaluate PrEP delivery in real-world settings. While steps in the spectrum of engagement in HIV care have been defined and used to identify gaps and build interventions to improve health on the individual and population level, a similar framework has not been developed for daily PrEP in HIV-uninfected populations. We propose a cascade of PrEP delivery as a model to define metrics of success in PrEP implementation programs. Description: Adapting models of engagement in HIV care, we define 6 key steps in the cascade of PrEP delivery: 1) identification of potential PrEP candidates (including confirmed HIV-negative individuals who meet behavioral eligibility criteria); 2) individual decision to adopt PrEP as a prevention strategy; 3) successful referral and linkage of individuals from the testing site to the PrEP program; 4) initiation of PrEP among those assessed to be medically and behaviorally eligible; 5) retention in the PrEP program over time; and 6) maintaining adherence and persistence to PrEP medication to achieve a detectable drug level associated with protection. Clinic-based metrics (steps 4-6) can be obtained through data collected at the PrEP delivery site, while measures on identification, interest, and referrals (steps 1-3) may require use of existing and novel outreach and surveillance strategies (eg, use of electronic health records). Lessons Learned: The PrEP cascade provides a framework for understanding individual and structural factors which may determine the overall public health impact of PrEP programs. These metrics can evaluate the relative magnitude of gaps at each stage of PrEP delivery and whether gaps vary by key populations (eg, men of color, young men who have sex with men); findings may signify the need for targeted interventions to achieve equity in PrEP outcomes across diverse populations. Recommendations: We suggest use of a cascade of PrEP delivery to plan data collection in upcoming PrEP demonstration projects and to evaluate their success. Use of common metrics will also allow for meaningful comparisons across different PrEP programs. Once populated with actual data from these projects, modeling can be conducted to evaluate the impact of potential interventions targeting various stages of the PrEP cascade with the goal of maximizing public health impact.


OBJECTIVE: Preexposure prophylaxis (PrEP) with emtricitabine/tenofovir disoproxil fumarate (FTC/TDF) reduced HIV acquisition in the iPrEx trial among men who have
sex with men and transgender women. Self-reported sexual risk behavior decreased overall, but may be affected by reporting bias. We evaluated potential risk compensation using biomarkers of sexual risk behavior. DESIGN AND METHODS: Sexual practices were assessed at baseline and quarterly thereafter; perceived treatment assignment and PrEP efficacy beliefs were assessed at 12 weeks. Among participants with >1 follow-up behavioral assessment, sexual behavior, syphilis, and HIV infection were compared by perceived treatment assignment, actual treatment assignment, and perceived PrEP efficacy. RESULTS: Overall, acute HIV infection and syphilis decreased during follow-up. Compared with participants believing they were receiving placebo, participants believing they were receiving FTC/TDF reported more receptive anal intercourse partners prior to initiating drug (12.8 vs. 7.7, P = 0.04). Belief in receiving FTC/TDF was not associated with an increase in receptive anal intercourse with no condom (ncRAI) from baseline through follow-up (risk ratio [RR] 0.9, 95% confidence interval [CI]: 0.6-1.4; P = 0.75), nor with a decrease after stopping study drug (RR 0.8, 95% CI: 0.5-1.3; P = 0.46). In the placebo arm, there were trends toward lower HIV incidence among participants believing they were receiving FTC/TDF (incidence rate ratio [IRR] 0.8, 95% CI: 0.4-1.8; P = 0.26) and also believing it was highly effective (IRR 0.5, 95% CI: 0.1-1.7; P = 0.12). CONCLUSIONS: There was no evidence of sexual risk compensation in iPrEx. Participants believing they were receiving FTC/TDF had more partners prior to initiating drug, suggesting that risk behavior was not a consequence of PrEP use.


Objectives: Daily use of oral emtricitabine/tenofovir disoproxil fumarate (FTC/TDF) for pre-exposure prophylaxis (PrEP) decreases HIV acquisition. In HIV treatment, substitution of TDF or FTC/TDF for other antiretrovirals (ARV) or addition of TDF to an ARV regimen generally improves lipids, although decreases in HDL cholesterol have been seen. In a small study in seronegative subjects, 2 weeks' use of TDF decreased total and LDL cholesterol. We report the effects of prolonged treatment with FTC/TDF on lipids in the absence of HIV infection and other ARV use. Methods: In a metabolic substudy of iPrEx, an international randomized trial of PrEP in seronegative men who have sex with men, fasting serum samples for lipid measurements were collected at baseline and 24-week intervals and analysed centrally. Plasma tenofovir (TFV) and FTC levels were measured at weeks 24, 48 and 72, and intracellular TFV and FTC diphosphate were measured at week 24. Net changes in lipids are reported in those randomized to FTC/TDF who had detectable drug levels, compared with those randomized to placebo, as change in FTC/TDF minus change in placebo (95% CI). P-values are based on a linear mixed model. Results: 474 participants (237 FTC/TDF, 237 placebo) had baseline lipid measurements, with variable periods of follow-up. At baseline there were no significant differences between randomized groups in mean (plus or minus)sd levels (mg/dl) of triglycerides (103 (plus or minus)59) or total (163 (plus or minus)35), LDL (95 (plus or minus)28), HDL (47 (plus or minus)13), or non-HDL (116 (plus or minus)35) cholesterol. In those randomized to FTC/TDF, drug was detected in
109/185 participants at week 24, 78/153 at week 48, and 42/82 at week 72. At week 24, the FTC/ TDF group with detectable drug had modest but significant decreases in total (-9.2 [-14.5 to -3.8] mg/dl, P=0.001), LDL (-5.8 [-10.4 to -1.2] mg/dl, P=0.01), HDL (-3.6 [-5.5 to -1.8] mg/dl, P<0.001) and non-HDL (-5.4 [-10.5 to -0.4] mg/dl, P=0.03) cholesterol. At week 48, the significant decrease in HDL cholesterol persisted (-4.0 [-6.1 to -1.9] mg/dl, P<0.001), while other values tended to rebound. Triglycerides did not change significantly in any analyses. By week 72 there were no significant treatment differences in any lipid measured. Results were similar by intent-to-treat analysis or when data in those randomized to FTC/TDF with detectable drug were compared to those with no detectable drug instead of placebo. Conclusions: In HIV-negative men taking FTC/TDF for PrEP, there were small but statistically significant across-the-board decreases in cholesterol that were most pronounced at week 24 and tended to rebound by week 72. These results demonstrate an effect of FTC/TDF on cholesterol that is independent of HIV suppression.


BACKGROUND: Little is known about safety of and adherence to intermittent HIV PrEP regimens, which may be more feasible than daily dosing in some settings. We present safety and adherence data from the first trial of an intermittent PrEP regimen among Kenyan men who have sex with men (MSM) and female sex workers (FSW).

METHODS/PRINCIPAL FINDINGS: MSM and FSW were randomized to daily oral FTC/TDF or placebo, or intermittent (Monday, Friday and within 2 hours after sex, not to exceed one dose per day) oral FTC/TDF or placebo in a 2:1:2:1 ratio; volunteers were followed monthly for 4 months. Adherence was assessed with the medication event monitoring system (MEMS). Sexual activity data were collected via daily text message (SMS) queries and timeline followback interviews with a one-month recall period. Sixty-seven men and 5 women were randomized into the study. Safety was similar among all groups. Median MEMS adherence rates were 83% [IQR: 63-92] for daily dosing and 55% [IQR:28-78] for fixed intermittent dosing (p = 0.003), while adherence to any post-coital doses was 26% [IQR:14-50]. SMS response rates were low, which may have impaired measurement of post-coital dosing adherence. Acceptability of PrEP was high, regardless of dosing regimen. CONCLUSIONS/SIGNIFICANCE: Adherence to intermittent dosing regimens, fixed doses, and in particular coitaly-dependent doses, may be more difficult than adherence to daily dosing. However, intermittent dosing may still be appropriate for PrEP if intracellular drug levels, which correlate with prevention of HIV acquisition, can be attained with less than daily dosing and if barriers to adherence can be addressed. Additional drug level data, qualitative data on adherence barriers, and better methods to measure sexual activity are necessary to determine whether adherence to post-coital PrEP could be comparable to more standard regimens. TRIAL REGISTRATION: ClinicalTrials.gov NCT00971230.

BACKGROUND:: Despite evidence supporting pre-exposure prophylaxis (PrEP) efficacy, there are concerns regarding the feasibility of widespread PrEP implementation among men who have sex with men (MSM). To inform the development of targeted PrEP delivery guidelines, we characterized sexual risk trajectories among HIV-negative MSM.

METHODS:: At semiannual visits from 2003-2011, HIV-negative MSM (N=419) participating in the Multicenter AIDS Cohort Study provided data on sexual risk behaviors since their last visit. Based on reported behaviors, participants were assigned a sexual risk behavior (SRB) score at each visit as follows: (0) no insertive or receptive anal intercourse (IAI/RAI), (1) no unprotected IAI/RAI (UIAI/URAI), (2) only UIAI, (3) URAI with 1 HIV-negative partner, (4) condom-serosorting, (5) condom-seropositioning, and (6) no seroadaptive behaviors. Group-based trajectory modeling was used to examine SRB scores (<4 vs. >/=4) and identify groups with distinct sexual risk trajectories.

RESULTS:: Three sexual risk trajectory groups were identified: low risk (N=264; 63.0%), moderate risk (N=96; 22.9%; mean duration of consecutive high risk intervals approximately 1 year), and high risk (N=59; 14.1%; mean duration of consecutive high risk intervals approximately 2 years). Compared to low risk group membership, high risk group membership was associated with younger age (in years) (adjusted odds ratio [AOR]=0.92, 95% confidence interval [CI]: 0.88-0.96), being White (AOR=3.67, 95% CI: 1.48-9.11), earning an income >/=$20,000 (AOR=4.98, 95% CI: 2.13-11.64), distress/depression symptoms (CESD>/=16) (AOR=2.36, 95% CI: 1.14-4.92), and substance use (AOR=2.00, 95% CI: 1.01-3.97). CONCLUSION:: Screening for the socio-demographic and behavioral factors described above may facilitate targeted PrEP delivery during high risk periods among MSM.


There is increasing evidence that the use of antiretroviral agents (ARVs) can be a safe and effective means of preventing HIV infection. In fact, a combination of ARVs, tenofovir-emtricitabine, was recently approved by the US Food and Drug Administration (FDA) for use as "pre-exposure prophylaxis"(PrEP), and the US Centers for Disease Control and other regulatory authorities have issued guidance concerning PrEP use. Clinicians and policy makers are now faced with questions about the appropriateness of prescribing ARVs to healthy persons who are at risk of becoming infected with HIV, and those at risk of being infected must decide whether to use PrEP. In addition, researcher stakeholders must grapple with determining whether and how PrEP should be included in future HIV prevention research. In addressing such issues, it is important that their ethical
dimensions are identified. When using PrEP, 2 broad ethical domains are of special relevance: well-being and justice. Ethical issues related to well-being include safety, parameters of use, risk behaviors, resistance, stigma, and diversion. Those related to justice include access and competing priorities. In research involving PrEP, ethical issues include determining the appropriate control arm and whether PrEP should be included as a part of the prevention package provided to all at risk participants. Although PrEP could play an important role in HIV prevention, understanding and addressing the related ethical issues is critical to its safe, effective, and appropriate use in practice and future research. Copyright (copyright) 2013 by Lippincott Williams & Wilkins.


Intermittent dosing of pre-exposure prophylaxis (iPrEP) has potential to decrease costs, improve adherence, and minimize toxicity. Practical event-based dosing of iPrEP requires men who have sex with men (MSM) to be sexually active on fewer than 3 days each week and plan for sexual activity. MSM who may be most suitable for event-based dosing were older, more educated, more frequently used sexual networking websites, and more often reported that their last sexual encounter was not with a committed partner. A substantial proportion of these MSM endorse high-risk sexual activity, and event-based iPrEP may best target this population.
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Annex 2: Pre-exposure prophylaxis for people who inject drugs: 
A systematic review

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Systematic review write up

Background
An estimated 35.3 million people globally are living with HIV (UNAIDS, 2013). A number of prevention methods are available, from condoms to male circumcision, prevention of mother-to-child transmission to clean needles, but to date these have not been sufficient to stop the epidemic. In 2012 alone, an estimated 2.3 million people became newly infected (UNAIDS, 2013). Additional safe and effective approaches to HIV prevention are urgently needed.

People who inject drugs (PWID) have a disproportionate burden of HIV. Existing methods of HIV prevention for PWID include approaches used across populations to reduce sexual transmission as well as approaches specific to PWID to reduce HIV transmission through sharing unclean needles and other injection equipment. However, political and structural barriers prevent access to needle and syringe programs and opioid substitution therapy in many settings, and additional prevention modalities would be helpful for these populations.

PrEP is the use of an antiretroviral drug to block the acquisition of HIV infection by uninfected people. Proof of concept has long been established in the laboratory by animal studies and in real world application by the prevention of mother-to-child transmission and post-exposure prophylaxis. The safety of the drugs being considered for PrEP, tenofovir and emtricitabine, has been established through their use for treatment and in safety trials in uninfected people (Peterson et al., 2007). Five trials of effectiveness (Phase IIb and Phase III) of oral PrEP have been conducted in the last decade. These have examined the effectiveness of PrEP among PWID, serodiscordant couples, heterosexual women and high risk men who have sex with men (MSM).

Of the five effectiveness trials, only one trial examined efficacy among PWID: the Bangkok Tenofovir Study (Choopanya et al., 2013). This Phase III clinical trial tested whether daily tenofovir disoproxil fumarate (TDF) could safely and effectively prevent HIV infection among PWID in Bangkok, Thailand. Over 2400 PWID were enrolled in the study and randomly assigned to daily TDF or placebo. Participants were also provided regular HIV testing and risk reduction counseling. The primary outcome of the trial was HIV incidence, which was 0.35 per 100 person-years (py) in the TDF group (17 infections) and 0.68 per 100 py in the placebo group (33 infections), indicating a 48.9% reduction in HIV incidence related to PrEP (95% CI: 9.6, 72.2; p=0.01). Serious adverse events were not statistically significantly different between the two groups (p=0.35). Trial findings led the U.S. Centers for Disease Control and Prevention (CDC) to recommend PrEP be considered “as one of several prevention options for persons at very high risk for HIV acquisition through the injection of illicit drugs” (CDC, 2013).

This systematic review examined evidence to answer the following PICO question: Should oral PrEP (containing tenofovir (TDF)) be used for HIV prevention among people who inject drugs (PWID)? In addition, we reviewed the values and preferences about PrEP among people who use drugs and considered studies of cost and feasibility for the GRADE process.
Methods

**PICO question**

PICO 1: Should oral PrEP (containing tenofovir (TDF)) be used for HIV prevention among people who inject drugs (PWID)?

**P:** People who inject drugs

**I:** Oral PrEP (containing tenofovir (TDF))

**C:** Placebo

**O:** (1) HIV infection, (2) any adverse event, (3) any stage 3 or 4 adverse event, (4) condom use, (5) number of sexual partners, (6) injection frequency, (7) needle/syringe sharing

**Inclusion criteria**

To be included in the review, an article had to meet the following criteria:

4) Randomized controlled trial evaluating the use of oral PrEP (containing tenofovir (TDF)) to prevent HIV infection among PWID.

5) Measured one or more of the following key outcomes: (1) HIV infection, (2) any adverse event, (3) any stage 3 or 4 adverse event, (4) condom use, (5) number of sexual partners, (6) injection frequency, (7) needle/syringe sharing

6) Published in a peer-reviewed journal, or presented as an abstract at a scientific conference, between January 1, 1990 and January 1, 2014.

Only studies among people who inject drugs were included; studies among people who use, but do not inject, drugs were excluded, as HIV risk and transmission modalities differ between these groups. However, both terms were used in the search.

No restrictions were placed based on location of the intervention. No language restrictions were used on the search. Articles in languages other than English were translated where necessary.

Following the GRADE approach, if direct evidence from PWID populations was limited for one or more of the key outcomes, indirect evidence from other populations (men who have sex with men, or heterosexual men or women) would be used instead, but downgraded for indirectness. If evidence from other populations was limited, evidence from non-randomized but controlled studies would be used instead, but also downgraded for directness.

**Search strategy**

The following electronic databases were searched using the date ranges January 1, 1990 to January 1, 2014: PubMed, CINAHL (Cumulative Index to Nursing and Allied Health Literature), and EMBASE. Secondary reference searching was conducted on all studies included in the review. Further, selected experts in the field were contacted to identify additional articles not identified through other search methods.
Abstracts from the following conferences were searched from January 1, 1990 to January 1, 2014: International AIDS Conference (IAC) and IAS Conference on HIV Pathogenesis, Treatment, and Prevention (IAS). We had planned to search the Conference on Retroviruses and Opportunistic Infections (CROI) as well, but abstracts from this conference were no longer available online to the public at the time the search was conducted.

**Search terms**
The following terms were entered into all computer databases:

(“people who use drugs” or PWUD or “people who inject drugs” or PWID or “drug users” or IDU or IDUs) AND (“pre-exposure prophylaxis” or PrEP or tenofovir or TDF) AND (HIV OR AIDS)

These search terms were used both for the main systematic review (PICO question) and for the values and preferences review.

The search for abstracts was more difficult given the search engines available on conference websites. For each conference, a search was first conducted for all abstracts including the word “PrEP”. These search results were then further searched for keywords regarding PWID.

**Screening abstracts**
Titles, abstracts, citation information, and descriptor terms of citations identified through the search strategy were screened by two reviewers. 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 consensus.

Articles not meeting the inclusion criteria for the review, but presenting potentially interesting background information relevant to PrEP among PWID, including review articles, qualitative studies, cost or cost-effectiveness analyses, or descriptions of interventions without an evaluation component, were included in an annotated bibliography of additional articles.

**Data extraction and management**
Data were extracted independently by two reviewers using standardized data extraction forms. Differences in data extraction were resolved through consensus and referral to a senior team member from WHO when necessary. Study authors were contacted 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
Risk of bias was assessed using the Cochrane Collaboration’s tool for assessing risk of bias (Cochrane Handbook, chapter 8.5 – Higgins & Green, 2011). 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). Methodological components of the studies were assessed and classified as high, low, or uncertain risk of bias.

**Data analysis**

Data were analyzed according to coding categories and outcomes. If multiple studies reported the same outcome, meta-analysis would have been conducted using random-effects models to combine effect sizes with the program Comprehensive Meta-Analysis (CMA). Data were summarized in GRADE tables, summary of finding tables, and risk/benefit tables.

**Results**

Our initial database search yielded 183 citations and 243 conference abstracts; no additional studies were identified through other means (Figure 1). Once duplicates were removed, 392 records were reviewed and 131 article citations and 236 abstracts were excluded for being unrelated to the study topic. After review of the remaining 17 articles and 7 abstracts by two independent screeners, 16 articles were excluded for not meeting the study design criteria and were coded as background or values and preferences, while 6 abstracts were excluded for providing additional information on the included trial, but without reporting key outcomes. The remaining study (with data for PICO outcomes reported in one article and one conference abstract) was deemed eligible for inclusion in our review.

The one study that met all inclusion criteria was the Bangkok Tenofovir Study (Choopanya et al., 2013; Vanichseni et al., 2013). This study was a randomized controlled trial to assess whether daily oral use of tenofovir disoproxil fumarate (tenofovir) can reduce HIV transmission in injecting drug users. The trial was conducted in Bangkok, Thailand, where 2413 total participants were recruited from 17 drug treatment clinics. Participants’ ages ranged from 20 to 59 years (mean=32.4), 80% were male, and 63% reported injecting drugs in the past 12 weeks.

Using the Cochrane Risk of Bias tool, the study was judged to have low risk of bias across all of the following categories: random sequence generation (selection bias), allocation concealment (selection bias), blinding of participants and personnel (performance bias), blinding of outcome assessment (detection bias), and selective reporting (reporting bias). For selective reporting (reporting bias), the study was initially judged to have uncertain risk of bias. The study protocol was available, and all of the study’s pre-specified primary outcomes of interest were reported in the pre-specified way. However, for two secondary outcomes, condom use and number of sexual partners, outcomes that were predefined in the protocol were not available, or not available in the pre-specified way, in published reports. After contacting the study authors for additional information, data on these outcomes were shared with the review team that have not yet been published given the recent conclusion of the trial. Therefore, the judgment on selective reporting was changed to low risk. For incomplete outcome data (attrition bias), we noted that loss to follow-up was high relative to the number of events. Loss to follow-up was 14.9% in the PrEP group and 14.6% in the placebo group; additional participants from both groups withdrew from the study, died, or otherwise stopped follow-up. Although there were no differences in follow-up time,
withdrawal, or loss to follow-up between treatment groups, GRADE guidance notes that "large loss to follow-up in relation to the number of events always... raises the issue of a serious threat of bias" (Guyatt et al., 2011). Further, GRADE generally urges caution classifying a single RCT in a single location as an overall high quality of evidence (Guyatt et al., 2011). For these reasons, we made a judgment of high risk for this measure and downgraded the quality of evidence for potential risk of bias across all study outcomes (as most outcomes had relatively high loss to follow-up relative to the number of events, and the single trial was the only evidence across all outcomes). Finally, we calculated relative risks and 95% confidence intervals for outcomes where effect size estimates were not presented. Based on this analysis, in GRADE, we downgraded three outcomes – condom use, number of sexual partners and needle/syringe sharing – for imprecision because the 95% CI includes appreciable benefit or harm according to the GRADE general guideline of a relative risk of under 0.75 or over 1.25.

The study measured all seven key outcomes for this review: (1) HIV infection, (2) any adverse event, (3) any stage 3 or 4 adverse event, (4) condom use, (5) number of sexual partners, (6) injection frequency, and (7) needle/syringe sharing. Results for each outcome are presented below.

**HIV infection**

Incident HIV infection was significantly reduced among participants in the tenofovir study arm as compared to the control arm using both an intention-to-treat analysis and a modified intention-to-treat. In the intention-to-treat analysis, there were 17 incident cases of HIV infection out of 1204 participants in the tenofovir study arm and 35 incident HIV infections out of 1209 participants in the control group, resulting in a 51.8% reduction in HIV incidence (95% confidence interval (CI): 15.3-73.7, p=0.01). In the modified intention-to-treat analysis (excluding 2 control participants who were HIV-positive at enrolment), there were 17 incident cases of HIV in the tenofovir group out of 4843 person-years (py) for an incidence of 0.35 per 100 py and 33 incident cases of HIV in the control group out of 4823 py for an incidence of 0.68 per 100 py. Thus, in the modified intention-to-treat analysis, there was a 48.9% reduction in HIV incidence (95% CI: 9.6–72.2, p=0.01).

In age-stratified analyses, PrEP was effective in those age 40 and older, while there was no significant difference between PrEP and placebo in the age groups 20-29 or 30-39 (although results trended in a positive direction). For participants age 40 and older, the number of incident infections overall was small, with 1 incident infection out of 1066 py in the tenofovir group for an incidence of 0.09 per 100 py (95% CI: 0.002-0.52) and 9 incident infections out of 1052 py in the control group for an incidence of 88.9 per 100 py (95% CI: 41.1-99.4); this difference was statistically significant (p=0.01). For participants age 20-29, there were 11 incident infections out of 1976 py in the tenofovir group for an incidence of 0.56 per 100 py (95% CI: 0.28-1.00), versus 17 incident infections out of 1993 py in the control group for an incidence of 0.85 per 100 py (95% CI: 0.50-1.37); this difference was not statistically significant (p=0.30). For participants age 30-39, there were 5 incident infections out of 1801 py in the tenofovir group for an incidence of 0.28 per 100 py (95% CI: 0.09-0.65), versus 7 incident infections out of 1778 py in the control group for an incidence of 0.39 per 100 py (95% CI: 0.16-0.81); this difference was not statistically significant (p=0.55).

**Any adverse event**

There was no statistically significant difference in reported adverse events between the two study arms. In the tenofovir arm, 91% of participants (1098/1204) had an adverse event (10965 events total). In the
placebo arm, 90% of participants (1083/1209) had an adverse event (11550 events total). This difference between arms was not statistically significant (p=0.46).

**Any stage 3 or 4 adverse event**
Both study arms also reported similar rates of stage 3 and 4 adverse events. In the tenofovir arm, 13% of participants (156/1204) had a stage 3 or 4 adverse event (414 events total). In the placebo arm, 13% of participants (160/1209) had a stage 3 or 4 adverse event (389 events total). This difference between arms was not statistically significant (p=0.89).

**Condom use**
Condom use data were not reported in any published articles or abstracts at the time of the search, but the Bangkok Tenofovir Study authors were contacted and provided additional unpublished data for condom use outcomes. Participants who self-reported sex with a live-in or casual partner were then asked questions about condom use. A skip pattern error in the initial years of the study made data on condom use with casual partners unreliable. Therefore, we present data on condom use with live-in partners. At baseline, 6.5% (34/526) of tenofovir study arm participants with live-in partners reported always using condoms with those partners (vs. less than always condom use), compared with 8.5% (44/518) of placebo arm participants. At 12-month follow-up, these changed to 11.1% (41/369) in the tenofovir group and 11.3% (44/388) in the placebo group. At 12-month follow-up, this translates to a relative risk (RR) of 0.979 (95% CI: 0.656 to 1.463).

**Number of sexual partners**
Self-report of sex with more than one partner in the previous 3 months was 22% at enrollment across both study arms and dropped to 11% at the 12-month follow-up and 6% at the 72-month follow-up. Additional unpublished data were also shared by the study investigators. At the 12 month follow-up, reported number of sexual partners in the previous 3 months was not statistically significant between the tenofovir and placebo arms (p=0.181). At the 12 month follow-up, 44.9% (413/919) of tenofovir arm participants and 41% (394/960) of placebo arm participants reported no sexual partners in the past 3 months, 45% (414/919) and 47% (451/960) respectively reported 1 partner, 6.4% (59/919) and 7.5% (72/960) respectively reported 2 partners, 1.5% (14/919) and 2.1% (20/960) respectively reported 3 partners, and 2.1% (19/919) and 2.4% (23/960) respectively reported 4 or more partners. In regression analyses there were no interactions between time and treatment group for this outcome.

**Injection frequency**
Self-report of injecting drugs in the previous 3 months was 63% at enrollment across both study arms and dropped to 23% at the 12-month follow-up and 18% at the 72-month follow-up. Additional unpublished data were also shared by the study investigators. At the 12 month follow-up, reported injecting drugs in the previous 3 months was 22.1% (203/919) for the tenofovir arm and 23.3% (224/960) for the placebo arm; this difference was not statistically significant (p=0.520). In regression analyses there were no interactions between time and treatment group for this outcome.

**Needle/syringe sharing**
Self-report of needle sharing in the previous 3 months was 18% at enrollment across both study arms and dropped to 2% at the 12-month follow-up and 1% at the 72-month follow-up. Additional unpublished data were also shared by the study investigators. At the 12 month follow-up, reported needle sharing in
the previous 3 months was 2.3% (21/919) for the tenofovir arm and 2.4% (23/960) for the placebo arm; this difference was not statistically significant (p=0.874). In regression analyses there were no interactions between time and treatment group for this outcome.
Figure 1: Disposition of citations during the search and screening process

Records identified through database searching (N=183)

Conference abstracts identified (N=243)

Additional records identified through other sources (N=0)

Records after duplicates removed (N=392)

Records screened (N=392)

Records excluded after first review (N=131)

Abstracts excluded after first

Full-text articles/abstracts assessed for eligibility (N=24)

Full-text articles/abstracts excluded (N=22) because:
- Articles not meeting study design criteria; coded as background or values and preferences (N=16)
- Abstracts providing additional information on the included trial, but without key outcomes (N=6)

Studies included in the review (N=1) (primary outcomes reported in one article and one abstract)
Table 1: Risk-benefit table

<table>
<thead>
<tr>
<th>Factor</th>
<th>Explanation / Evidence</th>
</tr>
</thead>
<tbody>
<tr>
<td>Quality of Evidence</td>
<td>One RCT from a single country with some limitations.</td>
</tr>
<tr>
<td>Balance of Benefits vs. Harms</td>
<td><strong>HIV infection</strong>&lt;br&gt;Oral PrEP was associated with reduced risk of HIV in both intention-to-treat analysis (HR: 0.53, 95% CI 0.36-0.78, p=0.001) and modified intention-to-treat analysis (HR: 0.56, 95% CI 0.37-0.85, p=0.005).&lt;br&gt;&lt;br&gt;<strong>Adverse events</strong>&lt;br&gt;There were no significant differences in reported adverse events between the TDF and placebo arms for either any adverse event (91% vs. 90%, p=0.46) or grade 3 and 4 adverse events (13% vs. 13%, p=0.89).&lt;br&gt;&lt;br&gt;<strong>Condom use</strong>&lt;br&gt;Both the TDF and placebo arms reported increased condom use with live-in partners over the course of the study. At 12-month follow-up, intervention and control group rates were 11.1% and 11.3%, respectively.&lt;br&gt;&lt;br&gt;<strong>Number of sexual partners</strong>&lt;br&gt;Both the TDF and control study arms reported reduced number of sexual partners over the course of the study; however, there was no significant difference between study arms over time or at 12-month follow-up (p=0.181).&lt;br&gt;&lt;br&gt;<strong>Injection frequency and needle/syringe sharing</strong>&lt;br&gt;Both the TDF and control study arms reported reduced injection behavior and injecting with used needles over the course of the study. However, there were no significant differences between study arms over time or at 12 month follow-up (p=0.520 for injection frequency and p=0.874 for needle/syringe sharing).</td>
</tr>
<tr>
<td>Values and Preferences</td>
<td>A systematic review (see page 11) identified one published study examining acceptability of PrEP and factors likely to influence uptake. This quantitative study was conducted among 128 PWID in Ukraine. Most PWID said they would definitely (53%) or probably (32%) use PrEP if it became available. These results were generally maintained when participants were prompted on potential side effects, the need to combine condom use with PrEP, and the need for regular HIV testing. Route of administration was considered the most important attribute influencing PrEP uptake, with injections preferred over pills.&lt;br&gt;A WHO consultation qualitatively interviewed 21 PWID and experts, service providers and activists from all geographic regions. Qualified support for PrEP was based on its potential usefulness for some PWID in countries where other harm reduction options or not available and with good ART access. Resistance was based on perceptions that cheap, proven harm reduction interventions are already available for PWID; PrEP is not proven for PWID; unethical to give PrEP when not all PLHIV can get treatment; medicalizes the HIV response; investment should be made in other interventions (e.g., Hep C); and concern about hidden agendas. Ambivalent feelings expressed were based</td>
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<tr>
<td>Factor</td>
<td>Explanation / Evidence</td>
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<tr>
<td></td>
<td>on concerns that PrEP was too new and unproven; unnecessary and impractical for many PWID; skepticism about adherence; not a priority; and concern about undermining established harm reduction programs. The consultation concluded: “A recommendation for the use of PrEP as a harm reduction intervention for people who inject drugs is not supported by the community at this time.”</td>
</tr>
<tr>
<td>Resource Use</td>
<td>One conference abstract (Alistar 2011) examined cost-effectiveness of PrEP for PWID. The dynamic compartmental model used data from Ukraine and added oral PrEP for PWID (25% access) to a package of services including methadone maintenance therapy and antiretroviral treatment. In this scenario, adding oral PrEP for PWID was cost-effective at $12,240 per QALY gained. Oral PrEP alone became cost-effective for annual PrEP costs comparable to annual HIV care costs.</td>
</tr>
<tr>
<td>Feasibility</td>
<td>Concerns have been raised about the ethics of the Bangkok Tenofovir Study. Issues of criminalization, stigma and discrimination, and violence should be considered during implementation, especially where injection drug use is illegal. Issues of feasibility are for further discussion in the consensus conference.</td>
</tr>
</tbody>
</table>
Values and preferences literature review

Summary of findings

The comprehensive search of the literature identified one study reporting on values and preferences of people who inject drugs (PWID) about pre-exposure prophylaxis (PrEP) for HIV prevention. This study by Eisingerich, Wheelock et al. (2012) was a multi-country study of the acceptability of PrEP among various user groups and factors likely to influence uptake. This study included one population of 128 PWID from Ukraine (specifically, Donetsk, Kharkiv, Mykolayiv, and Vinnitsa). Data were collected between October 2010 and May 2011, prior to the release of any results from the PrEP trials. PWID were non-randomly sampled from needle-exchange points and NGOs.

Among the 128 PWID participants from Ukraine, a strong majority said that based on what they had heard, they would definitely (53%) or probably (32%) use PrEP if it became available. Of these, most (59%) said they would definitely take it as soon as it becomes available. These numbers decreased only slightly when researchers mentioned potential side effects of PrEP; when asked if they would take PrEP if it caused mild temporary side effects such as tiredness, headaches and gassiness, 28% said “yes, definitely” and 46% said “yes, probably”. A slightly smaller proportion (63%) said they would definitely or probably take PrEP if they had to pay for it. The majority (78%) said they would definitely or probably take PrEP even if they had to also use condoms, and 88% said they would take PrEP even if they had to be regularly tested for HIV.

Only a small percent (6%) said the thought of taking PrEP made them feel very or fairly anxious. Conversely, many thought that PrEP gave them a lot of hope (32%) or some hope (44%) for new possibilities in life. Many (43%) also said they would definitely or probably want their partner(s) to know if they were taking PrEP, although 25% said they would definitely or probably not want their partner(s) to know if they were taking PrEP. In terms of sharing and selling PrEP, 41% said that if PrEP were free of charge, they would definitely or probably share it with other people in need, while 9% said they would definitely or probably sell PrEP to others.

In terms of factors likely to influence PrEP uptake, route of administration was considered the most important attribute, with injections in the arm or buttocks preferred over daily or coitally-dependent pills. HIV testing frequency was the second most important attribute, while time spent obtaining PrEP and frequency of pickup were less important.

In summary, many PWID perceived PrEP as giving them hope and would consider using it as soon as it becomes available. These results were generally maintained when participants were prompted on potential side effects, the need to combine condom use with PrEP, and the need for regular HIV testing. Route of administration was considered the most important attribute of the presented alternatives.
Annexes

Annex 1. GRADE table

**Author** (s): Caitlin Kennedy and Virginia Fonner  
**Date:** 2014-03-11  
**Question:** Should oral PrEP (including tenofovir (TDF)) be used in people who inject drugs (PWID)?  

<table>
<thead>
<tr>
<th>Quality assessment</th>
<th>No of patients</th>
<th>Effect</th>
<th>Quality</th>
<th>Importance</th>
</tr>
</thead>
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<tr>
<td>No of studies</td>
<td>Design</td>
<td>Risk of bias</td>
<td>Inconsistency</td>
<td>Indirectness</td>
</tr>
<tr>
<td>HIV infection (follow-up mean 4.0 years; assessed with: intention to treat analysis)</td>
<td>1 randomised trials</td>
<td>serious</td>
<td>no serious inconsistency</td>
<td>no serious indirectness</td>
</tr>
<tr>
<td>HIV infection (follow-up mean 4.0 years; assessed with: modified intention to treat analysis)</td>
<td>1 randomised trials</td>
<td>serious</td>
<td>no serious inconsistency</td>
<td>no serious indirectness</td>
</tr>
<tr>
<td>Any adverse event (follow-up mean 4.0 years)</td>
<td>1 randomised</td>
<td>serious</td>
<td>no serious</td>
<td>no serious</td>
</tr>
<tr>
<td>Output</td>
<td>Consent for Condom (randomised trials)</td>
<td>Serious</td>
<td>No serious inconsistency</td>
<td>No serious indirectness</td>
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</tbody>
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1 Loss to follow-up was high relative to the number of events. Although there were no differences in follow-up time, withdrawal, or loss to follow-up between treatment groups. GRADE guidance notes that "large loss to follow-up in relation to the number of events always... raises the issue of a serious threat of bias" (Guyatt et al., 2011). Further, GRADE generally urges caution classifying a single RCT in a single location as an overall high quality of evidence (Guyatt et al., 2011). For these reasons, we have therefore downgraded the quality of evidence for potential risk of bias.

2 The 95% CI includes appreciable benefit or harm according to the GRADE general guideline of a RR of under 0.75 or over 1.25.
Annex 2. Annotated bibliography


BACKGROUND: Antiretroviral pre-exposure prophylaxis reduces sexual transmission of HIV. We assessed whether daily oral use of tenofovir disoproxil fumarate (tenofovir), an antiretroviral, can reduce HIV transmission in injecting drug users. METHODS: In this randomised, double-blind, placebo-controlled trial, we enrolled volunteers from 17 drug-treatment clinics in Bangkok, Thailand. Participants were eligible if they were aged 20-60 years, were HIV-negative, and reported injecting drugs during the previous year. We randomly assigned participants (1:1; blocks of four) to either tenofovir or placebo using a computer-generated randomisation sequence. Participants chose either daily directly observed treatment or monthly visits and could switch at monthly visits. Participants received monthly HIV testing and individualised risk-reduction and adherence counselling, blood safety assessments every 3 months, and were offered condoms and methadone treatment. The primary efficacy endpoint was HIV infection, analysed by modified intention-to-treat analysis. This trial is registered with ClinicalTrials.gov, number NCT00119106. FINDINGS: Between June 9, 2005, and July 22, 2010, we enrolled 2413 participants, assigning 1204 to tenofovir and 1209 to placebo. Two participants had HIV at enrolment and 50 became infected during follow-up: 17 in the tenofovir group (an incidence of 0.35 per 100 person-years) and 33 in the placebo group (0.68 per 100 person-years), indicating a 48.9% reduction in HIV incidence (95% CI 9.6-72.2; p=0.01). The occurrence of serious adverse events was much the same between the two groups (p=0.35). Nausea was more common in participants in the tenofovir group than in the placebo group (p=0.002). INTERPRETATION: In this study, daily oral tenofovir reduced the risk of HIV infection in people who inject drugs. Pre-exposure prophylaxis with tenofovir can now be considered for use as part of an HIV prevention package for people who inject drugs. FUNDING: US Centers for Disease Control and Prevention and the Bangkok Metropolitan Administration.

Values and Preferences


BACKGROUND: The use of antiviral medications by HIV negative people to prevent acquisition of HIV or pre-exposure prophylaxis (PrEP) has shown promising results in recent trials. To understand the potential impact of PrEP for HIV prevention, in addition to efficacy data, we need to understand both the acceptability of PrEP among members of potential user groups and the factors likely to determine uptake. METHODS AND FINDINGS: Surveys of willingness to use PrEP products were conducted with 1,790 members of potential user groups (FSWs, MSM, IDUs, SDCs and young women) in seven countries: Peru, Ukraine, India, Kenya, Botswana, Uganda and
South Africa. Analyses of variance were used to assess levels of acceptance across different user groups and countries. Conjoint analysis was used to examine the attitudes and preferences towards hypothetical and known attributes of PrEP programs and medications. Overall, members of potential user groups were willing to consider taking PrEP (61% reported that they would definitely use PrEP). Current results demonstrate that key user groups in different countries perceived PrEP as giving them new possibilities in their lives and would consider using it as soon as it becomes available. These results were maintained when subjects were reminded of potential side effects, the need to combine condom use with PrEP, and for regular HIV testing. Across populations, route of administration was considered the most important attribute of the presented alternatives. CONCLUSIONS: Despite multiple conceivable barriers, there was a general willingness to adopt PrEP in key populations, which suggests that if efficacious and affordable, it could be a useful tool in HIV prevention. There would be a willingness to experience inconvenience and expense at the levels included in the survey. The results suggest that delivery in a long lasting injection would be a good target in drug development.

Background studies


On June 12, 2013, the Thailand Ministry of Health and CDC published results from a randomized controlled trial of a daily oral dose of 300 mg of tenofovir disoproxil fumarate (TDF) that showed efficacy in reducing the acquisition of human immunodeficiency virus (HIV) infection among injecting drug users (IDUs) (1). Based on these findings, CDC recommends that preexposure prophylaxis (PrEP) be considered as one of several prevention options for persons at very high risk for HIV acquisition through the injection of illicit drugs.


PURPOSE OF REVIEW: Oral preexposure prophylaxis (PrEP) has shown HIV preventive efficacy for several key populations at risk for HIV infection including MSM and heterosexual men and women in HIV serodiscordant relationships. An efficacy trial of daily oral tenofovir among people who inject drugs (IDU) is underway in Thailand. RECENT FINDINGS: Although efficacy data is pending, there is emerging biological and public health plausibility data suggesting the utility of PrEP as an effective component of combination HIV prevention for IDU. Drawing from studies characterizing adherence to antiretroviral therapy for IDU, there are a range of scientific and operational considerations for the potential use of PrEP for IDU. We review here the available literature on the potential use of PrEP for IDU, barriers to uptake and adherence, and potential implementation science questions, which could address, and potently increase, the effectiveness of this intervention. SUMMARY: IDU remain the most underserved population in
the HIV response worldwide, and have a marked gap in prevention services, making PrEP a potentially promising addition to the prevention toolkit for people who use drugs and, for those already living with HIV infection, for their spouses and other sexual partners.


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BACKGROUND: The use of antiviral medications by HIV negative people to prevent acquisition of HIV or pre-exposure prophylaxis (PrEP) has shown promising results in recent trials. To
understand the potential impact of PrEP for HIV prevention, in addition to efficacy data, we need to understand both the acceptability of PrEP among members of potential user groups and the factors likely to determine uptake. METHODS AND FINDINGS: Surveys of willingness to use PrEP products were conducted with 1,790 members of potential user groups (FSWs, MSM, IDUs, SDCs and young women) in seven countries: Peru, Ukraine, India, Kenya, Botswana, Uganda and South Africa. Analyses of variance were used to assess levels of acceptance across different user groups and countries. Conjoint analysis was used to examine the attitudes and preferences towards hypothetical and known attributes of PrEP programs and medications. Overall, members of potential user groups were willing to consider taking PrEP (61% reported that they would definitely use PrEP). Current results demonstrate that key user groups in different countries perceived PrEP as giving them new possibilities in their lives and would consider using it as soon as it becomes available. These results were maintained when subjects were reminded of potential side effects, the need to combine condom use with PrEP, and for regular HIV testing. Across populations, route of administration was considered the most important attribute of the presented alternatives. CONCLUSIONS: Despite multiple conceivable barriers, there was a general willingness to adopt PrEP in key populations, which suggests that if efficacious and affordable, it could be a useful tool in HIV prevention. There would be a willingness to experience inconvenience and expense at the levels included in the survey. The results suggest that delivery in a long lasting injection would be a good target in drug development.


BACKGROUND: Cost-effectiveness studies inform resource allocation, strategy, and policy development. However, due to their complexity, dependence on assumptions made, and inherent uncertainty, synthesising, and generalising the results can be difficult. We assess cost-effectiveness models evaluating expected health gains and costs of HIV pre-exposure prophylaxis (PrEP) interventions. METHODS AND FINDINGS: We conducted a systematic review comparing epidemiological and economic assumptions of cost-effectiveness studies using various modelling approaches. The following databases were searched (until January 2013): PubMed/Medline, ISI Web of Knowledge, Centre for Reviews and Dissemination databases, EconLIT, and region-specific databases. We included modelling studies reporting both cost and expected impact of a PrEP roll-out. We explored five issues: prioritisation strategies, adherence, behaviour change, toxicity, and resistance. Of 961 studies retrieved, 13 were included. Studies modelled populations (heterosexual couples, men who have sex with men, people who inject drugs) in generalised and concentrated epidemics from Southern Africa (including South Africa), Ukraine, USA, and Peru. PrEP was found to have the potential to be a cost-effective addition to HIV prevention programmes in specific settings. The extent of the impact of PrEP depended upon assumptions made concerning cost, epidemic context, programme coverage, prioritisation strategies, and individual-level adherence. Delivery of PrEP to key populations at highest risk of HIV exposure appears the most cost-effective strategy. Limitations of this review include the partial geographical coverage, our inability to perform a meta-analysis, and the paucity of information available exploring trade-offs between early treatment and PrEP. CONCLUSIONS:
Our review identifies the main considerations to address in assessing cost-effectiveness analyses of a PrEP intervention—cost, epidemic context, individual adherence level, PrEP programme coverage, and prioritisation strategy. Cost-effectiveness studies indicating where resources can be applied for greatest impact are essential to guide resource allocation decisions; however, the results of such analyses must be considered within the context of the underlying assumptions made. Please see later in the article for the Editors' Summary.


OBJECTIVE: To examine condom-use decision making in the context of hypothetical pre-exposure prophylaxis (PrEP) efficacy among men who have sex with men who use alcohol and other substances during sex. METHODS: Substance-using men who have sex with men were recruited in 4 US cities for a behavioral intervention trial. Three groups were defined as follows: men who indicated that to not use a condom for receptive/insertive unprotected anal intercourse (UAI) while using PrEP, PrEP would need to be: (1) "almost always or always" effective (high efficacy); (2) effective "at least half the time or more but not almost always or always" (mid-range efficacy corresponding to recent PrEP trial results); (3) effective "less than half the time" (low efficacy). The mid-range efficacy group was compared with the low-efficacy group (as the reference) and to the high-efficacy group (as the reference). RESULTS: Among 630 men who never used PrEP, 15.2% were in the mid-range efficacy group for receptive UAI and 34.1% in the mid-range efficacy group for insertive UAI. Scores on difficulty communicating about safer sex while high were significantly higher in the mid-range efficacy group compared with each of the other groups for both receptive and insertive UAI. Men who seemed to be differentiating PrEP use by anal sex role also scored higher on communication difficulties, although scoring lower on condom intentions. CONCLUSIONS: Communication about safer sex while under the influence of alcohol or other substances and condom intentions are important factors to consider for HIV prevention interventions for PrEP users.


BACKGROUND: The Bangkok Tenofovir Study was launched in 2005 to determine if pre-exposure prophylaxis with tenofovir will reduce the risk of HIV infection among injecting drug users (IDUs). We describe recruitment, screening, enrollment, and baseline characteristics of study participants and contrast risk behavior of Tenofovir Study participants with participants in
the 1999-2003 AIDSVAX B/E Vaccine Trial. METHODS: The Bangkok Tenofovir Study is an ongoing, phase-3, randomized, double-blind, placebo-controlled, HIV pre-exposure prophylaxis trial of daily oral tenofovir. The Tenofovir Study and the Vaccine Trial were conducted among IDUs at 17 drug-treatment clinics in Bangkok. Tenofovir Study sample size was based on HIV incidence in the Vaccine Trial. Standardized questionnaires were used to collect demographic, risk behavior, and incarceration data. The Tenofovir Study is registered with ClinicalTrials.gov, number--NCT00119106. RESULTS: From June 2005 through July 2010, 4094 IDUs were screened and 2413 enrolled in the Bangkok Tenofovir Study. The median age of enrolled participants was 31 years (range, 20-59), 80% were male, and 63% reported they injected drugs during the 3 months before enrollment. Among those who injected, 53% injected methamphetamine, 37% midazolam, and 35% heroin. Tenofovir Study participants were less likely to inject drugs, inject daily, or share needles (all, p<0.001) than Vaccine Trial participants. DISCUSSION: The Bangkok Tenofovir Study has been successfully launched and is fully enrolled. Study participants are significantly less likely to report injecting drugs and sharing needles than participants in the 1999-2003 AIDSVAX B/E Vaccine Trial suggesting HIV incidence will be lower than expected. In response, the Bangkok Tenofovir Study enrollment was increased from 1600 to 2400 and the study design was changed from a defined 1-year follow-up period to an endpoint-driven design. Trial results demonstrating whether or not daily oral tenofovir reduces the risk of HIV infection among IDUs are expected in 2012.


Objective To investigate the attitude on pre-exposure prophylaxis (PrEP) among drug users from high-risk population of AIDS in western China and its influencing factors. Methods A total of 190 drug users were recruited by snowball sampling from high-risk population of AIDS including those involved in men having sex with men (MSM), female sex workers (FSW) and the spouse or sex partner (PAR) of HIV carrier in Chongqing, Sichuan, Guangxi and Xinjiang. Self-administered questionnaire survey was conducted with the assistance of investigators. Univariate and multivariate logistic regression was employed for statistical analysis. Results MSM, FSW and PAR accounted for 34.74% (66/190), 48.42% (92/190) and 16.84% (32/190) among the 190 drug users, respectively. The positive attitude rate for PrEP among drug users reached 70% in the premise of drug safety and effectiveness, which increased with favorable condition provided. The results of multivariate logistic regression analysis indicated that the factors significantly associated with the positive attitude for PrEP included awareness of AIDS seriousness (OR = 2.66, 95% CI: 1.14-6.25, P = 0.024 2), attitudes towards HIV patients (OR = 4.41, 95% CI: 1.68-11.58, P = 0.002 6, OR = 2.99, 95% CI: 1.05-8.54, P = 0.040 3) and virus detection of AIDS (OR = 1.94, 95% CI: 0.98-3.87, P = 0.058 1). Conclusion The attitude for PrEP among drug users from AIDS high-risk population is mainly related to the attitude for AIDS, AIDS-related knowledge and behavior, and preventive measures for AIDS, indicating that PrEP should be implemented and promoted with a sound social background, and education on HIV/AIDS prevention should be reinforced. Positive attitude towards AIDS prevention need to be developed among drug users by various behavioral therapies, so as to improve the attitude for PrEP among drug users with high HIV risks.
References

References for the systematic review write up


References for the values and preferences review of the literature

Annex 3: Values and preferences of key populations: consolidated report

This report was prepared to inform the World Health Organization Consolidated guidelines on HIV prevention, diagnosis, treatment and care for key populations development process.

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   3.1 Cross-cutting issues ................................................................................................. 114
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   3.4 Treatment and care, ART for prevention ................................................................. 120
   3.5 Harm reduction ....................................................................................................... 124
Mary Henderson (WHO consultant), provided the consolidated analysis of values and preferences and this final report. Alice Armstrong (WHO consultant) supported Mary Henderson and contributed through the consolidation and analysis of the young key population components of the consolidated report. Alice Armstrong also coordinated the collection of young key population values and preferences processes performed by numerous youth and community organisations as part of the development of the HIV and young key population technical brief series and included within this report (see listed below and Annex 6).

The individuals, community networks and organizations that carried out the values and preferences work are listed in table 1 within the methods section. Reference to their work is also listed below:

- Caitlin Kennedy & Virginia Fonner. Pre-exposure prophylaxis for men who have sex with men: a systematic review (see Annex 1) & Pre-exposure prophylaxis for people who inject drugs: a systematic review (see Annex 2).
- Mary Henderson. Values and preferences of people who inject drugs, and views of experts, activists and service providers: HIV prevention, harm reduction and related issues (see Annex 3.2).
- Mira Schneider. Values and preferences of transgender people: a qualitative study (see Annex 3.3).
- Youth Leadership, Education, Advocacy and Development Project. Access to Youth Friendly HIV services for Young Key Affected People (YKAP) in Asia. unpublished data.

Sincere thanks go out to all those involved in the consultations.
1. **Background**

WHO is consolidating existing guidance for key populations and including important new recommendations to address issues for which new evidence or experience have become available. The consolidated guidance will consider a range of elements that are common across all key populations as well as highlighting specific issues that are unique to individual population groups. It will guide and support countries to plan, develop and monitor acceptable and appropriate programmes that include a range of issues that affect members of key populations and their ability to access HIV prevention, treatment and care, and harm reduction services.

Key populations covered by this work include men who have sex with men (MSM), transgender people (TG), people who inject drugs (PWID), sex workers (SW), prisoners, migrants and adolescent and young people from key population groups (YKP).

An essential element of this work has been engaging and partnering with key population groups and networks to understand their values and preferences related to HIV and harm reduction service provision, to learn from their experiences and to incorporate their suggestions for building on existing effective programming. A number of global and regional processes explored the values and preferences of different key populations around different themes. This summary report highlights key messages that are common across all, or a number of, key population groups and notes other specific issues that are of particular concern to individual groups.

The results of this consolidation are presented in tables organized into five main topics:

- **Cross-cutting issues** (includes human rights, protection, criminalization, vulnerability, service delivery issues, social and interpersonal issues, access to services)
- **HIV prevention** (includes HTC, commodities, services and information)
- **Testing modalities** (includes consideration of access, clinic-based vs mobile and outreach services, and self-testing)
- **ART** (includes treatment and care services, ART for prevention)
- **Harm reduction** (includes the comprehensive package and related issues)
2. Methods

This consolidation comprises findings from 13 studies, group consultations, online surveys or literature reviews conducted from 2012–2014. Those are listed with authors in table 1.

Table 1. Contributing individuals, networks and organisations to the values and preferences

<table>
<thead>
<tr>
<th>KEY POPULATION</th>
<th>AUTHOR (ORGANIZATION OR INDIVIDUAL)</th>
<th>TOPIC(S)</th>
</tr>
</thead>
<tbody>
<tr>
<td>YKP</td>
<td>1. Youth Rise (YPWID)</td>
<td>Comprehensive harm reduction package</td>
</tr>
<tr>
<td></td>
<td>2. HIV Young Leaders Fund (YP who sell sex)</td>
<td>Experiences of young people who sell sex; exploring programmatic approaches and suggestions from YSW</td>
</tr>
<tr>
<td></td>
<td>3. Youth Voice Count (YMSMTG)</td>
<td>Self-stigma, HIV and human rights</td>
</tr>
<tr>
<td></td>
<td>4. UNFPA (YKP)</td>
<td>Access/availability to services and support</td>
</tr>
<tr>
<td></td>
<td>5. Youth LEAD (YKP)</td>
<td>Accessibility of services</td>
</tr>
<tr>
<td>MSM (multi-country)</td>
<td>6. MSMGF</td>
<td>HTC, access to services, ART for prevention, discrimination, violence and legal issues</td>
</tr>
<tr>
<td>MSM (multi-country)</td>
<td>7. Caitlin Kennedy (JHU)</td>
<td>PrEP (part of systematic review)</td>
</tr>
<tr>
<td>PWID (Ukraine)</td>
<td>8. Caitlin Kennedy</td>
<td>PrEP (part of systematic review)</td>
</tr>
<tr>
<td>PWID (multi-country)</td>
<td>9. Mary Henderson (independent consultant)</td>
<td>HIV prevention, ART for prevention, harm reduction, community distribution of naloxone</td>
</tr>
<tr>
<td>PWID (Vietnam)</td>
<td>10. Kristine Buchman and Masaya Kato (WHO, WPRO)</td>
<td>Early ART and periodic HIV testing</td>
</tr>
<tr>
<td>SW (South Africa)</td>
<td>11. Wits Reproductive Health Institute</td>
<td>PrEP</td>
</tr>
<tr>
<td>KP (South Africa)</td>
<td>12. GNP+ and AVAC</td>
<td>PrEP and TasP</td>
</tr>
<tr>
<td>Prisoners</td>
<td>13. Amee Schwitters (CDC)</td>
<td>Condoms, drug dependence treatment, HTC</td>
</tr>
</tbody>
</table>

Data from the reports were entered into a spreadsheet; findings were categorised by key population group; country/region; theme; values, views or experience; and preferences or recommendations. Common values and preferences across groups as well as issues specific to individual groups were identified through qualitative grouping and analysis. Findings reflecting the views of clear majorities of respondents or most of the KP groups are listed as common values and preferences or key messages. However, due to the variations in themes explored by different studies and reviews, analysis of findings may require further data collection to be conclusive.
3. **Summary of key findings**

The following tables present the common themes across all or most key population groups, and issues unique to specific groups or regions within each main topic area.

### 3.1 Cross-cutting issues

**Table 2. Values & preferences across key population groups: cross-cutting issues**

<table>
<thead>
<tr>
<th>COMMON VALUES / VIEWS / EXPERIENCES</th>
<th>COMMON PREFERENCES / RECOMMENDATIONS</th>
<th>ISSUES SPECIFIC TO INDIVIDUAL GROUPS, COUNTRIES or REGIONS</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Criminalization of key populations and specific practices associated with these communities undermines HIV prevention and harm reduction: Threat of harassment, detention is a major barrier to uptake of services; possession of condoms, drug paraphernalia used as ‘evidence’ of illegal behaviour.</td>
<td>Legal reforms and protections needed to reduce fear and to facilitate utilization of services and ensure that HIV prevention, treatment and care, and harm reduction are accessible and effective. <strong>WHO requested to take a strong position on this issue in partnership with other relevant bodies (UNODC, UNAIDS, and other relevant partners).</strong></td>
<td>PWID considered by many to be the most marginalized of all KP groups; decriminalization necessary to support uptake of services, retention in care and adherence to ART. Criminalization of HIV in some countries contributes to secrecy and leads to targeting of all KP and abusive application of laws, entrapment and inappropriate charges (aggravated assault, non-disclosure of HIV status) – ultimately, this fuels the epidemic in these countries.</td>
</tr>
<tr>
<td>2. Lack of protection; widespread experience of harassment, financial exploitation and physical and emotional abuse by local police.</td>
<td>Advocacy and legal reforms needed to help change the way that KPs are viewed and treated by law enforcement as well as by society. Accountability/enforcement mechanisms need to be developed and implemented to ensure that individuals’ rights are protected. Access to legal services.</td>
<td>In Nepal, YPWID can be abducted with parental consent and forced into abusive and long-term ‘rehabilitation programmes’. In some Middle East and North Africa (MENA) countries, PWID who seek services are reported to the police; bribes are paid to get overdose treatment without reports to police; PWID die of OD when peers fearful of calling for emergency services.</td>
</tr>
</tbody>
</table>
| 3. Critical enablers not sufficiently in place for KP:  
- Protection of human rights  
- Social and economic inclusion (including racism and loss of cultural identity in some settings where certain communities confront extreme social and economic exclusion)  
- Poverty, hunger, homelessness common across regions  
- Lack of access to basic health services, including mental health and | **WHO requested to take a strong position on broader societal issues when engaging with countries at highest levels of government.** | |

Annex 3
### COMMON VALUES / VIEWS / EXPERIENCES

- Psychological follow-up
- Stigma and discriminatory practices by key duty bearers in society (health system, law enforcement, educators)

### COMMON PREFERENCES / RECOMMENDATIONS

- Training, mentoring and professional support urgently needed for providers serving key populations.
- Guaranteed confidentiality required to establish trust and to encourage uptake of services.
- Peer-led services accompanied by peer support are considered the most acceptable and the most effective for all KP groups.

### ISSUES SPECIFIC TO INDIVIDUAL GROUPS, COUNTRIES or REGIONS

#### 4. Health provider issues:

Stigma, discrimination, judgmental attitudes, harassment, vocal hostility, complicity with police, lack of sensitivity, lack of understanding of KP-specific issues.

Breaches of confidentiality, with colleagues, with families of patients, with law enforcement.

Former or active injecting drug users often barred from providing services; this deprives PWID of valuable support and services from people with lived, shared experience.

In some countries, training and support are urgently needed at lower levels of the health system where providers have less capacity, professional support and understanding of KP issues; often little knowledge of updated recommendations that may affect KP.

#### 5. General lack of information about human rights, legal services, interventions.

A wide range of communication channels and media (including for low-literacy audiences) should be used to communicate lifesaving and other practical information for KP, including community-specific info.

YPK need education on their rights and mechanisms for reporting rights violations.

(Not: Not mentioned in other studies, but likely a common issue across all KP groups.)


All KP feel that services specific to their needs are preferable to services designed for the general public; at the same time, they request that certain services, such as ART, be delivered alongside other health services in order to remove the stigma attached to HIV-related services.

Outreach and mobile services preferred.

Services tailored for YKP are urgently needed. In general, YKP have a sense of being young and healthy, and they have a different perception of their risks and their needs for services; youth-targeted outreach and mobile services preferred. YKP reluctant to seek services with older members of the KP groups. Need to address the needs of YKP in ways that encourage utilization of services and minimize their exposure to abuse and arrest.

Prisoners have access to few services; confinement creates contradictions and challenges, e.g. in some places, NSP may be provided, but drug use is illegal and penalized; condoms may be provided but sex is prohibited. Comprehensive HIV prevention and harm reduction services and commodities should be available in prisons.

#### 7. Vulnerability due to lack of critical enablers in most settings.

Community-based services can help to reach the most vulnerable

YPK experience more acute, age-related vulnerability due to lack of...
<table>
<thead>
<tr>
<th>COMMON VALUES / VIEWS / EXPERIENCES</th>
<th>COMMON PREFERENCES / RECOMMENDATIONS</th>
<th>ISSUES SPECIFIC TO INDIVIDUAL GROUPS, COUNTRIES or REGIONS</th>
</tr>
</thead>
<tbody>
<tr>
<td>in society, but action at the government/policy level is also needed.</td>
<td>WHO requested to take a strong position on broader societal issues when engaging with countries at highest levels of government.</td>
<td>ID papers, exploitation from ‘gatekeepers’ and gangs, homelessness/lack of caregivers, blaming and shaming by families and in the education sector, poverty, mental health and lack of educational and employment opportunities.</td>
</tr>
<tr>
<td></td>
<td></td>
<td>YMSMTG experience violence, especially targeting young boys thought to be homosexual.</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Especially in Eastern Europe &amp; Central Asia (EECA), PWID are pushed to the edges of society, not considered as having families and friends, not considered worthy of health services, especially harm reduction.</td>
</tr>
<tr>
<td></td>
<td></td>
<td>In South Africa, SW who are marginalized or who work informally have little representation, creating challenges for advocacy and participation.</td>
</tr>
<tr>
<td>8. Social / Interpersonal issues:</td>
<td>Social mobilization, public information and awareness campaigns to reduce stigma and discrimination against KP.</td>
<td>MSM feel particularly affected by sexual and HIV-related stigma.</td>
</tr>
<tr>
<td>• Stigma and discrimination</td>
<td>Peer support for practical information, self-esteem, validation of personal choices and identities.</td>
<td></td>
</tr>
</tbody>
</table>
### 3.2 HIV prevention: HTC, commodities and services

#### Table 3. Values & preferences across key population groups: HIV prevention

<table>
<thead>
<tr>
<th>COMMON VALUES / VIEWS / EXPERIENCES</th>
<th>COMMON PREFERENCES / RECOMMENDATIONS</th>
<th>ISSUES SPECIFIC TO INDIVIDUAL GROUPS, COUNTRIES or REGIONS</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>1. Access to HTC services limited by:</strong></td>
<td>Community-based, mobile and outreach services tailored to specific KP needs.</td>
<td>MSM feel excluded by homophobia.</td>
</tr>
<tr>
<td>• Criminalization of KP behaviours</td>
<td>Integration of services; comprehensive services (HIV + other).</td>
<td>Age of consent is viewed as a barrier for most YKP, although many providers report making decisions about services in the best interest of young clients and waiving consent requirements when necessary. However, this can be risky for providers, and consent laws need to be reviewed where HIV prevention and treatment, sexual and reproductive health and harm reduction are concerned.</td>
</tr>
<tr>
<td>• Fear of harassment, detention, prosecution</td>
<td>Safe spaces for all KP.</td>
<td>Free services most important for YKP.</td>
</tr>
<tr>
<td>• Targeting by police</td>
<td>Legal reforms that recognize basic human rights and provide accountability and enforcement mechanisms.</td>
<td>Access enablers for YKP include outreach workers, peer educators, partners, brothels/pimps.</td>
</tr>
<tr>
<td>• Lack of protection</td>
<td>Need to make providers more accountable for breaches of confidentiality, harassment and all other unprofessional and discriminatory treatment of patients.</td>
<td>In MENA, YPWID face juvenile detention if they go for services.</td>
</tr>
<tr>
<td>• Societal fear and intolerance.</td>
<td>Community-based, mobile and outreach services tailored to specific KP needs.</td>
<td>In Vietnam, PWID required to attend testing with a peer educator in order to avoid fee; considered burdensome and a deterrent to seeking testing.</td>
</tr>
<tr>
<td>• Provider attitudes, harassment, coerced testing, lack of confidentiality, understanding, shaming of KP behaviours, poor communication skills</td>
<td>Services for prisoners not available in most countries.</td>
<td>In Nepal, YPWID can be abducted with parental consent and forced into abusive and long-term ‘rehabilitation programmes’.</td>
</tr>
<tr>
<td>• Structural issues, cost, distance, separated services</td>
<td>Limited services for YKP in most countries.</td>
<td>YKP need opportunities to return to school or for skills development and job placement.</td>
</tr>
<tr>
<td>• Individual issues such as HIV and sexual stigma, shame, self-stigmatization</td>
<td>Need access to info via many channels: a/v, hotlines, SMS technology, peer education.</td>
<td>YPWID report lack of info, misinformation, myths re contraception (beyond OC and condoms), emergency contraception and emergency HIV prevention (PEP); abortions common and YPWID often turn to</td>
</tr>
<tr>
<td>• Poor quality of services (waiting times, stigmatizing signage, provider attitudes and skills)</td>
<td>Need literacy programmes and info on ‘how to . . . ’ safely, info for partners and families.</td>
<td></td>
</tr>
</tbody>
</table>

#### 2. Availability of services limited by:

<table>
<thead>
<tr>
<th>COMMON VALUES / VIEWS / EXPERIENCES</th>
<th>COMMON PREFERENCES / RECOMMENDATIONS</th>
<th>ISSUES SPECIFIC TO INDIVIDUAL GROUPS, COUNTRIES or REGIONS</th>
</tr>
</thead>
<tbody>
<tr>
<td>• Services delivered only in formal health system settings</td>
<td>Community-based, mobile and outreach services tailored to specific KP needs; more flexibility for reaching isolated or marginalized communities</td>
<td></td>
</tr>
<tr>
<td>• National priorities</td>
<td>Services for prisoners not available in most countries.</td>
<td></td>
</tr>
</tbody>
</table>

#### 3. Information lacking re services and specific interventions.

<table>
<thead>
<tr>
<th>COMMON VALUES / VIEWS / EXPERIENCES</th>
<th>COMMON PREFERENCES / RECOMMENDATIONS</th>
<th>ISSUES SPECIFIC TO INDIVIDUAL GROUPS, COUNTRIES or REGIONS</th>
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<tr>
<td>Need access to info via many channels: a/v, hotlines, SMS technology, peer education.</td>
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<td>Need literacy programmes and info on ‘how to . . . ’ safely, info for partners and families.</td>
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<td>COMMON PREFERENCES / RECOMMENDATIONS</td>
<td>ISSUES SPECIFIC TO INDIVIDUAL GROUPS, COUNTRIES or REGIONS</td>
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</tr>
<tr>
<td>4. Condom use important regardless of new interventions but insufficient supply of condoms and lubricants in most settings.</td>
<td>Need to increase supplies (of male and female condoms) in most settings; reduce costs where currently too high (typically in countries where moralistic policies in place).</td>
<td>dangerous alternatives such as black market supplies, self-abortions and non-medical OD management. For MSM, knowledge about services and resources supports self-esteem, the freeing sense of being 'out', autonomy</td>
</tr>
</tbody>
</table>
| 5. Reasons for testing:  
  - Knowing one’s HIV status  
  - Access to related services  
  - Ill health  
  - Coercion  
  - Pregnancy | Increasing uptake of testing is important to reduce late diagnosis and for enrolment in related prevention, treatment and care services as well as for monitoring purposes, but barriers must be addressed and enablers identified and reinforced.  
  Rapid testing key to increasing uptake for most KP. | SW report insufficient supply of female condoms and criminalization of possession in some countries  
  YKP report no/low condom use and no/low contraceptive use; poor condom negotiation skills.  
  YSW and YMSM report incentives for unsafe sex: more money, pressure from clients, pressure from partners, knowledge about improved HIV treatment creates a false sense of security/protection.  
  Especially important for prisoners but not widely available. |
|  |  | YPWID in one USA setting receive financial incentives for testing; without incentives they would not test as much  
  In SA reasons for testing among all KP also include rape and sense of responsibility |
### 3.3 Testing modalities

Values and preferences around different testing modalities were explored only with PWID and young members of the PWID community.

**Table 4. Values & preferences across key population groups: HIV testing**

<table>
<thead>
<tr>
<th>COMMON VALUES / VIEWS / EXPERIENCES</th>
<th>COMMON PREFERENCES / RECOMMENDATIONS</th>
<th>ISSUES SPECIFIC TO INDIVIDUAL GROUPS, COUNTRIES or REGIONS</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Most PWID reluctant to seek testing unless provided at sites where harm reduction services received; stigma and fear of harassment and prosecution, as with most other health services provided at public facilities.</td>
<td>Rapid testing considered the most acceptable for KP; reduces waiting time as well as costs for transport to take a test and return for results, repeated exposure to judgmental providers and risk of legal consequences.</td>
<td>PWID in MENA most reluctant to seek testing services as they may be reported to police, or detained.</td>
</tr>
<tr>
<td></td>
<td>Mobile and outreach services considered the most accessible and acceptable testing modality; assumption of peer support connected with these services</td>
<td>YPWID in one setting in the USA get financial incentives for testing; most would not get a test without the incentive.</td>
</tr>
<tr>
<td></td>
<td>Confidentiality is essential – in some settings, women who receive a positive diagnosis are sent out of the home.</td>
<td>In Nepal, YPWID risk abduction and forced rehab when they seek any services; need safe spaces and outreach workers to provide testing in this setting.</td>
</tr>
<tr>
<td></td>
<td></td>
<td>In Vietnam, mobile services for PWID acceptable only in urban areas where some level of anonymity is assured.</td>
</tr>
<tr>
<td></td>
<td>Late diagnosis a fundamental problem for PWID in Latin America.</td>
<td></td>
</tr>
<tr>
<td>2. Very little experience or awareness about self-testing</td>
<td>Most PWID feel this is not a good option due to the lack of counselling, referrals and follow-up; only acceptable where no other options exist and where full information is provided regarding taking the test, understanding the results and the importance of seeking follow-up services for confirmation of results, counselling and follow-up service.</td>
<td></td>
</tr>
<tr>
<td>3. Peer support and peer-led services are key to uptake of testing for PWID.</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
### 3.4 Treatment and care, ART for prevention

The use of antiretrovirals was considered in different studies in the context of treatment and care services, and in the context of prevention, specifically pre-exposure prohylaxis (PrEP), post-exposure prophylaxis (PEP), treatment as prevention (TasP) and early initiation of ART.

**Table 5. Values & preferences across key population groups: treatment, care and ART for prevention**

<table>
<thead>
<tr>
<th>COMMON VALUES / VIEWS / EXPERIENCES</th>
<th>COMMON PREFERENCES / RECOMMENDATIONS</th>
<th>ISSUES SPECIFIC TO INDIVIDUAL GROUPS, COUNTRIES or REGIONS</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Barriers to treatment and care</td>
<td>ART best delivered through KP-specific services, especially for PWID (harm reduction services); where ART only available in hospitals, some KP will not go for services.</td>
<td>SW note the challenges of adherence given the unpredictability of their working life, including travel away from their homes where they access treatment services.</td>
</tr>
<tr>
<td>Provider-related issues – stigma, judgmental attitudes, lack of understanding of KP issues and needs, lack of confidentiality, insensitivity, pressure/coercion to initiate treatment, warnings of death if treatment not initiated</td>
<td>KP prefer to access ART and related services through outreach services and NGOs; peer support for adherence valued highly</td>
<td>YKP are particularly excluded, as there are so few services that are set up and staffed to serve the particular needs of young members of key populations – with assurances of safety, confidentiality and comprehensive services.</td>
</tr>
<tr>
<td>For some KP, criminalization of behaviours is a disincentive to seek services until absolutely necessary, resulting in late diagnosis and poor health outcomes on ART</td>
<td>Need more info on ART – clarifying individual health benefits, benefits of starting earlier, evidence around relationship between viral load and HIV transmission, info on side effects, the importance of adherence to lifelong treatment and strategies for adherence, addressing myths around ARVs.</td>
<td>Adult KP and YKP consider this an urgent issue.</td>
</tr>
<tr>
<td>Registration as a PWID (when starting treatment) can affect job opportunities and freedom to travel, create other sources of discrimination and harassment</td>
<td>While ART is often difficult for KP to access as it relies on adherence and retention in services that are often perceived as hostile to KP, most people say that it is a good thing – people feel better, they look better and it gives individuals a sense of taking charge of their lives.</td>
<td></td>
</tr>
<tr>
<td>Parental consent required for YKP</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Distance and cost to services</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Irregular and unsustainable NGO services</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

<p>| 2. PrEP | Should be an individual choice based on full information about the implications – adherence to a daily pill regimen, possible resistance, side effects | SW views generally favourable; viewed as additional protection, esp in cases of rape; concerns about misunderstandings re preventing STI and pregnancy, funding/sufficient supplies, concern about reducing community cohesion between HIV+ and HIV- people; must be offered alongside other health and |
| Possibility of stigmatization (association with HIV) | If offered, should be only in the context of comprehensive services, not as a substitute for proven interventions. | |
| Concerns about resistance |  | |
| Lack of information and awareness |  | |
| Concerns about misuse (selling to others, stealing) |  | |
| Prisoners, SW and MSM |  | |</p>
<table>
<thead>
<tr>
<th>COMMON VALUES / VIEWS / EXPERIENCES</th>
<th>COMMON PREFERENCES / RECOMMENDATIONS</th>
<th>ISSUES SPECIFIC TO INDIVIDUAL GROUPS, COUNTRIES or REGIONS</th>
</tr>
</thead>
<tbody>
<tr>
<td>Anne x 3</td>
<td>121</td>
<td>treatment services, and need to continue to promote condoms so that HIV prevention not reduced to taking a daily pill. Info needs to be comprehensive and transparent, the importance of continued safe sex practices, side effects, resistance, need for regular testing and the correct use of periodic PrEP. Promotion and delivery need to be community-led.</td>
</tr>
<tr>
<td>considered most in need of PrEP due to increased exposure to risk</td>
<td>Significant objections based on concerns that the availability of PrEP will undermine the availability and quality of proven harm reduction interventions.</td>
<td><strong>MSM</strong> have concerns about reducing sexual inhibitions, and side effects and cost; interest linked to perception of not having to use condoms; support declined slightly when provided with more info about implications of PrEP.</td>
</tr>
<tr>
<td></td>
<td></td>
<td><strong>PWID</strong> generally not supportive except in countries where harm reduction inadequate (esp in EECA); chaotic lives of most PWID would make adherence and retention in care very challenging; not ethical when millions of people who are HIV+ and currently eligible for ART can’t get it; most importantly, no necessary when there is a proven package of harm reduction interventions that can be made available (they are generally low-cost and easy to implement, in contrast to PrEP). Some PWID feel that the discussions about PrEP distract from the real problem facing the community, which is Hep C.</td>
</tr>
<tr>
<td></td>
<td></td>
<td><strong>YPWID</strong> who are very reluctant to seek services, who have very chaotic lives and who don’t generally perceive themselves at risk.</td>
</tr>
<tr>
<td><strong>3. PEP (only explored two studies with MSM and PWID)</strong></td>
<td>Clear need to improve awareness and knowledge around PEP.</td>
<td>Most <strong>MSM</strong> noted never having been offered PEP and expressed a high desire to have it made available through gay-friendly CBOs. Most said they would take it if it were available and free or low</td>
</tr>
<tr>
<td></td>
<td></td>
<td><strong>PWID</strong> in one study of 128 PWID in Ukraine, majority of participants would take it; numbers decreased slightly when more info about side effects was provided (as with MSM study); injections preferred over daily pills.</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Highly unfeasible for <strong>YPWID</strong> who are very reluctant to seek services, who have very chaotic lives and who don’t generally perceive themselves at risk.</td>
</tr>
<tr>
<td>COMMON VALUES / VIEWS / EXPERIENCES</td>
<td>COMMON PREFERENCES / RECOMMENDATIONS</td>
<td>ISSUES SPECIFIC TO INDIVIDUAL GROUPS, COUNTRIES or REGIONS</td>
</tr>
<tr>
<td>-------------------------------------</td>
<td>--------------------------------------</td>
<td>----------------------------------------------------------</td>
</tr>
<tr>
<td>cost, and if offered in a safe location, such as the CBOs where the consultation took place. They also highlighted the need for strong education campaigns regarding PEP in the context of other prevention strategies. <strong>Lack of Awareness and Knowledge.</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Little awareness of the availability of PEP – everyone has a right to know about it, but in most places <strong>PWID</strong> will have difficulties accessing PEP due to provider attitudes toward PWID; PWID will be reluctant to ask for it as it may expose them to prosecution or additional stigma and harassment. Not considered feasible for most PWID who do not have the conditions of life or support to be able to adhere to the treatment for 30 days.</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Better for <strong>PWID</strong> to have a dependable supply of clean needles and condoms.</td>
<td></td>
<td></td>
</tr>
<tr>
<td>4. Early initiation of ART (only explored with PWID, MSM and a group of KP in SA)</td>
<td><strong>MSM</strong> view early initiation favourably although unsure of feasibility.</td>
<td></td>
</tr>
<tr>
<td><strong>KP</strong> in SA feel that that this should be available for all members of KP who are HIV+.</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Views of <strong>PWID</strong> are mixed:</td>
<td></td>
<td></td>
</tr>
<tr>
<td>• Unlikely when most PWID who are eligible for ART now are not getting it and late diagnosis is common</td>
<td></td>
<td></td>
</tr>
<tr>
<td>• PWID are reluctant to go for services in general</td>
<td></td>
<td></td>
</tr>
<tr>
<td>• Easier ways to reduce transmission in ways that do not place an unnecessary burden on PWID</td>
<td></td>
<td></td>
</tr>
<tr>
<td>• Intervention is mostly for the public’s health – interventions should be concerned with the individual’s health</td>
<td></td>
<td></td>
</tr>
<tr>
<td>• Concerns about resistance</td>
<td></td>
<td></td>
</tr>
<tr>
<td>• Could be beneficial to some with full information on side effects, adherence etc.</td>
<td></td>
<td></td>
</tr>
<tr>
<td>COMMON VALUES / VIEWS / EXPERIENCES</td>
<td>COMMON PREFERENCES / RECOMMENDATIONS</td>
<td>ISSUES SPECIFIC TO INDIVIDUAL GROUPS, COUNTRIES or REGIONS</td>
</tr>
<tr>
<td>----------------------------------</td>
<td>----------------------------------------</td>
<td>-------------------------------------------------------</td>
</tr>
<tr>
<td>Better to start when one is feeling well, adapt to adherence</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Must be a fully-informed individual choice</td>
<td></td>
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</tr>
</tbody>
</table>

It is noted that there is not much information about early initiation of treatment or new recs on ARVs – there need to be better strategies at country level for dissemination of this info at all levels of the health system so that providers as well as the public know all the current options for HIV treatment and prevention. **This is a health equity issue as well as a basis for advocacy in settings where options are limited and governments are not ensuring access to critical interventions.**

Early treatment can be very beneficial to individuals in countries where HIV is criminalized; if PLHIV are encouraged to begin treatment early, they will achieve viral suppression and be less vulnerable to charges of ‘aggravated assault’.

**5. TasP (only explored in one study with mixed KP participation):**

| Concerns about placing burden of protecting others on the shoulders of PLHIV. |
| Can reduce stigma and motivate people to test. |
| Opportunity for more sexual partners and unprotected sex. |
| Good for society as well as the individual. |
| Negative views: pill burden, reluctance to take meds when feeling well, fear of increased risk-taking, taking ARVs associated with disclosure and having to live openly with HIV, and all are not ready to do this, especially in settings where ARV clinics have separate entrances |
3.5 Harm reduction

The comprehensive harm reduction package provides an evidence-based set of interventions that can protect injecting drug users from acquiring and transmitting HIV and other blood-borne diseases while supporting other physical and mental health needs. Two studies—one focused on adult PWID with some participation of young injectors, and one focused only on YPWID—explored community views on the package in terms of access, usefulness, gaps or weaknesses and other related issues.

Table 6. Values & preferences across key population groups: harm reduction

<table>
<thead>
<tr>
<th>COMMON VALUES / VIEWS / EXPERIENCES</th>
<th>COMMON PREFERENCES / RECOMMENDATIONS</th>
<th>ISSUES SPECIFIC TO INDIVIDUAL GROUPS, COUNTRIES or REGIONS</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>1. Criminalization</strong> is the single most important issue undermining the potential effectiveness of harm reduction.</td>
<td>Drug law reform is needed for many reasons; in the context of HIV, it is essential to facilitate scaling up of harm reduction as well as utilization of services.</td>
<td>YPWID are particularly at risk of juvenile detention (MENA) or forced rehab (Nepal) due to criminalization of injecting drug use and their age. Fear of such consequences discourages YPWID from seeking the harm reduction services they need.</td>
</tr>
<tr>
<td><strong>2. Access to harm reduction</strong> is uneven within countries and across regions; criminalization of drug use and moralistic views restrict availability of services in some regions (EECA, MENA), while in regions where harm reduction has been more widely available, political and economic factors are causing a shift toward a focus on recovery and services that are seen as maintaining or supporting drug use (NSP and OST in particular) are being cut back.</td>
<td><strong>WHO is requested to take a strong position on the importance of specific components of the comprehensive package,</strong> namely: - NSP - OST - ART - Condoms</td>
<td>YPWID are less visible than older injectors and they are often reluctant to be identified as PWID; outreach services, including comprehensive information and education, are urgently needed for this group.</td>
</tr>
<tr>
<td>Most countries do not view the endorsed interventions as a comprehensive package; countries pick and choose the interventions that they are most comfortable with, or that are easiest to implement.</td>
<td>There is recognition of the importance of all nine interventions, and countries should be strongly encouraged not to deselect those that are considered problematic in certain places.</td>
<td>Age of consent is viewed as a barrier for most YKP, although many providers report making decisions about services in the best interest of young clients and waiving consent requirements when necessary. However, this can be risky for providers, and consent laws need to be reviewed where HIV prevention and treatment, sexual and reproductive health and harm reduction are concerned.</td>
</tr>
<tr>
<td>Access often limited by distances, service disruptions and limited operating hours.</td>
<td>Few of the people who need harm reduction services can speak for themselves, or their voices are not heard: <strong>WHO is in a position to speak and be heard by governments, and a stronger, more assertive position on harm reduction is needed.</strong></td>
<td>In regions where criminalization and societal values demonize or marginalize the PWID community most brutally (especially in EECA, MENA and South Asia), action is needed to support activists and help increase awareness, tolerance and respect for human rights.</td>
</tr>
<tr>
<td>Reluctance to seek services in public facilities due to stigma, provider attitudes and fear of prosecution.</td>
<td>Growing focus on recovery is resulting in cutbacks in some services, making them difficult to access and affecting the emphasis and quality of services that are available.</td>
<td>The needs of women injectors are not being met: separate spaces to rest, access harm reduction as well as sexual and reproductive health services, take showers, get peer...</td>
</tr>
<tr>
<td>COMMON VALUES / VIEWS / EXPERIENCES</td>
<td>COMMON PREFERENCES / RECOMMENDATIONS</td>
<td>ISSUES SPECIFIC TO INDIVIDUAL GROUPS, COUNTRIES or REGIONS</td>
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<tr>
<td>------------------------------------</td>
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<td>---------------------------------------------------------</td>
</tr>
<tr>
<td>Safe injecting spaces / low threshold centers are needed.</td>
<td>Condoms are expensive in MENA countries and usually only available in pharmacies; abstinence pushed by authorities and religious leaders. In settings where needles are difficult to get, sharing is common; lack of NSP services does not reduce injecting drug use.</td>
<td>WHO is requested to take a stronger position on the availability of harm reduction in prisons. Loss of Global Fund resources is affecting harm reduction in some countries (Russia, Argentina).</td>
</tr>
</tbody>
</table>

3. **Critical enablers not in place** in most settings; harm reduction cannot be effective without attention to these (see Section 3.1).

- Protection of human rights, poverty reduction, interventions to address hunger, homelessness, access to basic services, are all necessary to support harm reduction.
- Critical enablers should be added as a necessary conditions for effective implementation of the harm reduction package.
- The degree to which critical enablers are prioritized varies dramatically across regions; many PWID, experts and providers believe that there will be little progress on HIV and Hep C prevention and treatment as long as these issues are neglected.

4. **Insufficient focus on Hep C**, considered a much greater concern for the PWID community than HIV.

- Include drug sharing equipment kits as part of the harm reduction package.

5. **Acceptability of services** is affected by a lack of peers.

- Peer-led service delivery, including peer support is viewed as optimal service delivery model for PWID.

6. **Targeted information** needs to be more specific to the needs of PWID and less moralistic.

- Topics and information need to be more specific, e.g. safe injecting, vein and mouth care, OD prevention and management, prevention of Hep C. Other important topics include sexual and reproductive health, HIV prevention, and information about services that support PWID and where they can be found or contacted.
- Information needs to accommodate different literacy levels and lifestyles as well as the need for broader societal awareness campaigns for tolerance and destigmatization: print material, audio-visual channels, drama, media, SMS technology.

7. **Community distribution of naloxone** is urgently needed.

- There is an urgent need for community distribution of naloxone in all settings where people inject opiates.
- There are no downsides to making this intervention available on a...
<table>
<thead>
<tr>
<th>COMMON VALUES / VIEWS / EXPERIENCES</th>
<th>COMMON PREFERENCES / RECOMMENDATIONS</th>
<th>ISSUES SPECIFIC TO INDIVIDUAL GROUPS, COUNTRIES or REGIONS</th>
</tr>
</thead>
<tbody>
<tr>
<td>wide scale to all PWID and their families and friends.</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Training should always include information about the importance of rescue breathing in all OD situations.</td>
<td></td>
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<tr>
<td>Nasal spray and pre-loaded syringes are preferred.</td>
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</tr>
</tbody>
</table>
Annex 3.1: Values & preferences of MSM: the Use of Antiretroviral Therapy as Prevention

February 2014

Commissioned by the World Health Organization (WHO)

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Acknowledgements

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Mohan Sundararaj, MBBS, MPH, Sr. Public Health Associate
The WHO is developing consolidated guidelines on HIV and key populations. The aim of this project is to bring together the existing WHO guidance for key populations and include important new material to fill in defined gaps. The consolidated guidance will consider a range of elements that are common across all key populations as well as highlighting the specific issues which are unique to the individual population groups.

As part of the development of these guidelines, to be released in 2014, the WHO department of HIV/AIDS has commissioned the Global Forum on MSM and HIV (MSMGF) to conduct a qualitative study into the values and preferences among men who have sex with men (MSM) globally. The study will be focused on values and preferences

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related to Pre-Exposure Prophylaxis (PrEP).
1 BACKGROUND

Men who have sex with men (MSM) are 19 times more likely to be infected with HIV than the general population in low- and middle-income countries (Baral, 2007 #3392). Prevalence among MSM is higher than that of the general population in nearly every country reliably collecting HIV and AIDS surveillance data. For example, compared with HIV prevalence in the adult general population, research conducted as early as 2002 suggested that infection levels among MSM in Latin America were seven times higher in Honduras, 10 times higher in Guatemala and Panama, 22 times higher in El Salvador and 38 times higher in Nicaragua (Soto, 2007 #3099). This is a pattern that repeats itself in Africa, Asia, Eastern Europe and the Caribbean (Beyrer, 2012 #3374).

Randomized controlled trials have shown the prevention potential of biomedical interventions like pre-exposure prophylaxis (PrEP) among MSM and early initiation of antiretroviral treatment to prevent forward transmission between serodiscordant heterosexual couples (Cohen, 2011 #3662; Grant, 2010 #3661). These findings are consistent with observational and ecologic studies that have noted the association between HIV treatment and reductions in new HIV infections (Anglemyer, 2011 #3663; Das, 2010 #3664).

Although these biomedical advances are promising, it is important to define the structural, interpersonal and individual factors that will affect access and uptake of these interventions. For example, MSM face widespread and ongoing human rights abuses and discrimination globally (Ottosson, 2007 #3660). As of May 2010, 76 countries had criminal penalties for same-sex acts between consenting adults. Criminalization of and violence towards sexual minorities cause social dislocation, influence transnational migration, and fuel human rights abuses, heightening the risk for HIV transmission and driving those most at need away from prevention, care, treatment, and support services.

It is important to understand the values and preferences regarding the use of ART as prevention among MSM within the contexts in which they live. This report uses 1) secondary analyses of quantitative survey data; 2) focus group interviews with MSM from five cities in three countries in Africa; and 3) individual interviews with HIV service providers and advocates from 10 countries to explore values and preferences within diverse political and social environments.
2 METHODS

The MSMGF project team, formed in January 2014, included Dr. Sonya Arreola, Mr. Keletso Makofane and Dr. George Ayala. Dr. Arreola and Mr. Makofane developed the protocols for the 1) secondary data analyses of the Global Men’s Health and Rights (GMHR) study’s survey data (collected in 2012); and 2) qualitative analyses of ART-related narratives from focus groups conducted in Africa as part of GMHR 2012, and 2014 individual qualitative interviews with MSM and HIV service providers. The WHO reviewed and made recommendations for revisions to the qualitative individual interview protocol. Upon approval of protocols by the WHO project team, secondary analyses and interviews began.

2.1 2012 GMHR Study

2.1.1 Secondary Quantitative Data Analyses

GMHR 2012 included a global online survey to assess availability of and access to STI and HIV testing and prevention services among MSM across eight regions.

From 23 April to 20 August 2012, we recruited a global convenience sample of MSM to complete the 30-minute online survey. Survey participants were recruited via the MSMGF’s networks of community-based organizations focused on advocacy, health, and social services for MSM. The MSMGF sent email blasts advertising the survey to its approximately 3,500 online members who represent 1,500 organizations in over 150 countries. Partner organizations also disseminated information about the survey through their respective regional and global listserves, as well as to local MSM through word of mouth. In addition, the MSMGF recruited participants from online social networking sites popular with MSM in Africa, Asia, Europe and Latin America. Participation in the survey was completely voluntary and anonymous.

2.1.2 Secondary Qualitative Analyses: Focus Group Discussions

In 2012, the MSMGF worked with the African Men for Sexual Health and Rights (AMSHeR) and local partner organizations in South Africa, Kenya, and Nigeria to conduct focus group discussions with MSM in Pretoria, Johannesburg, Nairobi, Lagos, and Abuja. A total of 71 MSM participated across 5 focus groups. In order to protect the confidentiality of the participants, demographic information was not collected.

For purposes of this overview, findings relevant to values and preferences regarding use of ART as prevention were reviewed and summarized.
2.2 2014 In-depth Individual Interviews

Together with the WHO, the MSMGF developed a verbal consent script and interview guide (see Appendix I) that was appropriate for use with MSM via Skype and telephone. Questions centered on general background and experiences as a MSM where they live; HIV testing experiences; and values and preferences regarding the use of ART for prevention (PrEP, PEP, early initiation of ART). Additionally, there were questions regarding discrimination, violence and legal issues.

Participants (randomly drawn from sub-categories in the MSMGF online database defined by HIV status, age group [≤24 years old vs. >24 years old], and region) were recruited through individual email invitations. From February 24 to March 3, 2014, eleven individual interviews were completed with MSM and HIV service providers from Australia, England, Indonesia, Lebanon, Liberia, Mexico, Nigeria, Paraguay, United States and Zambia. One interview was conducted in Spanish and 10 in English.

Table 1. Summary Table of Methods and Demographics

<table>
<thead>
<tr>
<th>METHODS</th>
<th>2012 GMHR 2ndary Analyses Quantitative</th>
<th>2012 GMHR 2ndary Analyses Qualitative</th>
<th>2014 In-depth Individual Interviews</th>
</tr>
</thead>
<tbody>
<tr>
<td>Criteria for participation</td>
<td>Male</td>
<td>MSM</td>
<td>MSM</td>
</tr>
<tr>
<td></td>
<td>MSM</td>
<td>Consent to participate</td>
<td>Consent to participate</td>
</tr>
<tr>
<td>Recruitment</td>
<td>Email blasts to MSMGF’s networks of CBOs</td>
<td>Invitations to community members in respective cities through MSMGF partner organizations</td>
<td>Individual email invitations</td>
</tr>
<tr>
<td></td>
<td>Dissemination through partner organizations global list serves</td>
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<tr>
<td></td>
<td>Word of mouth.</td>
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<td></td>
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<tr>
<td></td>
<td>Online social networking sites</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Data source</td>
<td>Survey data</td>
<td>Focus groups</td>
<td>In-depth individual interviews</td>
</tr>
</tbody>
</table>
### DEMOGRAPHICS

<table>
<thead>
<tr>
<th>N</th>
<th>4,005 participants</th>
<th>71 MSM across 5 focus groups</th>
<th>11</th>
</tr>
</thead>
</table>

**Regions / Countries**
- Western Europe, Northern Europe and North America = 80%
- Asia = 25%
- Eastern Europe and Central Asia = 16%
- Latin America = 14%
- Sub-Saharan Africa = 10%
- Oceania = 6%
- Middle-East and North Africa = 2%
- Caribbean = 2%

- Nigeria
  - Lagos
  - Abuja
- Kenya
  - Nairobi
- South Africa
  - Pretoria
  - Johannesburg
- Australia
- England
- Ghana
- Indonesia
- Lebanon
- Liberia
- Mexico
- Nigeria
- Paraguay
- United States
- Zambia

<table>
<thead>
<tr>
<th>Age</th>
<th>≤ 24: 17%</th>
<th>Not collected</th>
<th>≤ 24: 4</th>
</tr>
</thead>
<tbody>
<tr>
<td>&gt; 24</td>
<td>83%</td>
<td>Estimate: half ≤ 24</td>
<td>&gt; 24: 7</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Sero-status</th>
<th>18% HIV positive</th>
<th>Not collected</th>
<th>35% HIV positive</th>
</tr>
</thead>
</table>

Estimate: 40% HIV positive
3 MAIN FINDINGS

3.1 2012 GMHR Study Findings

3.1.1 Secondary Quantitative Analyses Findings
There were 4,005 respondents included in this analysis. Of these, 17% were 24 years of age or younger and 81% had post-secondary education. There was a broad representation of regions, with 80% of respondents residing in Western Europe, Northern Europe and North America; Asia (25%); Eastern Europe and Central Asia (16%); and Latin America (14%). The rest of the participants resided in Sub-Saharan Africa (10%); Oceania (6%); Middle-East and North Africa (2%); and the Caribbean (2%). Half of the respondents reported having middle to high income, and one fifth (18%) had low or no income.

3.1.1.1 Predictors of HIV Services Utilization
Adjusting for demographics and barriers and critical enabler variables, utilization of HIV sexual prevention services (condoms and condom-compatible lubricants), and HIV testing was positively predicted by higher Community Engagement and higher Connection to the Community. Utilization of HIV testing was also positively associated with comfort with healthcare provider. Utilization of condoms and condom-compatible lubricants was negatively associated with higher perceptions of homophobia.

Utilization of HIV treatment was positively related to comfort with provider, and was positively related with past experiences of provider stigma.

Utilization of behavioral interventions and information, education, communication services was positively associated with community engagement and connection to community. In addition, utilization of HIV education materials for gay men and other MSM was negatively related to perceptions of homophobia; and use of prevention-focused one-on-one sessions and self-help groups was positively associated with comfort with provider.

Use of services for substance use and the prevention of blood borne infection was positively associated with community engagement and use of substance abuse treatment was positively associated with comfort with provider.

Past experiences of provider stigma were associated with higher use of substance abuse treatment, higher use of HIV treatment, and higher use of in-person HIV behavioral interventions (risk-reduction program, one-on-one sessions and self-help groups). Past experiences of provider stigma were not associated with utilization of HIV education materials.

Finally, past experiences of gay/MSM-targeted violence were associated with higher
utilization of HIV risk-reduction programs and HIV education materials. Past experiences of gay/MSM-targeted blackmail was associated with higher utilization of prevention focused one-on-one or group sessions, but negatively associated with HIV risk-reduction programs.

3.1.1.2 **PrEP Acceptability**
The majority of respondents were comfortable with the idea of PrEP (See table below). Twenty six percent were somewhat or very uncomfortable with “using HIV medications to avoid becoming infected with HIV”. A quarter (24%) was neither comfortable nor uncomfortable and half were somewhat or very comfortable. More than half of the participants (52%) had low PrEP knowledge; they did not know what “PrEP” was and had never heard of taking ART medications to prevent HIV infection. 56% of respondents reported being likely to use PrEP if it were approved, 48% reported likely to use PrEP in a pill-a-day regimen, and 19% reported being likely to use it if it was associated with uncomfortable side effects. The sites which participant recommended as places where PrEP should be available were healthcare provider’s office (68%), Non-Governmental Organization (66%), Public Health Clinic (71%), HIV Clinic (70%), and STI Clinic (62%).
Very Likely | 790 (24)
Would use PrEP in a pill-a-day regimen

Very Unlikely | 562 (17)
Somewhat Unlikely | 556 (17)
Neither Unlikely nor Likely | 587 (18)
Somewhat Likely | 836 (25)
Very Likely | 757 (23)

Would use PrEP if it had uncomfortable side-effects

Very Unlikely | 1236 (37)
Somewhat Unlikely | 907 (27)
Neither Unlikely nor Likely | 553 (17)
Somewhat Likely | 420 (13)
Very Likely | 183 (06)

*PreP Should be delivered at

Health Care Provider’s Office | 68 (2731)
Non-Governmental Organization | 66 (2636)
Public Health Clinic | 71 (2857)
HIV Clinic | 70 (2789)
STI Clinic | 62 (2468)

*the responses to this question were not mutually exclusive

In the multivariable analysis, acceptability of PrEP was negatively associated with community engagement (OR=0.83, 95%CI: 0.71 – 0.97), and negatively associated with perceived stigma against the use of PrEP (OR=0.47, 95%CI: 0.43 – 0.51) adjusting for demographics, barriers and critical enablers, and PrEP knowledge. Knowledge about PrEP was independently associated with PrEP acceptability with respondents who had
the lowest score on knowledge, had higher acceptability of PrEP than those with medium knowledge (OR=0.77, 95%CI: 0.63 – 0.93) and those with high knowledge (OR=0.71, 95%CI: 0.58 – 0.87).

3.1.1.3 Conclusions: 2012 GMHR Survey Findings

The 2012 GMHR quantitative findings suggest that most MSM around the world are excited about the promise of PrEP and find it an acceptable strategy for HIV prevention. However, as with other healthcare services, the implementation of PrEP has to account for barriers and critical enablers that shape utilization of healthcare services by MSM. The finding that PrEP acceptability decreases with greater PrEP knowledge and more community engagement may appear paradoxical. However the findings make sense in the context of the findings on barriers to HIV services. It is likely that as men learn more about PrEP, the implications of implementing PrEP become evident; and that community engagement serves as a proxy for increased knowledge. In local environments with varying degrees of criminalization of homosexuality, sexual and HIV stigma, provider stigma toward MSM, and lack of knowledge about ARVs, it is makes sense that MSM are hesitant to endorse PrEP without caveats.

The quantitative findings also hint at ways to maximize the impact of PrEP: by enhancing other healthcare services, strengthening MSM communities creating safe spaces for care. The qualitative findings help to explain these findings further.

3.1.2 Secondary Qualitative Analyses: Focus Group Discussions Findings

All focus group participants were MSM. During the course of the five focus group discussions, it also became evident that all focus groups included some men living with HIV. Participants came from a broad range of age groups and education level, as well as from both urban and rural settings.

Structural barriers of access to HIV services included criminalization of homosexuality, high levels of stigma and discrimination, homophobia in health care systems, and poverty. These barriers create an environment where blackmail, extortion, discrimination, and violence against MSM are allowed to persist. MSM are forced to hide their sexual behavior from health care providers, employers, landlords, teachers, and family in order to protect themselves and maintain a minimum livelihood.

The inability of MSM to reveal their sexual behavior to health care providers was associated with misdiagnosis, delayed diagnosis, and delayed treatment, leading to poor health prognosis and higher risk of transmitting HIV and other sexually transmitted infections to partners.

Conversely, negative consequences of structural barriers were moderated by the
existence of safe spaces to meet other MSM, safe spaces to receive services, access to competent mental health care, and access to comprehensive health care.

Participants described the community-based organizations where the focus groups took place as examples of safe spaces where they could be themselves, receive respectful and knowledgeable health care, and in some cases receive mental health services—all of which bolstered their self-esteem and increased their motivation to take care of themselves and each other.

PEP and PrEP discussions revealed that men had little knowledge about either one. Where knowledge existed, there was often confusion about the distinction between them and when or why to use them (except one physician and one researcher). After a brief definition of PEP, most participants noted never having been offered PEP and expressed a high desire to have it made available through gay-friendly CBOs. Most said they would take it if it were available and free or low cost, and if offered in a safe location, such as the CBOs where the consultation took place. They also highlighted the need for strong education campaigns regarding PEP in the context of other prevention strategies.

After a brief definition of PrEP, many men responded favorably to the idea of using PrEP. However, as men inquired further about the evidence for efficacy, safety and use, their enthusiasm declined. Narratives regarding PrEP in all five focus groups turned toward concerns about introducing PrEP in the contexts of their respective cities where homophobia is rampant, HIV service providers treat MSM poorly, access to basic HIV services is limited, and fear of disclosure is high. Men in the focus groups concluded that it was inappropriate to offer PrEP without first addressing concerns about: Safety (MSM disclosure by association and stigma), Disinhibition (“men will over-rely on PrEP and stop using condoms”); Cost (“Not enough money for ART for PLWH, let alone PrEP”); Resistance (“people who seroconvert will have one fewer ART regimen option”); Adherence (“men already share ART with other PLWH, or run out of pills, or spread out the dosage so it will last longer”); and Lack of Awareness and Knowledge (“there is too much confusion about ART, PEP and PrEP”; “people do not know one from the other”, “Some people think “ART is a cure”).

Nonetheless, most men noted that if PrEP were to become available, AND if structural and social issues were addressed, they would consider taking PrEP themselves or recommending it to others. Few men asserted that there was nothing that would convince them to take PrEP.

3.1.2.1 Conclusions: 2012 GMHR Focus Group Study Findings
Findings from the qualitative analysis of the 2012 focus groups suggest that most MSM in Africa have no, inaccurate, or limited knowledge about PrEP. Excitement about the
idea of taking a daily pill that would protect men from HIV infection was very high. However, as they learned more about PrEP, and considered issues of safety, disinhibition, cost, resistance, adherence, and lack of knowledge, they expressed concern about introducing prep in their respective cities and countries without seriously considering the numerous barriers and facilitators to accessing HIV-related services.

As excited as participants were about the idea of PrEP, they strongly recommended that PrEP be considered only in the context of a comprehensive sexual health approach that addresses the barriers to accessing basic HIV services in safe, MSM-friendly settings.

### 3.2 2014 In-depth Individual Interviews Findings

Participants in the individual interviews lived in urban cities; had high levels of education; and were, or had previously been involved in MSM-HIV service provision, advocacy or research. All participants had had HIV testing more than once and three men were living with HIV. Most had traveled extensively for HIV-prevention related work and, therefore, could compare values and preferences across political, cultural and social contexts that varied by country or region. Although personal experiences varied, overall, differences in values and preferences varied only in degree (or salience).

#### 3.2.1 HIV Services

Barriers to accessing HIV services included the following:

- **Policy and Legal**
  - Criminalization of homosexuality
  - Lack of legal protections for MSM
- **Institutional**
  - Police harassment independent of legal rights
  - Legal authorities’ failure to protect MSM from violence or discrimination
  - Provider sexual stigma and discrimination
  - Provider HIV stigma
  - Provider lack of knowledge regarding MSM sexual health
  - Provider lack of training regarding HIV
  - Meta messages portraying MSM as HIV disease
  - Lack of safe spaces to socialize
  - Lack of safe spaces to have sex
- **Social / interpersonal**
  - Societal sexual stigma and discrimination
  - Societal HIV stigma and discrimination
  - Family rejection
Facilitators to accessing HIV services included the following:

- **Policy and Legal**
  - Laws that protect rights of MSM
  - Policies that recognize and provide equal rights and privileges to MSM
- **Institutional**
  - Safe spaces where men can socialize
  - Safe spaces where men can express their sexuality with another man/men
  - Comprehensive health services that include but are not limited to HIV services
  - Mental health care services provided by trained psychologists or other mental health providers to address psychological distress, histories of sexual violence & suicidality
  - Trained and non-judgmental health providers
- **Social / interpersonal**
  - Community engagement
  - Freedom to be open about homosexuality in public
  - Accepting sexual norms
  - Family reunification programs
- **Individual**
  - Feeling free to be “out”
  - Knowledge about HIV services and resources
  - Self esteem regarding sexuality

### 3.2.2 Values and Preferences Regarding Use of ARVs as Prevention

All participants indicated that ART was readily available in urban settings where they lived, and less so in rural settings. Barriers to accessing ART was related primarily to fear of disclosure to family, co-workers or friends about HIV positive serostatus and, in some case, disclosure of being MSM.

Participants noted that early initiation of ART as a prevention strategy was endorsed by all their respective countries and in most, this policy was implemented. However, in countries with limited investment in HIV services, participants stated that it was difficult
enough to provide ART for patients with CD4 counts of 250 or lower, such that providing ART at 500 CD4 counts was rare.

Similarly, participants were enthusiastic about the use of PEP. PEP was available in all countries, mostly through National AIDS programs. However, in some countries it was accessible to very few, primarily hospital and clinic health providers. In these settings, PEP knowledge is very low among MSM and accessing it is very difficult unless one pays for it and knows someone who will provide it. Additionally, in some countries where PEP is available, presumably for all who might need it, PEP providers judge MSM harshly if they ask for it and sometimes refuse to provide PEP. In countries where it is widely available, participants recommend accessing it through MSM-friendly CBOs and clinics to avoid judgment.

Participants had mixed thoughts about the use of PrEP. Although all participants were hopeful about PrEP as an added prevention tool among others, they all harbored serious concerns about implementing it in contexts with:

- high levels of sexual and HIV stigma,
- poor provider training regarding MSM sexual health and HIV,
- high provider stigma toward MSM and PLWH,
- poor access to HIV services generally,
- infrastructures that are suffering to provide basic services and treatment,
- limited knowledge about ART generally,
- lack of social support, and
- lack of legal protections for MSM

As a result, participants advised against its use in current settings unless these concerns were addressed. In particular, participants advocated for improvements for the availability of and access to:

- Comprehensive health care provision including:
  - Sexual health services
  - HIV-specific services
  - Mental health services
- Inclusion of LGBTQ- or MSM-specific CBO expertise in designing programs
- ART- and PrEP-specific education campaigns
- Infrastructure development and capacity building to support PrEP implementation
- Follow-up protocols to address adherence to ART and eventually PrEP
• Safe spaces for community engagement and social programs for MSM

3.2.3 Conclusions: 2014 In-depth Individual Interviews Findings
The findings from the in-depth individual interviews further elucidate the quantitative and qualitative 2012 GMHR study findings. Consistent with the GMHR findings, the individual interviews reflected a high level of enthusiasm for ART-based prevention strategies, including early ART initiation, PEP and PrEP. However, as with the GMHR results, participants had serious concerns about implementing PrEP without careful consideration of the contexts where PrEP might be introduced. Participants stressed the importance of assessing and, based on results, addressing: local levels of sexual and HIV stigma; provider attitudes and knowledge about MSM sexual health needs; availability accessibility and use of basic HIV services; knowledge about ART-based prevention strategies; community engagement, safety, and legal protections for MSM. Overall, participants were between willing and eager to support PrEP implementation to the extent that these concerns are addressed.

4 LIMITATIONS
As with all cross-sectional observational data, GMHR 2012 survey data findings are limited in their ability to show evidence of causality. Additionally, generalizability of findings is limited because online survey participants self-selected to participate in the survey (qualitative methods seek depth of understanding, not generalizability, by design). For example, the data are biased toward men who have access to the internet, and they may have different experiences from those who do. Another limitation is that men who participated in focus groups and interviews were predominately from urban cities. It is possible that men from rural settings have different concerns about the use of ARVs for prevention. Nonetheless, the consistency of findings across two time points and three different methodologies, suggests that the findings reported in this report are valid and robust.

5 OVERALL CONCLUSIONS and KEY MESSAGES
Together, the GMHR Study and individual interview findings underscore the need to improve global efforts to ensure that MSM have access to basic HIV prevention and treatment services before we can fully realize the potential of well thought-out, locally-relevant combination prevention strategies that include use of ART as prevention. Structural, community, and individual-level barriers and facilitators to HIV service access must be addressed at multiple levels.

Gay men and other men who have sex with men, as well as HIV service providers, advocates and researchers, find PrEP an acceptable strategy for HIV prevention in
theory. The finding that PrEP acceptability wanes as PrEP knowledge increases suggests an urgent need for the dissemination of more and better information about HIV prevention strategies generally as well as about PEP and PrEP specifically. Adequately addressing MSM knowledge and perceptions of ART will be critical to MSM’s ability to make informed decisions regarding acceptance and use of these approaches as part of combination HIV prevention.

As with other HIV services, the implementation of PrEP also has to account for barriers and critical enablers that shape utilization of healthcare services by MSM. Given the positive impact of community engagement and comfort with service providers on access to services, findings also suggest that supporting MSM-led community-based organizations to provide safe spaces for MSM to access services and connect with the local gay community may be a highly effective strategy for addressing these issues. PrEP implementation will be most acceptable to MSM in the context of comprehensive health services that are provided in safe spaces by non-judgmental health providers.

In summary, we need to work hard to ensure contexts where appropriateness, accessibility, availability, safety and quality are carefully considered and addressed.

6 IMPLICATIONS FOR WHO GUIDLINES
The findings from all three analyses have several implications for PrEP implementation.

1) Conceptually, PrEP is an acceptable prevention strategy among most MSM. However, PrEP knowledge is limited, and increased knowledge reduces enthusiasm for PrEP—likely due to increased concerns about the implications of introducing PrEP in settings with extensive barriers to the most basic HIV prevention services (e.g., lubricants). Addressing concerns about PrEP implementation will be essential for successful PrEP implementation, uptake and efficacy.

2) It will be important to assess the barriers and facilitators of existing HIV prevention strategies in a given community and context. This should occur in collaboration with local CBOs (including advocates, providers and researchers) who have crucial cultural sensitivity, knowledge and trust of MSM. This process should include an assessment of local levels of:

- Sexual and HIV stigma
- Provider attitudes and knowledge about MSM sexual health needs
- Availability accessibility and use of basic HIV services
- Knowledge about ART-based prevention strategies
- Laws that criminalize sex between men
- Safety
- Legal protections for MSM
- Community engagement
- Availability, accessibility, and use of basic HIV services
- Other concerns particular to the location (identified by local CBO staff)

3) Based on the assessment, and in collaboration with local CBOs, it will be helpful to develop a plan to:

- Address identified barriers
- Support/enhance facilitators/enablers needed
- Assess changes over time

4) Strengthening local community and health systems will be beneficial in reducing barriers and enhancing facilitators of PrEP implementation; improving uptake of and adherence to PrEP among men who choose to use take it; and enhance sustainability of implementation efforts.
APPENDIX I

Antiretroviral Therapy as Prevention Interviews with MSM
Interview Guide

FACE PAGE

This section to filled in using panel data on participant and/or information that arises from interview.

Age _____

Country / Region _________________________

HIV testing
Have you ever taken an HIV test?

☐ No
☐ Yes
☐ Prefer not to answer

If yes, do you wish to disclose the results of your test?

☐ No
☐ Yes ☐ Seronegative ☐ Seropositive

Current relationship status

☐ In a serodiscordant relationship
☐ In a seroconcordant relationship
☐ Not in a relationship
☐ In a relationship but status not disclosed to partner
1. Introduction

Explanatory notes in blue
Additional prompts or info to look for in green

To briefly describe the project related to this interview: WHO is developing consolidated guidance on HIV and KPs, bringing together existing guidance for separate key population groups and including important new information to address defined gaps. One of the new areas in the guidelines will be looking at PrEP for MSM. Values and preferences related to these services are a vital component that will inform the new recommendations.

Length of interview: 1 hour (if you have time constraints, I will make every effort to make our conversation shorter)

Primary goal: To have a conversation about a number of specific topics that affect you or that you have experience with as a man who has sex with men. I want to focus on your experience, your opinions and what you think or feel about the topics covered, and how your experiences have influenced your views.

Overview: I’ll ask some general questions about your background and your experiences as a MSM where you live, but mostly about your experiences, values and preferences regarding the use of ART for prevention (PrEP, PEP, early initiation of ART, and some questions about your HIV testing experiences and preferences.

If participant is involved with advising about or providing services for MSM ask: I will also ask your views from a service provision perspective in relation to the topics discussed.

If there are any other topics that you would like to raise relative to the main topics we discuss, please feel free to do so, as I will include any additional topics or issues in the report.

Important reminder: You may decline answers to any questions or discussion of any topics at any time.
Recording our conversation: I would like to make an audio recording of our conversation to be sure that I am able to capture your contribution in as much detail and as accurately as possible. I do not keep any identifying information about you personally, so there is no way to identify you in the report. If you prefer that I not record our conversation, I will only take written notes. In either case, our conversation is completely confidential. Please let me know what you are more comfortable with. After we’ve spoken, if you have any further thoughts to share with me, please feel free to email me with your follow-up inputs.

At this time, do you have any further questions or concerns?

Emphasize at this point that you want to hear about the individual’s actual experiences and views, not those of his/her organization or those that are considered legal or acceptable in their country. They may mention these differences of perspective or setting, but their personal views are of primary importance for this interview.

2. Verbal consent

Before we move on, I will need to obtain your verbal consent to be interviewed. Would you like to participate in this interview?

Make sure to receive verbal consent to participate.

If participant says “NO”, thank him and discontinue interview.

If participant says “YES”, begin the interview.

☐ Verbal consent was NOT obtained from the study participant

☐ Verbal consent was obtained from the study participant

3. Background information

Thank you again for agreeing to participate in this interview. I would like to begin by asking you to share a little about yourself.
1. How do you identify yourself sexually?
2. What is your living situation?
3. What is your relationship status?
4. What is it like for you living as (however he identifies regarding MSM) in your country?

### 4. HIV testing experience / modalities (if not addressed previously)

I’d like to ask you a few questions about HIV testing as it concerns you and other members of your community.

**Community members:** Can you briefly tell me about your HIV testing experience?

- Where tested / type of setting (hospital / clinic / stand-alone HTC / mobile clinic / community-based service provider / self-test)
- Was it easy or difficult to get a test? Specific barriers / facilitators to access?
- What do you feel is the optimal testing modality/setting for yourself? For others in your community? Please explain. Advantages / disadvantages of different options?
- What are the most important issues you see in providing HIV testing services for MSM?
- HIV self-testing is becoming increasingly more available, via the internet (online purchase) and over-the-counter in pharmacies. Some countries are considering supporting community groups to supply HIV self-test kits. What are your thoughts about self-testing for yourself and for others in your community?

**Experts / service providers:** As an expert / someone who advises on services for MSM / service provider:

- What are your general thoughts about providing HIV testing for MSM?
- In your view, how has this been delivered most successfully?
- HIV self-testing is becoming increasingly more available, via the internet (online purchase) and over-the-counter in pharmacies. Some countries are considering supporting community groups to supply HIV self-test kits. What are your thoughts about self-testing?

### 5. Current prevention approaches/practices

**Community member**

1. What interventions are you currently using to protect yourself from getting HIV / to prevent transmission of HIV to a partner? (Follow up regarding: Condoms and Lube, Individual/Group/Community level interventions, Provider-initiated testing and counseling for HIV and STI, Individual and Group Risk Reduction Counseling)
2. What barriers do you experience / have you experienced in accessing prevention interventions? For young respondents: Especially as a young MSM?
3. What has assisted / does assist you in accessing these interventions?
4. What additional prevention interventions do you think will be helpful to you and others in your community?
5. What other strategies would be helpful to improve access to prevention interventions?
PROBES: For each questions use following probes as appropriate

>>> What kinds of prevention programs exist in your country? (individual, group, and community level programs)

>>> How accessible are (each of the categories)

>>> Has a health care provider ever talked about (each of the categories) with you?

>>> How should (each of the categories) be delivered to MSM?

>>> How is it received by MSM in your country?

>>> What do you think about it?

>>> How would you organize prevention programs?

>>> If not offered in country,

>>> Is this viable in your country?

>>> How would it be received?

>>> How would you improve the conditions for meeting sexual health needs of MSM?

Experts / service providers

1. In your setting/experience, what current prevention strategies are being used / are available for MSM?

2. In your setting/experience, what barriers do MSM experience in accessing prevention interventions?

3. In your setting/experience, what current strategies are helping MSM to access prevention interventions?

4. In your setting / experience, how do the needs of young or adolescent MSM differ from older members of the community and how are their particular needs be addressed by services?

5. In your setting/experience, what additional prevention interventions do you think would benefit MSM?

6. In your setting/experience, what other strategies would you suggest to improve access to prevention interventions for MSM?

6. ARVs for prevention

There are a number of prevention interventions that involve the use of antiretrovirals (some of which you have mentioned) that the new guidelines are looking into, and we would like to explore these with you.

6a) PrEP (pre-exposure prophylaxis)

Community member

If the respondent has mentioned PrEP in the response to Section 4, go to Question 3 –

1. Are you aware of PrEP?
**Yes**

a) Do you feel you have a good understanding of PrEP, or would you like me to give you more information? If the respondent asks for more info, go to explanation below.

**No (or if answer is incomplete)**

b) Explanation:

Pre-exposure prophylaxis (or PrEP or Truvada) is the use of antiretroviral drugs by HIV-negative people to reduce the risk of or getting HIV. Recent studies have shown that people who took PrEP pills every day were less likely to become infected with HIV.

Several studies have shown that PrEP can prevent someone acquiring HIV from sex and one study has shown that it can also prevent HIV from sharing needles. Studies have also shown that PrEP or antiretrovirals for people who are HIV-negative are safe and cause few, minor side effects. PrEP does not protect against other blood-borne viruses, hepatitis, STIs, or pregnancy.

---

2. Check understanding: Is that explanation useful? Do you have any questions? How would you explain PrEP to someone?

3. What are your views on PrEP as a preventive option for yourself?

4. Would you be interested in taking PrEP for HIV prevention if it was available?

<table>
<thead>
<tr>
<th>Yes</th>
<th>a) Why would you consider it?</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>b) What would help you to make a decision about using PrEP as a prevention intervention?</td>
</tr>
<tr>
<td></td>
<td>&gt;&gt;&gt; More information – What information would you require for making a decision about taking PrEP?</td>
</tr>
<tr>
<td></td>
<td>&gt;&gt;&gt; Support from health provider</td>
</tr>
<tr>
<td></td>
<td>&gt;&gt;&gt; Better access</td>
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<td></td>
<td>&gt;&gt;&gt; Peer influence</td>
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</table>

<table>
<thead>
<tr>
<th>No</th>
<th>c) Why would you not consider PrEP?</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>d) What would help you to make a decision about using PrEP as a prevention intervention?</td>
</tr>
<tr>
<td></td>
<td>&gt;&gt;&gt; More information – What information would you require to make a decision about taking PrEP?</td>
</tr>
<tr>
<td></td>
<td>&gt;&gt;&gt; Support from health provider</td>
</tr>
</tbody>
</table>
5. What do you think are potential benefits of taking PrEP on a daily basis for HIV prevention?
6. What do you think are potential challenges of taking PrEP on a daily basis for HIV prevention? For young respondents: Any particular challenges related to being an adolescent MSM?
7. How do you feel about PrEP vs other harm reduction options / current prevention strategies that are available?
8. Do you have a strong feeling or preference for one particular option (esp among NSP/OST/PrEP)? Please explain.
9. Are you aware of the views of other MSM regarding PrEP?

**Experts / service providers**

1. What are your views on PrEP as a prevention option for MSM? Are those views the same for adolescents and young MSM? Please explain.
2. Are MSM aware of PrEP?

<table>
<thead>
<tr>
<th>Yes</th>
<th>a) What are their views?</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>b) How have most of them been informed about PrEP?</td>
</tr>
<tr>
<td></td>
<td>c) Is the information they present with correct?</td>
</tr>
</tbody>
</table>

| No  | d) Why do you think this is the case? |

3. If PrEP was available, should it be offered to MSM?

<table>
<thead>
<tr>
<th>Yes</th>
<th>a) What would be your rationale for offering PrEP?</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>b) In what circumstances should PrEP be offered?</td>
</tr>
<tr>
<td></td>
<td>c) What support would service providers require to be able to offer PrEP?</td>
</tr>
<tr>
<td></td>
<td>&gt;&gt;&gt; Up to date information</td>
</tr>
<tr>
<td></td>
<td>&gt;&gt;&gt; Standard operating procedures and policies</td>
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<tr>
<td></td>
<td>&gt;&gt;&gt; Ongoing/reliable supply</td>
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<table>
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<tr>
<th>No</th>
<th>d) What is your rationale for not offering PrEP?</th>
</tr>
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<tbody>
<tr>
<td></td>
<td>&gt;&gt;&gt; Potential concerns/challenges of offering PrEP to MSM in relation to service provision? What strategies could be used to address these concerns/challenges?</td>
</tr>
<tr>
<td></td>
<td>&gt;&gt;&gt; Potential concerns/challenges in relation to your clients? – What strategies</td>
</tr>
</tbody>
</table>
could be sued to address these concerns/challenges?

e) What would assist in improving the acceptability of PrEP to you as a provider?

6b) PEP (post-exposure prophylaxis)

Community member

If the respondent has mentioned PEP in the response to Section 4, go to Question 3 –

1. Are you aware of PEP?

<table>
<thead>
<tr>
<th>Yes</th>
<th>a) Do you feel you have a good understanding of PEP, or would you like me to give you more information? <em>If the respondent asks for more info, go to explanation below.</em></th>
</tr>
</thead>
<tbody>
<tr>
<td>No</td>
<td>b) Explanation:</td>
</tr>
<tr>
<td></td>
<td><em>Post-exposure prophylaxis (or PEP) is the use of antiretroviral drugs by HIV negative people AFTER possible exposure to HIV to reduce the risk of getting HIV.</em></td>
</tr>
</tbody>
</table>

2. Check understanding: Is that explanation useful? Do you have any questions? How would you explain PEP to someone?

3. What are your views on PEP as a preventive option for yourself?

4. What do you think are the benefits of taking PEP for HIV prevention?

5. What do you think are the challenges of taking PEP for HIV prevention? – What strategies could help to address these challenges? For young respondents: Are there particular challenges for taking PEP related to being a young MSM?

6. Have you ever taken PEP?

<table>
<thead>
<tr>
<th>Yes</th>
<th>a) Can you tell me about the situation in which you decided to take it?</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>b) Who offered it to you?</td>
</tr>
<tr>
<td></td>
<td>c) Where did you access it? Was it easy to get hold of?</td>
</tr>
<tr>
<td></td>
<td>d) What was the recommended protocol? Number of days? Follow-up testing?</td>
</tr>
<tr>
<td></td>
<td>e) Did you take the whole course of PEP as prescribed?</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Yes</th>
<th>--</th>
</tr>
</thead>
<tbody>
<tr>
<td>No</td>
<td>How long did you take it? Why did you stop?</td>
</tr>
</tbody>
</table>
f) What was your experience of taking PEP?
>>> Easier / harder than other prevention options?
>>> Pill burden?
>>> Side effects?
>>> More stigmatizing / less stigmatizing?
If negative, how could it be improved?

g) Would you take it again?

h) Why have you not taken it before?

<table>
<thead>
<tr>
<th>Not available</th>
<th>If offered to you, would you accept it?</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>What would help you to make a decision about PEP?</td>
</tr>
<tr>
<td></td>
<td>&gt;&gt;&gt; More info – what sort of info would you need?</td>
</tr>
<tr>
<td></td>
<td>&gt;&gt;&gt; Support from health provider</td>
</tr>
<tr>
<td></td>
<td>&gt;&gt;&gt; Better access</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Offered but refused</th>
<th>What were your reasons for not taking it?</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>What would help you to make a decision about PEP?</td>
</tr>
<tr>
<td></td>
<td>&gt;&gt;&gt; More info – what sort of info would you find most helpful?</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Have never needed it</th>
<th>Would you be interested in taking PrEP for HIV prevention?</th>
</tr>
</thead>
</table>

7. How do you feel about PEP vs other harm reduction options / current prevention strategies?
8. Do you have a strong feeling or preference for one particular option (esp among NSP/OST/PrEP)? Please explain.
9. Are you aware of the views of other MSM regarding PEP?

Experts and service providers:

1. What are your views on PEP for MSM who have had a possible exposure to HIV? Are those views the same with regard to adolescents and young MSM? Please explain.
2. What are the benefits of PEP for MSM with possible exposure to HIV?
3. What concerns do you have with offering PEP to MSM with possible exposure to HIV?
   a) In relation to service provision
   b) In relation to your clients (MSM)
   c) In relation to adolescent and young clients
**Service providers only:**

1. Have you ever prescribed PEP for MSM?

<table>
<thead>
<tr>
<th>Yes</th>
<th>a) Tell me about your experiences prescribing PEP for MSM</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>b) What challenges did you as a SP face?</td>
</tr>
<tr>
<td></td>
<td>c) What challenges did your clients face? – What strategies helped you / your client to address these challenges?</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>No</th>
<th>d) Why have you not offered PEP?</th>
</tr>
</thead>
<tbody>
<tr>
<td>Not available</td>
<td>--</td>
</tr>
<tr>
<td>Not appropriate</td>
<td>Please explain</td>
</tr>
<tr>
<td>Offered, client refused</td>
<td>Main reasons for refusing?</td>
</tr>
<tr>
<td></td>
<td>How to improve acceptability?</td>
</tr>
<tr>
<td></td>
<td>&gt;&gt;&gt; Access, info….</td>
</tr>
</tbody>
</table>

2. If you offer PEP to MSM how many ‘courses’ of PEP would you feel comfortable with offering in a 12-month period to an individual? Please explain.

**6c) Early initiation of ART**

**Community members (HIV+ only):**

*If the respondent has mentioned early initiation of ART in the response to Section 4, go to Question 3 –*

1. Are you aware of early initiation of ART?

<table>
<thead>
<tr>
<th>Yes</th>
<th>a) Do you feel you have a good understanding of early initiation of ART, or would you like me to give you more information? If the respondent asks for more info, go to explanation below.</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>b) Explanation:</td>
</tr>
<tr>
<td></td>
<td>Early initiation of ART is the start of ART by people with HIV at CD4 count above</td>
</tr>
</tbody>
</table>
In 2013, WHO recommended individuals start ART when CD4 is ≤500 (vs. previous guidance of CD4 ≤350). WHO does not currently recommend starting ART when someone’s CD4 is >500 except for people with HIV and active TB, for people coinfected with HIV and Hepatitis B and evidence of severe chronic liver disease, or for partners with HIV in serodiscordant relationships who should be offered ART to reduce transmission to uninfected partners; in all of those cases they should start (or be offered) ART regardless of CD4 count. However some countries are now recommending or considering recommending that all MSM should also be recommended to start ART regardless of CD4 count.

Taking ART, whatever your CD4 count, can reduce HIV transmission to others, either through sex or through sharing equipment. WHO recommends that everyone with a CD4 of 500 or below should be on ART for their health and to prevent transmission to others. While it is not known whether taking ART when you have a CD4 >500 is actually beneficial for your own health, it does have a preventive effect. This early ART initiation is sometimes called ‘treatment as prevention’ or TasP. Some people suggest early ART (CD4 > 500) should be recommended for all MSM to help prevent transmission to others.

2. Check understanding: Is that explanation useful? Do you have any questions? How would you explain early initiation of ART

3. If HIV seropositive: Are you on ART? (Or: You have told me that you are on ART…)

<table>
<thead>
<tr>
<th>Yes</th>
<th>a) When did you start?</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>b) Did you start because of your health status or for prevention reasons? Or other? (&gt;&gt;&gt; to start a family) Please explain your answer.</td>
</tr>
<tr>
<td></td>
<td>c) If it was for prevention:</td>
</tr>
<tr>
<td></td>
<td><strong>If for prevention</strong></td>
</tr>
<tr>
<td></td>
<td>Did you face any particular challenges in starting ART for prevention reasons? If so, what were they?</td>
</tr>
<tr>
<td></td>
<td>What benefits do you see or have you experienced in starting ART for prevention?</td>
</tr>
</tbody>
</table>

| No  | d) What is your view on early initiation of ART (CD4 500 or above) as a preventive intervention? |
|     | e) Is this something that you would consider if it was available where you live? |
|     |   **Yes** Why would you consider this? |
What would help you to make a decision about early ART?

>>> More info – what info would you find most helpful?

>>> Support from service providers

>>> Access

What are your potential concerns or challenges you might have starting ART at a higher CD4 count (or before you feel sick?) – What strategies do you think could be used to address these challenges?

No 

Why wouldn’t you consider it?

What would assist in improving the acceptability of early initiation of ART?

Experts and service providers:

1. What are your views on early initiation of ART? Are those views the same for adolescent and young MSM? Please explain.
2. What are the potential benefits of offering early initiation of ART to MSM?
3. What are your concerns of offering early initiation of ART to MSM?
   a) In relation to service provision
   b) In relation to your clients
   c) In relation to adolescent and young clients
4. What strategies do you think could be used to address these challenges?
5. What do you advise your MSM clients about early initiation of ART? Same for adolescent and young clients?

Service providers only:

1. Have you ever prescribed early initiation of ART for MSM?

Yes 

a) Tell me about your experiences

b) What challenges did you as a service provider face?

c) What challenges did your clients face? What strategies helped you/your client to address these challenges?

No 

d) Why have you not offered early initiation of ART to MSM?

Not available

Not appropriate Please explain
7. Discrimination/Violence

If discrimination or violence issues arose during interview: Earlier you talked about whatever discrimination or violence issues he mentioned. I would like to ask you some further questions about that if it is OK with you.

If not previously discussed, I would like to ask you some questions about how MSM are received in your country.

How are MSM treated in your country?
What are the attitudes of health providers towards MSM?
How do health providers treat MSM?
How have these attitudes and experiences affected the ability of MSM to access sexual health services?
What experiences have you had with violence directed at you or other men because of being MSM?

7. Legal Issues

How does the legal system affect your to access to HIV services (e.g., criminalization of homosexuality)?
What kinds of legal assistance do MSM need?
Where do MSM go for legal assistance?
How does the legal system respond to MSM?
9. Closing

Thank you very much for your time – I appreciate your willingness to share your personal experiences, views and feelings. Is there anything else that you would like to add at this time?

Once we have collected all the data required for this study, we will prepare a report that will be made available as part of a larger report, which will be available on our website at www.msmgf.org.

Reminder - Please be assured that I will not include in the report any identifying information about you personally.

Please feel free to contact MSMGF staff if you have any questions or would like to provide feedback. You may have these contact details from an earlier email but would you like me to repeat this information for your convenience?

If participant says yes: You can contact me, Sonya Arreola at SArreola@msmgf.org if you have any questions or comments or George Ayala at GAyala@msmgf.org.

Thank you again for your time today. Is this a good time to end the call?
Annex 3.2: Values and preferences of people who inject drugs, and views of experts, activists and service providers:

HIV prevention, harm reduction and related issues

Author: Mary Henderson (WHO consultant)
April 2014

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Summary

A values and preferences study of people who inject drugs explored the experiences and views of 32 people around HIV prevention, HIV testing modalities, ART for treatment and prevention, harm reduction and community distribution of naloxone. The key findings reveal some common views across regions as well as some experiences and views that are specific to a community, country or region. The study was conducted from January–March 2014 and included 25 members of the PWID community and 7 experts or service providers who work closely with this community. Nineteen individuals participated in in-depth interviews, 2 participants responded by email due to language restrictions and 11 individuals participated in a group discussion of the same issues covered in the interviews.

The main findings regarding PWID community preferences on key issues are summarized in the box below.

Needle and syringe programmes are considered the single most important HIV prevention strategy for people who inject drugs.

Opioid substitution therapy is considered a vital intervention for its direct benefits and for the access to a range of other HIV prevention and harm reduction services.

For HIV-positive PWID, viral suppression through ART—with condom use—is understood as beneficial for prevention of transmission.

HIV testing is delivered most effectively for PWID when it is offered alongside other harm reduction services.

PWID will seek testing only at safe, confidential sites staffed by knowledgeable, non-judgmental providers.
Rapid testing can reduce late diagnosis and loss to follow-up of PWID.

Self-testing is an acceptable option for PWID only in settings where there is no access to safe, confidential HIV testing. However, there are significant reservations about self-testing due to the lack of critical support from counsellors and other health providers.

PrEP is considered unacceptable, unnecessary or unfeasible by most respondents for ethical and practical reasons.

PEP is considered a useful prevention intervention by most respondents, but most PWID are not aware of it or can not access it, and 6 of those in favour felt that most PWID would be reluctant to ask for it.

Early initiation of ART is considered a good option for PWID by 14 of 19 respondents, as long as it is a fully informed and individual choice, not a coerced or punitive measure enforced by the state or others only for the public health benefit.

Criminalization of drug possession and use is the most important issue facing PWID: without drug law reform harm reduction will not have the impact needed to protect PWID and to prevent the spread of disease.

The larger issues that influence the potential impact of harm reduction interventions are poverty, homelessness, mental illness, social exclusion and joblessness.

Key interventions (NSP, OST, HTC, ART) should be prioritized to support advocacy and accountability.

Community distribution of naloxone should be added to the list of harm reduction interventions.

Naloxone is a cheap, safe, easy-to-use, life-saving drug. It should be available for community distribution to people who inject drugs, their peers and their families.

Pre-loaded syringes or nasal spray are preferred.

The importance of rescue breathing must be emphasized along with distribution of naloxone.
1. Introduction

The global response to HIV has been strengthened by an understanding of the importance of reducing new infections among the key populations at greatest risk of HIV acquisition and transmission and improving their access to vital treatment and care services. In an effort to accelerate this work, WHO is consolidating existing guidance on separate key population groups and incorporating additional information based on new insights and evidence. This guidance will consider a range of HIV prevention, treatment and care issues that affect all key populations, and it will highlight specific concerns and recommendations that reflect the unique needs of individual groups.

People who inject drugs (PWID) are one of the key population groups requiring more focused attention. Countries that have implemented a comprehensive harm reduction approach have seen significant declines in new injecting drug-related HIV infections;\(^1\) however, outside of sub-Saharan Africa, 33% of all new HIV infections are among PWID, and in countries where HIV incidence is increasing, 70–80% of HIV cases are among PWID.\(^2\) Other data confirm that the target set for 2015 in the 2011 UN Political Declaration on HIV/AIDS for reducing HIV transmission in this community is not yet in sight:

*The world is not on track to reduce HIV transmission among people who inject drugs by 50%, as recent evidence suggests little change in the HIV burden in this population. HIV prevalence among people who inject drugs remains high – up to 28% in Asia. HIV prevention coverage for people who inject drugs remains low, with only two of 32 reporting countries providing the recommended minimum of at least 200 sterile syringes per year for each person who injects drugs. Among 35 countries providing data in 2013, all but four reached less than 10% of opiate users with substitution therapy. In addition to exceptionally low coverage, an effective AIDS response among people who inject drugs is undermined by*

\(^{1}\) UNAIDS 2012 Global report.

punitive policy frameworks and law enforcement practices, which discourage individuals from seeking the health and social services they need.\(^3\)

One aspect of the WHO guidance development process involves engaging with communities to understand their values and preferences regarding elements of potential recommendations that will have a direct impact on their lives; their views and experience are considered along with systematically reviewed evidence and expert opinion. In this way, guidance can be more responsive to the needs of individuals who are confronting the challenges being addressed by new recommendations and guidance.

This report summarizes the findings of a qualitative study that explored the perspectives and experiences of active drug injectors and former PWID regarding HIV prevention and harm reduction services, and the ways they can be supported to protect themselves from HIV infection and to reduce transmission of HIV to others. Other key issues of concern to the PWID community were also discussed, including the need for greater attention to prevention and treatment of hepatitis C and the need for community distribution of naloxone. It also takes note of the views of technical experts, NGO-based service providers and activists, several of whom identify themselves as members of the active injecting drug community or advocates for the rights and well being of this community.

2. Methods

An independent consultant conducted the study to ensure impartiality in the interviews and in the analysis of findings. Thirty-five prospective participants—members of the PWID community, experts, activists and service providers—were identified through international and regional networks and invited to participate in semi-structured, in-depth interviews regarding their personal experiences with and perspectives on:

- HIV prevention strategies;
- HIV testing modalities;
- The use of antiretrovirals for prevention of HIV;
- The comprehensive harm reduction package;
- Community distribution of naloxone.

\(^3\) UNAIDS 2013 Global report.
Twenty-six people agreed to participate, and 19 people were actually able to participate in interviews, while 2 respondents provided written answers due to language constraints. In addition, 11 young injecting drug users (ages 16–25) participated in a group discussion of the interview topics led by one of the study participants who works with an organization serving the needs of young homeless people in San Francisco, USA. Those findings are also included in this report, comprising the views of 32 individuals (ages 16–57 years).

Two interview guides were developed in a consultative process with WHO and other experts in the field, one for PWID community members (Annex A) and one for experts and service providers who did not identify themselves as PWID (Annex B). The different sets of questions reflect a distinction between the values and preferences of PWID community members—the primary focus of this study—and the views of those who work closely with the community but who may not have the same personal experience on the topics covered. Where views of the two groups differ, this is noted. Interviews were 1–1.5 hours in length, and they were recorded with participants’ permission; recordings were used only by the interviewer to facilitate analysis and ensure accuracy of quotes. All participants gave their verbal consent to participate in the study.

Due to the limited number of participants in this study, the content of interviews was not categorized as majority or minority positions; findings were analysed by assessing the level of support for new interventions being proposed and highlighting areas where positive views were qualified by concerns around ethics, feasibility, acceptability or other issues. Unique views are also included in the report as they contribute important perspectives to the analysis of findings and should be noted in the guidance development process. Findings are summarized in boxes at the opening of each topic section, and the narrative report reflects the analysis of findings as they emerged in interviews. Direct quotes are used to capture the detail and tone of participants’ contributions. However, quotes are not identified by gender or country in order to maintain the anonymity of respondents; some views are identified by region where conditions and experiences appear to be significantly different from other regions. In general, references are not made to individual countries unless in relation to specific data.

3. Participant profiles
Table 1. Participant profiles by gender and WHO region

<table>
<thead>
<tr>
<th></th>
<th>AFR</th>
<th>PAH</th>
<th>SEAR</th>
<th>EUR</th>
<th>EMR</th>
<th>WPR</th>
</tr>
</thead>
<tbody>
<tr>
<td>Women</td>
<td>2</td>
<td>7</td>
<td>--</td>
<td>2</td>
<td>2</td>
<td>2</td>
</tr>
<tr>
<td>Men</td>
<td>2</td>
<td>8</td>
<td>3</td>
<td>4</td>
<td>--</td>
<td>--</td>
</tr>
</tbody>
</table>

Age range of participants is 16–57 years.

Table 2. Participant profiles by self-identification and injecting drug use

<table>
<thead>
<tr>
<th></th>
<th>Member of PWID community</th>
<th>Expert/Activist/Service provider</th>
</tr>
</thead>
<tbody>
<tr>
<td>Current injecting drug use</td>
<td>16</td>
<td>(5)</td>
</tr>
<tr>
<td>Former injecting drug use</td>
<td>9</td>
<td>2 (7)</td>
</tr>
<tr>
<td>Never used or no answer</td>
<td>--</td>
<td>5</td>
</tr>
</tbody>
</table>

Numbers in parentheses indicate current or former injecting drug users who identify as members of the PWID community as well as experts, activists or service providers for the community.

Contributors to this study live in urban areas; 18 people work in a wide range of settings: community-based services in capital cities and provincial towns, international, regional and national networks of PWID (or drug users more generally) based in urban areas in the North and South, street-based and mobile services in all regions. Eleven participants in a group discussion are homeless young people who inject drugs and 1 participant affiliated with a university focuses primarily on research. None of the participants were service providers in public health settings.

---

4 One service provider from Europe works in Africa; 2 PWID and 1 expert from Europe work with international networks; 1 expert from Western Pacific works with an international network; 11 adolescents and young people who inject drugs (in the USA) contributed views during a group discussion facilitated by a study participant.

5 Two respondents who self-identified as former injectors reported that they are likely to use injecting drugs again in the future; their inputs reflect an ongoing concern about their own access to harm reduction services.
4. **Study findings**

4.1 **Current HIV prevention practices among PWID**

Box 1. Key findings regarding HIV prevention and PWID

1) **Needle and syringe programmes** are considered the single most important HIV prevention strategy for people who inject drugs. Where NSP is not available, it is understood that not sharing injecting equipment is the most essential strategy.

2) **Opioid substitution therapy** is considered a vital intervention for its direct benefits and for the access to a range of other HIV prevention and harm reduction services.

3) For HIV-positive PWID, **viral suppression through ART** — with condom use — is understood as beneficial for prevention of transmission. However, in many countries, PWID are reluctant to seek testing and treatment services due to stigma, health provider attitudes and fear of prosecution; this often results in late diagnosis and poor adherence if treatment is initiated.

Almost all participants consider needle and syringe programmes (NSP) the most important HIV prevention strategy for PWID. A requirement of ‘exchange’ should not be a key feature of these programmes, especially in countries where possession of a syringe or drug residue are grounds for suspicion or prosecution. Safe disposal should be facilitated through distribution of bins and, where possible, outreach services for collection of used needles and syringes. Where NSP is not available, respondents recognize the importance of not sharing injecting equipment, but this is not always an option. In these cases, access to sterilization supplies is considered a good, though not optimal, strategy.

Opioid substitution therapy (OST) is considered nearly as important as NSP, not only for the reduction of needle use but also for the stabilizing effect of this intervention, which supports effective adherence to ART for HIV-positive PWID as well as access to a range of other prevention and harm reduction interventions. Less than half of participants mentioned condoms as a preferred preventive strategy, and 7 participants noted routine HIV testing as beneficial.

NSP and OST are generally available in western European counties, Canada, US and Australia, although access often depends on many structural and individual factors. In countries where these services have been relatively easy to access in the past, some respondents note that austerity measures and changing
political climates, as well as increasing political and social pressure for recovery and rehabilitation over maintenance and harm reduction objectives, are prompting cutbacks in services, reducing access to and uptake of services, negatively impacting quality of services, undermining harm reduction programmes and potentially exacerbating HIV and hepatitis C epidemics. One respondent Europe described a government ‘payment by results’ approach, which incentivizes services for the number of clients who are moved out of programmes; in the case of OST services, this could have negative impacts on the PWID community when individuals are pushed to leave before they are clinically or psychologically ready. Another European provider and member of the PWID community who works at a mobile needle distribution site has also noticed a greater focus on recovery among colleagues; this person is emphatic about the need to support people to stay healthy, regardless of their choices about injecting drug use.

In other regions, availability of these services has always been uneven, and NSP and/or OST services are usually located—when they are available—in more densely populated areas, restricting access to those who live outside of catchment areas.

In some countries of Southeast Asia, Africa and the Southern Cone region of Latin America, HIV prevention and treatment are prioritized over harm reduction services for PWID, which, when available, are generally limited to major cities. However, most respondents noted that “PWID are often the last in line” for ART; many injectors are reluctant to seek services due to the negative attitudes of providers, fear of prosecution and the stigmatization they experience in general, and providers are reluctant to prescribe ART for patients they consider unstable and unlikely to adhere to treatment. Three respondents who are also NGO service providers expressed it more starkly: some public service providers feel that medications are wasted on injecting drug users.

Three of the 6 HIV-positive respondents have been on ART for many years and are virally suppressed; 2 of them are in stable relationships and usually use condoms, while 1 of them is not in a relationship. Three respondents living with HIV are active injectors, and they all rely on needle and syringe programmes to prevent transmission and to protect themselves from acquiring other blood-borne viruses.

One HIV-positive PWID (who has been on ART for 6 years) feels that ART in general is not an option in some south Asian countries given the reality of most injectors’ lives.
“ART is not a priority. PWID know about ART, but their drug use is their #1 priority and there is no time for other things, including seeking treatment. But the basic conditions of life do not even allow PWID to keep a pill box with ART meds in a safe place”.

When this respondent encouraged a homeless peer to seek and adhere to treatment, the person replied:

“Yes, we can be on treatment, but [gesturing to a pill box] where would I put this pill box for the next 30 days?”

Poverty, homelessness, stigma and lack of basic services are the most significant barriers to HIV prevention for people who inject drugs. Criminalization of drug use and HIV transmission in many countries also serves as a powerful deterrent to PWID when deciding whether or not to seek testing or other preventive and treatment services.

4.2 HIV testing modalities

Box 2. Key findings regarding HIV testing modalities

1) HIV testing is delivered most effectively for PWID when it is offered alongside other harm reduction services.

2) PWID will seek testing only at safe, confidential sites staffed by knowledgeable, non-judgmental providers.

3) Rapid testing can reduce late diagnosis and loss to follow-up of PWID.

4) Self-testing is an acceptable option for PWID only in settings where there is no access to safe, confidential HIV testing. However, there are significant reservations about self-testing due to the lack of critical support from counsellors and other health providers.
Most respondents feel that regular HIV testing is important for the PWID community, but they report that PWID are very reluctant to seek testing unless it is available through other services that they use and trust. When they do get tested at a public facility, they often do not return for results due to negative experiences with health providers, stigma and fear. In some settings they are apprehensive about getting another lecture about quitting their injecting practices. In some settings the risks are greater where young injectors are apprehended and forced into rehabilitation against their will. Consequently, late diagnosis and late initiation on ART is a common concern among service providers.

Access to HIV testing for people who inject drugs is facilitated when they feel safe and supported to learn their HIV status and to take the follow-up measures that may be necessary. Several respondents mentioned ‘low threshold centers’\(^6\) as a particularly good environment for HIV testing for the PWID community because of the holistic and no-judgmental approach to serving the injecting community's needs.

Self-testing is viewed in a positive light in terms of increasing opportunities for knowing one’s HIV status as long as there are clear instructions for how to do it, what the results mean and where to go after taking a test. However, almost every respondent expressed reservations about an injector with a chaotic life and little support using a self-testing kit and having to deal with a positive diagnosis alone, with possibly little information about next steps for counselling, confirmatory testing and care.

### 4.3 Antiretrovirals for prevention

Box 3. Key findings regarding the use of antiretrovirals for prevention

1) **PrEP** is considered **unacceptable, unnecessary or unfeasible** by approximately 24 of 32 respondents for ethical and practical reasons. There were 8 positive views of PrEP, but 4 of those were qualified by concerns about feasibility in many settings, significant barriers to ART for PLHIV in the general population who are eligible, stigma that discourages PWID from using services and the far more urgent challenges facing PWID in many countries: poverty, homelessness, hunger, illness and criminalization.

\(^6\) Low threshold centers offer a space where marginalized people who use drugs can cope with difficult life situations and reduce the harms associated with their drug use. These centers generally provide health services and referrals on a walk-in basis; food, showers and peer support; and safe injecting spaces.
2) **PEP** is considered a **useful prevention** intervention by 14 of 21 respondents, but **most PWID are not aware of it or can't access it**, and 6 of those in favour felt that most PWID would be reluctant to ask for it. More advocacy is required to inform the community about this intervention, to develop policies that focus on the importance of PEP for PWID and to work with law enforcement where PWID risk prosecution when seeking health services at public facilities.

3) **Early initiation of ART** is considered a **good option for PWID** by 14 of 19 respondents, as long as it is a fully informed and individual choice, not a coerced or punitive measure enforced by the state or others only for the public health benefit. However, 7 of those respondents did not think it was feasible in their settings.

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**Pre-exposure prophylaxis (PrEP)**

Ten of 32 respondents had not heard of PrEP or were not sure of what it involved. Eight respondents expressed positive views about PrEP as an HIV preventive option, although 4 of them acknowledged that they did not know very much about it. Four respondents’ views were positive but with reservations. Fourteen respondents were unequivocally opposed to PrEP, while only 1 of a group of 11 young injectors spoke favourably about the intervention, the others expressing concerns or ambivalence.

In general, respondents were uncomfortable with an intervention that is imposed on individuals for the public’s health.

> “The possibly negative effect on the individual’s health and wellbeing is not being considered as having the same value as the public health benefit. There is the old narrative about drug users as disease transmitters, and there’s not enough attention to the needs of drug users as individual human beings and whether this intervention has real benefits for the individual who injects drugs.”

> “[Many PWID] understand PrEP as a way to put the responsibility on drug users (with all of the implications they have to face in terms of toxicity, side effects, daily meds) rather than a collective, societal effort [to promote harm reduction].”

> “In the EECA region [eastern Europe and central Asia], people are deeply alarmed by the possibility of their governments picking up on PrEP. [It] raises a whole series of human rights threats and risks: registries that could be shared with the police, compulsory attendance, a whole range of potential human rights infringements . . .”
“What are the side effects, what is the potential toxicity and what are the alternatives? An individual should have all the information to weigh the pros and cons, the toxicity, side effects, daily burden of meds as well as the benefits (which are more for the public’s health than for the individual’s).”

Three individuals expressed unqualified support for PrEP. One person lives in a setting where HIV prevention and harm reduction services are easily accessible, acceptable and affordable. While acknowledging that access to ART for those who are eligible is still inadequate, this person felt that any opportunity for protection against acquiring HIV would be desirable (this respondent is living with HIV). At the same time, this person believes that the acceptability of PrEP would depend on an individual’s comfort in society – a person who is vulnerable due to homelessness or social isolation might be less willing to engage with health services in order to access PrEP. One person who lives in a setting where criminalisation is a significant barrier to health services for PWID, and harm reduction is not easily accessible, had not heard much about it, but he felt that “the more degrees of protection the better”. One member of a group of young injectors felt that it would be a good thing “if I felt that I was continually putting myself at risk”.

Four respondents who support the idea of PrEP live or work in countries where criminalisation of drug use creates a context of persistent and acute fear, and where harm reduction is largely unavailable or difficult to access; however, they emphatically qualified their views in terms of:

- Uncertain feasibility in contexts where PWID are reluctant to access health services in general;
- Unlikelihood in contexts where there are major barriers to ART and significant shortfalls in coverage, even for those who are currently eligible;
- Current lack of awareness and information about this option; there would need to be full information about how PrEP works, the implications for adherence and resistance and costs to individuals;
- The chaotic quality of most injectors’ lives, which creates challenges for engagement with health care in general and adherence to ART or any other medical protocol even when it is needed as treatment for HIV or other health issues;
- The aversion to being associated with the HIV-positive community, which could add more stigma to already highly marginalized lives;
- Other more pressing needs for human rights shelter, food, health care, HIV treatment for PLHIV.

“If some doctors would prescribe PrEP for PWID, it would be really useful to prevent new infection. But in many EECA countries, to get PrEP a person would need to go to a doctor at the AIDS center, which is a horrible place, and to get there takes so much effort and is so connected to
stigma and discrimination. And these doctors do not see drug users as clients, they see them as drug users, people who will not take these medications, will just sell it or whatever . . .”

“PWID are not even aware [of PrEP] in eastern Europe. The situation is catastrophic. HIV-positive people cannot get ART, nobody discusses PrEP or PEP . . . not even service providers. In eastern Europe, [PWID are not an issue] until people are dying of overdose. There is not basic health for this community, so it’s too early to talk about PrEP. Some doctors and experts are discussing it, but people are hungry and they are homeless and they are just dying in the streets, so PrEP would not even be an option for them. It’s not a priority.

“It may be an option for some people but not for all. It has to be people who are going to take the treatment responsibly and look after their health. It sounds like a good idea, but the reality is in order to take medication, you need food, water, shelter, etc. Maybe PrEP is not a good idea unless people have the other conditions of life.”

“The challenge is that the people who could most benefit from PrEP are the [the people with the] most chaotic [lives], which in many cases are the people who would be least likely to comply with the programme—that’s the contradiction.”

Among the young PWID who participated in a group discussion, most7 were averse to the idea of a protocol that required daily medication, although some suggested that they might take it if there were an ‘incentive’.8

Fourteen other respondents were opposed to the idea of PrEP as an intervention for the PWID community at this time. Their views ranged from unequivocal rejection of the notion that ARVs should be used as a preventive intervention in light of continued shortfalls in access to ART for eligible PLHIV, to opposition to what is seen as a ‘medicalization’ of harm reduction, to a concern that HIV-negative PWID in some settings where awareness and understanding are very low would suffer additional stigma and harassment if they were to start taking an HIV-related drug regimen.

7 Exact number not reported.

8 Young PWID in this community have been receiving cash incentives for HIV testing through the UCSF/CAPS UFO study since 1997. See http://caps.ucsf.edu/ufo-study/
“Until we have the other interventions scaled up, I think PrEP is a step too far.”

“I am completely and utterly opposed to the use of PrEP for injecting drug users... supporting the use of PrEP for non-positive injecting drug users is... obscene. Until we have 100% treatment access for HIV-positive injecting drug users, [we should not have] discussions about the use of PReP for non-positive injecting drug users.”

“It’s not ethical or acceptable as long as most people do not have access to the basic conditions of life and as long as diagnostics are not adequate to providing a true picture or where epidemics are and the magnitude—HIV as well as Hep C, TB, etc—to determine what drugs and what quantities are actually needed.”

“The introduction of and backing of PrEP is part of a much larger agenda to medicalize the HIV response, which poses a very serious threat to community-based preventive responses—across all communities. In the context of PWID, the bio-medical magic bullet promise of PrEP, [especially for] governments who are resistant to harm reduction, will be seen as an excuse not to scale up or introduce [proven] harm reduction programming.”

“As a health issue it might be good, but from a social perspective [in India] I don’t think it would be a good idea... the stigma and discrimination would be worse for [PWID who started taking ARVs even though they are HIV-negative].”

“If IDUs take drugs for prevention this way, it would be hard to make them understand that they are not HIV-positive and it would be hard for the rest of the community and their families to understand. There is not enough information and understanding about this. As a health issue it might be good, but from a social perspective I don’t think it would be a good idea.”

Three experts speculated that pharma companies might have a lot to gain from a PrEP rollout.

“In Russia, with 1.8 million injecting drug users and a government adamantly opposed to harm reduction, they’re looking at a very large captive market.”
Many respondents noted that adherence to a daily protocol would be challenging for people who often have chaotic lives, and that poor adherence would increase the possibility of resistance to an important class of drugs, which an injector might eventually need for their own health.

“There are quite a lot of people who inject who are HIV-positive and who do not follow treatment; it could be a challenge to get people who are not positive on treatment like that, especially people who don’t take care of their general health on a regular basis.”

One respondent who is strongly opposed at this time can see how PrEP might be useful when many other conditions are met (e.g. harm reduction to scale and universal access to ART), but most of his peers see it as a distraction from better access to harm reduction which is needed immediately. Others expressed concerns that the availability of PrEP in some countries would undermine the critical message that NSP, OSP, HTC and ART are vital harm reduction interventions, and that services themselves might be cut back or closed if PrEP were rolled out. This is a particular threat with regard to hepatitis C prevention (a far greater problem than HIV for the PWID community), as PrEP does nothing to address this; in effect, PrEP could pose a double risk, undercutting proven options and undermining hepatitis C prevention. In general, PrEP is seen as unnecessary and a poor investment when proven, low-cost harm reduction interventions are already available, and which some countries are still not providing.

“Wouldn’t it make more sense to have clean injecting equipment?”

“For people who are concerned about high exposure to sexual transmission (e.g. MSM, SWs, TG), PrEP might be a good option, but for the injecting community it is more important to promote cheap and effective harm reduction, especially needle and syringe programmes. The priority should be availability of clean needles.”

“It’s a very expensive way to reduce the risk of HIV transmission, when we know that NSP and handing out harm reduction supplies is such an effective way to reduce HIV, and a lot cheaper. I would rather see a focus on the 15 million people who can’t get access to ARVs, rather than trying to get injecting drug users on PrEP.”
"It might be a good thing, but it’s not necessary. The priority is to work on harm reduction [referring to the current comprehensive package]."

**Post-exposure prophylaxis (PEP)**

Most respondents believe that PEP is an important intervention that PWID have a right to know about and to access, but that the community is generally not aware of PEP as an option. Some people feel that the availability of clean needles helps to remove a need for PEP among PWID (as long as they engage in protected sex), and for most people this would be preferable to seeking PEP in a public health facility. In some settings PWID would be reluctant to ask for PEP due to laws that would require providers to report drug users seeking services to the authorities; fear of prosecution would be more compelling than fear of HIV for most people in those settings.

"We need to start by decriminalizing drug users, then spread awareness about interventions like PEP."

Two service providers felt that in some countries PWID would be unlikely to be given PEP due to stigma and marginalization of drug users as well as the cost of the drugs.

"PEP should be available to drug users but it’s not. Drug users are considered as taking a known risk and so perhaps don’t ‘deserve’ to get it."

Furthermore, in many settings where active injecting drug users can’t go to health care facilities to ask for ART if they are HIV-positive, they are even less likely to be able to go to an ER and ask for PEP because they used a possibly contaminated syringe; stigma is a powerful deterrent to seeking services, as is the fear of having one’s drug-using history become part of a permanent electronic health record.

"It should be available for all. But [in Tanzania] they don’t have access to clean syringes, so 100% have been exposed. So all PWID should get it, but we can’t even get them to clinics in the first place—it’s about stigma, it’s about money, it’s about lack of trust, so it’s difficult to imagine PEP as an option [in this setting]."

"There is a value judgment element. There’s more empathy toward a person who has been raped or a service provider [who has had a needle stick injury] than there is for a person who injects drugs, and this is excluding community members from a vital intervention."
“When a person who injects drugs asks for PEP, it is because s/he is very sure that s/he’s been exposed to HIV by a needle. When someone is that sure that they’ve been exposed, they should absolutely be given PEP regardless of the reason for the exposure.”

Several respondents, PWID community members and experts, two of whom had personal experience with PEP, felt that this was a good intervention as long as the individual had an understanding about the process and some level of stability in terms of housing and a support network to help the person cope with the process and the side effects. Some providers might be reluctant to provide PEP for young injectors because of consent issues.

One participant, a member of the PWID community as well as a technical expert, shares a more nuanced view of PEP for PWID: investment in PEP would be a diversion from the real issue. His position is that people who inject drugs should not be in a situation where they need to re-use needles. While unprotected sex might be more pleasurable than protected sex, and some people might choose to take that risk, there is nothing pleasurable about sharing needles, and it is not a choice that people would make voluntarily. He feels that UN guidance on targets for harm reduction is part of the problem; e.g. 200 syringes/year is not an adequate supply for a daily user, and the recommendation should be as many needles and syringes as any individual needs.

“We don’t expect people to re-use condoms, we shouldn’t be expecting people to re-use syringes. And that is effectively what we’re being expected to do. Harm reduction programming is nowhere near the scale at which it needs to be, and that, for me, is a greater imperative than PEP. If we’re choosing where to put resources, we should be putting them into pro-preventive measures. ”

When asked about limiting an individual to a certain number of courses over a period of 12 months, 2 service providers felt that there should be no limits, but that prescribing PEP required considerable counselling, support and follow-up, along with information for more effective prevention strategies.

**Early initiation of ART**
Early initiation is viewed favourably by 14 of the 19 people who responded to the question, but 7 respondents felt that is was not at all feasible in their settings due to criminalization, stigma, and general lack of ART for PLHIV who are currently eligible. Most of those in support of early initiation would be opposed if this were a mandatory measure imposed on the HIV-positive injectors.
One expert expressed concern that the way that some ART recommendations are worded facilitates imposition of treatment without the real consent of the patient.

“Even when the recommendation says that ART should be offered, in some countries, saying ‘no’ to a physician is not really an option, so those patients are effectively being forced into treatment. And you can be blamed and marginalized further if you refuse this treatment.”

Another member of the community and a technical expert pointed out the view that there is an important omission in the Consolidated ARV guidelines in that early treatment is not recommended for people with hepatitis C, as it is for people with hepatitis B; several respondents assert that hepatitis C is actually a much larger concern to PWID than HIV.

A more widely held view among respondents is that the health of the individual must be the first concern, and that early treatment must be an individual choice. Most respondents rejected the notion of the public health benefit as more important than the individual’s wellbeing.

“There is a concern that in some countries this will be used to identify possible ‘vectors’ of transmission, especially among key populations and to force them into treatment to prevent transmission to others.”

“This notion that a given population is disproportionately contributing to transmission is stigmatizing; it’s about others being more comfortable with the idea of starting around CD4 500, not the individual.”

However, in many places, there is a more urgent need for other support services for HIV-positive PWID, better treatment literacy, and universal access to HIV treatment for those who are eligible before early initiation of ART is a viable or acceptable option.

“Service delivery would be problematic, there are already long lines and overcrowded clinics. There would have to be more clinics just to serve the current population [who are eligible for ART].”
“Most people are just not ready to make a decision about treatment at that point, there are so many implications to consider (including that you have to take charge, carry the meds with you everywhere and deal with those issues as well) and so many other things to deal with.”

“Pills make you feel sick. If you are feeling well and you are not convinced you need this, adherence will be difficult.”

One member of the community who is also a service provider felt that in EECA countries, especially in Russia, doctors would never offer drug injectors early initiation on ART because of the low value placed on their lives.

“PWID are pretty much outside of society in Russia, and nobody in the MoH will ever think that drug users have families and friends, they simply can’t conceive of this. They think that PWID are people who live on the street, have no friends or family, and of course they can infect only each other, which [in the view of the MoH] is good.”

A similar view is held by a respondent in Asia who first noted that he liked the new ARV guidelines on treatment initiation, because he thinks starting earlier is good for all PLHIV. However he sees other, more fundamental issues as needing more urgent attention.

“CD4 count is not the issue for PWID. Just to get them to the ART center is difficult, they are dirty and public transport doesn’t even want to take them. There are no mobile services, and ART is only available through the government hospital, it is very unrealistic to [think about getting] PWID on ART early. People do not care about them, and they need so many other things: food, clean water, they sleep in the streets, they have nothing. So ARVs are not really important.”

Another member of the community and a service provider in a country where HIV transmission is illegal notes that early initiation can be an excellent strategy for PLHIV to achieve viral suppression and avoid criminal prosecution, especially when there are aggressive efforts to find and arrest people who are suspected of ‘criminal’ behaviour.
A member of the PWID community in a setting where very few eligible people have access to ART notes that many service providers are not even aware of the new guidance on ARVs (recommending initiation at a higher CD4 level). He feels that early initiation might be a good idea in theory but a long way from reality in his setting where most PWID are reluctant to get an HIV test.

4.4 Comprehensive harm reduction package

Box 4. Key findings regarding the comprehensive harm reduction package

1) **Criminalization** of drug possession and use is the most important issue facing PWID: without drug law reform harm reduction will not have the impact needed to protect PWID and to prevent the spread of disease.

2) The larger issues that influence the potential impact of harm reduction interventions are poverty, homelessness, mental illness, social exclusion and joblessness. WHO must take a stronger position on the **social determinants of health** in order to ensure the effectiveness of the comprehensive harm reduction package.

3) **Key interventions (NSP, OST, HTC, ART)** should be prioritized to support advocacy and accountability.

4) **Community distribution of naloxone** should be added to the list of harm reduction interventions.

Of the 21 adult participants who responded to questions about the comprehensive harm reduction package 9 18 felt that the package was good in terms of its usefulness as reference points for advocacy. However, availability is uneven within countries and across regions. Respondents point out that access to OST in eastern European and central Asian countries is extremely limited, and it is prohibited in Russia, Turkmenistan and Uzbekistan. Poverty, homelessness, criminalization and disregard for human rights in other regions such as the Southern Cone countries of Latin America and in South Asia place harm reduction low on a list of priorities for governments and for PWID themselves. In some Eastern Mediterranean countries, there are high rates of hepatitis B, hepatitis C and TB affecting PWID, but there is little attention paid to harm reduction related to those diseases. Governments in North America and Europe are cutting back on services in order to push recovery.

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9 The comprehensive harm reduction package is considered by WHO, UNAIDS and UNODC to include needle and syringe programmes, opioid substitution therapy, HIV testing and counselling, ART, condoms, targeted information and education and screening and treatment for STI, and screening and management of HBV, HCV and TB.
Respondents highlighted a number of weaknesses in terms of the way the package was developed, the way it is presented, and in terms of missing elements.

"Very dry and technical set of recommendations . . . and it has not been prepared on the basis of any consultation with the community."

Some participants feel that it would be helpful to view harm reduction as a process as well as a set of interventions. This would allow for a less limiting approach to harm reduction that also recognizes issues such as drug consumption limits, crack pipe distribution.

One person felt that the only 3 that matter are NSP, OST and ART, but he added that getting PWID enrolled in ART was a huge challenge. Six other respondents believed that the package would be more useful if WHO would take a stronger position on the necessity of NSP and OST, two interventions that are critical to both HIV and hepatitis C prevention, but which are less available in many countries for social, political and financial reasons. The WHO, UNODC, UNAIDS Technical Guide for setting targets related to access to HIV prevention, treatment and care for PWID emphasizes the importance of a comprehensive approach, with high levels of coverage, to significantly reduce HIV transmission and other harms. However, most countries are not doing this.

"With a list like this, countries can ignore the ones they don’t like and choose to implement the easier ones, and still say they are doing harm reduction. WHO should make a clear emphasis on NSP and OST. It is not possible to deliver good harm reduction programmes without appropriate coverage of OST. A WHO recommendation is a powerful tool for advocates, especially in countries like Russia. It provides more ammunition for advocates and sends a clearer message to governments. As it stands now, with the 9 interventions, each one seems to have the same importance, and this is not the case."

Others would prefer that NSP, OST, HTC and ART be presented as the core, non-negotiable interventions.

"There has been a sense that if you do some on the list (condoms etc, things that a bit more marginal for PWID), then you’re doing something at least . . . if you aren’t doing these top 4, and you aren’t doing all of them, then you’re not going to be hitting the 50% reduction rates that we can achieve in HIV epidemics among PWID."

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10 WHO, UNODC, UNAIDS technical guide for countries to set targets for universal access to HIV prevention, treatment and care for injecting drug users – 2012 revision.
In terms of pieces that are missing from the harm reduction package, and number of additional elements were suggested:

- More explicit and non-moralistic information and education (life skills education for young PWID, safe injecting practices, vein and mouth care, overdose prevention);
- More explicit reference to the need for harm reduction services for prisoners, or a prison-specific harm reduction package;
- Attention to the specific needs of women at service delivery sites;
- The importance of safe injecting spaces as part of harm reduction service delivery sites;
- Psychological follow-up;
- Community distribution of naloxone.

Several respondents commented on the importance of peer-led services and outreach, deeper partnerships with civil society and a more community-centered approach to delivering harm reduction services.

"Sex workers have blazed the trail on community-led services. It's now accepted that services should be provided by and for sex workers, and the same applies to the IDU community. What has tended to happen has been quite the opposite; we are excluded from working in services that are aimed at our community."

Many respondents see the issue of harm reduction as something that extends beyond a list of 9 interventions. Some spoke at length about the need to address the social determinants of health before harm reduction can have a real impact on HIV and other epidemics. Issues such as poverty, shelter, hunger, mental health, joblessness and social and economic exclusion are all barriers to effective harm reduction. In some countries, racism and loss of cultural identity of entire groups of people, e.g. the aboriginal community in Canada, have a profound effect on the HIV epidemic within sub-groups of the PWID community. Some of these issues are systemic and need to be addressed by governments, but WHO and other international bodies are in the best position to engage on these issues at the highest levels.

Critical enablers such as the legal environment, access to justice and human rights must be addressed before harm reduction objectives can be achieved. Ten respondents mentioned the lack of access to harm reduction in prisons as a major concern. Almost every respondent called for decriminalization of injecting drug possession and use; this is considered the key that will unlock the response to HIV. Currently, penalties for possession and use send PWID to prisons, where they are often denied protection and harm reduction services; create climates of stigmatization and fear, which discourage PWID from seeking vital services; and fuel the distrust and exclusion that PWID experience as marginalized members of society.
“We can’t talk about HIV and the injecting drug community without looking at global drug prohibition. And we certainly can’t talk about getting to the ‘3 zeros’\(^\text{11}\) without really comprehensive drug law reform.”

The UNAIDS strategy for 2011–2015 echoes this view:

Social and legal environments that fail to protect against stigma and discrimination or to facilitate access to HIV programmes continue to block universal access. Countries must make greater efforts: to realize and protect HIV-related human rights, including the rights of women and girls; to implement protective legal environments for people living with HIV and populations at higher risk of HIV infection; and to ensure HIV coverage for the most underserved and vulnerable communities.\(^\text{12}\)

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\(^{11}\) Zero new infections, zero AIDS-related deaths, zero discrimination

4.5 Community distribution of naloxone

Box 5. Key findings regarding community distribution of naloxone

1) **Naloxone is a cheap, safe, easy-to-use, life-saving drug.** It should be available for community distribution to people who inject drugs, their peers and their families.

2) Community distribution of **naloxone should be added as an element of the comprehensive harm reduction package.**

3) **Pre-loaded syringes or nasal spray** are preferred.

4) The importance of **rescue breathing** must be emphasized along with distribution of naloxone.
“Naloxone saves lives.”

“We deserve to live, to be okay, to have more chances. We have lives of value, we are people, too.”

“People are dying every day in Russia. The quality of drugs is changing every day because heroin is often not available and so people have to take whatever they can find, and it’s very difficult to find the right doses, and so overdose happens all the time. Naloxone used to be more available with Global Fund money and it was so successful, and service providers distributed naloxone in the communities, and it helped a lot and saved a lot of lives. But GF has not been operating since 2013, now there is [not enough] naloxone.”

The discussions of community distribution of naloxone were brief and the views were clear. Thirty-one respondents (one is based in a country where injecting drug use is limited to stimulants, and naloxone was not discussed) expressed unqualified support for making naloxone widely available without prescription and without burdensome conditions. Three respondents acknowledged that overdose is not a significant problem in their settings, however they felt that naloxone should be available to every person who injects opiates.

“Availability with prescription (as is the case in many countries) is not enough—it needs to be in the hands of peers, families etc, so that it is easily available.”

Many respondents feel that resistance to making naloxone more widely available to the PWID community and their families and friends can have a dramatic effect in terms of further marginalization of members of the community, reinforcing a sense of alienation from society, which only makes injecting drug users more reluctant to seek and use vital harm reduction and other health services. In many countries, continued criminalization of PWID also deters peers from getting emergency assistance when someone has overdosed.

“There’s something so symbolic about naloxone. It’s a life-saving intervention. If you say community distribution is not worth [doing], it’s a value judgment on our lives.”

“What does that say about us if you’re willing to let us die when there’s such a preventative option in place? [Even if] you oppose harm reduction fundamentally, not being willing to save
our lives feels so alien and says so much about what you think about us, and then that affects how we want to engage in services.”

In general, availability of naloxone is variable across regions. In Europe and North America, availability is becoming more widespread but there is not universal access, and it can still be difficult to get naloxone for peer distribution. In most countries where naloxone is legal and available for community use, there are usually conditions that require a prescription and training. In almost all of those cases, only a small amount is given to each person, generally a 2ml vial, which may be sufficient for 1 or 2 doses, depending on the situation. Respondents who mentioned the doses all felt that it would be better to have larger quantities available for community distribution.

Ideally, a sufficient and consistent supply of naloxone for peer workers to distribute along with basic training could create a cascade out to all members of the community. Training must continue to emphasize the importance of rescue breathing; one respondent worries that widespread availability of naloxone could overshadow the critical importance of this overdose management strategy. Another respondent feels that rescue breathing must be designated as preferable to chest compressions which are advised in her setting, but which result in additional trauma (e.g. cracked ribs).

In sub-Saharan Africa and South Asia, availability is much more limited. In most cases, only health professionals are allowed to administer it; in some cases, health providers themselves are not aware of it. In many Eastern Mediterranean countries, naloxone is available only at government health facilities, and only some first responders have access to it; however, administration of naloxone requires a doctor’s permission, which in turn triggers a report to the police.

“Often people will be thrown on the street to die because they are afraid of trouble with the police.”

One respondent in sub-Saharan Africa raised the issue of health information systems as an issue to be addressed when advocating for naloxone.

“Current death registration masks the real extent of the problem; death caused by OD is called ‘pulmonary embolism’, so we don't have the real numbers to use when we advocate for wider distribution of naloxone.”
Arguments against community distribution of naloxone are considered to be baseless.

“The main resistance is based on a belief that people will feel safer and engage in more high risk behaviour and try to get as close to OD as possible, because we have naloxone sitting there. It’s a ridiculous argument. It’s true, for some users this is part of the game, getting as close as possible without overdosing. But if you know what it’s like to go over and then get brought out with naloxone, which is not a pleasant experience, then actually getting your ‘stone’ right makes much more sense than being reckless, you can enjoy it without being interrupted. The arguments against naloxone just don’t add up. And there are complexities to the situation that don’t fit with this simplistic assumption that people will act more recklessly (e.g. there may be other substances such as alcohol that are changing the way the body is processing the drug, or a health condition that makes the drug act differently).”

“Dealing with overdose is scary. There are no downsides to having naloxone. We could be saving people’s lives! When you work with this community, you lose so many people. People’s lives could be saved so easily, it’s so easy to administer, it’s so logical. The reality is that people hate drug users... and some people feel it’s a waste of money if you’re using it for drug users.”

When asked if there are any downsides to community distribution of naloxone, one respondent summed up the views of all participants:

“None. What kind of question is that?”

4.6 Adolescent and young people who inject drugs

While the issues of young injectors were not a main focus of this study, respondents in all regions signalled the urgent need to develop more youth-specific services for young PWID, including clinic-based, mobile and outreach services. Some service providers noted their lack of expertise for addressing the needs of young people who use injecting drugs, and they understand that young people are not comfortable seeking services in places where older injectors congregate. Another problem is that young people do not have the same type of peer support that older injectors have when services are staffed by current or former injectors. Peer counsellors who share lived experience with young injectors can provide opportunities for building relationships and supportive networks that promote good HIV prevention and harm reduction practices. Service providers also noted that most young injectors do not

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13 Several respondents feel that there should be more members of the community involved in service delivery as the shared experience promotes greater trust in service providers, stronger peer support and more effective advocacy.
self-identify as members of the PWID community; they are injecting on an occasional, recreational basis, they are generally healthy, and they do not feel a need to seek HIV prevention or harm reduction services.

Regarding PrEP and early initiation of ART, most respondents feel that initiation of a daily, lifelong regimen would be unacceptable for young PWID as the decision is complex and adherence would be extremely challenging. Furthermore, there is not enough evidence about the long-term effects of either of these interventions in adults, much less young people. One expert who works with a global youth-led network for reducing drug-related harm noted that it was already very difficult for HIV-positive young PWID to access ART—due to chaotic lives, exclusion from OST which has a stabilizing effect that can facilitate ART initiation and adherence and stigmatization which discourages young PWID from seeking services—and that early initiation of ART is not a feasible option for young members of the PWID community.

Consent is an issue that concerns providers with regard to young clients. However, service providers who participated in the study said that they would provide a young injector the prevention and harm reduction services requested. Some providers would encourage the individual to involve a parent or guardian, but many young injectors live on the street or apart from family, and they would be unlikely or unable to do this. The most important thing for providers is that a young person understands the implication of the service or intervention being offered.

Most respondents who have some interaction with young injectors said that they would not support the use ARVs for prevention by young PWID due to concerns about adherence, side effects, resistance and other potential complications related to their age and lack of supportive services for adolescents and young people who inject drugs.
5. **Conclusion**

Four issues were the main focus of this values and preferences study:

**The introduction of PrEP as a harm reduction intervention for people who inject drugs.** This was not supported by a majority of the participants in this study.

**The comprehensive harm reduction package.** Participants felt that prioritization and additional components could make the package a more effective tool for advocacy and for strengthening the response to HIV and hepatitis C.

**Community distribution of naloxone.** Participants assert, with no reservations, that this life-saving intervention is absolutely necessary and should be made available immediately to injecting drug users, their peers and their families.

**Experience and preferences around HIV testing modalities.** Introduction of more peer outreach and mobile services and as well as broader availability of rapid testing are seen as starting points for addressing low uptake of HIV testing by members of the PWID community. Self-testing is not viewed favourably due the lack of counselling, support and referrals for follow-up services.

Participants in this study emphasized the need for more attention to critical enablers that fundamentally determine the accessibility and effectiveness of harm reduction for injecting drug users:

- Human rights including empowerment of the PWID community for advocacy and equity
- Poverty, homelessness and hunger
- Stigma and discrimination
- Equitable access to HIV prevention, treatment and care, and harm reduction services as well as basic health care
- Legal environment and criminalization of drug use and HIV
- Social and economic inclusion and re-integration
- Psychological support
Participants also drew attention to four key messages that address fundamental gaps or weaknesses in current responses to HIV among the injecting community:

1. Hepatitis C is a bigger problem than HIV for PWID.

2. Youth-specific services are urgently needed.

3. Policies and services for prisoners are urgently needed.

4. Decriminalization of injecting drug use is the key to effective harm reduction.

Study participants represented a diversity of social and economic backgrounds. Their experiences as injecting drug users, service providers or researchers contributed important insights on the challenges facing the PWID community as they seek protection of their fundamental rights to health, decent conditions of life, a place in society and a voice at the table. While the study was limited in terms of the number of participants, the consensus was loud and clear: marginalization of people who inject drugs—through criminalization and lack of protection, violence and abuse, denial of medical and harm reduction services, poverty, homelessness, stigma, intolerance, fear and moralistic societal norms—will continue to force the community to live in secrecy and fear, to support transmission of HIV and other blood-borne viruses, and to undermine efforts to achieve the ‘3 zeros’.
Annex 3.3: VALUES AND Preferences of Transgender people: A Qualitative study

Author: Mira Schneiders
2014

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African Sex Worker Alliance
Asia Pacific Coalition on Male Sexual Health (APCOM)
Asia Pacific Network of People Living with HIV/AIDS (APN+)
Asia Pacific Trans Network (APTN)
Coalition of Asia Pacific Regional Networks on HIV/AIDS (7 Sisters)
FHI 360 Cambodia
GenderDynamiX
Global Action for Trans* Equality (GATE)
Global Forum on MSM and HIV (MSMGF)
ILGA EUROPE: Equality for lesbian, gay, bisexual, trans and intersex people in Europe
India Network of Sexual Minorities
Naz Male Health Alliance
Oogachaga Counselling and Support (OC)
OUT Well-Being
Rainbow Identity Association (RIA)
Red de Personas Trans de Latinoamérica (REDLACTRANS)
Sampoorna: A Network of Trans Indians across the Globe
S.H.E, Social, Health And Empowerment Feminist Collective of Transgender and Intersex Women of Africa
TGEU – Transgender Europe
Totem Jeunes
Transgender and Intersex Africa (TIA)
TRANSGENDER Asia Research Centre
Transgender Network Switzerland
Ana Coimbra
Sam Winter
### Abbreviations and acronyms

<table>
<thead>
<tr>
<th>Abbreviation</th>
<th>Full Form</th>
</tr>
</thead>
<tbody>
<tr>
<td>AFRO</td>
<td>WHO Regional Office for Africa</td>
</tr>
<tr>
<td>ART</td>
<td>antiretroviral therapy</td>
</tr>
<tr>
<td>EMRO</td>
<td>WHO Regional Office for the Eastern Mediterranean</td>
</tr>
<tr>
<td>EURO</td>
<td>WHO Regional Office for Europe</td>
</tr>
<tr>
<td>HIV</td>
<td>human immunodeficiency virus</td>
</tr>
<tr>
<td>HTC</td>
<td>HIV testing and counselling</td>
</tr>
<tr>
<td>LGBT</td>
<td>lesbian, gay, bisexual and transgender</td>
</tr>
<tr>
<td>MSM</td>
<td>men who have sex with men</td>
</tr>
<tr>
<td>NGO</td>
<td>nongovernmental organization</td>
</tr>
<tr>
<td>PAHO</td>
<td>Pan American Health Organization/WHO Regional Office for the Americas</td>
</tr>
<tr>
<td>PEP</td>
<td>post-exposure prophylaxis</td>
</tr>
<tr>
<td>PrEP</td>
<td>pre-exposure prophylaxis</td>
</tr>
<tr>
<td>SEARO</td>
<td>WHO Regional Office for South-East Asia</td>
</tr>
<tr>
<td>STI</td>
<td>sexually transmitted infection</td>
</tr>
<tr>
<td>UNAIDS</td>
<td>Joint United Nations Programme on HIV/AIDS</td>
</tr>
<tr>
<td>UNDP</td>
<td>United Nations Development Programme</td>
</tr>
<tr>
<td>WHO</td>
<td>World Health Organization</td>
</tr>
<tr>
<td>WPRO</td>
<td>WHO Regional Office for the Western Pacific</td>
</tr>
</tbody>
</table>
Definitions of key terms

**Transgender** is an umbrella term for all people whose internal sense of their gender (their gender identity) is different from the biological sex they were assigned at birth. Transgender people choose different terms to describe themselves. Someone born female who identifies as male is a transgender man. He might use the term “transman”, “Female to male (FtM)” or “F2M”, or simply “male” to describe his identity. A transgender woman is someone born male who identifies as female. She might describe herself as a “transwoman” “Male to Female (MtF), “M2F” or “female” (1).

**Cis-gender** is the opposite of transgender and refers to someone whose biological sex matches their gender identity (1).

**Hetero-normative** describes a world view that promotes heterosexuality as the normal or preferred sexual orientation.

**Hormone therapy** (also known as cross-gender hormone therapy or hormone replacement therapy) is a health intervention used by many transgender people. Hormones can be used to feminize or masculinize one’s appearance in accord with one’s gender identity. Physical appearance is often used to support assumptions about someone’s sex, and hormone therapy can help a transgender person to be recognized as the appropriate gender (1).

**Transition** refers to the process transgender people undergo to live in their gender identity. This may involve changes to outward appearance, mannerisms or to the name someone uses in everyday interactions. Transitioning may also involve medical steps such as hormone therapy and surgery (known as gender-affirming surgery) (1).
Executive summary

The World Health Organization’s (WHO) HIV Department has developed consolidated guidance on HIV among key populations, including transgender persons (2). As part of this process, a qualitative “values and preferences” study was conducted with transgender individuals from across world regions. The aim of these interviews was to ensure that transgender people’s experiences with regard to HIV and broader health issues were captured and to foster better understanding of transgender-specific HIV and health issues. Specifically, the interviews sought to discover barriers and enablers as well as suggested strategies with regard to HIV information, prevention, testing, treatment, access to health services and other needs specific to transgender health.

To develop this values and preferences report, a three-stage process was employed. First, a desk scoping-review was carried out to gather available evidence about transgender people and HIV. Second, a two-round Delphi consultation was conducted via an electronic survey to invite experts in the field of transgender health to inform the design of the interview guide. Third, in-depth telephone interviews were carried out with 14 transgender individuals from across WHO regions.

Selective sampling was employed to identify a range of transgender men and women from different WHO regions and age groups, with differing HIV statuses and stages of transition. 14 transgender individuals (11 transgender women; 3 transgender men) took part in an in-depth interview. Respondents came from AFRO, WPRO, SEARO, PAHO and EURO regions; no transgender individuals from EMRO could be identified who would agree to take part in the interviews. The respondents’ ages ranged from 22 years to 60 years. Three out of the 14 transgender individuals interviewed were living with HIV and three did not know their HIV status.

Respondents said that friends, the transgender community and the Internet were an important source of information, support and empowerment. However, many participants perceived the overall scarcity of transgender-specific health information – particularly on hormone treatment and gender-affirming surgery – as well as the trustworthiness of existing sources of information as a severe challenge. Overall, many of the respondents felt that more information on transgender-specific health concerns needs to be available and accessible, while existing HIV information needs to be tailored to address transgender people.
With regard to seeking **HIV testing and counselling (HTC)**, commonly mentioned barriers included hetero-normative environments that are not sensitive to transgender people; service-providers low levels of competency in transgender-specific issues; and transgender people’s low levels of trust in service-providers. Fear of HIV, which was related to external and internalized stigma, was also a barrier to seeking HTC. These services should be rapid, free, confidential and transgender-friendly in order to increase the number of transgender individuals who seek testing. Staff should also be trained to give advice or make referrals to other transgender-specific health services, such as hormone treatment. NGO-based testing, mobile clinics or community drop-in centres were also viewed as desirable modes of delivering HTC to the transgender community.

**HIV prevention** strategies were discussed, including sexual transmission, transmission through injections and the use of antiretroviral therapy (ART) to prevent transmission. While access to condoms was generally described as easy, other **prevention commodities** such as dental dams and lubricants were often unavailable. Despite the availability of condoms, low self-esteem, societal pressures and the fear of experiencing rejection from sexual partners were barriers to using them consistently.

The use of hormone **injections** appeared to vary widely between individuals and settings, with the majority of interviewees not considering the use of injections as a major HIV related concern. Injecting other substances such as silicone for gender-affirming body modification was reported as a major health concern in some settings.

Overall there was very little knowledge on **pre-exposure prophylaxis (PrEP)** and **post-exposure prophylaxis (PEP)** among the transgender individuals interviewed. Very little information on PrEP and PEP appeared to be circulating within the transgender community, and information that was available was targeted towards men who have sex with men (MSM) only. There were divergent opinions about whether PEP and PrEP should be promoted among the transgender community. Further research on the appropriateness and acceptability of PrEP and PEP among transgender individuals is suggested.

Three out of the fourteen individuals interviewed were living with HIV and taking **ART**. Among these individuals, stigma and discrimination from the health system and ART
side-effects were described as challenging. HIV negative interviewees had concerns over possible interactions between ART and hormone therapy and the effectiveness of both treatments when taken together. Education and empowerment around ART, and the creation of treatment services in which transgender people feel comfortable and addressed in their transgender-specific HIV related concerns, were regarded as helpful for improving uptake and adherence to ART among those interviewed.

Transition-related concerns were found to be the major health priority among transgender individuals interviewed. The overall lack of transition-related information and services in the public health system, with regard to both hormone treatment and gender-affirming surgery, were seen as the greatest challenges to transgender people in achieving their highest attainable state of health. Transitioning was perceived as a vital pre-requisite for other physical and psychological aspects of health. Self-administered hormone use was widespread and reliance on non-medical guidance was common. Many individuals expressed concern over the potential adverse effects of non-supervised hormone use and wished to access non-discriminating, transgender-specific guidance through the health-care system. Similarly, those who desired to seek gender-affirming surgery also faced multiple barriers through the health-care system, including lack of services, high costs, long waiting times, poor capacity and poor quality of services. Resulting psychological distress was commonly mentioned, with some individuals describing their depression and suicidal ideation as direct results of being unable to access gender-affirming treatments. In conclusion, providing competent and non-discriminatory transition related treatment and care services through the public-health system is considered vital for improving physical and psychological health among transgender people.

The results of this qualitative values and preferences survey, alongside technical reviews of existing evidence, has informed the development of the HIV consolidated guidelines for key populations as pertaining to transgender people. Furthermore, this report may also be used to inform interventions at multiple levels, including HIV research, programmes, policy and advocacy.
Introduction and background

Transgender people are disproportionately affected by a variety of physical and mental health risks. Stigma and discrimination, and a lack of prevention, treatment and care tailored for transgender people combine to exacerbate health risks. Transgender-specific health needs are often severely neglected in policy, research and service provision across the globe.

A high burden of HIV is one of the major health disparities facing transgender people worldwide. Numerous social, economic and individual factors combine to heighten transgender people’s risks of acquiring HIV and thus make them a key population in need of HIV prevention, treatment and surveillance. A recent global meta-analysis of HIV prevalence among transgender women documented 19.1% HIV prevalence among 11,066 transgender women across 15 countries, with the odds ratio of HIV infection among transgender women compared to the general population being 48.8 (3). A meta-analysis conducted in 2008 among US-based transgender women reported 27.7% HIV prevalence, with 73% of transgender women being unaware of their HIV status (4). A global systematic review on sex work and HIV revealed 27.3% HIV prevalence among transgender women who were engaged in sex work (5). While these studies document a high burden of HIV, predominantly among transgender women in the United States, quality data on HIV prevalence among transgender men and women from other regions, as well as studies estimating the size of the global transgender population, are urgently needed.

Despite their HIV related needs and risks, transgender people continue to be neglected and underrepresented among key populations (6, 7). Transgender community groups have voiced growing concerns over the discrepancy between their health needs and the funding, research and programmes allocated towards them, and have urged United Nations agencies to systematically address these gaps (8). With HIV among the leading health issues facing transgender people, WHO has been working regionally to address HIV and some of the broader health concerns facing transgender populations (9, 10, 11, 12). There is an urgent need to further address the HIV related needs of transgender people worldwide, as well as the underlying structural, social, individual and biomedical factors underpinning the HIV epidemic among this key population.
The WHO’s HIV Department has consolidated normative HIV guidance for key populations, including transgender people (2). As part of this process, a background-scoping exercise on the current global state of evidence around transgender people and HIV was conducted. Next, experts in the field of transgender health and HIV were consulted in order to identify gaps in existing knowledge around HIV and transgender health. Finally, a values and preferences survey, in the form of qualitative interviews with transgender people, was conducted to ensure that the voices of transgender men and women were considered in the guideline process. Specifically, the interviews attempted to capture the experiences, needs, values and preferences of transgender people with regards to HIV prevention, treatment and care.

This report summarizes the findings of the qualitative interviews conducted among transgender people from across WHO world regions. The results of this qualitative survey, alongside technical reviews of existing evidence, have informed the development of the sections of the HIV consolidated guidelines relevant to transgender people.

Methods
Prior to conducting the values and preferences interviews, a desk scoping-review on HIV and other health-related needs among transgender people was completed. The scoping exercise gave an overview of HIV related epidemiology, prevalence, risk factors and access to health services among transgender people globally. It also provided an overview of existing WHO guidelines and recommendations with special considerations for transgender people and HIV. Research gaps and recommended ways forward for WHO were highlighted. The document concluded that conducting values and preferences interviews with a sample of transgender men and women from across world regions should be a priority action for WHO in light of the development of the 2014 key populations consolidated HIV guidelines.

The Delphi process
In preparation for the values and preferences interviews, an online Delphi consultation was conducted with a group of experts in the field of transgender health and HIV, to gain consensus on the most important topics for inclusion in the in-depth interviews. The Delphi method is a structured process for collecting and distilling knowledge from a group of experts using a series of questionnaires, which are then summarized for further opportunities for controlled feedback of opinions. The Delphi consultation was conducted in two rounds via an electronic survey using Survey Monkey. Summarized responses from Round 1 were returned to participants, along with the Round 2 questionnaire, which excluded those questions on which consensus had already been reached.
Annex 3.3

Round 1 Delphi
WHO Regional offices were informed of the Delphi consultation and asked to provide contacts to key regional experts in transgender health and HIV to be included in the Delphi exercise. Using these contacts, together with well-known experts from academia and international organizations, a total of 44 individuals were invited via e-mail to participate in the Delphi exercise. A week following the initial invitation, the link to the Round 1, 27-item survey questionnaire (see Annex 1) was sent out and the survey was kept open for one week, with one reminder e-mail sent out one day prior to survey closure. Round 1 was completed by 24 experts (a 54.4% response rate). Respondents were anonymous to one another, and only the research team was able to access details of those participating. Responses to each question were summarized using descriptive statistics.

Round 2 Delphi
Based on Round 1 analysis, the Round 2 survey was developed, including a summary of all items on which there was consensus (which was predetermined as being 51% agreement by respondents on any given question (13)). All items with less than 51% agreement, as well as any novel topics raised in Round 1, were included in this second questionnaire for the purpose of ranking.

The 24 experts who had participated in Round 1 were sent an e-mail summary of Round 1 results and the link to access the Round 2 survey. The survey link was kept active for one week, with one reminder e-mail sent one day before closure. Eighteen experts participated in Round 2 (a 75% response rate among those who had participated in Round 1). Following analysis, participants were again informed of the results of Round 2.

The in-depth interviews
Transgender participants who took part in the values and preferences interviews were recruited using a convenience, snowball sampling method. Experts who had been contacted through the Delphi process were asked to provide contact details of transgender individuals from their networks or Region to partake in the in-depth interviews. Based on the contacts provided, 72 transgender individuals were identified and personally invited via e-mail to take part in the interviews. Further recruitment of transgender individuals was done via advertisements circulated through social media websites, organizational networks and mailing lists. Thirty-five transgender networks and organizations, representing all major regional transgender networks and NGOs as well as key local networks, were contacted via e-mail and asked to forward an invitation to their transgender members.
The recruitment letter (see Annex 2) included a link to a short Survey Monkey online survey (see Annex 3), in which transgender individuals were asked to register their interest in taking part in an in-depth interview by providing basic sociodemographic information. The short online survey was completed by 34 transgender individuals. In an attempt to achieve equal regional representation and capture a wide range of varying persons with regard to age, gender, transition stage and HIV status, 19 transgender individuals were invited to take part in an interview. Fourteen individuals agreed to be interviewed and interviews were arranged on an individual basis.

Interviews were conducted in December 2013 and January 2014 by an independent consultant, via telephone or Skype. A semi-structured interview guide which was developed based on the results of the Delphi consultation and scoping review was used to guide interviews (see Annex 4). Topics covered in the interviews included HIV knowledge, prevention, testing and counselling, treatment and care, antiretrovirals as prevention and other health concerns. Open-ended questions were used to encourage in-depth expression of personal experiences, opinions and perspectives by interviewees.

At the start of each interview, the interviewer verbally reviewed the participant information sheet which the participant had been sent prior to the interview, before taking verbal consent (see Annex 5). Interviews took 50–90 minutes to complete. All interviews were conducted in English, with the exception of one, which was conducted in Spanish, using a Spanish–English translator arranged by the interviewee.

All interviews were recorded and then transcribed verbatim by the consultant. Information provided during the interview as well as the short online survey was anonymized so that only the consultant was able to access personal details of interview participants.

Transcribed interviews were entered into the qualitative analysis software QDA Miner Lite. Each interview was then re-read and coded thematically using the software. Coding was organized into topics covered on the interview guide, while novel themes and topics emerging out of the data were also included. Content for each code or theme was then retrieved separately and all quotations pertaining to one theme or
code were re-read and analysed for content. The narrative section on each theme was then written.
Respondent demographic and psychosocial profiles

Tables 1–3 provide an overview of the basic demographic information of the 14 transgender individuals interviewed. Eleven transgender women\(^ {14} \) and three transgender men\(^ {15} \) were included in the interviews. Respondents came from Brazil, El Salvador, Fiji, France, India, Indonesia, Philippines, the Russian Federation, Singapore, South Africa, Thailand and the United States, representing five different WHO Regions. (For the Eastern Mediterranean region no transgender individuals could be identified who would agree to take part in the interview.) Respondents’ ages ranged from 22 years to 60 years. All except one participant were working with transgender or health-related organizations. Three out of the 14 transgender individuals interviewed were living with HIV and taking ART. Eight respondents reported being HIV negative, while three did not know their HIV status. Of these three, two reported never testing for HIV in the past.

Table 1. Respondent profile by gender and region of residence

<table>
<thead>
<tr>
<th></th>
<th>AFRO</th>
<th>WPRO</th>
<th>SEARO</th>
<th>PAHO</th>
<th>EURO</th>
<th>EMRO</th>
</tr>
</thead>
<tbody>
<tr>
<td>Transgender woman</td>
<td>2</td>
<td>2</td>
<td>3</td>
<td>3</td>
<td>1</td>
<td>-</td>
</tr>
<tr>
<td>Transgender man</td>
<td>-</td>
<td>1</td>
<td>-</td>
<td>1</td>
<td>1</td>
<td>-</td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td>2</td>
<td>3</td>
<td>3</td>
<td>4</td>
<td>2</td>
<td>-</td>
</tr>
</tbody>
</table>

Table 2. Respondent profile by gender and age

<table>
<thead>
<tr>
<th></th>
<th>19-29</th>
<th>30-39</th>
<th>40-49</th>
<th>50-60</th>
</tr>
</thead>
<tbody>
<tr>
<td>Transgender woman</td>
<td>4</td>
<td>4</td>
<td>2</td>
<td>1</td>
</tr>
<tr>
<td>Transgender</td>
<td>1</td>
<td>2</td>
<td>-</td>
<td>-</td>
</tr>
</tbody>
</table>

\(^ {14} \) Transgender women are people whose current gender identity is female or transgender female but who were assigned male sex at birth.

\(^ {15} \) Transgender men are people whose current gender identity is male or transgender male but who were assigned female sex at birth.
Table 3. Respondent profile by HIV status

<table>
<thead>
<tr>
<th>HIV status unknown</th>
<th>HIV -</th>
<th>HIV +</th>
</tr>
</thead>
<tbody>
<tr>
<td>Transgender woman</td>
<td>3</td>
<td>5</td>
</tr>
<tr>
<td>Transgender man</td>
<td>-</td>
<td>3</td>
</tr>
<tr>
<td>Total</td>
<td>3</td>
<td>8</td>
</tr>
</tbody>
</table>
Key Findings

Topic 1: HIV and transgender health-related information: access and sources

**SUMMARY BOX: HIV and health-related information**

**Supportive factors and enablers:**

- Sources of information relating to HIV and transgender health that were identified by interviewees were: friends and the transgender community; the Internet and social media; transgender and HIV organizations; UN agencies; national governments and research and academia.
- Friends and the transgender community appear to play a vital role in creating, distributing, validating and endorsing information on HIV and transgender health-related issues.
- Information was commonly sought out and shared on the Internet and social media sites.
- Information was sought both from within the transgender community and outside: the transgender community itself served as an important resource in creating and sharing information and knowledge with regards to transgender health, while individuals working in transgender health-related organizations also turned to governments, UN agencies and academia to look for validated information which could then be adapted to the local context.

**Challenging factors and barriers:**

- A lack of transgender-specific information and research was seen as the greatest barrier to accessing information on HIV and other health issues.
- Many transgender individuals perceived themselves as being a minority within the lesbian, gay, bisexual and transgender (LGBT) community, and conflation of their issues with those of men who have sex with men issues in particular was perceived negatively.
- Information specific to transgender people and research into hormone use and its potential impacts and interactions on HIV prevention, risks and treatment was also widely said to be lacking.
- The trustworthiness and language barriers associated with available transgender-specific information sourced from the Internet was raised as a concern by a few participants.

**Suggested solutions:**

- Information on HIV and other health-related information should be made specific to transgender men and transgender women, and they should not be addressed as a sub-population within LGBT or heterosexual HIV frameworks.
- Transgender-specific health information should be available in ways that do not exclude transgender people who are illiterate, non-English speaking and non-Internet users.
- More research should be done on transgender-specific health issues, such as potential interactions between gender-affirming treatment and ART treatment.

**Supportive factors and enablers**

Nearly all individuals interviewed reported friends and the transgender community as the prime source of HIV and other health-related information, peer support and a strong sense of community. Exchange of information occurred both through face-to-
face and virtual connections with other transgender individuals. Across respondents, friends and the transgender community were portrayed as a vital source of information, support and empowerment.

“We take care of each other and that goes a huge long way towards helping ameliorate the difficulties that we're facing in trying to get information... we're not just lonely, single people out in the cold waiting for the door to open and for us to be brought in. We have amazing communities already, we take care of each other... and I would say, that's one of the best things about being trans.”

Transgender man, 31, United States

A majority of interviewees mentioned the importance of the Internet and social media in providing health-related information, included social network sites and transgender-specific blogs.

Many reported actively searching the Internet for information on hormone use, gender-affirming surgery and health-care services and service-providers, as well as to connect to peers. Using the Internet to access HIV specific information was mentioned less frequently.

“When I started my hormone therapy, I started going into Facebook groups and checking information on what they are taking ... I also could find some online resources from some Canadian reports on hormone therapy and other transition methods.”

Transgender woman, 29, Brazil

“Some older transgenders shared their experience of using the hormones and other things... I read a lot of Internet because I cannot get any access from the medical practice, medical providers...”

Transgender woman, 22, Indonesia
Responses also suggested that the majority of information consulted on the Internet by transgender people largely came from the transgender community itself or was in some way endorsed by the transgender community, and hence was considered more trustworthy. Furthermore, numerous responses suggested that the high reliance on information from peers and the Internet was due to a lack of information elsewhere, such as through the medical system or research.

“If I’m on Facebook or if I’m on Tumbler and I see WHO recommending that this is a set of recommendations and this is what you should do, this is what you should not do... I won't share that, I won't tweet that. But if it’s coming from someone who is prominent in his region or her region, or someone who is a known figure somewhere, who is part of the community, and then I will say, “Oh yes hey, if she is endorsing it or he is endorsing it, there must be some truth in it.”

Transgender man, 29, Singapore

All except one interviewee worked in transgender- or health-related organizations, reporting these as important sources of information on HIV and broader health issues. This is likely to have had a strong bearing on the level of information available to the transgender individuals interviewed here. Some of these individuals explicitly mentioned directly seeking out information related to HIV and transgender health from publications from government, UN agencies and academic research and then contextualizing such information to fit their local needs.

“Our main source of information is coming from the UNO, the manuals that United Nations gave us and still continues to give us.”

Transgender woman, 35, El Salvador

“In terms of latest technologies, latest medications, even interventions, things of that nature, we normally get it through our funders.”

Transgender woman, 44, United States
**Challenging factors and barriers**

A lack of transgender-specific information overall was perceived by the majority of transgender people interviewed as the major barrier to accessing HIV and transgender-health related information. Among individuals not self-identifying as men who have sex with men, several perceived the conflation of transgender issues with other LGB issues – and in particular with MSM issues – as frustrating. Though a less common experience, some individuals also said that the discourse on HIV in their context was predominantly targeted at heterosexuals. This was seen as preventing transgender-specific issues from being adequately addressed.

“The sad thing is that trans women are lumped within those MSM approaches, within those MSM statistics, within those MSM interventions. Transwomen are not MSM. Once you start focusing on MSM and you include transwomen, you have already missed us.”

Transgender woman, 31, South Africa

The main gaps in information identified by transgender individuals pertained to gender-affirming surgery and hormone use, including concerns about potential interactions with ARTs and HIV test results. Furthermore, a lack of transgender-specific information on HIV prevention and effective interventions was identified as a major gap.

“I did not know whether hormones have any interference with the test results and I can’t find anything on that at all... it was just hard because there are times whereby my results came back inconclusive, so I get positive results, I get negative results, during my screening test... And I also don’t know how effective treatment is when one is on hormones.”

Transgender man, 29, Singapore

Some participants reported that efforts were being made to target HIV messaging towards transgender populations, but they still felt frustrated by these efforts. Others raised concerns about the complete absence of transgender-specific HIV awareness information in their countries, feeling that their needs for information were not being addressed.
“Even if UN agencies – UNAIDS or UNFPA or all these UN agencies or regional agencies talking about HIV – [are] making sure that we also prioritize key populations, it’s still not reflected in terms of awareness messaging and packaging. There is still no specific awareness information available, or material that’s specific to our needs. So I don’t think that it’s fully addressed... They can have their conversation in their offices, but its not reflected in the information that is going around in the community. There are no television, newspaper or printed materials on the specific needs of transwomen and transmen and how they can protect themselves from HIV. It's still the old same heterosexual packaging.”

Transgender woman, 28, Fiji

The uncertain reliability and trustworthiness of available information on transitioning, particularly on the Internet, was described as a frustration and concern by several individuals.

“It is very frustrating, the information is out there but you don't know which one you can trust... Using social media, I think it's a good platform but we need to know how to really seek out this information and whether it is true or it is not.”

Transgender man, 29, Singapore

A few participants said that language barriers to transgender-specific information available on the Internet present a challenge to illiterate or non-English speaking transgender people. Limited access to the Internet was also a barrier to accessing relevant information for some.

“I haven't found any website or information written in Thai about hormones for transgender. I found some article in English. But it's lucky for me that I can read, I can write English. But for the [other] people, especially for the transgender in Thailand, it’s just very difficult for them... to understand the scientific term, the vocabulary and the term they use.”

Transgender woman, 29, Thailand
**Suggested strategies for improving access to HIV information**

Many transgender individuals suggested that addressing transgender health needs separately from the needs of LGB populations was an important step towards providing access to HIV and other health information for transgender people. Two participants suggested that information on HIV and health should be made specific to transgender women and transgender men, to ensure that their specific needs are met. Furthermore, some participants urged that transgender-specific health information be accessible to illiterate, non-English speaking and non-Internet using transgender people, by making it available in local languages and in nonverbal forms, such as by using the creative arts.

“And one other thing that needs to be highlighted is that transgender people are transgender men and transgender women. When we work on key affected populations we call them MSM, we call them women and girls, but then when it comes to transgender, it’s “transgender”. But there are actually two genders in transgender: there are men, there are women.”

Transgender man, 29, Singapore

**Topic 2: HIV testing and counselling (HTC)**
Challenging factors and barriers:

- Hetero-normative, judgemental and non-transgender sensitive services were perceived as the greatest barrier to seeking HTC among many individuals interviewed.
- The fear of getting a positive result also prevented some from seeking testing.
- Some individuals mentioned concerns over confidentiality, long waiting times at testing facilities, having to travel long distance to a testing facility, a lack of follow-up or referrals and the cost of testing as further challenges.
- The importance of receiving counselling and support after testing and the absence of this during self-testing was highlighted by some individuals.

Supportive factors and enablers:

- For many individuals, the importance of knowing one’s HIV status was the primary motivating factor for seeking HIV testing.
- Encouragement from peers and access to fast or free testing – including free rapid testing – were factors that encouraged several individuals to get tested.
- Confidential and transgender-sensitive testing services were seen as vital enablers for wanting to get tested.

Suggested strategies:

- HIV testing should be confidential, free and rapid where possible.
- Testing services should be transgender-sensitive and non-judgemental.

Challenging factors and barriers

Among those who had been tested for HIV, a majority perceived the hetero-normative and non-transgender sensitive testing environment to be a major problem. Respondents commonly felt stigmatized, discriminated against, unwelcome and misunderstood, making it difficult to raise their concerns. Subsequently, some respondents strictly avoided such testing environments.

“The problem is that if you get tested... the people who provide testing think very much hetero-normative, heterosexually... which makes it very hard for a trans person to sort of raise your issues to them. So it's not a sort of a place where I would go unless it's absolutely, absolutely necessary, and I can imagine – and I know this from being in the community – that a lot of people refuse to go for that reason.”

Transgender woman, 30, South Africa
Some transgender people reported being perceived as cis-gendered people when they went for HTC. Thus they perceived the risk assessment to be of little help, or even annoying.

“The testing itself was very [hetero-]normative, because the person who tested me first of all read me as a cis-gender woman and the questions that he asked in the risk assessment was the questions that would be applicable for a cis-gender woman with a vagina... the risk analysis was not proper and it was based on an assumption and on some misconceptions.”

Transgender woman, 31, South Africa

Overall, a low level of trust in service providers at testing centres was expressed. Many transgender individuals felt they had to educate the health-care staff to be more knowledgeable on transgender-related HIV issues and more sensitive towards transgender clients. This was described as an “overwhelming explanation” and an uncomfortable experience overall. A few interviewees also reported experiencing similar barriers at settings which they felt should have been less hetero-normative, such as at LGBT clinics and international conferences.

“I don’t want to have to go to test somewhere every time where I feel I have to educate the nurse on my risk and my risk behaviour.”

Transgender woman, 31, South Africa

“...if you are working in an LGBT clinic you have a responsibility to recognize that there are trans people there, we are not the hugest population, but we’re there and we might not look like what you think... and it’s not my responsibility to do your job for you.”

Transgender man, 31, United States

Some individuals also felt reluctant to getting tested because of their fear of testing positive. They described feeling nervous, scared or emotional prior to taking their test and “not ready to deal with whatever is going to be said”, describing HIV as a “scary disease”. Aside from these fears, reactions from society and the possibility of not being
allowed gender-reassignment surgery were perceived as risks associated with a positive HIV test.

“It takes a lot psychologically to get up in the morning, to sit in those long lines, to test... When I went for testing the other day ... I went into the counselling room, I was counselled, I left without testing because I wasn't sure whether I am ready to deal with whatever is going to be said there.”

Transgender woman, 31, South Africa

“How do you live and how do you deal with the reaction from the society when you got the result, especially when it is positive? People are afraid to get an HIV test ... they have no idea what to do if they have the positive result... Some people believe that if you have HIV, it means you're going to die soon... And yes, when it comes to the workplace... people living with HIV are not accepted.”

Transgender woman, 29, Thailand

Some participants voiced concerns over the confidentiality of getting an HIV test. A few participants also identified the long distance to a testing facility, long waiting time at the facility, and the direct and indirect costs associated with HIV testing as further barriers to getting tested.

“Transgender women, for example if they live in a specific zone where they have health care there, they don’t go to that clinic, but they go very far away from their home to take the test ... because for example there are neighbours or friends or somebody who knows them and who might make public their result.”

Transgender woman, 35, El Salvador

A lack of follow-up on HIV test results and referral to other services in the case of a positive test result were mentioned by a few participants as barriers to retaining transgender individuals in HIV care.
“The reason why I didn’t go back for my results was that there was no follow-up… I was actually expecting them to follow up on all of the people that were testing. But no one called me for my results.”

Transgender woman, 28, Fiji

Two participants reported never having been tested for HIV. They expressed no real need to get tested, primarily due to a low self-perceived level of HIV risk.

“It didn’t come to my mind that I have to go for the HIV test or that I don’t have to go. … since I am not into that much of unsafe sexual practice, I don’t get tested at the moment.”

Transgender woman, 40, India

A few participants spoke about the possibility of self-testing, raising concerns about the lack of professional support and counselling in such circumstances.

“I think that is a bit of a risk because you don’t know how people are going to be able to handle their status. I for example would not want to self-test. I do think there is value in a trained person like a counsellor coming to test you… Because if you self-test, you don’t always know all the facts… So if I am positive and I have tested myself, who will be able to answer those questions for me?”

Transgender woman, 31, South Africa

**Supportive factors and enablers**

When asked what motivated individuals to seek testing for HIV, interviewees generally expressed a desire to know their own status. Having access to easy, fast and free testing which is at the same time confidential and transgender-friendly was seen as an important prerequisite for getting tested. Rapid testing was viewed as desirable, due to the fact that results could be obtained quickly. Providing testing that is explicitly targeted towards transgender people or which involves transgender peers at the testing facility also encouraged individuals to get tested.
“My guy friend told me that there is a free test and the results will come out after an hour... I really want to try it. Because it’s easy, it’s fast and it’s free... to know your status is much better than you don’t know anything about your status.”

Transgender woman, 22, Indonesia

“What motivated me to join this test was because it was targeting a specific group – it was targeting our group.”

Transgender woman, 28, Fiji

Suggested strategies for improving HIV testing and counselling

The majority of transgender individuals interviewed agreed that having access to confidential testing was essential to improve the HIV testing experience. Some additionally mentioned the necessity of having access to free testing. The view that HIV testing facilities should become transgender-inclusive, transgender-sensitive and non-judgemental was pervasive across respondents. Specifically, interviewees felt that testing services should be “welcoming”, “friendly” and offer “positive advice” to transgender clients, in order to make them feel more comfortable. Many felt that training and sensitizing staff on transgender-related health needs and risks could help achieve this and challenge the current hetero-normative approach of testing and counselling. Several individuals expressed the view that staff should be trained to offer advice – or at least be able to make a referral – on other important transgender-related health issues, such as hormone treatment, gender-affirming surgery and mental-health services.

“[HTC providers] need to make sure that there is confidentiality. There is a lot of confidentially issues... and these need to be resolved in order for people to start wanting to get tested... It's also about education: people who provide the testing should be taught about trans-specific issues in terms of HIV, they should be taught to provide transgender-friendly services.”

Transgender woman, 30, South Africa

“Because we live in a community that’s so small... I would want to go to a hospital where no one would totally know me or see me entering. Most of the facilities and the locations of the clinics where testing is currently underway... are very visible to
the public... So if I were to go to for testing again, it would have to be somewhere very secluded, or maybe a mobile clinic, that would come at night and do testing for key populations..."

Transgender woman, 28, Fiji

Some interviewees also suggested that offering testing through transgender-based organizations such as NGOs in the form of community drop-in centres or mobile clinics would be a successful strategy for increasing the uptake of HTC among transgender people.

"I don't really like going to hospitals and things like that. I would like to suggest that if there was something to motivate me to go for testing, it would be like a drop-in community centre for trans women that offers different kinds of services, as well as testing. That would be a really good initiative to actually get a lot of key populations to come for testing..."

Transgender woman, 28, Fiji

**Topic 3: HIV prevention: access and barriers**
**SUMMARY BOX: HIV prevention: access and barriers**

**Prevention of sexual transmission:**

- With the exception of prison settings, where lack of condom availability was described as a major challenge, the large majority of transgender individuals perceived condom access as easy and presenting few barriers.
- Difficulty in accessing other prevention commodities such as dental dams and lubricants, and the lack of transgender-specific marketing of prevention commodities, were raised as challenging factors.
- Low self-esteem, societal pressures and fear of rejection by sexual partners were seen as major barriers to consistent condom use by some interviewees.
- Traditional and medical circumcision as an HIV prevention measure for transgender women should be regarded with caution, as transgender women may feel violated by such “male-oriented” practices.

**Prevention of sexual transmission through injections:**

- Risk perceptions of HIV transmission associated with injections of hormones, silicone and other gender-enhancing substances varied widely among interviewees and settings.
- Injections by health-care staff as well as unsafe injections were reported, with the latter being more common for the illegal injection of gender-enhancing substances such as silicone.
- Access to clean needles was generally described as easy in most settings, but needle exchange programmes serving transgender people were not available.

**Antiretrovirals for prevention: PrEP and PEP:**

- Less than half of the transgender individuals interviewed had heard of PrEP or PEP.
- Available information came mostly through HIV related research or work, predominantly targeted towards men who have sex with men or sex workers, while awareness within the transgender community at large was assumed to be very low.
- The major barrier identified with regard to PEP and PrEP was the lack of transgender-targeted information.
- Further barriers that were mentioned included the cost of such treatments, a lack of access through the health system, potential side-effects, interactions with hormones and being on chronic medication.

**Prevention of sexual transmission**

With the exception of prison settings, access to condoms, either commercially or through NGO programmes, was said to be easy by the large majority of interviewees. However, access to other prevention commodities such as dental dams and lubricants was described as more difficult, with supplies often unreliable.
Despite the availability of condoms, several individuals reported not using condoms with their sexual partner consistently. Some transgender individuals saw low self-esteem, societal pressures and fear of experiencing rejection from sexual partners for wanting to use a condom as barriers to practicing safe sex. The value of practising safe sex was sometimes perceived as secondary to the desire to avoid feelings of rejection and social isolation. Within sex work, clients’ objection to using condoms was also described as a barrier to consistent condom use. Furthermore, one transgender man raised concerns over the marketing of prevention commodities for transgender men, suggesting that current marketing did not specifically address them.

“The fact that someone wants to have sex with us would mean that he doesn’t mind my genitals, he doesn’t mind my body, he doesn’t mind anything about me – and do I [therefore] have the right to ask for safer sex? I mean, I might just turn him away and he would just brush me off like every other rejection that I have gotten like that living as a [transgender] person… It’s more about wanting a kind of belonging and not wanting to be rejected again. Especially in that moment of passion, you really hate to be rejected. And once [sex without a condom] happens, it’s something that keeps happening. You just keep thinking that this is normal, it’s safe, you have not gotten [HIV] and it’s safe to continue like that, because this must be the way to go to not get rejected.”

Transgender man, 29, Singapore

“There is a lot of information out there about how gay men have sex. And a lot of that I think makes it difficult for trans men, particularly those who are just newly transitioning and newly wondering about… what kind of sex they need to have, how much agency they have to control the circumstances under which it happens, and as a result what kinds of situations they put themselves in with regard to HIV or other kinds of STIs… You just pile onto all of this the hard time growing up, the hard time getting into relationships, the hard time transitioning, the hard time trying to feel like you are a normal functioning member of whatever social group you are in. If that were easier, then maybe we would have a little bit more energy for things like taking care of ourselves… And that all factors into… the decisions I was making around [questions like,] Is my life really worth it or do I want more to try to belong just for this little moment and forget about the consequences?”

Transgender man, 31, United States
A few interviewees cautioned that circumcision for prevention of sexual transmission was a potentially challenging HIV prevention strategy with regards to transgender women. Circumcision of transgender women was seen as a violation of bodily autonomy and female gender identity and one interviewee explicitly advised against inclusion of transgender women in circumcision practice.

“Many trans women feel that that circumcision is a violation of their gender identity because the circumcision itself goes beyond the snipping of the foreskin... it means society then sees them as men, which is the very notion that trans women reject. And our government is also encouraging medical male circumcision as an HIV prevention strategy. That is problematic because it looks at it from a “one size fits all” kind of approach.”

Transgender woman, 31, South Africa

**Prevention of transmission through injections**
Most of the transgender individuals were uncertain of the prevalence and frequency of hormone injections within their respective transgender communities. Nonetheless, the large majority of interviewees did not personally perceive the use of hormone injections as a major HIV related concern.

The reported mode of administering hormone injections varied by setting, with some participants reporting self-administration of hormones to be a common practice, while others said that hormone injections were administered by health-care staff and were thus perceived as safe. Yet in other settings, only oral hormone use was reported.

“Some girls who are travelling for leisure or business will buy a horde of injectable hormones from Thailand, for example, and they would bring it over to the Philippines and then they would have an injection party... and the nurse will inject them. So it's... a very clean procedure and its quite safe.”

Transgender woman, 36, Philippines

Some interviewees saw injections of soft tissue fillers such as silicone as a noteworthy problem within the transgender community. Mostly, silicone use was said to occur within lower-income groups and within transgender individuals working in the sex industry. One
transgender woman reported that she had experienced numerous health problems as a consequence of receiving these injections. Most other participants were concerned by and hence avoided silicone injections, yet acknowledged that the comparatively low price of illegal injections was an incentive to use them. One participant further mentioned the injection of recreational drugs, in an attempt to cope with depression and social discrimination, as an additional HIV related risk factor within the transgender community.

“Beauty salons... provide silicone injection for their nose, their breasts, their hips...Those who [perform the injections] are not professional nurses or doctors. They just get it from the black market ... Especially [those transgender people] who have occupation as prostitutes, they use that to enhance their beauty, their sex appeal... Illegal injections using silicone oil are quite prevalent here... because of the general poverty of trans people in my country, because they cannot afford gender-affirming surgery in either public or private [sectors], they... opt to get illegal injections from quacks.”

Transgender woman, 22, Indonesia

Access to clean needles was generally said to be easy. Most transgender individuals mentioned being able to buy clean needles through a local pharmacy. None of the interviewees mentioned needle exchange programmes serving transgender people. A few participants recognized the cost of buying clean needles as a barrier to their use.

“I think in some ways part of the problem is that they [the state government] don’t think about our community a lot. Needles for the most part are for people who inject drugs... there is probably one place that does provide thicker-gauge needles that are hormone needles here... Our community not only injects hormones but they also inject other physical enhancers.”

Transgender woman, 44, United States

Antiretrovirals for prevention: PEP and PrEP
Overall knowledge on PrEP and PEP was low, with less than half of those interviewed having heard of either. Most knowledge on the subject appeared to come from professional contexts, i.e. among respondents working in health care or HIV related areas. There was general consensus that knowledge on PrEP and PEP was very scarce
within the transgender community at large. Information on PrEP appeared to be even less available than information on PEP, with the latter being mostly spread through sex worker networks.

One transgender woman mentioned that information on PrEP and PEP sometimes became available in the community through research studies, and criticized the fact that such studies generally targeted men who have sex with men and were thus not widely accepted within the transgender women community.

“One unfortunately, in our community there is not a lot of knowledge about PrEP or PEP... There have been studies that have targeted MSM and they still include us in that and obviously we don’t consider ourselves men, so because of that, people obviously don’t participate... there has not been something that is specifically targeted to us, in regards to PEP and PrEP. And I guess once they do that, it’s going to be something specific and obviously I am thinking the community is going to be welcoming... Even if at least they hire a trans person to recruit other trans women that would definitely make a difference, because in some ways you can convince people to participate.”

Transgender woman, 44, United States

Apart from the general lack of information on PEP and PrEP in the transgender community, the high cost of these treatments, lack of access through the health system, potential side-effects, interactions with hormone treatments and a general aversion to taking yet another chronic medication (in the case of PrEP) were raised as further barriers to access. A few participants said that they did not consider PrEP or PEP to be relevant prevention options for themselves, explaining that they exclusively practised safe, low-risk sex and thus did not see the need for such treatments.

“Especially the trans sex workers, they know that if they have been raped, they need to access PEP, but for many reasons, some of them do not access PEP, because of issues within the health system. There are issues of discrimination and issues of prejudice... because if you are transgender, you often get denied this treatment.”

Transgender woman, 30, South Africa
“I would want a nurse to ask me if I go for PEP for example whether I am on any other medication, whether I am on hormones, because we don't know whether those hormone drugs might interact with post-exposure prophylaxis. So that is certainly a consideration for me and something that I think about very often.”

Transgender woman, 31, South Africa

Opinions and feelings on whether PEP and PrEP should be promoted among the transgender community were mixed. In general feelings towards PEP were more positive, while some expressed reservations about promoting PrEP. However, most participants said they had no or very little knowledge on the use of PrEP and PEP and thus few felt certain about whether they would make use of these treatments or about the acceptability of such strategies within their transgender communities.

“PrEP and PEP, especially for those gay trans men who are in a serodiscordant relationship, I think this information should be made available; at least we know that there are other preventive choices when it comes to sex, it's not just about condoms.”

Transgender man, 29, Singapore

“Yes, it [PEP] is wonderful. It should be written everywhere that it exists.”

Transgender woman, 60, France

“For me personally it’s appropriate to focus on using condoms... How do we create circumstance in people’s lives where they feel like they don’t need to be in dangerous situations around sex? And if people are totally fine, they have good jobs, they feel like they have everything that they need and [then] they still have the kind of sex where they feel like they would want to be on PrEP: great.”

Transgender man, 31, United States

**Topic 4: Antiretroviral therapy (ART)**
SUMMARY BOX: ART

Challenging factors and barriers:

- Discrimination and stigma in the health system can result in outright refusal of treatment by health-care providers or actions that otherwise deter transgender individuals from seeking treatment.
- Stigma associated with ART may prevent transgender individuals from wanting to access it.
- Side-effects of ART were perceived as a challenge for gender expression, with one individual describing being unable to take hormone treatment while on ART due to adverse side-effects.
- The lack of access to treatment in prisons was raised as a major challenge for transgender people in prison.
- There were widespread concerns about harmful interactions between ART and hormone therapy.
- Many individuals criticized the general lack of guidance from the health-care profession to address these concerns.

Supportive factors and enablers:

- Education and empowerment of transgender people around accessing ART are an essential step to encourage transgender people to seek treatment.
- Adherence to treatment is supported if treatment services make transgender individuals feel supported, comfortable and that their specific needs are addressed.

Suggested strategies:

Challenging factors and barriers

Three of the 14 interviewees reported that they were living with HIV and taking ART. One HIV positive transgender woman described an instance of discrimination from her doctor, where she had been refused treatment. Another transgender woman described the side-effects of her ART as a major challenge to her gender expression. Having herself been incarcerated in the past, she emphasized that the HIV related needs of transgender women in prisons were not being met, including access to ART and prevention commodities. A third transgender woman raised some of the challenges faced by other transgender women in her community in accessing treatment, explaining that stigma and discrimination in health-care settings and low levels of knowledge around ART within the transgender community commonly prevent transgender women from accessing treatment after testing HIV positive.

Among the majority of interviewees who were HIV negative, several people raised concerns around the possible interactions between ART and hormone therapy and the effectiveness of both treatments if taken together. One individual explicitly questioned...
whether he would be willing to go on ART, given his uncertainties around possible interactions. Many transgender individuals perceived the lack of guidance from the health-care profession on ART for individuals on hormones as a major challenge. A general sense of anxiety and concern was evident in participants’ discussions around ART.

“I don’t know how effective treatment is when one is on hormones… I do think that this information is necessary, because in the event that I found that I am positive, [the] next question I ask myself is do I want to spend another sum of money being on another medication for the rest of my life, just like the hormones? So unless it’s proven, I don’t see the importance or the urgency for me to go on ART.”

Transgender man, 29, Singapore

“I think when we talk about HIV, it should take into account what are the medications that we are on; what are the possible risks, what are the possible interactions when somebody goes onto ARV treatment as a trans person. The medical practitioners should be able to sit down with them and tell them: Seeing as you are on hormones, and now you are going onto ARVs, these are the risks, these are the considerations. That should be discussed. Definitely it’s about a comprehensive package of health.”

Transgender woman, 31, South Africa

**Supportive factors and enablers**

Those individuals who were taking ART were asked to discuss factors which they believed supported adherence to ART. Being empowered and educated around ART and feeling comfortable to discuss potential concerns with a health-care professional were seen as important factors for enabling transgender people’s adherence to ART.

“I think for trans women who are HIV positive and have been conscientious about their health, who have been empowered… who are accessing medical services and who have a doctor and who are taking medication, they continue to do that because they are empowered like that… I think once a trans woman is able to get comfortable with a doctor and is comfortable enough to listen to the doctor and to take their medications regularly, then they continue to go to the doctor regularly.”
Transgender woman, 44, United States

**Topic 5: Hormone treatment**
Attitudes towards hormone therapy

Many interviewees described their prevailing and distressing experiences of gender dysphoria. For the large majority, this resulted in an intrinsic and urgent desire to start transition. In most cases, transition started with hormone treatment. Many respondents felt that transitioning was an essential step for reducing feelings of gender dysphoria and depression, enabling integration into society, feeling complete and comfortable in one’s body and allowing one to “get on with life”.

“It was like [I was] a shadow of myself… it just felt like sand in my fingers, I couldn't hold on to who I was supposed to be and why I was there and how I was supposed to be presenting myself… Every day as I walked down the hallway, towards the woman's bathroom, staring at myself in this mirror, being like, “Who is

SUMMARY BOX: Hormone treatment

Challenging factors and barriers:

- An overall lack of gender transition services through the public health system was reported as a major barrier to accessing hormone treatment.
- The large majority of transgender individuals perceived doctors and health professionals as having little knowledge about hormone use and thus being of little value in aiding their hormone treatment.
- Accessing hormones through the public health system was repeatedly described as costly, time-consuming, unhelpful and stigmatizing. In some instances, the public health system even denied the individual’s choice to transition.
- The large majority of transgender people interviewed reported engaging in self-medicated hormone therapy as a consequence of the above barriers.
- Transgender individuals who self-medicate voiced major concerns about potential harmful side-effects of unmonitored hormone treatment, as well as about the sustainability/availability and quality of hormones acquired on the black market.
- Some transgender individuals are unable to access any sustainable source of hormones in their countries.

Supportive factors and enablers:

- The outcomes of hormone treatment were described as supporting psychological wellbeing and self-actualization.
- Sharing knowledge and experiences within the transgender community and having peer support with regard to hormone treatment were important for achieving transitioning goals.
- Having access to hormones over the counter and without prescription would be welcomed by transgender women in transition.

Suggested strategies:

- Train and sensitize relevant health-care professionals to provide information, guidance or referrals to transgender individuals seeking hormone treatment, in a non-judgemental, non-stigmatizing environment.
- Reduce long waiting times created by having to go through numerous gatekeepers and lengthy psychological assessments in order to access hormone treatment through the public health system.
that?” And that was probably the tipping point actually, weirdly; after all of the suicidal thought and all of the stupid things that I had gone through in terms of interactions with people… it was really that literally not recognizing who that was in the mirror walking down the corridor every day. And I decided that I had three options, really: I could kill myself, which was an option. I could go back to [my home country] and try to figure out how to transition there… Or I could transition [here]. And I discounted the first two options and went with the third.”

Transgender man, 31, United States

“I think if I had the opportunity to take hormone treatment, maybe my breasts and my body will be different and make me feel more comfortable with my gender identity and the way that I look… I get depression sometimes and I feel really sad sometimes… because [the way that] people see you is the way that they treat you. So I feel very, very uncomfortable right now that I don’t have the opportunity to have support or some doctor to help me with… my hormone treatment to make my body look like my gender identity. There are some times that I look in the mirror and I think that I want to kill myself. That’s what I feel.”

Transgender woman, 36, El Salvador

“The hormones change a lot, my skin got smoother, and the shape of my face nowadays is completely changed. I have a small breast… the skin changed, the figure turn to be more feminine. Step by step… I feel good, because I wanted to be a woman.”

Transgender woman, 29, Thailand

**Challenging factors and barriers**

The large majority of transgender individuals interviewed described access to hormones as one of the biggest health struggles they faced in everyday life. Across interviewees, a lack of information and guidance on hormone treatment from the health-care system and from medical practitioners was identified as the primary barrier. Interviewees often described high costs, complicated and lengthy processes and intrusive questioning as barriers to accessing hormones through the health-care system. Some individuals reported a complete lack of access to hormones through the health-care system.
“There is a dearth of doctors and experts on trans health care… It’s quite hard to find trans friendly medical practitioners who would actually listen to you and take care of your health needs… It’s also trial and error because as an endocrinologist, they really did not study hormone replacement therapy when they were in medical school, so it’s an experimental phase for them to see what works and what doesn’t work. And of course it’s patients who will have to bear with this experimental phase.”

Transgender woman, 36, Philippines

Stigma and discrimination by health professionals was a common experience encountered by the survey participants when accessing hormones through the health-care system. For example, several individuals described instances of medical practitioners trying to “convert” them back, i.e. to make them change their mind about transitioning, or outright refusing to administer hormone treatment.

“I was supervised by a psychiatrist who was trying to change my mind… My doctor believed she can help me reconcile myself with my birth sex. So it was very difficult to speed up the process, because I was asking for hormones and she was telling me let’s wait.”

Transgender man, 31, Russian Federation

As a consequence of the numerous challenges associated with accessing hormones through the public health system, most interviewees engaged in self-medicated hormone use, as this was perceived to be easier than trying to access hormones through the health-care system. The majority of these individuals reported taking oral contraceptive pills obtained at the local pharmacy. A few individuals reported using injecting hormones, which they obtained from overseas, through friends or through the Internet.

“I cannot get any access from the medical practice, medical providers, so I just read [about] it in the Internet… Most [transgender people] are doing self-medication too. It’s really rare to find transwomen who [deal] with the doctor for hormone replacement therapy. It’s expensive and the doctor also has stigma and discrimination.”
Transgender woman, 22, Indonesia

Concerns relating to possibly harmful side-effects of prolonged hormone use were expressed by a large majority of individuals.

"Unfortunately from what I read so far there might be some side-effects that are not symptomatic, so I am concerned that... the hormones I am taking to have the desired hormone levels are also damaging my liver."

Transgender woman, 29, Brazil

One HIV positive transgender woman explained having stopped hormone use because she lacked medical supervision and feared health complications induced by the hormone treatment.

Several interviewees raised concerns around the availability of hormones acquired both through the informal market and through the public health system. Some participants additionally expressed worry over the quality of illicit hormones and the high cost associated with self-financing access to high-quality hormones.

"I get my hormone treatment from a local clinic... where there is no streamlined service package for trans folks... I personally have had to be very strategic, and I formed a patient-provider relationship with one of the nurses who understands the issue, but if I get there and she is on leave, then I'm really in [difficulty]... Also there are a lot of stock-outs... It really is affecting me greatly, because if there are no hormones, it means also the hormone structure in my body is affected... it is affecting the way that I present in society, because if I go off my hormones, sometimes the hormone imbalance affects my mood, it aggravates the depression. It also relates to how confident I am, because the hormones help me in my female presentation. So if I don't have access to those hormones, it really sets me back in terms of my transition."

Transgender woman, 31, South Africa
Supportive factors and enablers
Throughout many of the interviews, a strong sense of individual and collective agency in coping with the lack of professional guidance and provision of hormones by the health system was evident. Most individuals self-medicated their hormone use, as a strategy to overcome the stigmatization and numerous barriers associated with the public health-care system. Self-medicated hormone use was seen by many as enabling “more control” over transitioning, by reducing outside determination and influence on transitioning goals. Being able to purchase hormones over the counter or through the pharmacy without prescription was welcomed by transgender women in several countries. Overall, a strong sense of community, peer support and sharing of knowledge and experiences with regards to hormone treatment were described as important supportive factors by those taking hormones.

“A group of us just decided … we should just start experimenting on one another... The first time was really quite exciting and we all learned something together... We can control the amount of dose we want to take and we know what I’ll be taking, at least. For a lot of us it’s a lot of experimenting [with] the different dosage of testosterone and seeing what it can do to us... This is something the doctor here would not be able to do; you can’t request for a large amount of hormones; they would not recommend that and they would not do it. So if you are doing it yourself, you can try and see what works best for you.”

Transgender man, 27, Singapore

Suggested strategies for improving hormone treatment
When asked what would improve access to hormone treatment, there was a general consensus that health professionals need to be trained to deal competently with gender transition issues, or at a minimum be able to make referrals to existing services. Some individuals also felt that doctors should be able to provide recommendations on self-administered hormone use, in order to make this common practice safer.

"We need to educate the health-care professionals so that they understand how to distribute hormones, but also understand that they can do it. Because a lot of doctors don’t really know that they are allowed to do it. So they just need to be told you can do this and this is how you do it. It’s just very simple. And then every primary health care facility should be able to distribute hormones, because they are on the essential medicines list."
Transgender woman, 30, South Africa

A few individuals in countries where hormones were available through the public health-care system indicated that reducing the number of gatekeepers and lengthy psychological assessments required prior to starting hormone treatment would help to significantly ease hormone access.

“Hormone treatment in South Africa is available, but it's also very challenging, because you have to work through the psychologist and the social workers... Otherwise, it's not really available to trans people, you can’t walk in and say I want to have hormones, without having had the necessary counselling or without a prescription. The doctors won’t write that prescription for you if you have not been to the counselling and well-being component of the transitioning process... The waiting in queues for services in local clinics is very challenging if you are also holding down a job.”

Transgender woman, 31, South Africa
Topic 6: Gender-affirming surgery
Nearly all individuals interviewed reported major difficulties in accessing gender-affirming surgery through the public health system. The few individuals who had access to gender-affirming surgery through their public health care system felt deterred by long waiting lists, arbitrary and lengthy gatekeeping mechanisms and the pathologizing nature of accessing such treatments through the public system.

“A lot of trans women will always tell you that they feel as if they are born in the wrong body and it's a really, really overwhelming experience to go through life with a body when you don't feel comfortable enough to shower in front of other
people, to dress in front of other people and to have sex with whom you want to have sex with... So it's a really, really difficult space to be and it affects one personally. My wait on this waiting list [for gender-affirming surgery], I won't say that my depression is because of this, but it has definitely added to the depression from which I suffer... I know some of the white trans women who have sold their houses, or have sold their car and they went to Bangkok and had the surgery... I don't have that luxury... I have been on the waiting list at one of those [centres] for the last 14 years."

Transgender woman, 31, South Africa

“The thing about the public health-care system is that it’s still pathologizing and they have a mandatory two-year psychological treatment that’s required. There is a big waiting line to get surgery. I have met people who have been waiting for 5 to 10 years... so it's quite frustrating... It’s very unlikely you are going to get something if you don't have a diagnosis for transsexualism or gender identity disorder."

Transgender woman, 29, Brazil

Two interviewees reported an inability to access gender-affirming surgery in their country due to a complete lack of such services through the public health system.

Due to the numerous challenges associated with accessing gender-affirming surgery through the public health system, those wishing to undergo surgical transition often sought out private options for getting surgery. Among these individuals, the high costs of privately financing gender-affirming surgery were identified as a major barrier.

Many respondents had little trust in the technical ability of medical professionals and the quality of gender-affirming surgery, for both publicly and privately financed surgery. Concerns over post-surgery complications and associated financial hardships deterred several individuals from undergoing gender-affirming surgery. One participant raised concerns over the potential increased sexual risk of acquiring HIV associated with having a neo-vagina. Another participant suggested that some transgender women undergo non-medically licensed and often dangerous surgical procedures due the high costs of high-quality surgery.
“Something that I have been thinking about recently is that there is not a lot of literature that speaks to the vulnerabilities of bodies to HIV post-transition. What are the risks of having sex with this surgically created vagina? Is it the same as the anal risk; is it the same as the vaginal risk in CIS-gendered women?”

Transgender woman, 31, South Africa

**Supportive factors and enablers**

Some of transgender individuals interviewed strongly expressed that transition surgery was a vital pre-requisite to “get on with life” and achieve psychological wellbeing.

“[Having breast removal surgery] was amazing. That was probably the biggest barrier that I had [experienced to my sense of self]. Going back to the idea of recognizing myself in the mirror: You can look all kinds of ways [with regard to] your face, but [once you no longer] have breasts, you are a dude. Period, end of report.”

Transgender man, 31, United States

“I had to take on a loan to get my surgery, because I just wanted to get it over and done with so I can quickly get on with my life. Because it was just not possible for me to get out and get a job with the kind of body that I had and I just wasn’t comfortable at all.”

Transgender man, 29, Singapore

The strong desire to undergo transition appeared to drive many transgender individuals to find ways to overcome the numerous barriers to surgery. As with hormone treatment, several individual successfully found strategies, including actively seeking the necessary information, making connections through transgender networks and peers and/or travelling overseas to undergo surgery.

Having the financial resources to pay out of pocket for surgery appeared to be the single most important factor to enable transgender individuals to have gender-affirming
surgery. This financial ability enabled several individuals to access private health care in their country or to travel abroad (commonly to Thailand) to access higher-quality surgery.

“Actually, there are many clinics or hospitals where you can get the plastic surgery or the SRS [sex reassignment surgery] in Thailand. Many of them are of a high standard… There are different levels of price that you can choose and for myself my financial status at that time was quite ok. So I think I had more choice than other people who are struggling with their financial status. Most of the information is available on the Internet: the name of the hospital, of the clinic, the details of the doctor – where they graduated or the field in which they are expert.”

Transgender woman, 29, Thailand

Having strong connections to transgender peers and thus benefiting from shared knowledge, experiences and recommendations regarding surgery also appeared to be a valuable strategy to help overcome barriers to surgery. A supportive and transgender-friendly clinical environment was highly valued by those individuals who had undergone surgery and led to such places being recommended further within the transgender community.

“The problem that we have to face again is that there is no licence... So it means that if you want to have surgery, you need to choose a doctor yourself. And you need to [find out] how good the doctor is also yourself. Normally we do it through the patients, some trans people network. So we just ask each other about results of surgeries and surgeons and ask them about results of surgeries.”

Transgender man, 31, Russian Federation

“...I got some contacts and then they started connecting me with some other people who are like me and then we started talking and then we went for the surgery in the same hospital together [in Thailand]... It was very nice because we were able to walk out of our rooms and just talk to one another... So that’s where I got more information on surgery, on hormones or how to actually take care of the scars... It was very welcoming, I would say. And it’s really very warm, which is something that we won’t be able to experience in normal health-care settings here.”
Suggested strategies

Being able to access gender affirming-surgery through the public health-care system was seen by many interviewees as essential for meeting transgender people’s physical and mental-health needs. Many interviewees felt that removing complex and lengthy gatekeeping mechanisms was important for improving access and reducing delays to gender-affirming surgery. The quality and professional capacity of those performing gender-affirming surgery were a common reason for concern among many of those interviewed, which suggests a need to further develop and disseminate global guidance and standards of care for gender-affirming surgery.
Conclusion

“We are in 2014 and it’s ridiculous that health care and service providers are still ignorant about who we are and what our needs are. So it is the responsibility of our policy-makers, our government, to ensure that our human and civil rights are met; and health care is a universal human right and we as trans individuals should get the services that we need.”

Transgender woman, 44, United States.

Some of the challenges that were most commonly raised across individuals and regions were a lack of transgender-specific health information and services, and stigma and discrimination from society and from health-care professionals. Past experiences of discrimination, and the fear or anticipation of experiencing discrimination, commonly influenced by the experiences of transgender peers, resulted in many transgender people actively avoiding contact with health services. Furthermore, external and internalized HIV stigma also presented barriers to transgender people seeking HIV testing and undergoing treatment. Concerns over potential interactions with hormone treatment and possible adverse side-effects of HIV related medication (including ART, PrEP and PEP) were widespread. High levels of concern about the lack of transgender-specific health information and research were evident among interviewees.

Across responses, other needs, both health-related (including physical and psychological needs) and needs beyond health (such as economic needs) were commonly prioritized over HIV related needs. These findings suggest that addressing the health- and non-health related needs that transgender people identify as priorities is a prerequisite for successfully addressing their HIV related needs.

The results of this qualitative values and preferences survey highlight the numerous challenges that persist with regard to transgender people’s access to HIV and other health services. Additionally, numerous enabling and supportive factors as well as strategies were suggested from within the transgender community. These insights present an important opportunity for developing transgender-sensitive and transgender-specific HIV and broader health services, with the goal of ensuring that transgender people are able to enjoy the highest attainable standard of health.
“The last thing that I want to say is that transgender people deserve to live with the same condition of life as any individual in any society, as any people, with the same rights, not only health rights, but in general all rights.”

Transgender woman, 35, El Salvador
References


Annexes

Annex 1: 27-item Delphi online survey questionnaire
Transgender people and HIV

Introduction to this survey

This survey aims to collect expert opinion on key issues relating to transgender people and HIV. Results from this survey will inform the design of values and preferences interviews among transgender people, which will be conducted as part of developing WHO consolidated HIV guidance for key populations.

This survey should take around 10 minutes to complete and consists of the following five sections:

1) Terminology
2) Risk groups
3) Risk factors
4) Strategies and enabling factors
5) Optional: other key issues

For the purpose of this survey, the following definitions will be used:

Transgender women*: People who were assigned ‘male’ at birth and have a feminine gender identity and/or feminine expression.

Transgender men*: People who were assigned ‘female’ at birth and have a male gender identity and/or masculine expression.

Most questions refer specifically to either transgender women* or transgender men*, so please note this difference while responding to each question. Questions are kept broad and are meant to capture general trends at a global scale.

Basic respondent information

* 1. Please note: your personal information will be anonymous to all other respondents and will be kept confidential.

Name:

Organisation:

Duty Station/Country:

Email Address:

Terminology

Which terms do you consider most appropriate to describe the various groups of transgender people? (multiple answers possible)
### Transgender people and HIV

2. People who were assigned ‘male’ at birth and have a female gender identity and/or feminine expression:

- [ ] Transgender woman
- [ ] Trans woman
- [ ] Male to female
- [ ] Other (please specify)

3. People who were assigned ‘female’ at birth and have a male gender identity and/or masculine expression:

- [ ] Transgender man
- [ ] Trans man
- [ ] Female to male
- [ ] Other (please specify)

4. Are there other categories of transgender/ gender variant people that should be considered with regard to HIV vulnerability? (please specify and define)

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### Risk groups
**Transgender people and HIV**

*5. Which level of HIV risk do you associate with each group of transgender persons?*

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Other (please specify and type level of associated risk)

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**Risk factors**

The following questions focus on issues that potentially make transgender women* and transgender men* more vulnerable to HIV infection.

For each question, please give your opinion on how important/relevant you feel each issue is in terms of putting transgender women* and transgender men* at increased risk of HIV infection?

**6. Sexual risks – Transgender WOMEN***

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# Transgender people and HIV

## 7. Sexual risks - Transgender MEN*

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## 8. Injecting risks - Transgender WOMEN*

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### Transgender people and HIV

#### 10. Transitioning - Transgender WOMEN*

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#### 11. Transitioning - Transgender MEN*

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### Transgender people and HIV

**12. Access to prevention programs and health services – Transgender WOMEN***

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**13. Access to prevention programs and health services – Transgender MEN***

<table>
<thead>
<tr>
<th>Issue</th>
<th>Very Important</th>
<th>Moderately Important</th>
<th>Unimportant</th>
<th>Uncertain</th>
</tr>
</thead>
<tbody>
<tr>
<td>Lack of transgender men* specific health services</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Discrimination of transgender men* by health workers</td>
<td></td>
<td></td>
<td></td>
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</tr>
<tr>
<td>Lack of tailored HIV prevention and treatment programs for transgender men*</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Low levels of HIV related knowledge among transgender men*</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Low levels of HIV testing (and resulting knowledge of HIV status)</td>
<td></td>
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</tr>
<tr>
<td>Low demand for health services by transgender men* (as a result of discrimination and perceived lack of services)</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Other (please specify and type importance ranking)</strong></td>
<td></td>
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</tr>
</tbody>
</table>

*Indicates areas that are particularly important to transgender individuals.
### Transgender people and HIV

#### 14. Socio-economic risks – Transgender WOMEN*

<table>
<thead>
<tr>
<th>Risk</th>
<th>Very Important</th>
<th>Moderately Important</th>
<th>Unimportant</th>
<th>Uncertain</th>
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</thead>
<tbody>
<tr>
<td>Economic marginalization</td>
<td>○</td>
<td>○</td>
<td>○</td>
<td>○</td>
</tr>
<tr>
<td>Homelessness</td>
<td>○</td>
<td>○</td>
<td>○</td>
<td>○</td>
</tr>
<tr>
<td>Social isolation</td>
<td>○</td>
<td>○</td>
<td>○</td>
<td>○</td>
</tr>
<tr>
<td>Physical abuse and violence</td>
<td>○</td>
<td>○</td>
<td>○</td>
<td>○</td>
</tr>
<tr>
<td>Discrimination from and limited access to education</td>
<td>○</td>
<td>○</td>
<td>○</td>
<td>○</td>
</tr>
<tr>
<td>Low prioritisation of HIV amongst other competing health needs</td>
<td>○</td>
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</table>

Other (please specify and add importance ranking)

#### 15. Socio-economic risks – Transgender MEN*

<table>
<thead>
<tr>
<th>Risk</th>
<th>Very Important</th>
<th>Moderately Important</th>
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</thead>
<tbody>
<tr>
<td>Economic marginalization</td>
<td>○</td>
<td>○</td>
<td>○</td>
<td>○</td>
</tr>
<tr>
<td>Homelessness</td>
<td>○</td>
<td>○</td>
<td>○</td>
<td>○</td>
</tr>
<tr>
<td>Social isolation</td>
<td>○</td>
<td>○</td>
<td>○</td>
<td>○</td>
</tr>
<tr>
<td>Physical abuse and violence</td>
<td>○</td>
<td>○</td>
<td>○</td>
<td>○</td>
</tr>
<tr>
<td>Discrimination from and limited access to education</td>
<td>○</td>
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</tr>
<tr>
<td>Low prioritisation of HIV amongst other competing health needs</td>
<td>○</td>
<td>○</td>
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</tr>
</tbody>
</table>

Other (please specify and add importance ranking)

#### 16. Structural Barriers – Transgender WOMEN*

<table>
<thead>
<tr>
<th>Barrier</th>
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<th>Moderately Important</th>
<th>Unimportant</th>
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</thead>
<tbody>
<tr>
<td>Transphobia, stigma and discrimination</td>
<td>○</td>
<td>○</td>
<td>○</td>
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</tr>
<tr>
<td>Criminalization</td>
<td>○</td>
<td>○</td>
<td>○</td>
<td>○</td>
</tr>
<tr>
<td>Lack of legal recognition of gender status</td>
<td>○</td>
<td>○</td>
<td>○</td>
<td>○</td>
</tr>
<tr>
<td>Incarceration</td>
<td>○</td>
<td>○</td>
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Other (please specify and add importance ranking)
# Transgender people and HIV

## 17. Structural barriers - Transgender MEN*

<table>
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<th>Uncertain</th>
</tr>
</thead>
<tbody>
<tr>
<td>Transphobia, stigma and discrimination</td>
<td>○</td>
<td>○</td>
<td>○</td>
<td></td>
</tr>
<tr>
<td>Criminalization</td>
<td>○</td>
<td>○</td>
<td>○</td>
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<td></td>
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<tr>
<td>Incarceration</td>
<td>○</td>
<td>○</td>
<td>○</td>
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<tr>
<td>Other (please specify and 1 pe importance ranking)</td>
<td>○</td>
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</table>

## 18. Co-morbidities – Transgender WOMEN*

<table>
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<tr>
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</thead>
<tbody>
<tr>
<td>STI co-infections</td>
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<tr>
<td>Mental health problems</td>
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<tr>
<td>TB</td>
<td>○</td>
<td>○</td>
<td>○</td>
<td></td>
</tr>
<tr>
<td>HBV</td>
<td>○</td>
<td>○</td>
<td>○</td>
<td></td>
</tr>
<tr>
<td>HCV</td>
<td>○</td>
<td>○</td>
<td>○</td>
<td></td>
</tr>
<tr>
<td>Other (please specify and 1 pe importance ranking)</td>
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</table>

## 19. Co-morbidities – Transgender MEN*

<table>
<thead>
<tr>
<th></th>
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</thead>
<tbody>
<tr>
<td>STI co-infections</td>
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<td>Mental health problems</td>
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<tr>
<td>TB</td>
<td>○</td>
<td>○</td>
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<tr>
<td>HBV</td>
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</tbody>
</table>

### Strategies and enabling factors

The following questions focus on [transgender-specific strategies](http://www.example.com) to address HIV vulnerabilities. Other strategies are already universally recommended for all key populations, including transgender people. These include condom programming, testing and counseling, treatment, prevention and control of sexually transmitted infections, needle and syringe programming, opioid substitution treatment and others.

Which of the following are important strategies for addressing HIV vulnerabilities among [transgender women*](http://www.example.com) and [transgender men*](http://www.example.com) specifically?

---

Page 8
## Transgender people and HIV

### 20. ART related prevention - Transgender WOMEN*

<table>
<thead>
<tr>
<th></th>
<th>Very important</th>
<th>Moderately important</th>
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</tr>
</thead>
<tbody>
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<td>Pre-exposure prophylaxis (PrEP)</td>
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<td>O</td>
</tr>
<tr>
<td>Post-exposure prophylaxis (PrEP)</td>
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<td>O</td>
<td>O</td>
</tr>
<tr>
<td>Early initiation of ART for all transgender women*</td>
<td>O</td>
<td>O</td>
<td>O</td>
<td>O</td>
</tr>
<tr>
<td>Early initiation of ART for serodiscordant couples</td>
<td>O</td>
<td>O</td>
<td>O</td>
<td>O</td>
</tr>
<tr>
<td>Other (please specify and type importance ranking)</td>
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</table>

### 21. ART related prevention - Transgender MEN*

<table>
<thead>
<tr>
<th></th>
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<td>Pre-exposure prophylaxis (PrEP)</td>
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<tr>
<td>Post-exposure prophylaxis (PrEP)</td>
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<td>O</td>
<td>O</td>
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<tr>
<td>Early initiation of ART for all transgender men*</td>
<td>O</td>
<td>O</td>
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</tr>
<tr>
<td>Early initiation of ART for serodiscordant couples</td>
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<tr>
<td>Other (please specify and type importance ranking)</td>
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</table>

### 22. Health service provision and delivery - Transgender WOMEN*

<table>
<thead>
<tr>
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<th>Moderately important</th>
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<th>Uncertain</th>
</tr>
</thead>
<tbody>
<tr>
<td>Transgender women*-specific behavior change counseling and information</td>
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<td>O</td>
<td>O</td>
<td>O</td>
</tr>
<tr>
<td>Transgender women*-specific facility-based health services</td>
<td>O</td>
<td>O</td>
<td>O</td>
<td>O</td>
</tr>
<tr>
<td>Transgender women*-specific facility-based outreach</td>
<td>O</td>
<td>O</td>
<td>O</td>
<td>O</td>
</tr>
<tr>
<td>Transgender women*-specific safe spaces (drop-in centers)</td>
<td>O</td>
<td>O</td>
<td>O</td>
<td>O</td>
</tr>
<tr>
<td>Transgender women*-specific community-based (peer) outreach</td>
<td>O</td>
<td>O</td>
<td>O</td>
<td>O</td>
</tr>
<tr>
<td>Transgender women*-specific social media interventions</td>
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<td>O</td>
<td>O</td>
<td>O</td>
</tr>
<tr>
<td>Other (please specify and type importance ranking)</td>
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</tbody>
</table>
### Transgender people and HIV

#### 23. Health service provision and delivery - Transgender MEN*

<table>
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<th>Service</th>
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</thead>
<tbody>
<tr>
<td>Transgender men-specific behavior change counseling and information</td>
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</tr>
<tr>
<td>Transgender men-specific facility-based health services</td>
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<tr>
<td>Transgender men-specific facility-based outreach services</td>
<td></td>
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<tr>
<td>Transgender men-specific safe spaces (drop-in centers)</td>
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<tr>
<td>Transgender men-specific community-based (peer) outreach</td>
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<tr>
<td>Transgender men-specific social media interventions</td>
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</tr>
<tr>
<td>Other (please specify and 1 pe importance ranking)</td>
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</table>

#### 24. Transgender-specific interventions - Transgender WOMEN*

<table>
<thead>
<tr>
<th>Intervention</th>
<th>Very important</th>
<th>Moderately important</th>
<th>Unimportant</th>
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</tr>
</thead>
<tbody>
<tr>
<td>Cross gender hormone therapy (CGHT)</td>
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<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Sex reassignment surgery (SRS)</td>
<td></td>
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<td></td>
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</tr>
<tr>
<td>Other (please specify and 1 pe importance ranking)</td>
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</table>

#### 25. Transgender-specific interventions - Transgender MEN*

<table>
<thead>
<tr>
<th>Intervention</th>
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<th>Unimportant</th>
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<tbody>
<tr>
<td>Cross gender hormone therapy (CGHT)</td>
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</tr>
<tr>
<td>Sex reassignment surgery (SRS)</td>
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<tr>
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</table>
### Transgender people and HIV

#### 26. Structural interventions - Transgender WOMEN*

<table>
<thead>
<tr>
<th></th>
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</thead>
<tbody>
<tr>
<td>Community empowerment and peer-led support interventions</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Creation of an enabling environment for transgender people (non-discrimination laws, policies and legislation)</td>
<td></td>
<td></td>
<td></td>
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</tr>
<tr>
<td>Inclusion of transgender women* in research and clinical trials for HIV prevention and treatment</td>
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</tbody>
</table>

*Other (please specify and 1 pe importance ranking)

#### 27. Structural interventions - Transgender MEN*

<table>
<thead>
<tr>
<th></th>
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<tr>
<td>Creation of an enabling environment for transgender people (non-discrimination laws, policies and legislation)</td>
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<td></td>
<td></td>
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</tr>
<tr>
<td>Inclusion of transgender men* in research and clinical trials for HIV prevention and treatment</td>
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<td></td>
</tr>
</tbody>
</table>

*Other (please specify and 1 pe importance ranking)

### Key issues for HIV among transgender people.

#### 28. Please add any other important topics/issues which were not covered or any other points which you would like to raise? (optional)

Thank you for participating in Round 1 of the "transgender people and HIV"...
## Transgender people and HIV

Your responses will help ensure that the most important topics are covered in the values and preferences interviews with transgender people.

You will be contacted again in the following weeks with an invitation to participate in the Round 2 of this survey.

Please contact consultant Mira Schneiders (schneidersm@who.int) with any further questions.
Annex 2: Recruitment text included a link to a short online survey

Dear XXX,

I am working at the HIV Department at the World Health Organization in Geneva. We are in the process of updating guidelines on HIV prevention, treatment and care for key populations, including specific issues for transgender people. For this, we want to take into account the voices of transgender women and men, by documenting some of the diverse experiences, values and preferences from around the world.

WHO is preparing to conduct anonymized in-depth interview with a small number of transgender individuals who are interested in sharing some of their personal stories. Specifically, we hope to learn more about how transgender women and men may be affected by HIV and other health issues, what their specific HIV related risks, challenges and needs are, and what successful strategies may exist to reduce HIV vulnerability.

If you are interested to participate in an in-depth interview, please fill out this short survey:

ACCESS THE SHORT SURVEY HERE: https://de.surveymonkey.com/s/3DBX73D

All personal information and answers given in this short survey will be kept confidential and will only be used for the purpose of selecting individuals for the in-depth interviews.

Further information to survey participants:

What will happen if I fill out this survey?

If you fill out this survey, you are letting us know that you are interested in being interviewed. As we are trying to get a global picture and can interview only a small number of transgender women and men, we will select people from different regions of the world and with a range of different experiences to take part in these interviews. Therefore, you may or may not be invited for an interview if you fill out this short survey. You will hear back from us within one week. We thank you for filling in this short survey.
and apologize in advance if you do not become selected for an in-depth interview.

What will happen if I am invited to take part in an interview?

If you are invited to take part in the interviews, we will contact you with more information regarding the interviews. Interviews will be conducted by telephone or Skype at a time most convenient for you. The interview will last around one hour and will be voice recorded and then typed up electronically. The information you provide is confidential and only the interview team will have access to your personal information. Your response will be anonymous in that your personal information will not be matched with anything you say in the interviews.

Before we start the interview, you will be given more details about the interviews and we will ask for your verbal informed consent.

Do I have to become involved?

Participation in this short survey and in the in-depth interviews is strictly voluntary and you do not have to become involved at all. You can also decline to take part at any point later in time without explanation and without further consequences for you.

Unfortunately we are unable to pay for your involvement in this survey or the subsequent in-depth interview. We are very grateful for your time and support.
# Transgender people short survey

## Introduction to this survey

WHO is preparing to conduct anonymised in-depth interviews with a small number of transgender individuals to inform the development of HIV guidelines for key populations.

By filling out this survey, you are letting us know that you are interested in being interviewed. As we can interview only a small number of transgender women and men from different world regions and with a range of experiences, you may or may not be invited for an interview if you fill out this survey. We apologise in advance if you do not become selected for an in-depth interview and thank you for your support.

**Confidential survey:**

Any identifying information you provide in this survey will be kept confidential and can only be accessed by the interview team at WHO. The information you provide below will not be shared and is only used for purposes of selecting interview candidates.

*Participation in this short survey is strictly voluntary and you do not have to answer any of the questions you do not want to.*

## Basic information (1/3)

Any identifying information you provide in this survey will be kept confidential and can only be accessed by the interview team at WHO. The information you provide below will not be shared and is only used for purposes of selecting interview candidates.

### *1. Personal information*

<table>
<thead>
<tr>
<th>Name:</th>
</tr>
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<tbody>
<tr>
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<table>
<thead>
<tr>
<th>Primary occupation/primary source of income:</th>
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</table>

### *2. How would you describe your level of English?*

- Very good (I speak and understand English fluently.)
- Good (I speak and understand well with occasional mistakes.)
- Intermediate (I can speak and understand reasonably well with some problems.)
- Elementary (I can say and understand a few things in English.)
- Beginner (I do not speak any English.)

If "Elementary" or "Beginner": is there another language(s) you want to be interviewed in?

### Gender identity (2/3)
### Transgender people short survey

**3. What is your current gender?**
- [ ] Male
- [ ] Female
- [ ] TransMale/Transman
- [ ] TransFemale/Transwoman
- [ ] Genderqueer
- [ ] Decline to state
- [ ] Other

Other (please specify):

**4. What sex were you assigned at birth?**
- [ ] Male
- [ ] Female
- [ ] Decline to state

**5. Sexual orientation (tick all that apply)**

Who do you feel physically, romantically, and/or emotionally attracted to?
- [ ] Attracted to Transwomen
- [ ] Attracted to Transmen
- [ ] Attracted to cis-woman (non-Transwoman)
- [ ] Attracted to cis-men (non-Transwoman)
- [ ] Attracted to Genderqueer people
- [ ] Not sure
- [ ] None
- [ ] Decline to state
- [ ] Other

Other (please specify):

### Information related to HIV (3/3)

As we want to ensure that our interviews take into account the experiences of people at risk of HIV or living with HIV, we will now ask you some questions that relate to HIV. This will help us select a range of individuals with different HIV-related characteristics for the in-depth interviews.

You do not have to answer any of these questions if you do not want to.
Transgender people short survey

6. Have you ever been tested for HIV? (optional)
   - [ ] Prefer not to say
   - [ ] Yes
   - [ ] No
   - [ ] Not sure

7. What is your HIV status? (optional)
   - [ ] Prefer not to say
   - [ ] Positive
   - [ ] Negative
   - [ ] Don't know

8. Have you had any kind of gender affirming surgery/ sex reassignment surgery? (tick all that apply)
   - [ ] Prefer not to say
   - [ ] None
   - [ ] Top (chest) surgery
   - [ ] Bottom (genital) surgery
   - [ ] Other

   Other (please specify): [ ]

Thank you!

Thank you very much for completing this short survey.

The information you provided will be kept confidential and will not be shared.

As we are trying to capture a diverse range of experiences and can only interview a small number of transgender women and men, we will select people from different regions of the world and with a range of different experiences to take part in these interviews.

We will contact you within the next week to let you know if you have been selected for the in-depth interview.

We are very grateful for your time and support.

Please contact Mira Schneiders (schneidersm@who.int) with any questions you may have.
Annex 4: Interview guide

**GENERAL QUESTION STRUCTURE**

The following broad/open ended questions and probes will be applied to each interview topic:

**1) Personal experience**
- Can you tell me a bit about your experience with xxx?
- What was it like xxx?
- Could you give me some examples from your experience?
- How did that make you feel?
- How do you think other people in your trans community experience xxx?
- How has xxx impacted your life?
- How accessible is xxx in your setting?

**2) Benefits and Enablers**
- What motivates/motivated you to do xxx?
- How do you address/access xxx?
- What enabled/helped you in this situation to xxx?
- What do you think are the benefits of xxx?
- How effective do you think xxx is?

**3) Barriers and Challenges**
- What were some of the challenges to xxx?
- What do you perceive as the main barriers to xxx?
- Did you experience any difficulties in this situation?
- What prevented you from doing/accessing xxx?

4) Suggested strategies/ solutions

- What would help/assist you in/to get/access xxx?
- What information would you need to do/get xxx?
- What would be most beneficial/helpful to you in this situation?
- How do you think this problem could be addressed/solved/improved?
- How could things be made easier for you in this situation?
- How should xxx best be offered to transgender people in xxx?

In case of questions to interviewer during interview:

- That's a good question; I will get back to it at the end of the interview. For now I am interested in your experience…
- I will make a note of question and answer it at the end of the interview (if possible, or else say you will follow up via email with an answer).

INTRODUCTION AND VERBAL CONSENT

1. Read consent form, answer any questions and then ask participant for verbal consent (start recording at this time)
2. Commence the interview

SECTION 1- SOCIO-DEMOGRAPHIC INFORMATION

If already gathered in online survey, don’t repeat:

Name:

Age:
SECTION 2 - HIV PREVENTION

HIV KNOWLEDGE AND ACCESS TO PREVENTION SERVICES

ICE BREAKER

First, I’m curious to hear a bit about your involvement in the trans community and with HIV issues more broadly.

What is your main source of information on HIV prevention (e.g. Internet, transgender friends and community, organizations working in HIV, health centres)

TRANSITIONING

Now, I want to ask you about transitioning. You said in the survey that you have had xxxx....
Tell me a bit about your **experience transitioning**? (e.g. age, where, how did you start)

*(if bottom surgery) You mentioned in the survey you had xxx:*

- did you experience and post operative complications?

How has transitioning **impacted** your life?

Did you face any **challenges** during this process?

If not mentioned yet; ask specifically about use of:

- Hormones (injection risks)
- MtF only: Silicone or other soft tissue fillers
  - What, how (injected?- if so access to clean needles?)
- Gender-affirmative surgery
  - Why desired or not, ease of access, what and how – medically supervised?

How would you ideally like to be able to access these services?

Do you see a role for integration of HIV services with other trans-specific health services (e.g. hormone treatment/gender reassignment surgery)?

**SEXUAL HEALTH**

Now, I would like to find out a bit more about your sexual health. If any of these questions make you feel uncomfortable and you prefer not to answer them, that is totally fine, just tell me so.

Could you tell me a bit about your sexual health needs?

So in the survey you indicated that you feel physically, romantically and/or emotionally attracted to XXXX.

Do you use prevention commodities to prevent HIV and STIs?
• How easy is it for you to access these?
• (if discordant relationship) explore PrEP, PEP, early initiation of ART

MENTAL HEALTH AND DRUG USE

Is access to clean needles and syringes a concern for you? (e.g. for use of injecting hormones, silicone, recreational drugs)

• (if yes) explore access to NSP and OST
• (if no) access in the wider community

How easily available are clean needles in your country/city and where do you get them from?

SECTION 3- TESTING AND COUNSELLING (only for those who have been tested)

You indicated on the survey that you have been tested for HIV and that your result is xxx

Can you tell me a bit more about your experience(s) getting tested?

• Place (e.g. public clinic, community based, private, NGO)
• Did you go alone or with a partner/friend
• How did you feel getting tested there?
• Can you tell me about getting the result?

SECTION 4- TREATMENT AND CARE (only for HIV +)

• What happened after getting the result (e.g. did you get referred to HIV treatment and care services)?
• What were you told about treatment?
• What do you know about when you start ART?
  o Early initiation of treatment, why yes or no

In an ideal world, what would HIV services be like for you?
- Do you prefer to have health services that are specific to trans people only or integrated into general health services
TREATMENT AS PREVENTION (only for HIV -)

Have you ever heard of pre-exposure prophylaxis (PrEP) or post-exposure prophylaxis (PEP)?

Have you ever used a medication or pill before (called PrEP) or after (called PEP) a time when you felt you were at risk of exposure to HIV?

a. What have you heard about PrEP or PEP?
b. Tell me a bit more about your experiences using xxx?
c. What did you think the benefits were?
d. Did you experience any difficulties with using xxx?
e. Is there much information available on PrEP/PEP in your community?

SECTION 5- OTHER HEALTH CONCERNS

Are there any other health topics or concerns, HIV or other that are important to you/OR the broader transgender community?

e.g.

1. Co-morbidities (TB, HBV, HCV, STI)
2. Opportunity to raise any other topics/concerns

DEBRIEFING

Thank you very much for taking part in this interview. WHO really appreciates your time and willingness to share very personal experiences, thoughts and feelings.

Once we collect all the data, it will be analysed and a report will be written and a copy sent to you (probably in late early March 2014).

Reminder: We will not use any identifying information about you in this report.

Would you be interested in being emailed a copy?

Yes _____ No _____
Further contact/questions/concerns: contact details provided
Annette Verster VersterAn@who.int

Would you mind if I contacted you later in case of any follow up questions?
Yes _____  No _____

ADDRESS QUESTIONS THAT CAME UP IN INTERVIEW

    Either answer question or say “I want to give you an accurate answer so let me check that question and get back to you soon with the answer”.
Annex 5: Participant Information Sheet

INFORMATION SHEET
VERBAL INFORMED CONSENT TO PARTICIPATE IN

Transgender people and HIV: Values and Preferences Interviews

We will be conducting interviews with transgender men and women to discover their HIV and other health related experiences and needs. This Information Sheet explains the interview process in detail to you in writing. Before the phone-interview will be conducted, the interviewer will again explain this information to you verbally.

We would like you to ask ANY question about any part of the interviews that you do not fully understand. After you understand all aspects of the interview, we will ask you to decide if you want to participate or not. Once you have verbally agreed to take part on the phone, we will give you a written copy of this Information Sheet to keep.

It is important that you understand that your participation in this interview is entirely voluntary; you do not have to take part if you do not want to.

Why are these interviews being done?
The WHO HIV Department is conducting interviews to learn more about HIV related needs among transgender women and men, globally. Specifically, we hope to explore HIV related risk behaviours, experiences with HIV and other health-care services, and the challenges and opportunities of successful HIV prevention, treatment and care among transgender people. This information will be considered by WHO in developing recommendations for HIV guidance for key populations, including transgender people. You are being asked to participate because you are a transgender individual and have expressed an interest in being interviewed by recently completing our short online questionnaire entitled “Transgender people short survey”.

___________________________________________________________________________
How many people will take part in these interviews?

Approximately 20 transgender individuals overall will be in this study.

What will happen if I decide to be in an interview?

If you agree to participate in this study:

1. You will be asked to provide us with a telephone number or Skype account name, at which you can be reached and a date and time which is convenient to you.
2. The interviewer will call you at the agreed date and time and talk to you on the phone for about one hour. The interviewer will be semi-structured, in that the interviewer will ask you some guiding questions and will give you the opportunity to respond freely and discuss any topics, which you feel are important to you.
3. The interviews will be voice recorded and then typed up on the computer by the interviewer. You will be assigned an interview ID-number by the interviewer and only the interviewer will have access to the file, which matches your ID-number to your name. The interview ID-number will ensure that your name will not be matched with anything you say later.
4. The content of the transcribed interviews will then be analysed by the interviewer and a report of the finding will be written and published. The report will include quotes from your and other interviews. No identifying information will be included in this report, but direct quotes from the interview will be used.

What risks can I expect from being in an interview?

There are some possible risks or discomforts related to being in this study. In particular, the interview includes personal questions about your past and current sexual activity, drug use and about transitioning, and you may feel shy or uncomfortable answering some of them. You do not have to answer any questions that you do not want to and can simply say so during the interview.

Are there any benefits from taking part in an interview?

No. There are no real benefits to you. WHO will learn more about how transgender women and men are affected by HIV and other health issues, in order to better understand their needs for HIV prevention, treatment and care.

Will all information about me be kept private?

Participation in any research may involve a loss of privacy, but information about you will be handled as confidentially as possible. A study file with your interview ID-number will be created for you electronically, and the recording of the interview as well as the transcript of the interview will be kept in your study file. Only the interviewer and the
team will have access to this file. After the analysis of the interviews is completed, all personal identifying information and recordings of interviews will be deleted. Transcribed version of the interviews will be stored electronically and will be published as part of a report. Any published information in writing or presented at scientific meetings will not include your name or other personal identifying information.

**Will I be paid to be in this interview?**

No, you will not receive any compensation for taking part in this interview.

**How long will the interview be if I decide to participate?**

If you decide to participate, you will have one telephone interview, which will take around 60 minutes (1 hour).

**Do I have to take part in these interviews?**

Taking part in these interviews is your choice and completely voluntary. You may choose either to take part or not to take part. If you decide to take part in this interview, you may leave the interview at any time and without explanation. No matter what decision you make, there will be no penalty to you.

**Who can answer my questions about this interview?**

If you have questions or concerns about these interviews, please contact the interviewer, Mira Schneiders at schneidersm@who.int or her supervisor, Annette Verster at VersterAn@who.int.

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PARTICIPATION IN THESE INTERVIEWS IS VOLUNTARY. YOU CAN DECLINE TO PARTICIPATE IN THE INTERVIEW AT ANY POINT, WITHOUT ANY PENALTY OR LOSS OF RIGHTS.
ANNEX 4: HEALTH INTERVENTIONS FOR PRISONERS

Update of the literature since 2007

Author: Amee Schwitters,
Affiliation: Centers for Disease Control and Prevention, Atlanta USA
Date: 2014-03

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1. Background and introduction

HIV remains a serious problem in prison settings. HIV prevalence continues to be higher in prisons than in the general population, although prevalence varies geographically. While most of the prisoners living with HIV or AIDS in prison contract their infection outside of prison walls, the risk of being infected, in particular through sharing of contaminated injecting equipment and through unprotected sex, is great (2007 document). High risk behaviour, including injection drug use, sexual activity, and tattooing/body piercing is widespread within prison settings leading to transmission of HIV and HCV. Several studies have demonstrated that HIV prevention programmes, including education, condom distribution, OST, and needle and syringe programmes, can be successfully implemented in prisons and other closed settings.

In 2007, as part of the writing of the *Effectiveness of Intervention to Address HIV in Prisons* an extensive literature review was conducted. During the writing of this document, an abbreviated updated literature review was conducted in 2014 focusing on materials developed between 2007 and 2014. The same search terms used in 2007 were again used in 2014 and included: “prison(s)”, “jail(s)”, “correctional facility(ies)”, “detention center(s)”, “prisoner(s)”, “inmate(s)”, “HIV”, and “human immunodeficiency virus”. These search terms were combined with the focus areas of this document (such as “condoms”, “sexual violence”, “HIV/AIDS education”, “medical male circumcision” etc). Publications including both adults and adolescents were included. Studies and materials presented in English and Spanish were included and an effort was made to collect materials from low-and middle-income countries. The initial search returned a total of 363 publications. After removal of duplicate articles presenting the same intervention, articles prior to 2007, non-relevant articles, and review articles including publications prior to 2007 a total of 70 articles remained and are presented in this report. Results from the 2014 review support the 2007 review. No articles were found directly contradicting publications from the 2007 review, nor the recommendations made in the 2007 report. The 2014 review supports the need for continued research in this area.

For each of the following prison-based HIV prevention focus areas, abbreviated summaries and recommendations are presented from the comprehensive 2007 WHO/UNODC/UNAIDS report, *Effectiveness of Interventions to Address HIV in Prisons*. Results from the 2014 review are presented below the abbreviated 2007 findings and recommendations and include reference summaries by focus area in tables from the 2014 review. Summaries and recommendations are presented by topic area and include: condoms, drug dependence treatment, HIV/AIDS education, sexual violence, HIV treatment, care, and support, HIV testing and counselling, and needle and syringe programmes. Unless noted otherwise, recommendations and findings apply to both adults and adolescent prisoners. For more detailed reading, the 2007 document can be obtained on the WHO website ([http://whqlibdoc.who.int/hiv/pub/ida/prisons_effective/en/](http://whqlibdoc.who.int/hiv/pub/ida/prisons_effective/en/)).

Terminology: In 2007 and again in this update, the term “prison” has been used for all places of detention and the term “prisoner” has been used to describe all who are held in such places, including adult and
juvenile males and females detained in criminal justice and prison facilities during the investigation of a crime; while awaiting trial; after conviction and before sentencing; and after sentencing.

2. Health Interventions in Prisons

2.1. Condoms

As stated in the 2007 document, there is evidence that provision of condoms is feasible in a wide range of prison settings. It has been found that condom access is unobtrusive to the prison routine, represents no threat to security or operations, does not lead to an increase in sexual activity or drug use and is accepted by most prisoners and prison staff once it is introduced. At the same time, there is evidence that making condoms available to prisoners is not enough – they need to be easily accessible and in various locations throughout the prison.

The 2014 updated review supports the current recommendations and continues to demonstrate that access to condoms does not increase sexual activity, nor are condoms a threat to staff security; condoms do however decrease transmission of HIV. Continued acceptance of access to condoms by prisoners and staff was found. Condoms should be delivered in an easily accessible manner and delivery in combination with HIV prevention education is encouraged.

2007 Recommendations:

1) Prison authorities in jurisdictions where condoms are currently not provided should introduce condom distribution programmes and expand implementation to scale as soon as possible.
2) Condoms should be made easily and discreetly accessible to prisoners so that they can pick them up at various locations in the prison, without having to ask for them and without being seen by others.
3) Together with condoms, water-based lubricant should also be provided since it reduces the probability of condom breakage and/or rectal tearing, both of which contribute to the risk of HIV transmission.
4) Education and informational activities for prisoners and for staff should precede the introduction of condom distribution programmes, which should be carefully prepared.
5) Female prisoners should have access to condoms as well as dental dams.

<table>
<thead>
<tr>
<th>Country</th>
<th>Study</th>
<th>Summary</th>
</tr>
</thead>
<tbody>
<tr>
<td>USA</td>
<td>Sylla M, et al (2010)</td>
<td>Likelihood of obtaining condoms increased after machine installation; sexual activity did not increase; staff acceptance of condom access increased.</td>
</tr>
<tr>
<td>Country</td>
<td>Study</td>
<td>Summary</td>
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<tr>
<td>USA</td>
<td>Leibowitz AA, et al (2012)</td>
<td>Condom distribution programme estimated to avert 25% of HIV transmissions among MSM inmates in K6G unit; condom distribution currently limited to one per week per prisoner.</td>
</tr>
<tr>
<td>Australia</td>
<td>Butler T, et al (2013)</td>
<td>Availability of condoms not associated with an increase in sexual activity. Condoms more likely to be used when available.</td>
</tr>
<tr>
<td>USA</td>
<td>Harawa N, et al (2010)</td>
<td>Over half of men reporting have had sex while incarcerated stated they use condoms provided by the jail. Condoms should continue to be provided along with lubricant. Condoms should be easily accessible and without limitations on number of condoms distributed.</td>
</tr>
<tr>
<td>Australia</td>
<td>Yap L, et al (2007)</td>
<td>Decrease in reports of both consensual male-to-male sex and male sexual assaults five years after the introduction of condoms into prisons. There exists no evidence of serious adverse consequences of distributing condoms and dental dams to prisoners in NSW. Condoms are an important public health measure in the fight against HIV and sexually transmitted diseases; they should be made freely available to prisoners.</td>
</tr>
<tr>
<td>USA</td>
<td>Bryan AD, et al (2009)</td>
<td>Adolescents received 1 of 3 group-based interventions: combined sexual and alcohol risk reduction (group psychosocial intervention [GPI] and motivational enhancement therapy [GMET]); sexual risk reduction only (GPI); or HIV/STD prevention information only (GINFO). Condom use frequency decreased over time, although GPI and GPI_GMET interventions mitigated this at follow-up assessments. Active interventions were significantly more successful than the GINFO condition and the pattern of effects favored the GPI_GMET, there were no statistically significant differences between GPI and GPI_GMET.</td>
</tr>
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</table>

### 2.2. Drug Dependence Treatment

As stated in the 2007 document, there is evidence that OST with methadone is feasible in a wide range of prison settings. Adequate prison-based OST programmes are effective in reducing injecting drug use and associated needle sharing and infections and they have been shown to have additional benefits for the health of prisoners participating in the programmes, for prison systems and for the community. OST may help to reduce risk of overdose deaths upon release; however strategies are needed to ensure continuity in
treatment of opioid users as they move between the community and prison systems. It remains crucial to make OST available in prisons because of its role in facilitating delivery of antiretroviral therapy in people who inject drugs.

In contrast to OST, there is little data on the effectiveness of other forms of drug dependence treatment as an HIV prevention strategy, however good quality, appropriate, and accessible treatment has the potential of improving prison security, as well as the health and social functioning of prisoners, and can reduce reoffending, as long as it provides ongoing treatment and support, post-release care and meet the individual needs of prisoners. In addition, reducing the number of people who are in prison or compulsory treatment and rehabilitation centers because of problems related to their drug use must be a priority.

The 2014 updated review supports the current recommendations and continues to demonstrate positive outcomes associated with drug dependence treatment in prisons including a reduction in high risk harmful behaviour and drug use, although delays in OST implementation in prisons may have a negative impact on the health of prisoners. Among studies including opinions of prisoners regarding OST and other drug dependence treatment, prisoners generally favored the availability of such programmes. Education should be provided in conjunction with or before introduction of OST and specific emphasis should be focused on ensuring linkage to treatment at release between prison-based health care and community-based health care to decrease potential relapse.

2007 Recommendations:

1) Prison authorities in countries in which OST is available in the community should introduce OST programmes urgently and expand implementation to scale as soon as possible. Particular efforts should be undertaken to ensure that prisoners on OST prior to imprisonment are able to continue this treatment upon imprisonment, without interruption.
2) In addition to OST, prison authorities should also provide a range of other drug dependence treatment options for prisoners with problematic drug use, in particular for problematic use of other substances such as amphetamines and cocaine.
3) Prison authorities should devote particular attention to the availability of treatment and social support services for prisoners on their release, and work in collaboration with relevant authorities to ensure that comprehensive aftercare services are available.
4) States should affirm and strengthen the principle of providing treatment, education and rehabilitation as an alternative to conviction and punishment for drug-related offences are available.

<table>
<thead>
<tr>
<th>Country</th>
<th>Study</th>
<th>Summary</th>
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<tbody>
<tr>
<td>Iran</td>
<td>Asl RT, et al (2013)</td>
<td>Findings of the urine analyses indicated a minimal yet consistent decrease in drug use over the six months. The pre and post- self-administered questionnaire data relayed modest changes in IDU risky behaviours associated with sexual practices;</td>
</tr>
<tr>
<td>Country</td>
<td>Study</td>
<td>Summary</td>
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</tr>
<tr>
<td>Spain</td>
<td>De la Fuente L, et al (2012)</td>
<td>However, many prisoners continued with risky behaviours even when participating in harm reduction measures, such as methadone maintenance therapy.</td>
</tr>
<tr>
<td>Malaysia</td>
<td>Bachireddy C, et al (2011)</td>
<td>OST and NEP introduction was a great advance, but the delay (8–25 years) in implementation and low level of NEP coverage could have limited their potential impact on the improvement of the health of incarcerated persons.</td>
</tr>
<tr>
<td>USA</td>
<td>Magura S, et al (2009)</td>
<td>Survey administered to HIV+ current prisoners. Participants were asked about sexual and drug behaviours in 30 days prior to current incarceration. Half (51%) believed OST would be helpful, 33% believed they needed OST after release to prevent relapse, and 70% wanted to learn more about OST. Among those with prior OST experience, 93% stated they would refer friends to treatment suggesting possibility for peer education.</td>
</tr>
<tr>
<td>USA</td>
<td>Eshrati B, et al (2008)</td>
<td>Participants randomly assigned to either buprenorphine or methadone maintenance. Completion rates were similar; no significant difference was found on post-release relapse between treatment groups.</td>
</tr>
<tr>
<td>USA</td>
<td>Gordon MS, et al (2009)</td>
<td>Knowledge about HIV transmission was high among prisoner population; however additional education should be targeted at prisoners to increase perceptions of effectiveness of health benefits of using harm reduction strategies surrounding drug use (i.e. NSP, clean syringes).</td>
</tr>
<tr>
<td>USA</td>
<td>Kinlock TW, et al (2009)</td>
<td>Methadone maintenance, initiated prior to or immediately after release from prison, increases treatment entry and reduces heroin use at 6 months post-release compared to counselling only.</td>
</tr>
<tr>
<td>USA</td>
<td>Garcia CA, et al (2007)</td>
<td>Prisoners were assigned to one of three groups: (a) Counselling Only: counselling in prison, with passive referral to treatment upon release; (b) Counselling + Transfer: counselling in prison with transfer to methadone maintenance treatment upon release; and (c) Counselling + Methadone: counselling and methadone maintenance in prison, continued in the community upon release. Counselling + Methadone participants were significantly less likely than participants in each of the other two groups to be opioid-positive or cocaine-positive.</td>
</tr>
<tr>
<td>Puerto Rico</td>
<td>Hedrich D, et al (2012)</td>
<td>Treatment completers compared with non-completers had significantly greater reductions in self-reported heroin use, cocaine use, and crime and were less likely to be opioid-positive according to urine drug testing.</td>
</tr>
<tr>
<td>Multiple</td>
<td>Hedrich D, et al (2012)</td>
<td>(Review) OMT was associated significantly with reduced heroin use, injecting and syringe-sharing in prison if doses were adequate. Pre-release OMT was associated</td>
</tr>
<tr>
<td>Country</td>
<td>Study</td>
<td>Summary</td>
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</tr>
<tr>
<td>Australia</td>
<td>Shearer J, et al (2007)</td>
<td>Oral naltrexone was an unpopular option among opioid-dependent inmates in this study. Agonist treatments were preferred. Funding support for the naltrexone provision was withdrawn after conclusion of study. Recommendation to continue with provision of methadone maintenance or buprenorphine maintenance and counselling.</td>
</tr>
<tr>
<td>USA</td>
<td>Sacks JY, et al (2012)</td>
<td>Effectiveness of prison-based treatment for women in general and therapeutic treatment in particular in reducing drug use, criminal activity, and exposure to trauma, and increasing mental health functioning and time until re-incarceration was demonstrated among participants.</td>
</tr>
<tr>
<td>USA</td>
<td>Springer SA, et al (2010)</td>
<td>Buprenorphine induction and stabilization was shown to be acceptable, tolerable and an effective treatment to prevent relapse to opiate use in released HIV-infected prisoners. It appears to be effective at maintaining HIV outcomes and potentially decreasing HIV-associated morbidity and mortality.</td>
</tr>
<tr>
<td>Malaysia</td>
<td>Wickersham JA, et al (2013)</td>
<td>Beginning 4 months before release, standardized methadone initiation and dose escalation procedures began with 5 mg daily for the first week and 5 mg/daily increases weekly until 80 mg/day or craving was satisfied. Participants were followed for 12 months post-release at a MMT clinic within 25 kilometers of the prison. Higher doses of MMT at time of release are associated with greater retention on MMT after release to the community.</td>
</tr>
<tr>
<td>India</td>
<td>UNODC (2013)</td>
<td>Retention rates were 98% of OST clients in prison settings. A significant reduction was found in the severity of dependence, craving for drugs and withdrawal symptoms. Decreases in high risk behaviour including injecting drug use, sharing of needles, and unsafe sexual activities were seen. Prison authorities noted improvements in health and personal hygiene among inmates. Challenges included unpredictable stays by prisoners, lack of linkage to community programmes at release, and frequent staff rotation.</td>
</tr>
<tr>
<td>USA</td>
<td>Freudenberg N, et al (2010)</td>
<td>Participants (N=552) were recruited in city jails and randomly assigned to receive an intensive 30-hour jail/community-based intervention or a single jail-based discharge planning session. All participants were also referred to optional services at a community-based organization (CBO). Assignment to REAL MEN and, independently, use of CBO services, significantly reduced the odds of substance dependence one year after release.</td>
</tr>
</tbody>
</table>

2.3. HIV/AIDS Education
As stated in the 2007 document, there is evidence that well-designed HIV/AIDS information and education programmes can improve prisoners’ knowledge about HIV/AIDS. Studies undertaken in a number of countries, including in low and middle income countries, have demonstrated a need for information and education programmes in prisons, and shown that well-designed programmes can improve prisoners’ knowledge about HIV/AIDS. Knowledge alone is insufficient, but it is a precursor to protection from infection. A few evaluations have indicated self-reported behavioural change (particularly upon release) as a result of prison-based educational initiatives, but the effectiveness of educational efforts is difficult to measure and it remains largely unknown whether they reduce HIV transmission among prisoners. HIV information and education programmes in prisons are more likely to be effective if developed and delivered by peers. A number of other factors appear to influence the effectiveness of informational and educational interventions including: a) the comprehensiveness of the programme; b) whether it is specific to the needs of the population; c) whether it is appropriate for the average prisoners’ reading and comprehension level; d) whether it has been designed with the input of prisoners; e) whether it is instructor-led or peer-based; f) time of offering of the programme; g) method used to distribute information; and h) whether the programme includes pre- and post-test counselling.

The 2014 updated review supports the current recommendations and continues to demonstrate the importance of peer-based HIV/AIDS education. HIV/AIDS education programmes should be comprehensive, yet easy to administer. Additionally, programmes should include focus on overall stigma reduction.

**2007 Recommendations:**

1) Considering that prisons are important settings for informational and educational programmes for both prisoners and staff about HIV and other infectious diseases, prison systems should establish well-designed programmes in all prisons.

2) Where possible, education delivered for prisoners by the prison system should be supplemented by peer education programmes that have been shown to be more effective in reaching prisoners.

3) Informational and educational programmes are but one component of an effective programme to manage HIV in prisons and must be supplemented by other programmes. In particular, prisoners must be provided with the prevention measures that enable them to act upon the information they receive.

<table>
<thead>
<tr>
<th>Country</th>
<th>Study</th>
<th>Summary</th>
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</thead>
<tbody>
<tr>
<td>South Africa</td>
<td>Sifunda S, et al (2008)</td>
<td>Control group and two experimental groups (Trained HIV- and HIV+ peer educator led groups). Twelve, 1.5 hour intervention sessions conducted over six weeks covering HIV/AIDS, STIs, nutrition, TB prevention and management, alcohol and other drug abuse, sexuality, and manhood/general life skills. Long-term results showed some differences in practicing safer sex and better sexual negotiation skills.</td>
</tr>
<tr>
<td>USA</td>
<td>Derlega VJ, et</td>
<td>Stigma towards persons living with HIV and inaccurate theories on HIV</td>
</tr>
<tr>
<td>Country</td>
<td>Study</td>
<td>Summary</td>
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<tr>
<td>Taiwan</td>
<td>Ko NY, et al. (2009)</td>
<td>The study findings showed that a brief TTM-based HIV education programme can be effective for drug-dependent inmates. TTM included one-hour lecture on transmission, prevention, symptoms, screening, and treatment of HIV associated with bloodborne viral infections and injection drug use. Included skill-building session on safe injection, needle cleaning, and disinfection, and condom use.</td>
</tr>
<tr>
<td>USA</td>
<td>Martin S, et al. (2008)</td>
<td>DVD targeted group was less likely than standard intervention groups to have unprotected sexual intercourse. Feedback shows that intervention must be brief and simple to administer.</td>
</tr>
<tr>
<td>USA</td>
<td>Grinstead O, et al. (2008)</td>
<td>Project START showed that enhanced intervention (EI) was more successful than single session intervention (SSI) in reducing sexual risk behaviours. Sessions were conducted by personnel outside of the correctional institution. Incentives were provided at week one and week twelve.</td>
</tr>
<tr>
<td>Switzerland</td>
<td>Fluhmann P, et al (2012)</td>
<td>HIV and Hep C information was presented to prisoners using a structured information exchange (StIE) model at the beginning of their prison sentence.</td>
</tr>
<tr>
<td>USA</td>
<td>Goldberg E, et al. (2009)</td>
<td>Participants were randomly assigned to one of three conditions: education intervention; education intervention with booster; or no systematic intervention. At 6 months, males in the education and booster groups sustained increases in knowledge scores. Females in these groups sustained increased condom attitude scores. Males in the booster group sustained increased prevention attitude scores. Females in the booster group reported more consistent condom use.</td>
</tr>
<tr>
<td>USA</td>
<td>Gurdin J, et al. (2008)</td>
<td>The intensive, short-term intervention consists of four, one-hour, small-group sessions focusing on health education issues, particularly HIV/AIDS. Following the intervention, programme participants expressed more favorable attitudes toward condoms, and were more likely to use condoms during intercourse, as compared with the comparison group of teens.</td>
</tr>
<tr>
<td>USA</td>
<td>Hurd NM, et al. (2010)</td>
<td>Examined the effectiveness of an adapted 4-session HIV prevention programme. Participants participated in either the 8- or the adapted 4-session HIVEd programme. Findings indicate participants in both programmes had positive changes at post interview across all study outcomes. No significant differences in changes between participants in the 4- and 8-session programmes were found.</td>
</tr>
<tr>
<td>USA</td>
<td>Robertson AR, et al (2011)</td>
<td>Adolescent girls incarcerated in a state reformatory were recruited/assigned to an 18-session health education programme or a time-equivalent HIV prevention programme. Post intervention, HIV risk reduction programme participants</td>
</tr>
</tbody>
</table>
2.4. Sexual Violence

As stated in the 2007 document, there is evidence from countries around the world that rape and other forms of sexual violence occur in prisons. This poses a serious threat to the health of prisoners, psychologically and physically, including the risk of HIV and other sexually transmitted infections. While some prison systems continue to deny the existence of the problem, fail to collect statistical data on sexual violence in prison, and neglect to provide prison staff training in recognizing, preventing, and responding to prisoner sexual violence, other prison systems have shown that it is possible to fundamentally change the way in which sexual violence is addressed in prison, within a relatively short timeframe. These systems typically adopt methods to document incidents of prisoner sexual violence, undertake prevention effort, provide staff training, undertake investigation and response efforts, and provide services to victims, including access to PEP.

The 2014 updated review supports the current recommendations and re-emphasizes that sexual violence does occur in prison settings. Structural interventions such as cameras and involving prison staff in sexual violence prevention should be implemented and the need to focus on violence prevention and coping in prisons is essential. In studies involving prisoner input, the importance of guards in preventing sexual assault was emphasized.

2007 Recommendations:

1) Prison systems should develop and implement multi-prong strategies for enhancing the detection, prevention, and reduction of all forms of sexual violence in prisons and for the prosecution of offenders.
2) Formal evaluations of the various components of the policies and programmes to address rape and other forms of sexual violence in prison should be undertaken.
3) Victims of sexual assault in prison should have access to post-exposure prophylaxis. In addition, prison systems should make PEP available in other cases in which PEP could reduce the risk of HIV transmission after exposure to HIV.

<table>
<thead>
<tr>
<th>Country</th>
<th>Study</th>
<th>Summary</th>
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<tr>
<td></td>
<td></td>
<td>demonstrated the acquisition of risk-reduction behaviours and improved condom application skill.</td>
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</table>
### 2.5. HIV Counselling and Testing

As stated in the 2007 document, there is evidence that programmes that make HIV testing and counselling easily accessible to prisoners on entry to prison and throughout incarceration result in increased uptake of testing and counselling. This is particularly true if HIV testing and counselling are part of a comprehensive care and treatment programme for HIV-positive prisoners and if HIV test results are kept confidential and those voluntarily disclosing their HIV-positive status do not face discrimination or abuse. In addition to access to HIV testing and counselling, prisoners need access to the means to protect oneself. Mandatory HIV testing is unethical and there is evidence suggesting that mandatory HIV testing and segregation of HIV-positive prisoners is costly, inefficient, and can have negative health consequences for segregated prisoners.

The 2014 updated review supports the current recommendations and emphasizes the importance of voluntary HIV testing in prisons and the offering of confidential counselling and testing as soon as
possible after prison entry to increase the likelihood prisoners are tested and that they receive their results before discharge or transfer.\textsuperscript{35-40} Additionally, rapid testing also increases the likelihood that prisoners will know their HIV status.\textsuperscript{41-44} HIV testing, including opt-out testing was accepted by the majority of prisoners and staff in the studies reviewed\textsuperscript{45-47} and was found to be more effective at case detection in one study comparing opt out and opt in testing among prisoners.\textsuperscript{48} HIV testing and counselling can be offered in conjunction with other risk reduction services such as provision of condoms and STI screening to increase effectiveness of HIV prevention efforts in prisons.\textsuperscript{49-50,40} For prisoners nearing release, HIV care and treatment should be made available through community settings.\textsuperscript{40,44}

\textbf{2007 Recommendations:}

1) Prison systems should provide easy access to HIV testing and counselling.  
   In particular, voluntary HIV testing and counselling:
   - should be easily accessible to all prisoners upon entry and during imprisonment
   - should always be confidential, and everyone being tested should give informed consent and receive counselling
   - should be closely linked to access to care, treatment, and support for those testing positive, and be part of a comprehensive HIV programme that includes access to prevention measures.

2) Prison systems should not adopt policies of mandatory testing and segregation, as they are counterproductive and can have negative health consequences, including for segregated prisoners.

<table>
<thead>
<tr>
<th>Country</th>
<th>Study</th>
<th>Summary</th>
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<tbody>
<tr>
<td>Jamaica</td>
<td>Andrinopoulos K, et al (2010)</td>
<td>Demonstration project provided mandatory opt-out testing for new prisoners and psychiatric patients and voluntary HIV testing for prisoners &gt; 6 months. Pre/post-test counselling provided. 63% accepted voluntary testing and 16% refused mandatory opt-out testing. Relatively high rate of acceptance for voluntary testing. Confidentiality was assured and HIV education was provided.</td>
</tr>
<tr>
<td>USA</td>
<td>Arp W (2009)</td>
<td>Prisoners were surveyed and asked if they believe inmates should be tested for HIV when they enter prison and when released from prison. Among surveyed inmates, 97% agreed inmates should be given a mandatory test for HIV and 99.7% agreed every inmate should receive treatment for HIV/AIDS when they have tested positive.</td>
</tr>
<tr>
<td>USA</td>
<td>Kavasery R, et al (2009)</td>
<td>Male prisoners accepted HIV testing at higher rates when opt-out testing was offered within 24 hours of incarceration.</td>
</tr>
<tr>
<td>USA</td>
<td>Kavasery R, et al (2009)</td>
<td>Female prisoners accepted testing in prison at higher rates when opt-out testing was presented immediately (within 24 hours) after incarceration. Prison staff stated they preferred to offer testing immediately because of high turnover rates.</td>
</tr>
<tr>
<td>USA</td>
<td>Duffus WA, et al (2009)</td>
<td>Retrospective cohort study demonstrated the lack of routine HIV screening in South Carolina correctional facilities fostered missed opportunities for earlier diagnosis of HIV for inmates. Routine screening and testing should be implemented in prisons to</td>
</tr>
<tr>
<td>Country</td>
<td>Study</td>
<td>Summary</td>
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<tr>
<td>USA</td>
<td>Jafa K, et al (2009)</td>
<td>HIV diagnosis was delayed among prison inmates because of a lack of testing in prison facilities. The importance of timely diagnosis and appropriate treatment is demonstrated by the high proportion of seroconverters who were infected with drug-resistant strains.</td>
</tr>
<tr>
<td>USA</td>
<td>Javanbakht M, et al (2007)</td>
<td>Prevention programmes existing in the MSM unit include individual level HIV education and prevention, condom distribution, and HIV and STI counselling. Screening resulted in a high prevalence of STIs and HIV.</td>
</tr>
<tr>
<td>USA</td>
<td>Beckwith CG, et al (2010)</td>
<td>Only 28% of participants in conventional cohort received HIV test results versus 100% in rapid test cohort. Rapid testing greatly improved the odds of receiving test results.</td>
</tr>
<tr>
<td>USA</td>
<td>Macgowan R, et al (2009)</td>
<td>Rapid testing was able to identify a considerable number of previously undiagnosed cases of HIV infection and greatly improved the number of prisoners receiving their results and the time in which results were delivered.</td>
</tr>
<tr>
<td>South Africa</td>
<td>Motshabi LC, et al (2011)</td>
<td>Majority of participants were knowledgeable about HIV transmission, however, barriers to preventing testing and counselling included: stigma, discrimination, lack of trust in health care professionals, poor or bad attitudes of health care professionals, and not knowing about availability of VCT. Programmes addressing stigma and discrimination among health care workers should be implemented.</td>
</tr>
<tr>
<td>USA</td>
<td>De Voux A, et al (2012)</td>
<td>Results from the EnhanceLink demonstration project suggest that HIV testing in jails can lead to new diagnoses of HIV infection and that these infections are being diagnosed substantially early on in the course of the disease. Rapid turnover was not found to be an impediment to jail-based HIV screening. Most inmates did not initiate care while detained. Linkage to care after release emphasized.</td>
</tr>
<tr>
<td>USA</td>
<td>Beckwith CG, et al (2011)</td>
<td>Staff and key informants interviewed about rapid HIV testing experience. Positive experiences were reported with rapid testing and the method was preferred over conventional testing models. Prisoners were reported to be more compliant when offered rapid testing versus conventional testing and staff workload was reduced. Universal agreement that immediate access to HIV test results is an advantage and benefit of rapid testing, especially with high turnover of prisoners.</td>
</tr>
<tr>
<td>USA</td>
<td>Strick LB, et al (2011)</td>
<td>Change in procedure from testing request to opt-in testing to opt-out testing in Washington State Jails increased testing among inmates from 5% to 72% to 90%, respectively. Opt-out testing was most effective at case detection.</td>
</tr>
<tr>
<td>USA</td>
<td>Tartaro C, et al (2012)</td>
<td>As part of the testing process, inmates are assured they will receive free medical care during the duration of jail stay and those that lack health insurance will receive outpatient treatment from a local service provider upon release. Rapid testing increases the number of inmates receiving test results before discharge. A large percentage of prisoners received their first HIV test in jail.</td>
</tr>
</tbody>
</table>
HIV and syphilis screening and condom distribution programmes were initiated in the MSM unit of the Los Angeles county jail. Modeling indicates that the intervention can avert many sexually transmitted infections at low cost and can save costs in a scenario in which inmates continue to engage in sexual activity as they do outside jail.

Multiple UNODC, UNAIDS, WHO (2009)
Review document on HIV testing and counseling in prisons. Evidence and current practices reviewed, minimum requirements for programs are given, and policy framework and recommendations included in the document. Prisons should introduce comprehensive HIV prevention programs that include: information and education, provision of condoms and water-based lubricant, needle and syringe programmes, other measures to decrease sexual transmission, drug dependence treatment, and HIV treatment, care, and support, including provision of ART.

2.6. HIV Care, Treatment, and Support

As stated in the 2007 document, there is evidence that antiretroviral therapy (ART) has significantly decreased mortality due to HIV and AIDS in countries where ART has become accessible. There has been a parallel decrease in the mortality rate among incarcerated individuals in prison systems in those countries. Providing access to ART for those in need in the context of prisons is a challenge, but it is necessary and feasible. Studies have documented that, when provided with care and access to medications, prisoners respond well to ART. Adherence rates in prisons can be as high as or higher than among patients in the community, but the gains in health status made during the term of incarceration may be lost unless careful discharge planning and linkage to community care are undertaken. As ART is increasingly becoming available in developing countries and countries in transition, it will be critical to ensure that it also becomes available in the countries’ prison systems.

Ensuring continuity of care from the community to the prison and back to the community, as well as continuity of care within the prison system, is a fundamental component of successful treatment scale-up efforts. Other measures could also have a positive impact on HIV care, treatment and support in prison. These include ensuring that prison health care be appropriately funded and evolve from the “sick call” model employed in many prison systems into a proactive system that emphasizes early disease detection and treatment, health promotion, and disease prevention. In the medium and longer-term, transferring control of prison health to public health authorities could also have a positive impact. Health care in prisons can be delivered more effectively by public health authorities than by prison management, if proper resources are provided and freedom of action of the new prison health authorities is guaranteed.

The 2014 updated review supports the current recommendations and emphasizes the importance of reducing HIV stigma and discrimination inside of prisons. To increase adherence in prisons,
Confidentiality should be assured and positive relationships with prison health staff are essential.\textsuperscript{51-53} To ensure continuation of treatment at release, linkage to community-based care and discharge with an adequate supply of ART are critical.\textsuperscript{55-58}

**2007 Recommendations:**

1) Prison systems should ensure that HIV-positive prisoners receive care, treatment and support equivalent to that available to people living with HIV in the community, including ART.
2) As ART becomes increasingly available in low and middle income countries, actors at the international, national, and regional and local levels should ensure that it also becomes available in prisons.
3) Efforts need to be undertaken by prison authorities, working with the other components of the criminal justice system and with external health authorities and NGOs, to ensure continuity of care, in particular, ART, from the community to the prison and back to the community, as well as within the prison system.
4) Where OST is available in the community, it should also be available in prisons, so that people on OST and ART are able to access both without interruption.
5) In the context of efforts to increase access to care and treatment, including ART, prison systems should provide easy access to HIV testing and counselling.

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<thead>
<tr>
<th>Country</th>
<th>Study</th>
<th>Summary</th>
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<tbody>
<tr>
<td>USA</td>
<td>Roberson DW, et al (2009)</td>
<td>Lack of confidentiality (visible medication lines), stigma, access to medication, and strained relationships with prison health staff negatively influenced ART adherence while incarcerated. ART programmes in prison should include inmate input, protection of medical information, and improved relationships between providers and inmates including stigma reduction strategies.</td>
</tr>
<tr>
<td>USA</td>
<td>Fontana L, et al (2007)</td>
<td>Prisoners stated a lack of continuum of care between prison and community during release period. Limited interaction and coordination between the two systems was noted. Discharge models for patients with HIV should follow previously demonstrated successful efforts to increase collaboration between prison system and community that increase retention in care.</td>
</tr>
<tr>
<td>Canada</td>
<td>Small W, et al (2009)</td>
<td>Delays in obtaining HIV care and treatment were noted. Poor relationships between prison health staff and prisoners negatively impacts adherence to treatment. High levels of stigma influences ability to take medication and resulted in missed doses. Problems ensuring continuity of treatment post-release were identified.</td>
</tr>
<tr>
<td>Namibia</td>
<td>Shalihu N, et al (2014)</td>
<td>Barriers to ART adherence included: insufficient privacy, stigma, lack of support for adherence, insufficient nutritional intake, market value of ARTs to exchange for money or other benefits, discrimination by prison staff, and lack of information about HIV transmission and care.</td>
</tr>
<tr>
<td>USA</td>
<td>Wohl DA, et al (2011)</td>
<td>Project BRIGHT randomized control trial found that an intensive case management intervention spanning the periods of incarceration and release of HIV-infected</td>
</tr>
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Annex 4

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<tr>
<th>Country</th>
<th>Study</th>
<th>Summary</th>
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<tr>
<td></td>
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<td>individuals was as effective for released prisoners as a comprehensive pre-release discharge planning programme in terms of accessing medical care over the year following release.</td>
</tr>
<tr>
<td>USA</td>
<td>Zaller ND, et al (2008)</td>
<td>Of all clients in Project Bridge, 45.8% secured housing, 71% were linked to mental health care, and 51% were linked to addiction services. Despite high levels of addiction (97%) and mental health disorders (34% on medication), ex-offenders were retained in health care for a year after being released from incarceration. Regular contact was deemed essential in building trust.</td>
</tr>
<tr>
<td>USA</td>
<td>Catz SL, et al (2011)</td>
<td>Interviewees reinforced the need to deliver confidential HIV prevention-related information in prisons to reduce stigma and safety threats. Prisons need to deliver timely updates on HIV prevention and information relating to HIV care in a manner that protects a person’s HIV status.</td>
</tr>
<tr>
<td>USA</td>
<td>Pant Pai N, et al (2009)</td>
<td>Continuous ART therapy in jail inmate's benefits CD4 cell counts and control of VL especially compared to those who never took ART. Although jail inmates on intermittent ART were more likely to lose CD4 cells and experience higher VL over time than those on continuous ART, CD4 cell loss was slower in these inmates as compared to inmates never on ART.</td>
</tr>
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</table>

2.7. Needle and Syringe Exchange Programmes

As stated in the 2007 document, there is evidence that NSPs are feasible in a wide range of prison settings and prison-based NSPs appear to be effective in reducing needle-sharing and resulting HIV infection. Additionally, prison-based NSPs have additional and worthwhile benefits including a reduction in overdose risk and decreased abscesses and they can facilitate referral to drug dependence treatment programmes and lead to an increase in the number of prisoners accessing such programmes. There is no convincing evidence of any major unintended negative consequences. To facilitate the success of NSPs, prisoners need to have easy, confidential access to NSPs, and prisoners and staff should receive information and education about the programmes and be involved in their design and implementation.
The 2014 updated review supports the current recommendations and demonstrates the occurrence of needle sharing in prisons while including documented cases of reduction in needle sharing practices after the introduction of a NSP, potential decrease in drug abuse, and a reduction of HIV infection after the introduction of a NSP. Prisoners and staff interviewed do not believe that NSPs increase drug use, but that they do improve hygienic living conditions.

### 2007 Recommendations:

1. Prison authorities in countries experiencing or threatened by an epidemic of HIV infections among IDUs should introduce needle and syringe programmes urgently and expand implementation to scale as soon as possible.
2. Additional research about prison-based NSPs should be undertaken to address remaining knowledge gaps.

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<thead>
<tr>
<th>Country</th>
<th>Study</th>
<th>Summary</th>
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<tbody>
<tr>
<td>Canada</td>
<td>Milloy MJ, et al (2013)</td>
<td>Analysis of data from a cohort of PWID from 1996-2012 showed that virus levels increased when persons were incarcerated stating hesitancy to disclose HIV status and treatment interruptions and treatment delays, and. Drug use continued while in jail, reinforcing the need for needle exchange programmes in prisons.</td>
</tr>
<tr>
<td>Spain</td>
<td>Ferrer-Castro V, et al (2012)</td>
<td>In ten years a total of 15,962 syringes were supplied to 429 users and 11,327 (70.9%) were returned. The prevalence of HIV infection decreased from 21% in 1999 to 8.5% in 2009, HCV prevalence from 40% to 26.1%. Most of the inmates and civil servants believe that the programme did not increase intravenous drug use and improves hygienic living conditions in prison.</td>
</tr>
<tr>
<td>Kyrgyzstan</td>
<td>Moller LF, et al (2008)</td>
<td>After development of a needle exchange programme in two prisons, needle sharing decreased from 20% to 8% during the study period.</td>
</tr>
<tr>
<td>Iran</td>
<td>Roshanfekt P, et al (2013)</td>
<td>Interviews were conducted with prisoners who stated they had received harm reduction services. Research shows that the programmes, including needle and syringe exchange, have a significant effect on reducing the abuse of drugs among the prisoners studied.</td>
</tr>
</tbody>
</table>

**References**

Annex 5: On the ground:

Programmes serving the needs of key populations

Annex to the Consolidated guidelines on HIV prevention, diagnosis, treatment and care for key populations

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2.2.5 Transgender people

2.2.6 Programmes that serve more than 1 key population group

3. CONCLUSION
ACKNOWLEDGMENTS:

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Afghan Family Guidance Association (Afghanistan), Agência Piaget para o Desenvolvimento – GIRUBarcelos AID Foundation East-West (Eastern European and Central Asian region), AIDS Myanmar Association Country-wide Network of Sex Workers (Myanmar), Aksion Plus (Albania), All-Ukrainian Public Center Volunteer (Ukraine), Anova Health Institute – Health4Men (South Africa), Australia Indonesia Partnership for HIV – HIV Cooperation Programme for Indonesia (Indonesia), Muslim Education and Welfare Association (Kenya), BCN Checkpoint – Projecte dels NOMS-Hispanosida (Spain), Boysproject (Belgium), Callen-Lorde Community Health Center – Health Outreach To Teens (USA), CARUSEL – Roma Harm Reduction Advocacy Project (Romania), Center of Excellence for Transgender Health – University of California, San Francisco (USA), Centre for Sexual Health and HIV/AIDS Research – Sisters with a Voice (Zimbabwe), Centre for the Development of People (Malawi), Community Healthcare Network (USA), Egyptian Family Planning Association (Egypt), Espolea, A.C. – Programa de Política de Drogas (Mexico), SHARPER project, FHI360 (Ghana), Fokus Muda – Indonesian Young Key Affected Population Forum (Indonesia), HIV Law Commission (Uruguay), International HIV/AIDS Alliance (Global), Karnataka Health Promotion Trust (India), Kimara Peer Educators and Health Promoters Trust Fund (Tanzania), La Comunidad de Trans-Travestis Trabajadores Sexuales Dominicana (Dominican Republic), LVCT Health (Kenya), Marsa Sexual Health Center (Lebanon), MCCNY Homeless Youth Services (USA), Médecins du Monde (Myanmar), Médecins du Monde (Tanzania), menZDRAV – Positive Life (Russia), MOSAIC Men’s Health Initiative (South Africa), Nai Zindagi Trust (Pakistan), National AIDS Control Program (Afghanistan), National Organization of Peer Educators (Kenya), National OST Programme of the National AIDS Control programme (Iran), Naya Goreto (Nepal), Naz Male Health Alliance (Pakistan), NewGen – Youth LEAD (Asia-Pacific region), PASMO/PSI – Combination Prevention Program for HIV in Central America (Central America), Pehchan – India HIV/AIDS Alliance (India), Re-Action! Consulting (South Africa), Red de Mujeres Trabajadores Sexuales de Latinoamérica y el Caribe (Latin America and the Caribbean), Re-You – Cebu Plus Association (Philippines), River of Life initiative (Philippines), Save the Children Fund (Thailand), Sex Workers Outreach Programme (Kenya), Silueta X Association (Ecuador), SMARTgirl, FHI360 (Cambodia), Social Awareness Service Organization (India), Soins Infirmiers et Développement Communautaire - Escale (Lebanon), South African Department of Health (South Africa), South African National AIDS Council (South Africa), St. James Infirmary (USA), STOP AIDS (Albania), Streetwise and Safe (USA), Test, Connect & Treat – AIDS Institute of the New York State Department of Health (USA), Thai Red Cross – Men’s Health Clinic (Thailand), The Initiative for Equal Rights (Nigeria), Transgender Education and Advocacy (Kenya), Vietnam Authority of HIV/AIDS Control, Ministry of Health and WHO Vietnam (Vietnam), Women for Women – UNODC (Ukraine), Youth Voices Count – Loud and Proud (Asia-Pacific region) and YouthCO HIV and Hep C Society – Mpowerment (Canada).
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**Guideline development group** of the WHO Consolidated guidelines on HIV prevention, diagnosis, treatment and care for key populations

**Inter-Agency Working Group on Key Populations**

**Virtual review group** for the HIV and young key populations technical brief series

**WHO staff, consultants and interns**: Alice Armstrong, Rachel Baggaley, James Baer, Pramudie Gunaratne, Mary Henderson, Cadi Irvine, George Mugambi, Michelle Rodolph, Graham Shaw and Annette Verster

Overall coordination: **Alice Armstrong** and **Cadi Irvine**
<table>
<thead>
<tr>
<th>ACRONYMS</th>
<th>Description</th>
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<tbody>
<tr>
<td>ART</td>
<td>antiretroviral therapy</td>
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<tr>
<td>ARV</td>
<td>antiretroviral drug</td>
</tr>
<tr>
<td>FSW</td>
<td>female sex workers</td>
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<tr>
<td>HIV</td>
<td>human immunodeficiency virus</td>
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<tr>
<td>HTC</td>
<td>HIV testing and counselling</td>
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<tr>
<td>KP</td>
<td>key populations</td>
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<tr>
<td>MMT</td>
<td>methadone maintenance treatment</td>
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<tr>
<td>MSM</td>
<td>men who have sex with men</td>
</tr>
<tr>
<td>NGO</td>
<td>non-governmental organization</td>
</tr>
<tr>
<td>NSP</td>
<td>needle and syringe programme</td>
</tr>
<tr>
<td>OST</td>
<td>opioid substitution therapy</td>
</tr>
<tr>
<td>PWID</td>
<td>people who inject drugs</td>
</tr>
<tr>
<td>STI</td>
<td>sexually transmitted infection</td>
</tr>
<tr>
<td>SW</td>
<td>sex workers</td>
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<tr>
<td>TG</td>
<td>transgender</td>
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<tr>
<td>UN</td>
<td>United Nations</td>
</tr>
<tr>
<td>YKP</td>
<td>young key populations</td>
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</tbody>
</table>
1. **BACKGROUND**

The five key populations—men who have sex with men, people who inject drugs, people in prison and confined settings, sex workers and transgender people are disproportionately affected by HIV; they have an increased risk of infection, and yet are the least likely to have access to HIV prevention, testing, and treatment services because of widespread stigma and discrimination. One in two new HIV infections worldwide are in these populations.

_HIV/AIDS will never be controlled without respectful and targeted engagement with these communities._\(^{16}\)

In July 2014, the World Health Organization Department of HIV released the *Consolidated guidelines on HIV prevention, diagnosis, treatment and care for key populations*\(^ {17}\) (henceforth referred to as the *Consolidated key population guidelines*) and a series of technical briefs, *HIV and Young Key Populations: Technical Briefs* (henceforth referred to as the *Technical briefs*)\(^ {18}\) Case studies documenting programmatic good practice were collected to supplement these documents.\(^ {19}\)

The *Consolidated key population guidelines* brings together existing WHO guidance on HIV prevention, diagnosis, treatment and care for men who have sex with men, people in prisons and other closed settings, people who inject drugs, sex workers and transgender people. The *Technical briefs* describe in detail the needs of young people in key populations; spotlight critical gaps in services to address those needs; identify areas that require further research; and examine complex and contentious issues in need of leadership and action from all stakeholders. For both documents, the case studies provide important real-world information on the challenges that programmes are facing and the successes they have

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\(^{19}\) The case studies presented in this annex include those that appeared in the guidance document and in the technical briefs.
achieved—especially at the community level—in their efforts to understand and serve the needs of the people who are at the greatest risk of acquiring and transmitting HIV.\(^\text{20}\)

This annex to the *Consolidated key population guidelines* presents case studies of good practice from national, community-based and community-led programmes around the world that work with key population groups who often experience structural and societal barriers to health and social services. These case studies offer practical examples of how the community and health-care providers can deliver accessible and acceptable services to key populations.

The case studies presented here describe work on the critical enablers\(^\text{21}\) that facilitate access to services and create an enabling environment for key populations to access services. The case studies also illustrate innovative approaches to service delivery that increase uptake of HIV services, harm reduction services and retention in care. Many of the programme descriptions feature practical details on implementation strategies. Contact information is provided for all programmes listed. All of the selected case studies demonstrate that focusing on critical enablers and improved service delivery for key population groups can have a positive impact on individual and public health outcomes.

The information in these case studies from a broad range of settings is intended to contextualize and animate the guidance and recommendations presented in the *Consolidated key population guidelines* and the *Technical briefs*.

### 1.1 Objectives

This compilation of case studies represents the achievement of 5 objectives:

1. Identify successful prevention, diagnosis, and treatment and care services and interventions that address the specific needs of key population groups.
2. Identify key aspects of good practice with regard to design, implementation and monitoring of programmes focused on critical enablers and service delivery.
3. Identify programmes that demonstrate good practice in addressing the needs of young people and adolescents in key populations.
4. Highlight gaps in reaching key population groups, including young and adolescent members of key populations.
5. Complement the *Consolidated key population guidelines* and the *Technical briefs* with practical, ‘how-to’ examples for strengthening critical enablers and service delivery for key populations.

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\(^{20}\) For detailed definitions of key populations, please see the *Consolidated guidelines on HIV prevention, diagnosis, treatment and care for key populations*, WHO 2014, [http://www.who.int/hiv/pub/guidelines/keypopulations/en/](http://www.who.int/hiv/pub/guidelines/keypopulations/en/).

\(^{21}\) ‘Critical enablers’ here refers to reviewing laws, policies and practices (including decriminalization and age of consent); reducing stigma and discrimination; preventing violence; and empowering the community.
1.2 Methodology

Online survey for solicitation of prospective case studies

An informal review of current literature shaped an online survey that solicited examples of programmes providing services to key population groups, including both adults and young people. Prospective contributors were invited to participate via a web link sent to a wide network of relevant parties, including: WHO regional offices and focal points; UN partners; key population and civil society networks; international and national NGOS; and individuals managing or implementing programmes. Initial contacts were requested to circulate the survey to their wider networks. The online survey took approximately 20 minutes to complete and included questions on general programme characteristics (e.g. key population group, country, region, organization; type of programme) and more detailed programme-specific information (e.g. description of activities, results/achievements, and monitoring and evaluation).

Participation was voluntary, and an option to exit the survey at any time was available. Organizations could also elect to maintain anonymity in publicly available documents. The survey was available in English in October 2013, and in Russian, Spanish and French in November 2013. The survey, in all languages, was closed on 24 December 2013.

Initial screening and draft submissions

Surveys that were not complete, did not provide programme name or contact information were excluded. The remaining surveys were translated into English, when needed, and exclusionary criteria were applied to all data collected from the online survey: programmes with fewer than 10 clients accessing their services per month, programmes that did not address any of the five key populations or monitor and evaluate their interventions, and other issues that deemed the data provided unsuitable for inclusion as a case study.

Potential case studies were then screened to maximize regional, national, key population and intervention type representation, as well as for evidence of appropriate monitoring and evaluation. Each programme example was reviewed to identify a ‘focus area’, which usually reflects a particularly interesting or innovative approach to provision of accessible, acceptable and affordable services for key populations. Around 20 programmes from each region were then provided a template and requested to submit a written case study (approximately 400 words), which included a description of their programme purpose, details regarding challenges, lessons learnt and successes, and where possible, information on the monitoring and evaluation that is used to measure progress.

Review and selection

Survey Monkey software was used.
Submitted case studies were reviewed and edited to improve standardization and quality. These studies were then reviewed by the Guideline Development Group and a Virtual Review Group for the HIV and young key populations technical brief series. While reviewing the studies, the two groups highlighted focus areas within the submitted case studies. Organisations were then contacted for additional information to address these focus areas. WHO writers worked closely with all organisations to finalize the case studies and ensure that the content was accurate and representative. Consensus was reached through a final selection process to include 38 case studies within the Consolidated key population guidelines and/or HIV and young key populations technical brief series. This web annex includes those 38 plus an additional 31 case studies.

1.3 Selection process

There was an enthusiastic response to the online survey, with over 400 programmes submitting general information, of which around 380 programmes met the criteria for consideration. Programmes responding to the survey presented interventions supported by government, UN agencies, bilateral partners, international and national non-governmental organizations and community-based organizations. Of the programmes that responded to the survey, 32% primarily serve communities of men who have sex with men, 27% serve sex worker communities, 21% serve people who inject drugs, 13% serve transgender communities and 7% serve individuals in prisons or other closed settings. A range of services are offered by these programmes, broadly including HIV testing and counselling, sexually transmitted infection (STI) screening and treatment, antiretroviral therapy (ART), needle and syringe programmes (NSP), opioid substitution therapy (OST), advocacy and social and economic support. Nearly 75% of submissions reported that they undertake monitoring and evaluation activities, while only around half were able to provide an internal or external evaluation report.

Submissions were then screened for geographical and programmatic representation, and follow-up information was requested for further consideration. Around 100 programmes serving adults or young people were requested to submit a written case study following a defined format, and nearly 90 programmes submitted draft case studies. Further follow-up questions and editing resulted in the inclusion of 38 cases studies in the Consolidated key population guidelines and Technical briefs and an additional 31 case studies that are included in this annex.

Figure 1. Selection process

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23 Around 80% of initial responses to the survey came from Africa, the Americas, Europe and Southeast Asia regions, while 5% of programmes had a global reach.
1.4 Case study profiles

This section presents summary profiles of programmes that contributed selected case studies. The programmes represented by case studies offer a range of services and interventions including HIV/STI
testing, counselling, treatment and care, harm reduction (including OST and NSP), SRH, support (social, psychological, legal and peer-led outreach), training and advocacy.

Figure 2. Regional representation

Selected case studies by WHO region

Africa
Americas
Europe
Eastern Mediterranean
Southeast Asia
Western Pacific
More than 1 region

Figure 3. Programme type
In the figure below, programmes serving young key populations (YKP) address all 5 of the key population groups covered in the guidelines and target individuals from 10-24 years of age. Programmes serving more than one group are usually serving MSM and TG, or MSM, TG and SW. Several groups also serve PWID along with other groups and a few serve all 5 KP groups.

Figure 4. Primary key population group/s served
2. CASE STUDIES

This section is organized into two sub-sections that reflect the presentation of the case studies in the Consolidated key population guidelines—those that address critical enablers and those that illustrate different approaches to service delivery. Each case study provides a brief description of the programme, including the purpose, focus area and important elements of programme activities. Most of the case studies also note key successes and challenges, in some cases mentioning how challenges were addressed and/or resolved.

An asterisk (*) denotes case studies that also appeared in the guidelines document or in the technical briefs on young key populations.

2.1 Programmes addressing critical enablers

2.1.1 Men who have sex with men

Canada | Community engagement and risk reduction*

YouthCO HIV and Hep C Society – Mp powerment
http://www.youthco.org/mpowerment

Mp powerment targets young gay men through a community engagement model in which educational programming on HIV, sexual health and harm reduction is provided within a wider context of social events. This approach aims to support young men who have sex with men to think of themselves as
part of a community, and to strengthen community norms for sexual health, coping with stigma, and risk reduction.

Social events provide a calmer environment than bars and clubs for young gay men to learn from each other and to form friendships. Events are publicized through social media, and between 10 and 20 men typically attend. Film viewings can be used as a springboard for discussion about community values and experiences. Alongside films, games and picnics, discussions are held on topics such as healthy relationships, experiences with shame, and HIV prevention. Through these events young men are invited to attend YouthCO workshops that support their education around HIV, safer sex and sexual wellbeing. Young gay men are the core organizers and leaders of all Mpowerment events, backed up by YouthCO staff members who are under 30 years of age.

The project has successfully reached hundreds of young gay men throughout British Columbia by empowering volunteers to become leaders within their own social networks. As the project also relies on staff to tap into their own social networks, it can be hard to maintain personal and professional boundaries, and YouthCO has found it important to support staff in their own self-care to avoid burnout. Mpowerment has also learned the importance of an accessible and youth-friendly community space (with condoms and lubricants freely available) where participants feel welcome and accepted.

### 2.1.2 People who inject drugs

**Afghanistan | Improving acceptability of harm reduction services**

**National AIDS Control Program**

[http://www.nacp-moph.org](http://www.nacp-moph.org)

The National AIDS Control Programme (NACP) works at the national and local levels to increase community acceptance of harm reduction services for people who inject drugs.

The NACP aims to provide a comprehensive package of harm reduction and social services for people who inject drugs in Afghanistan. The programme runs a fixed facility in an area with a high concentration of injecting drug users, and supports an outreach team to serve the needs of the community in surrounding areas and to reach people who are reluctant to use formal services. However, stigma, discrimination, detention and police violence are major challenges to service delivery. At the central level, NACP meets with law enforcement officials and ministry representatives to increase awareness of the issues that people who inject drugs face, and to help them understand the importance of harm reduction for the injecting community as well as for society in general. In the provinces, NACP conducts training and sensitization for police officers, community elders and ‘mollahs’ (religious leaders). Actual service providers are involved in these events to improve engagement between local stakeholders and the harm reduction services.
Stakeholders are also involved as much as possible in the planning and implementation of harm reduction services.

To date, NACP efforts have reached 8 of 34 provinces, and around 800 police officers have been trained; anecdotal reports indicate that harm reduction services appear to be better understood and accepted by communities in areas where NACP activities have taken place, and there are fewer reports of police harassment or violence. The high turnover in police departments, especially in the provinces, is an ongoing challenge that requires continuous work with those who are newly hired.

**Nepal | Meaningful participation in advocacy for protection of rights***

**Naya Goreto**


Recognizing the lack of specific laws or policies in Nepal to support people who inject drugs and the lack of services at the community level, Naya Goreto created *Bridging the Gap: Health and Human Rights Programme for the Key Population*. The programme aims to engage stakeholders across the spectrum, from parliamentarians to local councillors, public health officials to health volunteers, in advocacy on issues of concern to the community of people who inject drugs.

Naya Goreto emphasizes the meaningful participation of injecting drug users at all levels of the programme. More than 200 people from the community have been trained to lead activities ranging from situation analysis to advocacy campaigning and programme monitoring. The programme has brought together key stakeholders to establish a committee that lobbies for the health and human rights of people who inject drugs. Empowerment activities have included advocacy in small-group environments; forming advocacy networks for broader reach; linking people who inject drugs with experts and other concerned stakeholders for information on programmes and budgets; mobilization of community representatives to participate in consultation meetings with key government officials; lobbying duty bearers for the health and human rights of the injecting community.

Naya Goreto has built strong partnerships between people who inject drugs, creating a sense of solidarity to collectively address the issues that directly affect them. Such issues are now included in the yearly action plans of local government and civil society organizations. Annual budgets have been secured from local government bodies to conduct drug awareness programmes. A member of the injecting community now sits on the District AIDS Coordination Committee. Overall, there is greater community awareness of issues that affect people who inject drugs.

**Portugal | Decriminalizing drug use***

**Agência Piaget para o Desenvolvimento – GIRUBarcelos**

As of 2012, 21 countries had taken steps to decriminalize drug use and possession. For example, Portugal changed its legislation in 2001 to turn possession of controlled drugs into an ‘administrative offence’—those caught with drugs for personal use are sent to a ‘dissuasion board’ rather than face prosecution and possible incarceration. An independent study examined the impact of the changes and found that:

- The number of drug users in treatment expanded from 23,654 in 1998 to 38,532 in 2008.
- Between 2000 and 2008 the annual number of new cases of HIV among drug users fell from 907 to 267, a decrease attributed to the expansion of harm reduction services.
- Contrary to predictions, major increases in drug use did not take place; instead, evidence indicated reductions in problematic use, drug-related harms and overcrowding of the criminal justice system.

Community organizations continue to be essential to tackling stigma and discrimination and improving access to services. Agência Piaget para o Desenvolvimento, founded in 2004, works with vulnerable people and communities on access to health care, employment and education, seeking to empower these populations and reinforce social cohesion. They run GIRUBarcelos, a multidisciplinary outreach team working primarily with heroin and cocaine users and sex workers in northern Portugal, focusing their efforts on harm reduction. Through their efforts, discrimination towards people who use drugs, including by health-care professionals, has been reduced following regular meetings, mediation efforts between communities and service providers, debates and a local radio programme entitled ‘GIRU Conversations’. The presence of a peer educator on the team and the constant involvement of people who inject drugs are the cornerstones of programme interventions and considered critical to its success.

**Romania | Building bridges: advocacy for community acceptance**

**CARUSEL – Roma Harm Reduction Advocacy Project**
http://www.carusel.org

In 2012 CARUSEL developed an advocacy project to sensitize the National Agency for Roma (NAR) and other major Roma NGOs to the drug use situation in the community, especially regarding the vulnerability, stigma and discrimination that Roma drug users face. In order to build political will

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and commitment on these issues, CARUSEL recognized that community acceptance was the first step.

CARUSEL’s advocacy strategy includes dissemination of key human rights and public health messages, trainings for sensitization and capacity building, and field visits for data collection, outreach to community leaders and supervision of activities. Drug users themselves are involved in all project activities. A scholarship programme supports young people to attend the Roma Harm Reduction Summer School to develop outreach and harm reduction advocacy skills.

As a result of this work, NAR and other Roma NGOs are becoming more understanding of drug use in the Roma community, and there is greater acceptance of the users themselves. Roma NGOs are now providing financial assistance for CARUSEL to purchase harm reduction supplies and to provide technical expertise for reporting cases of human rights violations against all drug users. The needs of Roma drug users—including culturally appropriate harm reduction activities—are now addressed in the national strategy and action plans of the National Anti-drug Agency.

## 2.1.3 Sex workers

### India | Addressing violence and legal literacy*

Karnataka Health Promotion Trust  
http://www.khpt.org/

Karnataka Health Promotion Trust (KHPT) has been working on HIV prevention among sex workers for 10 years. Violence against the community served by KHPT is a particular concern, and addressing violence against sex workers requires partnership among like-minded organizations. When sex worker community members strongly expressed the need to prevent and address violence, KHPT responded by working closely with law enforcement and justice officials, sensitizing them to the realities faced by the community and to their needs for protection and services, while advocating that society's duty bearers not perpetrate or condone violence against sex workers. In partnership with KHPT:

- The State's Women and Child Welfare Department made services addressing violence against women available to sex workers.
- Community-based organizations worked with sex workers in 30 districts to alert them to their rights.
- The Alternative Law Forum and the National Law School of India developed and conducted legal literacy training for sex workers.
- The Centre for Advocacy and Research, a non-governmental organization, conducted media advocacy and trained sex workers as media spokespersons to talk about the violence they face, their resilience and their actions to prevent and respond to violence.
Latin America and the Caribbean | Regional collaboration for rights of sex workers

Red de Mujeres Trabajadores Sexuales de Latinoamérica y el Caribe (RedTraSex)
http://www.redtrasex.org

Red de Mujeres Trabajadores Sexuales de Latinoamérica y el Caribe (RedTraSex) is a regional network founded in 1997 by a group of national female sex worker organizations in Latin America and the Hispanic Caribbean for the defense and promotion of their rights. The network seeks the legal recognition of sex work; the elimination of social and institutional violence against female sex workers and the impunity that contributes to it; the repeal of legislation that criminalizes sex work; engagement with judicial and public civil servants to sensitize them to the problems of female sex workers; and participation of community members in spaces where decisions on issues that affect community are made.

Since 2012, RedTraSex has been working to reinforce the technical capacity and critical enablers that reduce the vulnerability of female sex workers to HIV through a regional strategy supported by the Global Fund. National organizations, led by female sex workers, coordinate activities within countries, while sub-regional units provide additional technical support as needed. Training of female sex workers strengthens knowledge and capacity for HIV prevention and increases the capacity of national partners for programme coordination, implementation, policy review and development, and review of the legal frameworks affecting the community. RedTraSex also works to ensure the participation of community members in the decision-making process, and to increase the awareness of strategic stakeholders, including law enforcement and health service providers, around gender issues and sex work. In addition, communication campaigns aim to influence public opinions around sex work and to reduce stigma, discrimination and violence. Partnerships with other organizations help to optimize the use of resources and to strengthen the overall impact of national and sub-regional efforts.

Monitoring and evaluation are conducted at the national and regional levels against country-specific baseline data that were collected in 2012. Impact of programme activities is measured in terms of female sex workers reached, contacted and trained as well as broader impacts on community attitudes, policy changes and legal reforms. Over 30,000 female sex workers from 14 countries have been reached by RedTraSex activities in 2013. However, stigmatization of the community and the lack of sex work regulations continue to fuel violence and police aggression. RedTraSex works to compel government accountability on these issues and to establish sex work regulations that will help to recognize and protect female sex workers throughout the region.

Tanzania | Income generation for young sex workers

Kimara Peer Educators and Health Promoters Trust Fund
http://142.177.80.139/kimara/

Kimara Peers, a community-based NGO, implements HIV prevention programmes in a low-income area of Dar es Salaam. Many programme participants are young adults (18–25 years) who sell sex. Kimara Peers also offers them the opportunity to take part in income-generating projects, which
are seen by participants as a way to supplement their sex work income or to replace their source of income as they seek to transition from sex work.

Almost 1,000 programme participants have been involved since the initiatives were first offered in 2007. In groups of up to 30, young people learn about a variety of issues, including health, self-management and how to spend, invest or borrow wisely as individuals and as a group. Twenty-five sex workers volunteer as trainers for the groups. Groups who save together can take out small loans to finance other income-generating projects. Some programme participants work individually, selling snacks, raising poultry, or working as hairdressers, while some income generation is done as a group. In either case, the young people work together on project design and other planning, and they agree on how to manage the resources they have acquired.

All programme participants are expected to demonstrate a commitment to the group's goals and the 'constitution' that the group draws up for itself. They also participate in weekly meetings where progress is discussed and problems are addressed.

### 2.1.4 Transgender people

**Kenya | Creating an environment for protecting transgender rights**

Transgender Education and Advocacy

http://www.transgenderkenya.com

Transgender Education and Advocacy (TEA) aims to raise awareness and advocate for the human rights of transgender people, and to educate the community on sexual and reproductive health and risks.

TEA facilitates consultations between transgender people, their families, relevant stakeholders, duty bearers and service providers to increase understanding and tolerance of transgender people. TEA addresses the discrimination, abuse, social and legal exclusion and health issues faced by transgender people through legal and policy channels in order to reduce the incidence and prevalence of HIV and other diseases that affect this community and to support the specific needs of transgender people, such as gender reassignment. Some key advocacy goals have included:

- Official recognition of transgender peoples’ names and gender identity in national ID cards, passports and other official documents;
- Preparation and implementation of a national guideline on gender reassignment that will facilitate inclusion of transgender health issues in mainstream health services;
- Publication of objective, sensitive and accurate articles in the national media;
- Anti-discrimination practices and policies.

To reinforce this advocacy work, TEA builds the capacity of transgender people to advocate for their rights, to take on leadership roles, and to confront the personal and structural challenges they face, particularly those within public health and social service settings. TEA also educates the
transgender community on how to avoid social and sexual risks, to embrace healthier lifestyles and to forge stronger links with their families.

TEA interventions have helped to increase the self-confidence of transgender individuals to confront social and legal challenges and to reduce cases of sexual violence and exploitation, especially among transgender women. The Medical Practitioners and Dentists Board of Kenya is in the process of developing guidelines for gender reassignment, an effort supported by TEA advocacy activities. However, transphobia is still a major constraint to progress in many areas.

2.1.5 Programmes that serve more than 1 key population group

Asia/Africa | Training health providers on the needs of young key populations *

International HIV/AIDS Alliance – Link up
http://www.link-up.org

The Link Up project aims to improve the sexual and reproductive health and rights of young people living with and affected by HIV with a focus on increasing access for young key populations to integrated sexual and reproductive health and HIV services. The programme does this by linking peer educators and their clients with community- or clinic-based integrated services. The project is implemented in 5 countries—Bangladesh, Burundi, Ethiopia, Myanmar and Uganda—by a consortium of community-based and service-delivery organizations, led by the International HIV/AIDS Alliance.26

Consultations with young key populations identified stigma by service providers as one of the main barriers to accessing services. In response, Link Up implemented a 5-day training programme for service providers in each country, with the objective of sensitizing them to the needs of most-at-risk young people, and thereby decreasing stigma and increasing client satisfaction. Members of young key population communities were involved at the country level to review the training material. Topics included service integration and linkages, as well as gender, sexuality, stigma and discrimination. Young people participated in the trainings and helped lead different sessions, including a lively panel discussion where they shared their experiences. This particular session had a great impact on providers, all of whom had worked with young people, but not necessarily with young men who have sex with men or young people who sell sex. The participants learned that they must take time to hear and understand the experiences of young key populations, and they appreciated the opportunity to address any feelings of discomfort about working with them.

26 Link Up is led by the International HIV/AIDS Alliance (IHAA). Its partner organizations in policy, research, and programme development are the ATHENA Network, the Global Youth Coalition on HIV/AIDS (GYCA), Marie Stopes International (MSI), Population Council, and STOP AIDS NOW! Implementing partners include local IHAA and Stop AIDS Alliance branches and linking organizations, including the HIV/AIDS and STD Alliance Bangladesh (HASAB); Organization for Support Services for AIDS (OSSA) in Ethiopia; Community Health Alliance Uganda (CHAU); and Alliance Burundaise contre le Sida (ABS) in Burundi.
Link Up has organized further capacity building for peer educators, social workers, midwives, nurse counsellors and clinical officers. All of these trainings include components on youth participation and gender and sexuality to ensure that services are youth- and key population-friendly and non-stigmatizing.

Asia-Pacific | Leadership and advocacy training*

NewGen – Youth LEAD
http://www.youth-lead.org

In 2011, Youth LEAD, a regional network of and for young key populations in 20 countries across Asia and the Pacific, created NewGen Asia, a five-day leadership course for YKP leaders. A technical working group, supported by young key populations, leaders of Youth LEAD, academic experts and UN partners developed the course over a period of a year.

The NewGen curriculum uses a range of participatory activities to build capacity to understand the personal, familial, institutional, structural and cultural influences that lead to HIV vulnerability; improve personal leadership strengths and skills for teamwork; develop presentation and public speaking skills on sexual and reproductive health, HIV and related issues; and understand and use data and evidence to inform advocacy. More than 200 young key population members have participated in NewGen training in Bangladesh, Brunei Darussalam, Indonesia, Myanmar, Philippines and Sri Lanka. More than 50 trainers have been trained regionally, and NewGen courses are planned for Cambodia, China and Thailand.

All stages of programme development were evaluated through multiple methods, including rapid feedback through video interviews of consenting participants; focus group discussions; in-depth interviews; and pre- and post-course evaluations. The Indonesia National AIDS Commission has adopted NewGen to train peer educators nationwide, and the International HIV/AIDS Alliance has integrated the training into its Link Up programme for young key populations on sexual and reproductive health. New community networks of young key populations have since been established in several countries, including Myanmar, and social media are used to sustain connections and support for participants.

Asia-Pacific | Addressing stigma through an awareness campaign*

Youth Voices Count – Loud and Proud
http://www.youthvoicescount.org

Loud and Proud is a regional advocacy campaign led by Youth Voices Count, addressing the issue of self-stigma and highlighting its links to the HIV vulnerabilities faced by young men who have sex with men and young transgender people in Asia.
Through the campaign, Youth Voices Count aimed to draw attention to the need for more timely services that tackle psychosocial issues and promote self-acceptance, self-confidence and health-seeking habits for young men who have sex with men and young transgender people. The campaign took place in four countries—Indonesia, Mongolia, Philippines and Viet Nam—and featured a series of in-country activities, community-friendly events and the production of four short videos. *Loud and Proud* built the capacity of young men who have sex with men and young transgender people to do advocacy using multimedia platforms and to leverage high-tech and social networks.

A core working group identified priority countries for the campaign and allocated a budget of approximately US $1,000, as well as a small amount of additional funding for community events and activities. The campaign was launched to coincide with the International Day against Homophobia and Transphobia. It was disseminated online using e-list servers and social media including Facebook, as well as through national partners. The videos were also displayed at a number of community events and international conferences.

**Indonesia | Training for positive prevention**

**Australia Indonesia Partnership for HIV – HIV Cooperation Programme for Indonesia**


The HIV Cooperation Programme for Indonesia (HCPI) supports training for positive prevention with the aim of empowering people living with HIV through improved self-esteem, confidence and ability to live healthier lives, with reduced exposure to infections for themselves and others.

HCPI supported the formation of a small collaborative team of seven people from national networks of people living with HIV and key populations formed to develop Positive Prevention facilitator training materials, based on their own experiences and knowledge. Positive Prevention facilitators are trained to incorporate the information and skills they learn into routine activities of existing peer support groups and NGO programmes. The materials target people who inject drugs and their partners; male, female and transgender sex workers and their partners; and men who buy sex and their partners. Four modules cover prevention of HIV and other sexually transmitted infections, disclosure of HIV status, adherence to antiretroviral treatment, and self-acceptance and coping with discrimination. External experts reviewed the modules, and they were field tested and launched in 2012.

Fifty-four people from 23 provinces—almost all of whom were key population community members—were trained using the four main modules as well as materials on sexual and reproductive health for people living with HIV and facilitation skills. Follow-up training for group facilitators and training of trainers for female sex workers was also conducted. Following a workshop for young members of key populations, the sex workers who had participated demonstrated increased knowledge and enthusiasm during regular peer support group meetings. They shared new knowledge with those who had not participated in the workshop, the information was correct and clearly explained, and they were able to articulate Positive Prevention concepts.
and principles. They demonstrated a higher comfort level speaking in front of others, and there was a greater sense of solidarity and empathy among the group.

A series of advocacy and socialization meetings with a broad range of stakeholders was also critical for support and integration of Positive Prevention in the national programme through the efforts of the National AIDS Commission. The training modules will need to be revised based on implementation experience and integrated into the next National Strategy and Action Plan. Results of facilitator training evaluations showed that all learning and skills indicators had improved significantly. A simple survey for assessing post-training behavioural and attitudinal change has been developed and will be distributed by the networks nationally in early 2014.

Indonesia | Engagement of young key populations on HIV and SRH*

Fokus Muda – Indonesian Young Key Affected Population Forum
https://www.facebook.com/FokusMuda; http://fokusmuda.wordpress.com/

Fokus Muda promotes the meaningful involvement of young key populations in the HIV and broader sexual health and rights response in Indonesia. The programme brings together young people aged 15–27 years for advocacy, capacity building and technical assistance, and to help them be effective leaders in representing young people's issues and securing rights for themselves.

To develop an advocacy toolkit for use by young key populations at the local level, the programme conducted extensive consultations and capacity building with young people who inject drugs, young people who sell sex, young men who have sex with men, young transgender people, and young people living with HIV from 11 provinces with high HIV prevalence. Capacity building sessions were held separately because of the differences between the profiles and interests of the various key populations. Each participant represented a local community-based organization and had been actively engaged with their community for at least one year. An additional national consultation meeting for young key population members was held.

Participants were encouraged to identify the issues of greatest concern for them. For young people who inject drugs for example, the issues were the lack of services specific to their needs and relevant harm-reduction programming. Outcomes and recommendations from the consultations were fed back to the participants and to other stakeholders, and formed part of the data used in advocacy about the government’s 2015-2019 National Strategic Plan on AIDS.

Uruguay | A national dialogue supports legislative change*

HIV Law Commission
http://www.hivlawcommission.org

In 2010 the United Nations Development Programme (UNDP) launched the Global Commission on
HIV and the Law to develop actionable, evidence-based recommendations for a response to HIV that protects and promotes the human rights of people living with HIV, and who are more vulnerable to HIV. The Commission's work focuses on generating constructive dialogues between civil societies and governments on issues related to HIV and the law, going beyond identifying problems to develop and share practical solutions.

In Uruguay a national inter-sectoral commission was organized by the Ministry of Health, the Ministry of Social Development, trade union organizations, the National Council for HIV/AIDS Response (CONASIDA), the Federation of Sexual Diversity and the Parliamentarian Commissioner for Prisons. This commission called for a national dialogue on HIV and human rights to harmonize and improve national legislation related to the HIV response. Conducted with the strong support of the UNDP Regional Office, UNFPA and UNAIDS, the two-month initiative provided an opportunity for people affected by and vulnerable to HIV to present evidence on issues that have been silenced by restrictive legal environments. Individuals and civil society organization presented almost three-dozen cases of human rights violations. Those involved: HIV-related issues of sexual orientation and gender identity; discrimination in health services, employment and education; sex work; police brutality; access to treatment; intellectual property; and the human rights of people living with HIV.

This national dialogue contributed to the development of a new, comprehensive HIV law. The final report of the dialogue, presented to parliament in May 2014, identifies gaps in legislation, laws detrimental to the HIV response and negligence in applying laws that would promote the response. In addition, it suggests best practices and makes recommendations from a human rights perspective. Advocacy and mobilization of civil society and lesbian, gay, bisexual and transgender groups have driven this dialogue, along with the concerted efforts and the partnerships of UN agencies, government and academia.

The CONASIDA Country Coordinating Mechanism will implement and follow up the main recommendations from the dialogue to support the HIV Law Project. Additionally, the recently developed National Institute on Human Rights in Uruguay, also affiliated with the dialogue, is now committed to advocating for and monitoring implementation of the updated laws.

**USA | Support services for homeless LGBTQI youth**

**MCCNY Homeless Youth Services**

[http://www.mccnycharities.org](http://www.mccnycharities.org)

The Metropolitan Community church of NY (MCCNY) Homeless Youth Services provides emergency housing each night for 14 lesbian, gay, bisexual, transgender, queer, or intersex (LGBTQI) young people aged 18–24 years. The programme is integrated with supportive services including HIV testing and counselling (HTC), mental health, medical care, syringe access, case management, anti-violence education and job training.
Services are developed through conversations with programme clients, who are considered the experts on their own experiences, and who understand the services they need. Staff attend a weekly 'house meeting' where clients talk about successes as well as gaps in services. Programmes are then developed in response to these conversations. For example, after transgender participants expressed a need for reliable, ongoing access to health services, the programme arranged for an on-site enroller to help them access benefits through the Medicaid programme. Transgender clients also expressed a need for hormone therapy, which led to a partnership with an HIV/AIDS coalition that takes referrals for hormone initiation and maintenance without waiting lists. Focus groups are conducted annually with programme participants to evaluate services. The clients are also encouraged to discuss programming needs with the executive director. Feedback is incorporated into programme monitoring and evaluation processes and reports.

In 2013, the programme assisted over 200 LGBTQI homeless youth to access transitional or long-term housing, and HTC and referrals were provided for 145 clients. Many former clients have returned to work with the programme as volunteers; some have become street outreach workers, volunteer nutrition advisors, facilitators for self-defense training, and even programme staff: the current HIV testing coordinator and case manager are former programme clients.

**USA | Youth-led advocacy against discrimination**

**Streetwise and Safe**
http://www.streetwiseandsafe.org

Streetwise and Safe (SAS) builds and shares leadership, skills, knowledge and community among lesbian, gay, bisexual, transgender, queer and questioning (LGBTQQ) youth of colour aged 16 to 24 years who experience criminalization, including youth who are—or are perceived to be—involving in selling sex. Many of these young people have experienced homelessness or are currently homeless, and many of them have sold sex for the things they need to survive.

SAS youth leaders conduct ‘know your rights’ workshops specifically tailored to LGBTQQ youth to share essential information about their legal rights as well as strategies to increase safety and reduce the harms of interactions with police and the court system. SAS also creates opportunities for youth to participate in policy discussions, speak out on their own behalf, and act collectively for their rights. SAS has been a leader in a campaign to end the discriminatory use of ‘stop and frisk’ procedures and other police misconduct. SAS youth testified before local and state government and successfully lobbied for changes to the New York City Police Department Patrol Guide to address violations of the rights of transgender and gender non-conforming people.

Currently, SAS is campaigning as part of the Access to Condoms Coalition to end the use of condoms as evidence in all laws penalizing the sale of sex under the New York Penal Law. Condoms found by police during stop and frisk encounters are sometimes confiscated or used as evidence for charges related to the sale of sex or trafficking. This practice particularly affects youth who are homeless or
without a stable place to live. As a result of SAS advocacy, in May 2014 the New York City Police Department announced that it would discontinue the use of condoms as evidence in certain of these offenses, although SAS wants to see more far-reaching policy changes. As an SAS campaign staff member points out, “Police and courts are never an appropriate solution for youth who are selling sex, let alone police practices that put youth at risk for HIV, STIs and unwanted pregnancies.”

2.2 Approaches to service delivery

2.2.1 Men who have sex with men

Ghana | Using social media to reach men who have sex with men*

SHARPER (Strengthening HIV/AIDS Response Partnership with Evidence-based Results)

The SHARPER project tested use of social media by community liaison officers (CLOs) to identify unreached men who have sex with men. The project launched ‘MSM.net’ in two locations, through informal mapping of the community’s networks. CLOs were selected from networks not previously reached by peer educators, and they received training on HIV, health information and services. The men were then reached by CLOs through social media using smart phones and laptop computers. ‘Reached’ is defined as receiving a risk assessment, information on HIV prevention and a referral to HIV testing and counselling (or another HIV service).

In 2013 more than 15,000 men who have sex with men were reached through Facebook (45.6%), WhatsApp (13.4%) and other social media platforms. In Accra 82% of the men reached by this approach had not had previous contact with a peer educator. In Kumasi 66% had never been reached before by any intervention. The CLO in Accra identified eight male sex worker brothels and networks previously unknown to the project and other organizations that serve the MSM community.

Social media proved to be an important means to reach the community that peer educators would not usually reach. This group tended to be older, more educated, single, have a higher monthly income, and (in Accra) to report a larger social network of men who have sex with men than those reached by peer educators. Key challenges included the selection of the ‘right’ community members

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to lead social media outreach, i.e. individuals who were already well networked with many entry points to the target communities.

**Malawi | HTC services for men who have sex with men**

Centre for the Development of People  
http://www.cedepmw.org

The Centre for the Development of People (CEDEP) was established in 2006 to address the needs and challenges of minority populations in Malawi in the context of human rights, health and social development. One of their projects aims to provide services that are friendly to men who have sex with men in an environment where homophobia and criminalization of same sex practices marginalize the community, resulting in poor access to services.

CEDEP peer educators identify and mobilize men who have sex with men through the snowballing technique. During outreach activities, they provide accurate HIV prevention information, distribute condoms and lubricants and provide referrals for cases that require a professional health provider and facility-based services. In addition, peer educators promote safer sex practices and support empowerment and self-efficacy to combat ‘self-stigma’. Sensitization of health service providers and other key stakeholders helps to improve access to HIV services, as well as the quality of those services, for men who have sex with men. Advocating for both a public health and human rights approach to the delivery of health services for community members enables health providers to understand the importance of non-discriminatory services. Men who have sex with men in the CEDEP target area report that stronger linkages with health providers have reduced stigma, and the use of peers has proven effective in mobilizing the community.

As of August 2014, CEDEP has trained 80 peer educators to work with the MSM community; this has led to greater mobilization of a previously hidden group of people and increased partnership with vital health services. CEDEP has supported the development of IEC materials in collaboration with peer educators, ensuring the appropriateness and effectiveness of information and messages. During CEDEP-facilitated focus group discussions, men who have sex with men have demonstrated strengthened confidence and capacity for activism, demanding information and increased access to services that address their specific needs, such as condom-compatible lubricants. More community members are now visiting the health facilities to access services, and health-care workers provide quantitative feedback through the peer educators on referrals and uptake of services.

**Nigeria | HIV prevention, care and support**

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28 Many individuals from key populations experience self-stigma, which occurs when they internalize the social myths and prejudices that family members, friends, health workers and society in general exhibit toward key populations. Self-stigma can cause shame and a loss of self-esteem, and it can provoke thoughts of self-harm and suicide.
The Initiative for Equal Rights
http://www.initiative4equality.org

The Initiative for Equal Rights (TIER) was established in 2006 as a response to the discrimination and marginalization of lesbian, gay, bisexual and transgender people in Nigeria, especially regarding access to health services. One of TIER's projects is the Integrated MARPs29 HIV Prevention Programme (IMHIPP)30 with a priority focus on men who have sex with men. IMHIPP seeks to reduce the impact of HIV on men who have sex with men, their sexual partners and their dependents by ensuring the provision of HIV prevention, care and support services in a legally constrained environment.

IMHIPP uses advocacy, communication and capacity building to address the needs of the community. Advocacy with key stakeholders promotes a better understanding of the human rights and needs of men who have sex with men and their families. Social media and community outreach are used to disseminate HIV information and education to the MSM and broader communities. Some men who have sex with men are selected for training in mentorship to serve as peer educators and supporters. To support uptake of services, referrals are made to pre-screened services with sensitive and knowledgeable providers who understand the needs and issues facing men who have sex with men; when individuals are uncomfortable seeking services alone, IMHIPP offers accompanied visits to health facilities. For MSM community members with AIDS-related illnesses, IMHIPP-trained providers deliver palliative care. Monthly field visits monitor the accuracy of prevention messages that clients are receiving. Field data are validated through telephone calls to verify that clients understand a minimum of three HIV prevention strategies.

Over 50 volunteers have been trained as peer educators, and over 5,000 members of the MSM community living with HIV have received HIV information and services, including ART and psychosocial support. An impact evaluation survey conducted in 2013 revealed that 73% of men who have sex with men reached through IMHIPP services reported correct and consistent use of condoms from November 2012 to April 2013 compared to 43% at the inception of the programme in 2009. Passage of the Same-Sex Marriage (Prohibition) Act in 2013 has prevented information dissemination and MSM community gatherings, resulting in the temporary suspension of some IMHIPP activities. This legislation is also likely to have caused a drop in the minimum number of clients reached each month from 250 to 80. As an initial response to this situation, TIER has added safety and security tips—e.g. avoiding the risks of cyber dating and secluded social venues;

29 MARP is the acronym for ‘most at-risk populations’; people at risk and/or criminalized for their behavior are now more widely referred to as key populations.

30 IMHIPP is funded by USAID (2009–2014) through Heartland Alliance International, which provides technical support, training and mentoring. http://www.heartlandalliance.org/international/
minimizing vulnerability to blackmail, extortion and arrest; and emergency hotline numbers—to its trainings and outreach events.

**Philippines | Mobile outreach to young men who have sex with men**

Re-You – Cebu Plus Association
https://www.facebook.com/re.you.9

In 2012, 41% of reported cases of HIV in the metropolitan area of Cebu, Philippines, were among young people. In response, Cebu Plus Association created a youth wing, Re-You, which runs Responsible Youth-on-the-Move, a community-based mobile education programme offering education and voluntary counselling and testing for HIV and other STI to young key populations. The great majority of those served are young men who have sex with men (aged 15–24 years).

Supported by Youth LEAD through the Robert Carr Civil Society Networks Fund, the programme uses a minivan to reach different locations within the metropolitan area and provide young people with services on the spot. Outreach areas include cruising sites and other places where young men who have sex with men gather. Services are usually offered at night, when community members are out and about and easier to contact. Outreach staff are themselves young MSM community members.

Some of the challenges faced by the programme include the cultural stigma associated with seeking professional help, and concerns about confidentiality. This has been addressed by securing referral agreements with HIV-proficient physicians and social workers at government clinics and other health-service providers. Re-You observed that most young men who have sex with men lack knowledge about available services, especially for STI management, while others were afraid to take an HIV test, doubting their ability to cope with a positive diagnosis. Re-You works to gain their trust by emphasizing that testing is voluntary and offering referrals to support services.

**Russia | Anonymous counselling in a constraining environment***

menZDRAV – Positive Life
http://www.menzdrav.org

In partnership with the NGO Phoenix PLUS, the menZDRAV Foundation offers services to young men who have sex with men who are living with HIV, ages 18–25, in six regions of the Russian Federation. As many young men are reluctant to attend support groups for fear that their sexual orientation or HIV status will be publicly identified, the Positive Life programme offers individual counselling via phone, social media and Skype.

In each of six cities, peer counsellors maintain a telephone hotline with a publicized number.
Counselling is also offered via Skype, and young men can send questions to counsellors via email, Facebook, Vkontakte or via a counsellor's profile on gay-oriented web sites. Counsellors offer callers information on sexuality, safe sex, STIs, adherence to ART, ARV side effects and disclosure of HIV status to sexual partners. Callers are also informed about project services and encouraged to visit the project office for assessments or referrals. Those who are reluctant to visit for fear of being identified can be referred to one of 20 medical specialists across the six regions that have been trained and sensitized to the specific needs of men who have sex with men who are living with HIV, and who will provide services without stigma or discrimination. There are about 80 trained peer counsellors, both project staff members and volunteers. All Positive Life counsellors take part in a centralized training. They receive further training and supervision at the project’s regional offices as well as from central office staff that travel to the regions.

Since the start of the project in 2012, around 3000 MSM community members living with HIV received informational materials, and around 15,000 individuals are regular users of the programme website. In 2013 Positive Life counsellors provided almost 1900 phone consultations and 1350 online consultations.

**South Africa | Expanding competence to serve men who have sex with men**

**Anova Health Institute – Health4Men**

[http://www.anovahealth.co.za](http://www.anovahealth.co.za)

The *Health4Men* project addresses men’s diverse sexual health needs, particularly those of vulnerable and marginalized groups including men who have sex with men. The project’s goal is to institutionalize competence in serving the MSM community in existing public clinics. The process involves:

- Sensitization, to change attitudes;
- Medical training, to expand knowledge;
- Mentoring, to translate knowledge into skill;
- Ongoing technical support, including consultation, training and mentoring, and provision of educational materials.

Under the leadership of the Anova Health Institute, *Health4Men* has developed two Centres of Excellence for men who have sex with men, in Cape Town and Johannesburg, each supported by satellite clinics. The clinics provide services for the MSM community, while outreach activities stimulate demand for services.

*Health4Men* has developed innovative training content and materials to equip nurses, counsellors and medical officers to respond to the special needs of men who have sex with men in a sensitive and empathic manner. In partnership with provincial departments of health, the project establishes at least one Regional Leadership Site in each province to serve as the hub for competency
development; nurse mentors and outreach teams operate from these sites. As of mid-2014, over 3000 health workers have been trained, 584 clinicians have been mentored and 64 clinics in four provinces have been declared medically competent to serve men who have sex with men. By the end of 2014, there will be over 120 competent sites across six provinces and, by the end of 2015, over 160 sites nationally.

South Africa | Increasing access, coverage and quality of services

MOSAIC Men’s Health Initiative
http://icap.columbia.edu

In 2012, ICAP at Columbia University in South Africa launched the MOSAIC Men’s Health Initiative to increase access, coverage and quality of HIV prevention services for men who have sex with men.

The programme supports MSM organizations to develop peer-led outreach and community-based HIV prevention activities. A complementary capacity building programme sensitizes health-care workers to the needs of men who have sex with men; those providers then form the programme’s referral network. Communities of practice including governmental agencies, civil society and MSM community organizations have been established to guide and lead the efforts. Peer outreach workers were recruited and trained on evidence-based HIV prevention interventions including use of HIV post-exposure prophylaxis (PEP). In addition, clinicians received training to bolster their knowledge and skills around MSM-related health issues, followed by on-the-job mentorship. MOSAIC offers a package of services that includes HIV counselling and testing (through mobile services, couples testing and home-based testing), STI diagnosis and treatment, substance abuse treatment, mental health services, male and female condom distribution, PEP, and linkage of HIV-infected men who have sex with men to HIV care and treatment programmes.

Since the inception of the programme, 13,980 men who have sex with men have received HIV prevention services, 2,010 health-care workers have received sensitization training, 269 clinicians have received clinical training, and 24 health facilities are being provided with ongoing mentorship. Anecdotal evidence suggests that the MSM community has become more aware of the availability of PEP. MOSAIC activities are implemented in line with plans that are linked to an M&E framework that specifies various indicators and targets; ongoing monitoring allows for performance appraisal and addressing gaps and challenges. The programme has demonstrated that local engagement platforms, such as communities of practice, can be used to increase coordination, and therefore, effectiveness of MSM-focused programming. Partnerships between stakeholders, MSM peer workers and the MSM community as well as sensitized and skilled health-care workers can overcome the barriers to the provision and accessibility of relevant HIV prevention services for men who have sex with men.

Spain | Community-based HIV and STI detection centre*
**BCN Checkpoint – Projecte dels NOMS-Hispanosida**

http://www.bcncheckpoint.com/

*BCN Checkpoint* is a community-based detection centre in the gay district of Barcelona that provides HIV, STI and sexual health services for men who have sex with men. Managed by the NGO Projecte dels NOMS-Hispanosida, *BCN Checkpoint* offers free rapid HIV and syphilis testing by peers, vaccination against hepatitis A and B, referrals and promotion of sexual health.

For those with HIV-positive results, the programme offers immediate peer support and information (by trained, HIV-positive peer counsellors) and referral within one week to the hospital’s HIV treatment unit. To ensure linkage to care, all recently diagnosed individuals are followed through a register. To encourage annual repeat HIV testing, *BCN Checkpoint* uses e-mail, text messages and telephone reminders.

Between 2007 and 2013 the programme performed over 22,000 HIV tests, detecting 756 new infections. Currently, nearly 90% of clients are linked directly to care, while 5% find their own care, and about 4% are in Barcelona only temporarily and obtain care in their home countries. Less than 2% of clients are lost to follow-up.

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**Thailand | Online channel to increase uptake of services***

**Thai Red Cross – Men’s Health Clinic**


The Men’s Health Clinic in Bangkok provides comprehensive and friendly services to men who have sex with men. One of the clinic’s tools to increase uptake of HTC is the first bilingual (Thai/English) ‘edutainment’ website for men who have sex with men (http://adamslove.org), launched in 2011.

The purpose of the website is to encourage regular HIV testing for men who have sex with men. To link website visitors to HTC services, a section titled ‘HIV Testing Site Near You’ offers information about how to obtain HTC at sites that are friendly to men who have sex with men in Bangkok and in other provinces. Other means of continuous demand creation for HTC services include mass media and targeted media activities such as regular columns in gay magazines, peer-driven interventions and celebrity meet-and-greet HIV testing events.

The number of clients who have obtained HTC services has increased almost fivefold, from 967 in 2008 to 4371 in 2012. The *Adam’s Love* website attracted more than 500,000 visitors in two years and has its own Facebook page as well, with more than 15,000 fans. Twenty-five per cent of Men’s Health Clinic clients report seeking HTC services because of the site.
2.2.2 People who inject drugs

**India | Community distribution of naloxone**

Social Awareness Service Organization  
[http://www.sasoimphal.org](http://www.sasoimphal.org)

Since 2000, the Social Awareness Service Organization (SASO) in Manipur has provided, among other services, opioid overdose management with free naloxone, through outreach (e.g. at shooting sites) and at drop-in centres. Through small meetings, individual contacts and counselling, SASO also provides information and education about drug overdose and its management to people who inject drugs and their family members.

The programme was scaled up and strengthened in 2008–09 to ensure wider coverage by involving key stakeholders to facilitate community distribution of naloxone. Ethical concerns about non-medical staff dispensing a medication to people who inject drugs have been overcome through demonstration of the life-saving nature of overdose management. Between 2004 and 2012 more than 450 overdoses were managed at five centres, and over 90% of those lives were saved. In addition, more than one-third of overdose clients have increased access to drug treatment and other health care, such as HIV/HCV testing and ART.

**Indonesia | HIV prevention for PWID**

Australia Indonesia Partnership for HIV – HIV Cooperation Programme for Indonesia  

HIV Cooperation Programme for Indonesia (HCPI) provides comprehensive HIV prevention and harm reduction for people who inject drugs.

Building links with and support for government health services is an essential part of the prevention model supported by HCPI, especially with regard to health services that operate at a community level. This approach facilitates access to early HIV testing and treatment, basic health care, methadone maintenance treatment (MMT), needle and syringe programmes, sexual and reproductive health services, and other services as required. Programme activities are implemented through partnerships that maximize the comparative advantages of community-based organizations (CBO) and government structures. CBOs are ideally positioned to conduct critical outreach in hotspots during peak activity periods, encouraging uptake of harm reduction services and providing condoms, prevention information and referrals to services. Linked closely with this work, public health centres and hospitals deliver therapeutic and preventive services such as MMT and NSP services, which are delivered along with safe injecting advice. Strong partnerships with the police, the National Narcotics Board, Ministry of Social Affairs and the justice system.
provide further engagement with key stakeholders and duty bearers.

Spreadsheet data of programme activities are provided by all partners on a monthly basis. Partners conduct an annual behavioural and client satisfaction survey of programme participants that uses an anonymous self-administered questionnaire in addition to questions about having had an HIV test, serostatus and satisfaction with CBO and health services.

In 2013, HCPI supported 18 CBOs in eight provinces to provide services to over 14,000 clients; 6,000 clients also obtained services at 103 HCPI-supported government health centres (Puskesmas) and four government hospitals. Needle and syringe sharing has decreased progressively, with 85% of people who inject drugs reporting in 2010 that they had not shared in the previous week, and 91% in 2013.\textsuperscript{31} After initial reluctance, the MoH is now taking responsibility for NSP, but they still have to commit to the funding for the millions of needles and syringes required by the programme annually. MoH increasingly provides most of the funding for MMT, ensuring its availability at a large number of government health services.

**Kenya | HIV and SRHR services for female drug users**

**Muslim Education and Welfare Association**

http://www.mewa.or.ke

The Muslim Education and Welfare Association (MEWA) provide HIV prevention services and treatment for drug dependence in Mombasa and Kilifi counties on the northern coast of Kenya. The project aims to improve access to HIV prevention by providing clean needles and syringes, treatment, care, and socio-economic support services, along with advocacy for opioid substitution therapy and for the human rights of key populations.

One program focus is reunification of female drug users (85% of whom live in the street) with their families as this can be very supportive of engagement and retention in care. The program also provides free meals—often an incentive for uptake of services—alongside harm reduction services. In addition, clients have access to free reproductive health and basic social services. For clients on ART and TB treatment, free accommodations are available to support treatment adherence. Entrepreneurship training and work placement opportunities are also offered to interested clients, as well as referrals to government agencies for access to micro-financing and job placement programmes. MEWA builds trust with their clients through consistent contact, strong referral systems to services not provided by the program and community-based mobile services. MEWA also provides support for children of people who use or inject drugs. In such cases, MEWA arranges for temporary custodial care and provides health, nutritional, material and psychosocial support for

\textsuperscript{31} KPAN & HCPI (2013) Injecting Drug User Behaviour and Service Satisfaction Survey
the child’s care and education, while providing referrals for the parents to services that can support the improvement of parenting skills related to education, hygiene, health care and family planning.

Reunification with family has been achieved with half of MEWA’s clients. Hotspot-based outreach services and individualized tracking have facilitated access to program interventions for over half of female drug users in the MEWA project area, increasing service coverage from 36% to 84%. Despite achievements, the program has also faced challenges. There has been resistance to needle and syringe services from the police force due to their perception that these promote drug use and crime, and current laws do not conform to new national guidelines and policies aimed at facilitating, promoting and improving service delivery to key populations. Through outreach, community dialogue and training workshops for police officials, MEWA is working to promote human rights, introduce policy changes and provide accurate information that dispels myths around harm reduction services. In addition, the physical presence of outreach workers in hotspots is helping to forge bonds between the community, law enforcement, people who inject drugs, and MEWA staff.

**Lebanon | Scaling up harm reduction services**

Soins Infirmiers et Développement Communautaire (SIDC) - Escale

[http://www.sidc-lebanon.org](http://www.sidc-lebanon.org)

Soins Infirmiers et Développement Communautaire (SIDC) is a non-profit organization that has provided harm reduction services since 1996 and outreach interventions since 1999. Through comprehensive service delivery paired with outreach and advocacy, SIDC is working to scale up services, increase uptake among the community of drug users, and support retention in care.

The first drop-in center (DIC) in the Middle East for people who inject drugs, *Escale*, was launched in 2010 in Beirut. *Escale* offers a variety of harm reduction interventions including HTC, referral and support for needle and syringe programmes and opioid substitution therapy, as well as psychosocial and legal support. In parallel to service provision, *Escale* encourages parents to support OST for their children. Advocacy is undertaken to counter stigma and discrimination against users and to promote drug law reform and referral to support and treatment centres instead of prison. *Escale* works with the Middle East and North Africa Harm Reduction Association (MENAHRA) and other agencies to run training workshops for stakeholders and service providers in order to strengthen understanding and tolerance of the PWID community.

From 2010 to 2012, *Escale* reached around 1,600 people who inject drugs, the majority of whom were aged 20-35 years, and 17% of OST patients in the country are managed by *Escale*. However, OST is not free in Lebanon, and many people in the PWID community cannot afford to pay for the service. Recruitment and retention of NSP outreach workers has been a challenge—hotpots are difficult to access, injecting drug users fear the police when carrying syringes on their person, and many are reluctant to ask for help due to long-term alienation.
**Mexico | Disseminating information through multiple channels**

**Espolea, A.C. – Programa de Política de Drogas**
[http://www.espolea.org](http://www.espolea.org)

Espolea, a youth-led organization in Mexico City, established a Drug Policy and Harm Reduction Programme in 2008. As part of their education activities, they use online and face-to-face channels of communication to provide practical, objective information about drugs and risk reduction to young people aged 15–29 years.

The organization has found that information is most effective when disseminated at places where young people use drugs, particularly electronic dance music festivals, rock concerts and cultural gatherings. Espolea sets up a stand as a safe space where young people can access information about drugs that may be consumed at these events. The materials reflect a pragmatic and realistic approach, emphasizing the risks, harms and recommendations for less harmful practices. The organization also facilitates workshops in schools and in communities where there are concentrations of most-at-risk young people. Espolea implements an active outreach strategy through social media, including Facebook and Twitter, and they maintain blogs on a variety of programmes and topics. One blog ([http://www.universodelasdrogas.org](http://www.universodelasdrogas.org)) serves as a databank on drugs and drug use; it has become the axis of the programme’s harm reduction campaign. Information is produced by staff and collaborators, and by other young actors in the region. Printed materials that are attractive to young people are also a part of outreach; those provide useful information and recommendations about nightlife, alcohol consumption, risky sexual behaviours, HIV and other STIs.

There remains a lack of political will to address these issues openly and with sensitivity due to continued stigma around drug use. Espolea seeks to address these negative attitudes through sensitizing, evidence-based publications (available on the website) and workshops with key stakeholders and policymakers that promote internationally accepted standards and practices. Through this work, Espolea hopes to see the needs and preferences of young people reflected in policy and governmental action.

**Pakistan | Increasing access to services**

**Nai Zindagi Trust**
[http://www.naizindagi.org](http://www.naizindagi.org)

The Nai Zindagi Trust has been providing comprehensive and evidence-based services to street-based people who inject drugs, their wives, sexual partners and children in selected districts of Pakistan for 25 years. They work in cooperation and collaboration with the public health-care system to avoid creating parallel services, and 60% of services are provided by Nai Zindagi partner organizations.
The main principle of Nai Zindagi work has been the involvement of PWID community members in programme design, implementation, evaluation and re-design to adjust to changing needs and trends—30–40% of outreach workers and field supervisors are former injectors. The programme prioritizes outreach over facility-based service delivery approaches. Comprehensive harm reduction (including needle and syringe programmes, and excluding opioid substitution therapy)\textsuperscript{32}, HIV and STI prevention, diagnosis, treatment, care and support services are offered, as well as a residential 2-month ART adherence program for people who inject drugs who are living with HIV. Access to skills training and employment for clients is also available. HTC and diagnostics (CD4) services have been expanded using point-of-care technologies. A real time management information system monitors service delivery and trends in order to adapt programme interventions to actual needs.

Over 600 individuals have been trained to provide a range of comprehensive services since the inception of current programme activities in 2012. Consistent and expanded outreach has supported harm reduction services for approximately 13,000 street-based people who inject drugs. Inclusion of sexual partners and children has been a significant intervention for prevention. Staff from four new organizations have been trained to provide services related to drug use and HIV. District AIDS Councils have been established in selected districts to reduce stigma and engage government and the public sector in order to facilitate access to health, social welfare and HIV-related services for Nai Zindagi clients.

Human resources are an ongoing challenge for the programme, along with the continued stigma, discrimination and harassment of people who inject drugs, including from law enforcement, which discourages uptake of services in the public sector. Nai Zindagi is currently sharing experiences and technical information with programmes in Nepal, Indonesia and Kenya.

**Tanzania | Scaling up harm reduction services*\textsuperscript{*}**

\textbf{Médecins du Monde (MdM)}  
\url{http://www.medecinsdumonde.org}

Médecins du Monde in Tanzania (MdM) provides comprehensive harm reduction services for people who use drugs, with special attention to women and to the critical enablers that facilitate uptake of services and consistent engagement with care.

Comprehensive harm reduction services provided by MdM include needle and syringe programmes and referral to opioid substitution therapy, as well as income-generating activities and referral to legal services. More broadly, MdM is involved in building the capacity of non-governmental and\textsuperscript{32} OST is not yet allowed in Pakistan; this remains a major gap and a challenge in serving the needs of the PWID community. For PWID in need of ART and with a CD4 below 500, Nai Zindagi offers a residential drug treatment programme.

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community-based organizations to run harm reduction services, especially drop-in centres with a range of support and services, including NSP. In addition,MdM encourages the establishment of dedicated centres and shelters for women, with additional health and support services offered for their children. The programme has supported the creation of national and district-level harm reduction committees with representation from governmental and non-governmental institutions, which take responsibility for resource mobilization among other activities. A continuous dialogue with municipal, district and national authorities and sensitization sessions for police, health providers and journalists have been important elements of the work. Partnership with all members of society is considered essential for scaling up harm reduction throughout the country.

Since 2011 more than 6000 people who use and/or inject drugs have received harm reduction services and in 2013 more than 2000 stakeholders were trained in harm reduction approaches and interventions. The establishment of the Tanzania Network of People Who Use Drugs and audiovisual training for peer educators support empowerment and advocacy activities.

Ukraine | Advanced strategies to increase coverage of interventions

International HIV/AIDS Alliance in Ukraine
http://www.aidsalliance.org.ua/

Since 2000 Ukrainian NGOs led by the International HIV/AIDS Alliance have provided essential harm reduction services, which reached up to 23% of the estimated population of people who inject drugs by 2007. Further scale-up included interventions that have been effective in bringing new clients to prevention and care services.

In 2007 the Alliance introduced Peer Driven Intervention (PDI), an advanced approach to outreach that uses the strength of social networks of PWID through incentive-based chain-referral recruitment and peer education. This methodology extended harm reduction services to underserved groups of people who inject drugs such as women and adolescents. PDI incorporates research component and collects data required to tailor services to specific sub-populations. PDI is also used to reach sex workers and street children.

In recent years new clients have been brought into the programme by shifting from individual to group level work, as well as working with couples that use drugs. Group-level interventions facilitated establishment and maintenance of contacts with many young people who use stimulants, while couples counselling assisted in reaching out to sexual partners of people who inject drugs.

In addition to NGO-based stationary points, pharmacies have been involved as secondary outlets for distribution of injecting instruments, other prevention commodities, and information for PWID community members who are reluctant to contact specialized harm reduction services. In certain parts of Ukraine involvement of pharmacies allowed the programme to increase overall coverage by as much as 10% within a year of introduction. The introduction of rapid HIV testing in community settings and a case management approach allows for earlier identification and linkage.
of those in need of HIV care. This has significantly reduced the time between HIV acquisition and treatment enrolment.

Application of these strategies has helped to improve harm reduction coverage, to extend services to different sub-populations of people who inject drugs and to meet their specific needs. The overall coverage of HIV prevention programmes in Ukraine, which includes harm reduction services for the PWID community and access to rapid testing for HIV, HCV and HBV, has now exceeded 60% of the estimated PWID population, and a significant reduction in the number of new HIV cases (from 771 cases in 2007 to 212 in 2013) has been observed among people who inject drugs aged 24 and younger.

**Ukraine | Gender-sensitive HIV services**

**Women for Women – UNODC**

The Women for Women initiative was developed to provide gender-sensitive HIV and harm reduction services for women who inject drugs, female partners of people who inject drugs and female ex-prisoners. The programme, initially piloted with the support of UNODC, was handed over to the municipal services in November 2013.

Six local NGOs that provide harm reduction services were awarded grants to incorporate gender-sensitivity into their services in order to provide comprehensive HIV and harm reduction services. These services include a wide range of tailored services for vulnerable women beyond standard harm reduction services such as gender-based violence prevention (including counselling for male sexual partners), legal assistance, child care, hygiene and food supplies, shelter, self-esteem skills building and job placement. Peer involvement is important to the delivery of many of these services, while linkages have also been established with local government clinics and social services. Women for Women helped to establish an ongoing dialogue between civil society organizations and local administrative structures that contributes to the sustainability of such services.

Training for the NGO staff as well as some government representatives included a study tour to Vienna to familiarize participants with the day-to-day running of HIV and harm reduction services for women and workshops on how to develop these services. Participants also received capacity building in outreach techniques, leadership and empowerment, advocacy, and fundraising.

Over the project grant period (2011–2012), 2036 women received services through the programme. The involvement of municipal service providers in harm reduction services for women in their own communities has helped to reduce stigmatization and discrimination. The challenge of financial sustainability is addressed by incorporating the programme activities into local service delivery structures; intensive training ensures that those NGO and government providers have the advocacy, management and fundraising skills needed for long-term sustainability of the services.
Vietnam | Decentralization facilitates earlier access to HIV services*

Vietnam Authority of HIV/AIDS Control, Ministry of Health and WHO Vietnam
http://www.vaac.gov.vn/

In 2012 the Vietnam Authority of HIV/AIDS Control in the Ministry of Health started pilot-testing a project to expand earlier access to HIV services for key populations, particularly for people who inject drugs, thus maximizing the therapeutic and preventive benefits of ART by enabling people to start treatment as soon as possible. The pilot project involved decentralizing HTC services from district facilities to commune health stations in Dien Bien and Can Tho provinces. The pilot project introduced such innovations as a fixed dose combination ARV formulation, point-of-care HIV and CD4 testing, and decentralized follow-up. The project actively engaged community partners, including peer educators, self-support groups and village health-care workers, providing them with community mobilization trainings and holding regular meetings to discuss outreach activities and challenges. Commune health station staff received training on HIV service delivery, including HIV testing using rapid tests, pre- and post-test counselling, adherence support, basic care and dispensing ARV drugs.

This decentralized, community-based model has been shown to promote earlier diagnosis and treatment. People diagnosed at communes have significantly higher median CD4 counts when starting ART (median 294 cells/mm$^3$) than those diagnosed at district facilities (median 88 cells/mm$^3$). Community outreach and building trust are recognized as critical to facilitating earlier access to HIV services among people who inject drugs.

2.2.3 People in prison or confined settings

Afghanistan | Harm reduction for female prisoners who inject drugs

Afghan Family Guidance Association
http://www.afga.org.af

Recognizing the acute risks faced by people in prisons and other closed settings, the Afghan Family Guidance Association (AFGA) provides comprehensive HIV prevention, treatment and care services for female prisoners, with a particular focus on harm reduction for female injecting and non-injecting drug users in prison settings.

Around 13% of the people who use drugs in Afghanistan are women, 18.8% of whom were living with HIV in 2010. AFGA undertakes advocacy through monthly meetings and other awareness-raising events with government, legislative bodies, prison staff and law enforcement to promote
gender sensitivity and rights-based programme approaches to reduce stigma and discrimination toward female injectors. As part of the programme, support groups for female prisoners have been established and peer educators for people who inject drugs have been trained in harm reduction approaches. As there are no health facilities or health staff on prison premises, AGFA has facilitated, since 2008, close coordination between the Ministry of Public Health, prison officials and the Ministry of Counter Narcotics to ensure that vital health services are available to female prisoners, and to identify injecting drug users in order to provide appropriate harm reduction services to them.

AGFA coordination activities have resulted in significant improvements in the prison health care delivery system and strengthening of the referral network for female prisoners, including those who inject drugs.

**Albania | Using incentives to increase uptake of harm reduction services***

*STOP AIDS*  
http://www.facebook.com/stopaids.albania

*STOP AIDS*, an NGO in Tirana, implemented an incentives programme with a group of young people who inject drugs to assess whether small incentives could motivate reduction in higher-risk behaviours associated with drug use, and increase alternative or less risky behaviours. These included getting clean needles and returning used ones, being tested for HIV, bringing new clients to the programme, and allowing home visits by *STOP AIDS* staff.

For six months, vouchers and coupons were used as incentives, redeemable for a variety of retail goods such as pre-paid phone cards, food, fuel, clothing and haircuts. Vouchers were accumulated in a clinic-managed bank account and distributed to clients once a week. The standard reward for participants ranged from 1 point (equivalent to US $1) for receiving harm-reduction kits, to 5 points for those who introduced a new client to the programme.

The programme was successful in significantly improving clients' attendance and uptake of some harm-reduction services, especially NSP, HIV and hepatitis testing, and introducing new clients and sexual and injecting female partners to the programme, compared to a control group who did not participate in the programme. More than half of the clients introduced programme staff to their family members and allowed home visits or counselling. However, voucher incentives seemed less effective for changing certain behaviours such as returning used needles, switching from injecting to non-injecting behaviours or adherence to opioid substitution therapy. Further study is needed to determine the sustainability of health-seeking behaviour change through incentives.

**Indonesia | Methadone maintenance treatment in prison***
Methadone maintenance treatment for incarcerated injecting drug users was pilot-tested in Kerobokan Prison, Bali, in 2005 after prison officials visited MMT programmes in Australian prisons. Accomplishments of the Kerobokan Prison pilot project include:

- Establishment of comprehensive harm reduction services (including MMT) and high levels of participation among prisoners with opioid dependence.
- The scaling-up of MMT, education and care, support and treatment services in 11 other prisons, detention centres and parole services; Kerobokan prison provides ongoing mentoring to many of these facilities.
- High levels of integration with other community health services in Bali, ensuring smooth transition from prison to community MMT programmes (and vice versa) and early or continuing access to HIV treatment.

Additionally, HIV testing and treatment now have been efficiently implemented in many prisons. More than 90% of high-risk prisoners have been tested, and a high proportion of those testing positive have begun ART.

As part of mainstreaming this initiative, in 2013 the Ministry of Health (MoH) and the General Directorate of Corrections signed a memorandum of understanding that the MOH would fully cover the cost of methadone. HCPI continues to provide training and limited financial support.

### Iran | Methadone maintenance treatment as HIV prevention

The National OST Programme of the National AIDS Control programme

http://www.menahra.org/en/

Iran has a concentrated HIV epidemic largely driven by injecting drug use. In 1996 an outbreak of HIV among people who inject drugs in prisons resulted in advocacy efforts targeting government, community and religious leaders for a policy shift from a zero-tolerance approach to harm reduction. The main harm reduction strategy used in Iran is opioid substitution therapy, mostly with methadone maintenance treatment.

There are an estimated 200,000 people who inject drugs in the country. By February 2014, 4275 drug treatment centres offered OST under the supervision of medical science universities, state welfare organizations or prison organizations. More than 95% of these centres are managed by private sector physicians. In 2013, approximately 480,000 opiate users (injecting and non-injecting) received MMT.33 The 2007 bio-behavioural surveillance survey revealed that among individuals

33 UNAIDS Global AIDS Response Progress Reporting 2014 (2013 data)
who had injected opioids during the past year, 33% received MMT; this proportion rose to 42.6% in the next bio-behavioural survey of 2010. In addition, the number of opiate-dependent prisoners receiving MMT steadily increased from 100 in 2002 to more than 38,000 in 2011.\textsuperscript{34} It is likely that this programme, along with other harm reduction services provided to Iranian inmates, has contributed to a decrease in HIV prevalence in this population from 3.8% in 2002 to less than 1.3% in 2011.\textsuperscript{35}

**Ukraine | Ensuring access to HIV services in juvenile detention**

**All-Ukrainian Public Center Volunteer**

http://www.volunteer.kiev.ua

All-Ukrainian Public Center Volunteer runs a programme that provides access to critical HIV prevention services for adolescents in juvenile detention. The programme targets adolescents considered most at risk for HIV infection, with a focus on underage individuals registered with law enforcement authorities and those who are incarcerated in juvenile detention centres.

One Volunteer intervention involves capacity building of providers who are working with vulnerable and confined adolescents to increase understanding of and sensitivity to their particular needs, to strengthen communication skills with this age group and to improve referral to appropriate services. A significant area of success was the introduction of courses for working with vulnerable adolescents in conflict with the law into the professional development training plan for the Bila Tserkva Academy of the Criminal Executive Service of Ukraine. To date, 1300 specialists have been trained, including psychologists from juvenile correctional and detention centres and criminal-executive inspectors (probation officers/staff) from all regions of the country.

Provider concerns about testing children under the age of 14 (the age of consent in Ukraine) were addressed through consultations with health managers and providers. However, legislative change to address age-related restrictions to services is problematic during political instability.

2.2.4 *Sex workers*

\textsuperscript{34} Shahbazi M, Farnia M, Rahmani K, Moradi Gh, Trend of HIV/AIDS prevalence and related intervention in Iranian Prisons in 13 years, Iranian J of Publ Health, Vol 43, No 4, April 2014

\textsuperscript{35} Marziyeh Farniaa, Bahman Ebrahimia, Ali Shamsa, Saman Zamani, Scale of MMT in prisons in Iran, Int J of Drug Policy, 2010
Cambodia | A branded approach to HIV services for sex workers

SMARTgirl

SMARTgirl, a national HIV programme, originally developed by FHI 360, aims to prevent and mitigate the impact of HIV and improve the sexual and reproductive health of the estimated 35,000 entertainment workers nationwide, many of whom are sex workers; among some groups of entertainment workers, HIV prevalence is as high as 14%.

SMARTgirl is a branded HIV prevention and SRH programme that seeks to create loyalty, to provide easy access to referrals and to be recognized as a source of trustworthy information delivered through trained peers. Through individual and group-level outreach, SMARTgirl peers provide HIV prevention information, commodities and referrals. Some locations also benefit from mobile STI screening and HIV testing services as well as family planning services. Recognizing the overlapping risks of many entertainment workers, SMARTgirl also supports harm reduction approaches including counselling and linkages to methadone maintenance treatment and needle and syringe programmes for entertainment workers who inject drugs. Since 2009, SMARTgirl has also been working to reduce stigma and discrimination by giving entertainment workers a voice at the national and local level through its health and social network.

SMARTgirl reaches nearly half of all entertainment workers in Cambodia in their workplaces. The programme’s health and social network now have approximately 10,000 members. In the year up to March 2012, 15,680 SWs received services, a coverage of 92% of the targeted group.

Ghana | Peer-led outreach with young women who sell sex*

FHI360, SHARPER project (Strengthening HIV/AIDS Response Partnership with Evidence-based Results)

To strengthen outreach to young women selling sex in Accra, the SHARPER project, through local implementing partners, recruited young female sex workers who were considered leaders within their peer group to work as peer educators in order to increase uptake of services and engagement in care.

Selected individuals took part in a 1-week training, followed by weekly supportive supervision meetings and monthly reviews with programme staff to discuss implementation challenges. Peer educators were paired with older women in the community, known as ‘peer protectors’, who provided them with guidance and support in handling difficult situations, making referrals and in planning their futures. Peer educators received a monthly stipend to cover transport and communication costs. Microplans helped peer educators to focus on priority issues and needs faced by young people selling sex. These included negotiation skills for safer sex, family-planning services
and commodities such as male and female condoms and water-based lubricant, and referrals to HIV testing and counselling, STI and other sexual and reproductive health services. Information and services were also provided in relation to preventing and addressing violence, whether by intimate partners, clients or the police.

Each peer educator worked with 10–15 young female sex workers each month. A significant challenge was the frequently chaotic and highly mobile lives of young female sex workers in Accra, which made regular contact difficult. In response, the programme offered peer-accompanied referrals to services and established linkages with other organizations that could provide critical support, for example in cases of human rights abuses and sexual violence, child care and parenting skills-building, nutritional support for young children and enrolment in the national health insurance scheme. In addition, the frequency of supportive supervision was increased from once to twice weekly.

Kenya | Community-based HIV and STI services

Sex Workers Outreach Programme – Nairobi, Kenya
http://swopke.blogspot.com

Affiliated with the University of Manitoba/University of Nairobi, the Sex Workers Outreach Programme (SWOP) promotes the health, safety and wellbeing of sex workers in Nairobi County and affirms their occupational and human rights. There are an estimated 30,000 sex workers in the project area, and the programme has grown from 3 to 9 service sites since 2008.

Working closely with the National AIDS and STI Control Programme (NASCOP) of the Ministry of Health, SWOP uses peer-led, hotspot-based mobilization and outreach services to provide acceptable and friendly HIV and STI prevention and care services to sex workers. Seven sites serve sex workers, and two facilities provide services to HIV-infected family members, friends and clients of sex workers. All clinics provide a comprehensive HIV prevention and treatment package and offer cervical cancer screening. Community members participate in decisions about where to locate service sites, with discretion and acceptability in mind. The outreach team coordinates and implements activities with a peer support team. Programme services, which include behavioural, biomedical and structural interventions, are free and adhere to national guidelines. Periodic trainings and performance reviews of peer leaders enhance the quality of services. As sex work is illegal in Kenya, linkages and partnerships with other organizations and government agencies working with key populations is critical.

In 2013, SWOP outreach activities made 103,000 (initial and repeat) contacts with sex workers, and HIV testing and counselling services were provided with 31,000 tests (initial and repeat) conducted. Strong peer networks and sharing of data between clinics through a virtual private network (VPN) helps reduce problems caused by the mobility of sex workers. SWOP has been instrumental in establishing clinical guidelines for the syndromic treatment of STIs, and syndromic management is
now part of the NASCOP health policy. However, there are challenges in supporting men who have sex with men who are also sex workers as they suffer double stigma and considerable hostility and persecution in the community. A high HIV incidence of 10.9 per 100 person-years has been noted among these male sex workers and SWOP is working closely with NASCOP and other stakeholders to address their specific needs. Another challenge is attrition of trained peer educators who move to other programmes, and constant retraining is necessary.

Myanmar | Outreach to young people who sell sex*

AIDS Myanmar Association Country-wide Network of Sex Workers

AIDS Myanmar Association (AMA) is a network of more than 2,000 female, male and transgender people who sell sex. The programme focuses on capacity building and community mobilization to advocate for the health and human rights of the sex worker community.

Working within a restrictive political environment, members of AMA have had to find innovative ways of reaching out to young people who sell sex to provide peer support and access to information and services, particularly in relation to their health. AMA community mobilization workers are trained to be particularly sensitive to the needs of young people and do not ask for any identifying information, such as their real names or ages, when conducting outreach activities. They provide STI and HIV prevention tools and strategies, links to sex worker-friendly health facilities for testing and treatment, and follow-up counselling and care for young people who sell sex who are living with HIV. In a context of stigma and discrimination, young people who sell sex are often reluctant to access services for fear of arrest or disrespectful treatment by health-care professionals. Follow-up care takes place in a safe and supportive environment and focuses on support for adherence to treatment; community mobilization workers also offer to accompany young people to their clinic appointments. AMA also provides support to people who sell sex who are imprisoned, particularly ensuring that young people, who have often been abandoned by their families, are given nutritional support while in prison. Upon release from prison, AMA works to reconnect young people with their families and friends to ease the transition back into the community.

Philippines | Contacting hard-to-reach males who sell sex*

River of Life initiative (ROLi)
http://www.projectpage.info/my-river-of-life

ROLi is an HIV risk reduction programme that uses a self-assessment toolkit, workshops and peer group work to help adolescent males who have sex with men assess and reduce their risk behaviours as individuals and groups, using the support of their peers and service-providers. The
programme serves 6,000 young people in the Philippines, the majority of whom are males aged 13–17 years. Approximately 80% are out of school and 90% live in poverty. Almost all of them sell sex and use drugs, and almost all identify as straight (heterosexual).

Because young males who sell sex are highly stigmatized and difficult to reach, the programme uses several channels for outreach on a peer-to-peer basis. One-on-one interactions and group activities take place through contact with young people in their communities, including on the street and in areas where men seek sex with young males. They are given the opportunity to take a risk self-assessment on the spot, or to sign up for a workshop held at a partner health facility. Peer outreach workers also do outreach online through SMS text messaging and through private chats with members of their social and peer networks.

Programme participants can join Facebook groups for moderated peer-to-peer discussions about behaviour change. In addition, peer groups organize campaigns showcasing inspiring stories of change through forums, film viewings and discussions, and awareness-building activities take place around village fiestas, festivals, World AIDS Day and anti-drugs events. Government-run clinics that partner with ROLi also provide one-on-one counselling and other services. The ROLi programme has been adapted to serve other young key populations, including females who sell sex and young people who inject drugs.

**South Africa | Mobile outreach to female sex workers**

Re-Action! Consulting
http://www.re-action.co.za

In conjunction with the Department of Health, Re-Action! runs a programme that aims to reduce new HIV infections among female sex workers and their clients in two rural districts of Mpumalanga Province. The programme also seeks to reduce the vulnerability of female sex workers to violence, exploitation, substance abuse and social exclusion through life skills mentoring for the women along with sensitization and outreach for the community and other stakeholders.

A nursing team runs a mobile clinic that offers free services including health risk screening, counselling and testing (including point-of-care CD4 testing); HIV treatment and care; and referral to other health and social services. To encourage retention in care, the team visits clients at least twice per week, at locations and times convenient to the women. A 28-day calendar helps to inform the FSW community when they might need emergency services and where they can obtain them. Nurses are trained in initiation and management of ART; if needed, most services, including ART and support for adherence to treatment, can be provided in clients’ workplaces. When clients default on treatment, outreach workers provide assistance, support and follow-up as required. To ensure confidentiality, outreach workers from outside the clients’ communities are assigned to provide HTC and referral services.
Re-Action! has reached about 4,100 female sex workers with services. Client satisfaction is high, and the programme’s low default rate of 2.3% is largely attributed to women moving elsewhere. Female sex workers report increased knowledge of the legal system and their basic rights and they are more aware of other organizations that provide support and services for sex workers. Nurses have overcome the security risks of working at night by building a good rapport with the local police force and with those who control the brothels.

**USA | Separate, peer-led services for sex workers**

**St. James Infirmary**
http://www.stjamesinfirmary.org

St. James Infirmary, located in San Francisco, USA is run by and for current and former sex workers, offers free, confidential and non-judgmental medical and social services. Services provided by the programme include primary medical care, HIV and STI testing, peer counselling, hormone therapy, acupuncture, massage, support groups, needle exchange and Narcan (naloxone) trainings. Services are supported by the Department of Public Health, private donations and foundation support.

The programme was developed to respond to the criminalization and stigma that sex workers experience, often resulting in inadequate or prejudicial healthcare, to the extent that many people will avoid seeking care in response to negative experiences. A peer-based, non-judgmental environment was created based on harm reduction principles so that sex workers are welcomed into a space where they can be honest about their lives and their needs. By prioritizing positive patient-provider dynamics, the clinic promotes and demonstrates an understanding of healthcare as a collaborative process that empowers as it heals. Many participants are referred from other medical establishments, social service organizations and prison programmes. Outreach and supply distribution is undertaken at strip clubs, commercial sex venues, massage parlours, and in the street. In 2011 a media campaign was organized to raise awareness of sex workers’ rights.

Since 1999, over 3,500 clients have accessed care and community space at the clinic, with an additional 30,000 contacts made with sex workers through St. James outreach and needle exchange; many clients have only accessed healthcare in emergency settings previously, and they express an unwillingness to seek services that are not specifically identified as serving the sex worker and/or transgender communities. Over 1,000 copies of a resource guide—covering sex work, harm reduction and transgender issues—have been distributed to community members and have been used as a training tool for service providers. Yearly evaluations are conducted using participant surveys and staff interviews.

**Zimbabwe | Comprehensive services for HIV prevention**

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Centre for Sexual Health and HIV/AIDS Research – Sisters with a Voice
http://www.ceshhar.co.zw

Centre for Sexual Health and HIV/AIDS Research (CeSHHAR) Zimbabwe runs the *Sisters with a Voice* programme, which provides integrated services for sex workers in multiple sites across Zimbabwe on behalf of the National AIDS Council. Collaboration with key government ministries (AIDS, Health, and Social Welfare) and the involvement of sex workers in implementation have contributed greatly to the programme’s successes.

Supported by a network of peer educators trained in participatory community mobilization and empowerment, the programme offers HTC, syndromic STI treatment, contraceptives, health education and legal advice. Cervical screening is being rolled out; nurses are being trained in visual inspection and treatment of pre-cancerous lesions using cryotherapy. Peer educators run community mobilization sessions that cover issues that concern sex workers (self-worth, behaviour change, contraception, HIV and cervical cancer), issues relating to clients and partners (communication, assertiveness, serodiscordance, sexual networks and multiple concurrent partnering) and issues relating to the ‘sisterhood’ (advocacy, stigma, rights and support).

Since 2009 the programme has expanded from 5 sites to a national network of 36 sites (6 fixed facilities and 30 outreach sites). By 2013 the programme had served more than 14,000 women. Moreover, at a site where two population-based surveys were conducted, the proportion of HIV-negative women who reported having a recent HIV test increased from 35% in 2011 to more than 70% in 2013. Over the same period, the proportion of women living with HIV who were obtaining ART increased from 28% to 45%.

### 2.2.5 Transgender people

**Dominican Republic | Increasing access to services for transgender sex workers**

La Comunidad de Trans-Travestis Trabajadores Sexuales Dominicana
http://www.cotravetd.blogspot.com; http://www.focusright.org

The Community of Dominican Transgender and Transvestite Sex Workers (COTRAVETD) is a sex worker-led collective formed in 2002 that prioritizes the issues and needs of transgender and transvestite sex workers, who face significant discrimination, abuse and detention in Dominican society, and whose rights are routinely violated.\(^{36}\)

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COTRAVETD provides human rights-based training for peer educators who engage with sex workers, gay and transgender people, and men who have sex with men. Peer educators provide information and support for a wide range of skills, services and referrals that address the sexual health needs of the community. They also help to build solidarity and trust between transgender sex workers through a support group that brings together younger transgender women with older and more experienced transgender women. In 2012, COTRAVETD piloted a sexual health approach to peer education, training 12 peer educators in principles of sex positivity (i.e. the view that sexual expression is essentially good and healthy), self-determination, autonomy and fairness. The personal nature of this approach helps peer educators to understand the complexity of their lives and the psycho-social and structural risks of HIV, and in turn, fosters outreach which goes beyond negative, disease-focused messages.

COTRAVETD interventions have significantly strengthened the capacity of peer educators and volunteers to address the needs of transgender and transvestite sex workers for appropriate services and referrals. COTRAVETD has also participated in a national consultation on sex work and broken down barriers of discrimination and misunderstanding by doing 12 radio and television interviews. With nearly 1300 sex workers reached through peer education, a reported increase in solidarity amongst sex workers and a reported increase in uptake of mobile clinic services it is clear that COTRAVETD approaches are effective.

**Ecuador | Healthy transitions for young transgender people**

*Silueta X Association*


Faced with the absence of an integral health policy covering the specific needs of the transgender population, and a lack of experienced and specialized health-care providers, the Silueta X Association started a programme to promote health among young transgender people and to prevent the health risks involved in non-professional feminizing hormone regimens.

A participative process was followed to design a project to meet demand for information regarding transition. Because doctors and nurses in the public-health sector would not facilitate workshops at times when transgender community members were available, the project used a private-sector doctor and an Ecuadorean endocrinology specialist based in Chile to train the Association activists and the target group. Around 160 young transgender people aged 15–29 years benefited directly. Existing peer communication was the main strategy to spread the word about the programme, via invitations on social networks and other virtual communication channels. This allowed the project to identify a new generation of potential users of feminizing hormone regimens.

Education on the risks of feminizing hormone regimens is still needed, including with other transgender organizations in Ecuador. After project funding ended, Silueta X continued to
incorporate information on proper feminizing hormone regimens as part of its training for those involved in HIV prevention, as well as in recreational and social events, such as beauty pageants.

**USA | Creating a welcoming environment for young transgender people***

**Callen-Lorde Community Health Center – Health Outreach To Teens**
http://www.callen-lorde.org/our-services/hott/

The Health Outreach to Teens programme (HOTT) in New York City serves lesbian, gay, bisexual, transgender and queer (LGBTQ) adolescents, homeless or unstably housed youth, and those living with HIV, through an on-site medical suite and a mobile medical unit. HOTT provides acute and primary care, mental-health services, HIV testing, case management and health education.

Around 11% of the 1,100 young people receiving services in 2013 identified as transgender, many of them being of colour, homeless or at risk of homelessness, and facing other psychosocial stressors. To engage and support these youth, the programme provides a trans-affirming environment, free care, and rapid access to appointments. HOTT staff also monitor risks and resiliencies, and connect clients to preventative services that emphasize a harm reduction approach.

To provide a trans-affirming environment, all HOTT staff (medical providers, nurses, case managers and HIV test providers), many of whom identify as members of the LGBT community, are trained in transgender-competent service provision. Trans-inclusive programme literature and health education materials are available. Providers use a harm reduction, trauma-informed approach to care, show clients how to manage transphobia in multiple environments (e.g. in workplace and correctional settings), and teach them self-harm prevention strategies. HOTT’s weekly transgender women’s support group, 'The Girls Room', successfully engages this hard-to-reach population and provides a safe space to explore and support transition. A Youth Advisory Board and The Girls Room provide feedback on transgender services, and annual clinic-wide surveys evaluate services.

**USA | Capacity building for transgender community services***

**Center of Excellence for Transgender Health – University of California, San Francisco**
http://www.transhealth.UCSF.edu

The mission of the Center of Excellence for Transgender Health is to increase access to comprehensive, effective and affirming health-care services for transgender and gender-variant communities. The ultimate goal is to improve the overall health and wellbeing of transgender people by developing and implementing programmes in response to community-identified needs. Core faculty and staff with diverse backgrounds and experience offer programmes informed by a national advisory board of 14 trans-identified leaders from throughout the United States of
The projects of the Center of Excellence address a wide range of health issues for transgender people. One activity is developing guidelines on a range of primary care topics, including primary and preventive care, hormone therapy, mental health, youth and surgery. Protocols have been published online (http://Transhealth.UCSF.edu/protocols). In addition, the Transitions Project helps build the capacity of community-based organizations to adapt, implement and evaluate evidence-based HIV prevention interventions for transgender communities.

**USA | Comprehensive transgender services in a community-based clinic**

Community Healthcare Network
http://www.chnnyc.org/

The Transgender Family Program was established in 2004 at the Community Healthcare Network (CHN) clinics in New York City to improve access to HIV prevention and linkages to primary health care. To understand how best to integrate comprehensive transgender services into a community health clinic, CHN undertook community mapping, consultations and forums and review of similar programmes. Importantly, the programme asked patients to form the Client Advisory Board to help guide integration and implementation of services for the transgender community.

Integrated services include transgender care, HTC, medical case management, support for treatment adherence, STI screening and treatment, prevention interventions and mental health and nutritional services. In addition, the programme provides risk reduction counselling, support groups, outreach, bilingual educational workshops and referrals to legal and social services. Recruitment strategies of staff members and trained peer leaders include face-to-face contacts, community-based activities and online methods including advertising and social media tools. Clients are encouraged to engage family members. This has proved to be an important strategy to encourage access and attendance.

Over 750 people have received transgender-specific services. Identified benefits of integrated transgender services include:

- Improved tolerance and long-term acceptance of, and sensitivity to this population in the broader community;
- Improved accessibility through convenient location of services;
- Flexible hours as a result of extended service capacity;
- Increased access to a range of in-house support services.

In addition, in-depth evaluation has found significant decreases in sex work, needle sharing and unregulated hormone injections, and increased likelihood of regular condom use.
2.2.6 Programmes that serve more than 1 key population group

Albania | Health and human rights for young key populations

Aksion Plus
http://www.aksionplus.net

Founded in 1992, Aksion Plus was the first youth NGO to address HIV through education of youth and awareness raising activities for the general population. The programme now supports health and human rights interventions in 6 cities for young people who inject drugs, young sex workers and young members of the LGBT community.

Aksion Plus provides direct services and referrals for HIV and other STI services, as well as the provision of opioid substitution therapy, including to young people in prisons and closed settings. Since 2000, Aksion Plus outreach workers also provide a needle and syringe programme along with condom distribution. Through information, education, life skills, counselling and capacity building Aksion Plus aims to empower young key populations. The participation of young members of key populations as peer educators has been identified as essential to ensuring the success of the interventions. Additionally, outreach workers are critical for creating and reinforcing the link between the YKP community and Aksion Plus while providing condoms, information materials, counselling and referrals. The programme also provides harm reduction training for other NGOs and government bodies specifically focusing on the needs of young people.

Belgium | Using social media for demand creation

Boysproject

Boysproject is a social organization for male and transgender sex workers in and around Antwerp, Belgium. Boysproject uses social media to create demand for social and medical services and to provide information and referrals to services.

To reach their target group, Boysproject, hosts an online forum specifically for male and transgender sex workers, www.info4escorts.be. The site offers information and chat boxes where individuals can ask questions and receive answers about sexual health and other related issues. Boysproject also provides a drop-in centre each Wednesday afternoon that is advertised online and via SMS; along with services and referrals from a social worker and a doctor, the drop-in centre offers a Dutch language course, a space for conversation, sharing experiences and food. Boysproject also works with the Institute of Tropical Medicine to provide HIV post-exposure prophylaxis, which is not well known by the sex worker community. Social workers play an important role in informing and accompanying individuals through the PEP process.
Boysproject services reached 298 sex workers (of which 165 were new contacts) in 2013, up from 229 (140 new contacts) in 2012. Around 1,130 invitations to the drop-in centre were sent out via social media in 2013, and 15–30 sex workers attend the Wednesday drop-in centre each week.

**Central America | Increasing access to HIV services for key populations**

**PASMO/PSI – Combination Prevention Program for HIV in Central America**

http://www.asociacionpasmo.org

The overall objective of the PASMO/PSI Combination Prevention Program is to increase access to HIV prevention interventions for key populations in six Central American countries.

The programme seeks to reduce prevalence of high risk behaviors; decrease hostility in social environments that foment and tolerate homophobia, stigma and discrimination; increase access to a minimum package of essential prevention and health services; and strengthen strategic information through research and monitoring. A comprehensive package of interventions is provided for each target population under each of the three combination prevention components: behavioral, biomedical, and structural. The minimum package of services includes participation in at least three behavior change communication interventions, referrals to screening and treatment of STIs and opportunistic infections, as well as referrals to medical care and referrals to structural services such as family planning, stigma and discrimination support groups, legal support and treatment for alcohol and drug abuse. These services are provided through close coordination with a diverse set of partners including, Ministries of Health, donors, local NGOs, private laboratories and public and private clinics. Hostility and discrimination are addressed through sensitization and training of health providers, community mobilization and sensitization of the media for accurate and balanced reporting on HIV and key populations. Methods used to reach key populations include mapping hot zones through existing databases and filed visits; ‘sweeping the zones’ activities in which all partners travel to hot zones to ensure that targeted KP communities have access to all the combination prevention interventions; and use of technology.

A total of 78,547 individuals have been reached since the start of the programme. Furthermore after close coordination with key stakeholders and through technical assistance on the Combination Prevention strategy materials and methodology to NGOs, to the El Salvador Ministry of Health and to the Global Fund prime recipient for HIV programming in El Salvador, the Combination Prevention strategy and methodology were adopted in El Salvador at a national level. Turnover in government poses challenges to increasing momentum to strengthen HIV prevention programming for key populations, and increasing insecurity in Central American countries causes a high level of movement of key populations, making it difficult to ensure that follow-up services are provided.

**EECA region | Collaborative client management**

**AID Foundation East-West**
AID Foundation East-West (AFEW) is an NGO currently working in Georgia, Kazakhstan, Kyrgyzstan, the Russian Federation, Tajikistan and Ukraine to reduce the impact of HIV on key population communities. Through client management initiatives, AFEW strengthens the capacities of local governmental, non-governmental and community providers, and supports coordination of local service provider networks and resources.

HIV client management is a collaborative process between the individual, the client manager, and local service providers aimed at improving access to appropriate and timely health and psycho-social care. Client managers assist individuals in assessing their specific needs and developing strategies to best address these needs. Due to high levels of discrimination against members of key population groups, clients are often accompanied to hospitals and government offices when seeking health, social or administrative services. Social workers and client managers usually come from key population communities; they are regularly trained on human rights issues, ethics and new approaches to working with target groups. AFEW regularly organizes national or regional workshops and other mass events for key populations to provide opportunities to share experiences and best practices.

Programme participants have noted improved collaboration and integration of services due to AFEW initiatives. The requirement of a local residency permit for access to services is a major obstacle to providing care to those from key populations. However, NGOs like AFEW have signed memoranda of understanding with local providers to ensure that those without local residency permits can access vital services.

**Egypt | Peer-led SRH services for young key populations**

*The Egyptian Family Planning Association (EFPA) uses outreach as an extension of its clinical services to engage with young people most at risk of acquiring HIV. Volunteer peer educators provide comprehensive, gender-sensitive, rights-based sexual and reproductive health education. Each clinic has two male and two female educators aged 18–25 years who are trained in comprehensive SRH education, HIV and other STIs, and communication skills; they are supervised by clinic staff and by an EPFA reproductive health officer and youth officer. Of the 56 EFPA educators, 30 have been trained to work specifically with young key populations, and some are themselves members of key populations.*

*The peer educators conduct outreach sessions with young people less than 18 years of age, primarily at government institutions for street children and orphanages. The sessions are offered at a location away from the clinic so that the participants do not appear to be seeking clinic services and to preserve confidentiality. The educators explain the services offered at the clinics, encourage the young people to attend and distribute condoms. Outreach is also done with members of young key populations who are not connected to specific institutions, such as truck and minibus drivers.*
In 2012, 81 peer-to-peer sessions reached almost 2,300 people, one-third of whom were men who have sex with men or young people who inject drugs. A youth committee meets on a quarterly basis to follow up with the implementation of the activities and to discuss obstacles and lessons learnt.

Parallel to this work, EFPA also endeavors to influence policy change that prioritizes the SRH needs of young people within the national health system.

**India | Strengthening MSM, transgender and hijra community systems**

**Pehchan – India HIV/AIDS Alliance**
[http://www.allianceindia.org](http://www.allianceindia.org)

India HIV/AIDS Alliance and consortium partners implement the Pehchan programme in 17 states with the aim of building and strengthening the capacity of 200 community-based organisations (CBOs) to provide HIV prevention programming to more than 450,000 men who have sex with men, transgenders and hijras (collectively, MTH).

Pehchan develops CBOs to serve as implementing partners with the National AIDS Control Programme, fosters community-friendly services within the health system, and engages in advocacy to improve the lives and wellbeing of MTH populations in India. The programme leverages and complements the government’s HIV prevention strategy for MTH community members by providing a broad range of additional services that support an enabling environment that encourages healthy behaviors. Partnership with government is key to programming at national scale. Pehchan has filled critical gaps in community capacity necessary to support the government to achieve significant HIV prevention coverage for MTH populations. The active involvement of MTH community members as programme managers and technical advisors has also enabled Pehchan to rapidly build trust in environments that are often inhospitable and to create high levels of community ownership.

Societal attitudes against homosexuality remain significant in India and discourage MTH community members from accessing HIV and other health services. The re-criminalization of homosexuality in India in late 2013 has created additional resistance and led to further stigma, discrimination and violence. Pehchan has developed Crisis Response Teams that work rapidly with victims of violence to ensure that police and other authorities respond appropriately. The programme has also initiated a national advocacy campaign to support decriminalization of homosexuality. HIV stigma within MTH communities is another challenge, and the programme’s outreach and counselling include efforts to reduce it.

Pehchan has coupled a coherent, comprehensive and sustained effort of capacity building and systems strengthening with effective community mobilization tied directly to HIV prevention services. The programme approaches that have worked can be adapted to other contexts and countries where sexual minority communities are underserved by HIV interventions.
For men who have sex with men and sex workers, LVCT Health provides essential services outside of traditional delivery settings and schedules in order to overcome the barriers to services and to consistent engagement in care faced by these key populations.

LVCT Health work is peer-led and involves communities in meaningful ways at all stages of the programme cycle. In order to effectively target project interventions, hotspots were mapped with community leaders and service providers who were sensitized to the importance of non-judgmental and appropriate services for key populations. Focus group discussions and client exit interviews with participants from key population groups informed the concept and design of the innovative programme. Engagement with bar owners and staff supported buy-in from these key collaborators, leading to the availability of condoms and lubricants in convenient dispensers.

Clients who receive an HIV diagnosis through LVCT Health testing services are linked to treatment and care services. HIV risk factors, types of STI and HIV status are entered into a national database, and cohort data are analyzed for trends, such as HIV prevalence by geographic location. Female sex workers receive routine STI and cervical cancer screening using visual methods; immediate diagnosis is provided, and those with lesions are referred to specialized centres for further management. Male sex workers are screened for STIs and other lesions and offered on site syndromic management and followed up in a facility setting.

LVCT Health reaches approximately 5,000 key population clients with HIV and sexual and reproductive health services every year, and over 80% of clients who are diagnosed HIV-positive are effectively linked to post-test services. LVCT Health has achieved above 85% retention in care and treatment for men who have sex with men and over 90% adherence to treatment (HAART). LVCT Health advocacy has led to the inclusion of key population issues in the HIV National Strategic Plan in Kenya, potentially opening the door to national scale-up of services. Consistent follow-up with this mobile population is done through telephone calls from counsellors and through a static site close to all hotspots for follow-up services or services between scheduled appointments. Collaboration with Ministry of Health and security agencies overcomes problems associated with providing services in insecure locations, ensuring the safety of staff and clients.
The National Organization of Peer Educators (NOPE) provides sexual and reproductive health and social services in a wide variety of settings. NOPE developed the Drop-In Service Centre (DiSC) model as a ‘one-stop’ approach for delivery of essential HIV services for female sex workers and men who have sex with men in 7 locations in Kisii and Kiambu counties.

Consultations and focus group discussions with FSW and MSM community members identified service gaps; this was followed by social and hotspot mapping and population size estimations. Stakeholder meetings—including bar owners, police, provincial administrators, religious and community leaders, along with FSW and MSM community representatives—took place within identified hotspots to provide information about the project and to encourage community buy-in. Following focus groups discussions, female sex workers and men who have sex with men participated in the selection of DiSC locations. Peer educators were selected and trained on how to run a DiSC, including setting it up, using a client flowchart, the referral and network pathway and the minimum services package. NOPE worked with the District Health Management Team to source commodities and for quality assurance of services. NOPE follows a performance-monitoring plan aligned with the national AIDS strategic plan and PEPFAR Next Generation Indicators. Routine data quality assessments and audits, supervision visits, data sharing forums and project progress meetings all ensure that robust monitoring and evaluation mechanisms are in place.

DiSCs have served 20,000 individuals who identify as members of FSW or MSM communities. Based on their experiences with this model, NOPE has contributed to the national guidelines for key populations and led the development of the national MSM peer education curriculum. Technical assistance from NOPE has allowed other organizations, such as Ishtar MSM and Keeping Alive Societies’ Hope, to assume responsibility for three of the DiSCs. One of the key lessons learned in establishing the DiSCs is that gaining the trust of key populations is imperative, especially in environments where laws and policies criminalize female sex workers and men who have sex with men for their behavior. While freestanding facilities are critical for key populations, sustainability will require integration of service delivery for these groups into the national health services as the communities and providers become more responsive to the needs of key populations. In the meantime, NOPE has successfully mobilized county health management teams to provide medical supplies and to second medical staff to DiSCs. Additionally, NOPE plans to partner with the private sector for eventual co-ownership of some of the DiSC sites.

**Lebanon | Anonymous services and outreach for key populations**

**Marsa Sexual Health Center**

[http://www.marsa.me](http://www.marsa.me)

Marsa Sexual Health Centre (Marsa) in Beirut offers sexual and reproductive health services to the public in a welcoming environment free of stigma and discrimination against age, sex, gender and sexual orientation. The center targets young people, unmarried sexually active women, and marginalized communities with limited access to SRH services, including men who have sex with
men and transgender people. Assuring clients of anonymity and confidentiality plays a key role in encouraging uptake of Marsa services. The center uses a unique file number for each client as a form of identification, and the client decides if they would like to provide further identifying information for their file. In addition, the staff of experienced and sensitized professionals is required to maintain confidentiality. Clients feel comfortable to open up to their care providers, disclose intimate details about their lifestyles and seek information from specialists, knowing that their identity will not be disclosed, even among staff members. Marsa does not advertise publicly; to share information about their services, the programme uses social media and the Internet, as well as street outreach campaigns and word-of-mouth.

Myanmar | Comprehensive harm reduction services

Médecins du Monde
http://www.medecinsdumonde.org

Médecins du Monde (MdM) implements a project focused on STI and HIV prevention, treatment, care and support along with other harm reduction interventions for female sex workers and men who have sex with men in the capital, Yangon, and for people who use drugs in Kachin State.

The programme strategy is based on the provision of a comprehensive set of high quality services provided free of charge at drop-in centres and clinics run directly by MdM. The programme was developed in close collaboration with the targeted key populations, with peers playing a crucial role not only participating in the activities but also in ensuring that the programme continues to meet their needs. A significant outreach component has been set up with social workers and peer educators in order to reach out to key populations in those locales where risky practices are taking place (e.g. place of work, sex establishments, injection sites, etc.). Provision of education, information and supplies helps to build trust and confidence; individuals can then decide if they want to visit the facilities where they can access more services. Strong relationships are also being built with local authorities to influence the operational framework and contribute to the adoption of evidence-based policies.

There has been a steady decrease of HIV prevalence among men who have sex with men, people who use drugs and sex workers in Myanmar in recent years. However, in the rural context, where the general population has very limited access to primary health care, offering a wide range of health services to people who use drugs only can be problematic. MdM has found that addressing the most basic health needs of the community, in addition to those of key populations, should be seriously considered when possible, in order to help strengthen programme acceptance and reduce resentment and misunderstandings. The greatest challenge will be to reinforce the emergence of local NGOs and other community-based groups so that most of the harm reduction effort, which currently depends on international NGOs, can be taken over by local organizations. Beyond service delivery, skills transfer and capacity building are becoming the priorities in Myanmar.
Pakistan | Community-based drop-in centres*

Naz Male Health Alliance
http://www.apcom.org/spotlight-naz-male-health-alliance-pakistan

Naz Male Health Alliance (NMHA) is a community-based organization in Pakistan addressing the health and psychosocial needs of young males who have sex with males\(^{37}\) and transgender people. As part of its ongoing work to empower these communities, the organization operates six service delivery centres in five cities, with 47,000 registered clients. Each site is divided into a clinic and a drop-in centre that provides a safe and relaxing atmosphere for low-income males who have sex with males and transgender clients. The centres are strategically located, close to hotspots for the MSM community and near concentrations of ‘hijra deras’ (dwellings of transsexual people). Drop-in centres and outreach activities are complementary; drop-in centres allow the establishment of long-term relationships with the clients, and outreach provides linkage to the drop-in centre. Service sites are separate for each key population group in order to effectively address their specific needs. Each centre has a multidisciplinary staff of around 15 people, including physicians who are STI specialists, a psychologist, and peer educators. The teams consist primarily of community members and more than 95% of staff are members of the MSM community and transgender people.

The Government of Pakistan has publicly stated that NMHA was responsible for a significant increase in newly registered HIV-positive males who have sex with males and transgender people in their public HIV treatment centres. NMHA makes special efforts to create strong linkages and partnerships with groups such as the National AIDS Control Programme, Rahnuma-Family Planning Association, the Asia-Pacific Coalition on Male Sexual Health, the Asia-Pacific Transgender Network and Youth Voices Count, along with other stakeholders.

South Africa | Training health-care workers to work with key populations*

South African National AIDS Council (SANAC) and the SA Department of Health (DoH)

Discriminatory attitudes of health-care providers towards people from key populations and “unfriendly” health facilities are barriers to access and uptake of services, contributing to poorer health outcomes.\(^{38}\) A multi-partner project led by SANAC and the DoH has developed an integrated approach to sensitize health-care providers on issues affecting key populations and to empower public health staff to interact appropriately (in terms of attitude and clinical expertise) with people from these communities. Trainings have been conducted in preparation for the implementation of

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\(^{37}\) Many clients served by NMHA are under 18 years of age, and so this term is preferred to ‘men who have sex with men’.


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the rollout of the *National Operational Guidelines for HIV, STI and TB Programmes for Key Populations in South Africa*. The full programme includes in-person training and mentoring.

Thirty trainers participated in an initial training of trainers workshop and were linked to local training centres and health facilities. In turn, they trained 420 health-care workers in six months. Where these trainings took place, people from key populations have reported improvements in health-care workers’ attitudes. Community trust in health providers has increased, as has the use of health facilities where the sensitization training has been linked with peer outreach and the HIV prevention education activities of civil society organizations. Further evaluation is planned to inform scale-up.

**Tanzania | Reaching young people through a drop-in centre***

Kimara Peer Educators and Health Promoters Trust Fund
http://142.177.80.139/kimara/

Kimara Peers, a community-based NGO, implements HIV prevention programmes in a low-income area of Dar es Salaam. Kimara opened 2 drop-in centres (DIC) near state-run health centres and dispensaries to provide outreach and services to people who use drugs (with a focus on injectors), including those aged 16–24 years. The DIC also serves young people who sell sex, as there is an overlap between the two populations.

The Kimara Peers staff at the DIC includes trained community outreach workers from the local area and a professional social worker. Outreach workers publicize DIC services when they are in the community as well as during larger public gatherings, such as for World Drug Day. Services offered at the DIC include individual and group psychosocial therapy and support, basic information on harm reduction, prevention of HIV and other STIs, condom use and prevention of viral hepatitis. Referrals are made for methadone-assisted therapy and treatment of STIs. Education and materials specially designed for young people on sexual and reproductive health, including HIV, are available. Referrals to government hospitals are made only with a young person’s consent, and confidentiality is maintained unless the young person gives permission for their parents or other family members to be informed and/or involved. The programme is seeking government approval for provision of clean needles and syringes at the DIC and by outreach workers.

**Thailand | Using ICT to reach young men who have sex with men and transgender people***

Save the Children Fund
www.savethechildren.org/site/c.8rKlIXMGlpl4E/b.6234243/k.C392/HIVAIDS.htm

Save the Children uses information and communication technologies (ICT) to enhance HIV prevention outreach to young men who have sex with men and transgender people in Chiang Mai, Thailand. The city is a major destination for sex tourism and has large numbers of migrants from
minority ethnic groups and from Myanmar. The project provides information on HIV prevention, treatment, care and support by tapping into social media most commonly used by the MSM community. These include Facebook, Line (a mobile phone application) and other websites and forums frequented by young men who have sex with men.

The project’s research indicated that non-HIV related content such as personal grooming, religious instruction and topical news would be an effective way to engage young men who have sex with men and young transgender people. Content is devised by project staff based on discussions with volunteers and other members of the MSM community, and is changed regularly to keep it fresh and topical. Outreach workers promote Mplus Chat, an app developed by a local NGO working with MSM groups; the educators then use this to establish a relationship with the young men who have sex with men and young transgender people. The project provides outreach workers with tablet computers, which help to engage the attention of young members of MSM and TG communities and makes communication easier in noisier environments like bars and clubs. The tablet is used to show the project’s website, provide content for discussion and to record contact details for later follow-up.

After initial contact is established, outreach workers continue to use ICT platforms to disseminate information on HIV prevention, treatment, care and support. Young men who have sex with men and young transgender people value continued online contact as a way to establish a trusting relationship with a counsellor while maintaining a degree of anonymity. This relationship enables outreach workers to promote accompanied referrals to free HIV testing.

USA | Low-threshold services for young key populations*

Test, Connect & Treat – AIDS Institute of the New York State Department of Health, Specialized Care Centers and Youth Access Program
http://www.health.ny.gov/diseases/aids/general/about/hlthcare.htm#specialized

The Test, Connect & Treat programme of the New York State Department of Health recruits high-risk adolescents and young adults (aged 13–24 years) for HIV testing. Young males who have sex with males are the population with the majority of new HIV diagnoses in the state. The programme emphasizes a broad range of low-threshold services. Those who are HIV-positive are immediately linked to care, while those who are HIV-negative are provided with risk reduction and prevention information and referrals to community services.

The programme is run through 14 Specialized Care Centres across the state, where multidisciplinary staff teams provide comprehensive and coordinated HIV and primary health care, mental health and supportive services on-site. Clinic services are made as accessible as possible through evening and/or weekend hours and walk-in appointments. Services are provided regardless of the young person’s ability to pay, and those without health insurance are assisted to apply for benefits and enrol in a managed care plan. For those who have eligibility through their
parents, providers work to ensure services are confidential. If a young person tests positive for HIV, they are given a medical appointment and linked to a social worker and a medical case manager.

The programme has formed partnerships with youth-friendly clinical-care and social-services providers. Case management assessments focus on the young person’s strengths and self-management skills, including his or her ability to attend medical appointments and adhere to treatment, which may be impeded by significant mental health, trauma and substance abuse issues. Case management has been found to be critical for adherence to treatment plans and positive health outcomes.

3. CONCLUSION
Around the world, in very different settings, hundreds of programmes are addressing the needs of key population communities who often live outside the reach of formal health and social welfare systems. They are working to ensure access to essential HIV and STI prevention, diagnosis, treatment and care that have been available to the general public for decades in many places. When faced by an array of social, legal and logistical constraints, programmes are developing innovative ways to reach and encourage uptake of services by individuals who are reluctant to expose themselves to the harassment, discrimination and legal consequences that often accompany delivery of health and social services.

The interventions featured in this compilation represent the leading edge of a new front in the response to HIV that recognizes the vital importance of critical enablers as well as innovation and courage when delivering services for key populations. While there are limitations inherent in presenting only a sample of case studies, and by limiting the length and content of the case studies, readers are encouraged to contact these programmes for more information and for inspiration to move this work forward.
Annex 6: HIV and young key populations: technical briefs

Annex 6.1 HIV and young transgender people: A technical brief

Annex 6.2 HIV and young people who sell sex: A technical brief

Annex 6.3 HIV and young people who inject drugs: A technical brief

Annex 6.4 HIV and young males who have sex with males: A technical brief
Annex 7.

Recommendation on ARV-related prevention: Language from 2014 version of the Consolidated guidelines on HIV prevention, diagnosis, treatment and care for key populations.

4.1.5 ARV-related prevention

4.1.5.1 Pre-exposure prophylaxis

WHO has developed new guidance concerning pre-exposure prophylaxis (PrEP) for inclusion in this publication. Full discussion of the guidance and its rationale is presented here.

Background and rationale

Oral pre-exposure prophylaxis of HIV is the daily use of ARV drugs by HIV-uninfected people to block the acquisition of HIV. Studies have demonstrated the effectiveness of PrEP in reducing HIV transmission among serodiscordant heterosexual couples, men who have sex with men, transgender women, high-risk heterosexual couples, and people who inject drugs (4, 74).

WHO encourages countries to undertake demonstration projects to gain experience in implementing PrEP safely and effectively (74).

Recommendations and guidance

ALL KEY POPULATION GROUPS

Where serodiscordant couples can be identified and where additional HIV prevention choices for them are needed, daily oral PrEP (specifically tenofovir or the combination of tenofovir and emtricitabine) may be considered as a possible additional intervention for the uninfected partner (conditional recommendation, high quality of evidence) (74).

Related recommendations and contextual issues for specific key population groups

NEW MEN WHO HAVE SEX WITH MEN

Among men who have sex with men, PrEP is recommended as an additional HIV prevention choice within a comprehensive HIV prevention package (strong recommendation, high quality of evidence).
Background

The conditional recommendations of 2012 to offer PrEP to men who have sex with men, transgender people and the HIV-negative partner in serodiscordant relationships in the context of demonstration projects (74) was reconsidered in 2014 in the light of evolving evidence. In addition, continuing high rates of HIV incidence are increasingly reported in men who have sex with men in all regions, despite the availability of current prevention interventions, suggesting that additional prevention options could be important.

The systematic review that provided the evidence base for the 2012 WHO guidelines on PrEP (74) was updated in January 2014. This review examined the following PICO39 question: “Should oral PrEP (containing tenofovir (TDF)) be used for HIV prevention among men who have sex with men?”

The review of values and preferences of men who have sex with men about PrEP also was updated in January 2014, through a review of published literature (see Web Annex 1 for the full report). Also, further values and preference research was undertaken by the Global Forum on MSM (MSMGF) (Web Annex 3).

Results

Combining results from the 2012 and 2014 searches for the systematic reviews yielded 764 citations and 139 conference abstracts. Following screening and review, four studies reported in five articles were deemed eligible for inclusion in the review. Of these, one was a Phase III efficacy trial, while three were smaller pilot feasibility/acceptability or extended safety studies. Given the differences in the studies’ purposes, drug regimens/dosing schedule and size/statistical power (and, thus, in imprecision and quality, according to the GRADE framework), only results from the primary Phase III efficacy trial were included in the GRADE tables. These are the results presented below. For further information on the other four studies, see Web Annex 1.

The primary Phase III efficacy trial meeting all inclusion criteria was the iPrEx trial (75). This was a randomized controlled trial to evaluate the safety and efficacy of once-daily oral tenofovir-emtricitabine (FTC-TDF) compared with placebo for the prevention of HIV acquisition among men who have sex with men and among transgender women. The trial involved 2499 participants in six countries: Brazil, Ecuador, Peru, South Africa, Thailand and the United States of America. All study participants were born male; 29 (1%) reported their current gender identity as female. The study measured all five key outcomes for this review: 1) HIV infection, 2) any adverse event, 3) any stage 3 or 4 adverse event, 4) condom use and 5) number of sexual partners.

**HIV infection.** Oral PrEP was associated with reduced risk of new HIV infection in both intention-to-treat analysis (HR: 0.53, 95% CI 0.36–0.78, p=0.001) and modified intention-to-treat analysis (HR: 0.56, 95% CI 0.37–0.85, p=0.005).

**Adverse events.** There were no significant differences in the rates of reported adverse events between the FTC-TDF and control arms for either any adverse event (RR: 0.99, 95% CI 0.94–1.04) for grade 3 and 4 adverse events (RR: 0.92, 95% CI 0.75–1.13).

**Quality of the evidence.** The quality of evidence was high for all outcomes, without serious

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39 PICO stands for “patients, intervention, comparison and outcome”.

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limitations.

**Values and preferences.** While the relevant literature has proliferated recently, the reported values and preferences on PrEP use of men who have sex with men and transgender people have remained fairly consistent with findings of the systematic review conducted in 2011.

Globally, awareness of PrEP among men who have sex with men continues to be limited, although several studies suggest awareness has increased since the release of the iPrEx results. Willingness to use PrEP varies across studies, but the majority report that 40% to 70% of respondents are willing to use PrEP.

Main factors that would influence PrEP use include effectiveness, side-effects and cost. Respondents also mentioned concerns about accessibility, mistrust of health-care providers, stigma and risk compensation. All studies measuring potential risk compensation found that at least some participants anticipated changing their sexual behaviour as a result of PrEP. Providers generally expressed awareness and support of PrEP, although few had prescribed it. Providers’ concerns included drug resistance, risk compensation, limited availability of ART (in Peru), poor adherence, lack of local guidelines and concern that PrEP does not fit well in current (US) models of care, which do not include frequent, regular clinic visits.

**Feasibility.** Oral PrEP for men who have sex with men has proved feasible in various trial settings and acceptability studies (including among young men who have sex with men). Implementation may prove challenging, however, where access to services and provision of alternative prevention tools are limited or lacking. Issues of criminalization, stigma and discrimination, and violence should be considered during implementation, especially where same-sex behaviour is illegal.

**Additional considerations**

In formulating the new recommendation, the Guidelines Development Group took into consideration the overall high quality of the evolving evidence base, with benefits clearly outweighing harms (see Web Annex 1). In addition, several new studies indicate no major variability in values and preferences, with men who have sex with men broadly in support of PrEP.

Data on the cost-effectiveness of PrEP vary widely, depending greatly on drug price. The Group noted that in low-income countries PrEP is considerably cheaper than in many middle- and high-income countries.

All men who have sex with men should have the opportunity to choose PrEP if they feel that it meets their HIV prevention needs. However, the choice is theirs to make. Men who have sex with men should be offered the full range of evidence-based HIV prevention options. The decision to use PrEP – and other prevention options – will be an individual one, based on lifestyle, preferences, sexual behaviour, experience with other prevention options and the environment, and it should always follow discussion with a specialized and specifically trained health worker. The decision to use PrEP is likely time-bound: It is not likely to be for life but rather only for a period when a man feels that he is at a higher risk of infection.

PrEP is best offered as one component of a comprehensive set of HIV prevention interventions.
Comprehensive HIV prevention programmes should include unfettered availability of condoms and lubricants, routine HIV testing, risk-reduction counselling and adherence coaching if PrEP is offered. In the introduction of PrEP, it will be important to assess the barriers and facilitators to existing HIV prevention strategies in the specific community and context. This assessment should be undertaken in collaboration with local key population-led and community-based organizations, advocates, providers, and researchers who have cultural sensitivity, knowledge and the trust of men who have sex with men. This process should include an assessment at local levels of:

- sexual and HIV stigma
- stigma associated with receipt of a particular prevention intervention
- provider attitudes and knowledge about the sexual health needs of men who have sex with men
- availability, accessibility, quality and use of basic HIV services
- knowledge and acceptability of ART-based prevention strategies
- laws that criminalize sex between men
- personal safety and security
- privacy and confidentiality protections
- legal literacy among and legal protections and services for men who have sex with men and their service providers
- community engagement
- other concerns particular to the location (identified by local staff of community-based organizations and recipients of services).

Based on the assessment, and in collaboration with local community-based organizations, it will be helpful to develop a plan to:

- address identified barriers
- mitigate risk to confidentiality, privacy, personal safety and security
- support and enhance facilitators and enablers as needed
- assess changes over time.

**PEOPLE WHO INJECT DRUGS**

- No new recommendation was made for use of oral PrEP for people who inject drugs.
- The existing recommendation to offer daily oral PrEP as an additional HIV prevention choice for the negative partner in a serodiscordant relationship remains relevant for people who inject drugs and are in a serodiscordant relationship (conditional recommendation, high quality of evidence) (74).

**Background**

In the scoping meeting of October 2013, the External Steering Group decided that the use of PrEP for people who inject drugs should be reviewed.
A systematic review included all studies published in peer-reviewed journals or presented as abstracts at scientific conferences between 1 January 1990 and 1 January 2014. This systematic review examined the following PICO question: “Should oral PrEP (containing tenofovir (TDF)) be used for people who inject drugs?” More detailed information on the systematic review is available in Web Annex 2.
Results

The search yielded 183 citations and 243 conference abstracts; following screening and review only one study (with data for PICO outcomes reported in one article and one conference abstract) was deemed eligible for inclusion in the review – the Bangkok Tenofovir Study (76, 77). This was a randomized controlled trial to assess whether daily oral use of tenofovir disoproxil fumarate (tenofovir), compared with placebo, reduces HIV transmission in injecting drug users. Conducted in Bangkok, Thailand, the trial recruited 2413 participants from 17 drug treatment clinics. Participants’ ages ranged from 20 to 59 years (mean=32.4), 80% were male, and 63% reported injecting drugs in the past 12 weeks. The study measured all seven key outcomes for this review: 1) HIV infection, 2) any adverse event, 3) any stage 3 or 4 adverse event, 4) condom use, 5) number of sexual partners, 6) injection frequency and 7) needle/syringe sharing.

**HIV infection.** Oral PrEP was associated with reduced risk of HIV in both intention-to-treat analysis (HR 0.53, 95% CI 0.36–0.78, p = 0.001) and modified intention-to-treat analysis (HR: 0.56, 95% CI 0.37–0.85, p = 0.005).

**Adverse events.** There were no significant differences in reported rates of adverse events between the TDF and placebo arms for any adverse event (91% versus 90%, p = 0.46) or for grade 3 and 4 adverse events (13% versus 13%, p = 0.89).

**Injection frequency and needle/syringe sharing.** Both the TDF and control arms reported reduced injection behaviour and less injecting with used needles over the course of the study. There were no significant differences between study arms over time or at 12-month follow-up (p = 0.520 for injection frequency and p = 0.874 for needle/syringe sharing).

**Condom use and number of sexual partners.** Both the TDF and placebo arms reported increased condom use with live-in partners and reduced numbers of sexual partners over the course of the study. There was no significant difference between study arms over time or at 12-month follow-up.

**Quality of the evidence.** The quality of evidence was moderate for all outcomes based on one RCT that was downgraded because of risk of bias due to a significant loss to follow-up (attrition bias).

**Values and preferences.** The systematic review described above identified one published study examining acceptability of PrEP and factors likely to influence uptake among people who inject drugs. This quantitative study involved 128 people in Ukraine. Most participants said that they would definitely (53%) or probably (32%) use PrEP if it became available. These results changed little when participants were prompted on potential side-effects, the need to continue condom use while taking PrEP and the need for regular HIV testing. Respondents considered route of administration the most important attribute influencing PrEP uptake; they preferred injections over pills.

Additionally, WHO commissioned a qualitative in-depth values and preferences survey. The survey interviewed 21 people who inject drugs as well as experts, service providers and activists from all geographic regions about their values and preferences regarding PrEP. Those
interviewed gave qualified support to PrEP based on its potential usefulness for some people who inject drugs in countries where other harm reduction options are not available and that have good ART access. Reticence about PrEP as a useful HIV prevention option for people who inject drugs was based on perceptions that investment should be made in other proven interventions that are already available (e.g. NSP, OST and hepatitis C screening, diagnosis and treatment), that PrEP is “not proven” for people who inject drugs, and that it is unethical to give PrEP when not all people living with HIV can get ART for treatment; and on concern about “hidden agendas”. The Guidelines Development Group concluded: “A recommendation for the use of PrEP as a harm reduction intervention for people who inject drugs is not supported by the community at this time.”

Feasibility. Groups of people who inject drugs (78) and some members of the Guidelines Development Group raised concerns about the operational feasibility of the Bangkok Tenofovir Study and whether it could be replicated in standard service delivery settings. In addition, members of the Guidelines Development Group commented that PrEP should not be seen as a substitute for NSP and other prevention programmes already proven to reduce the risk of HIV transmission among people who inject drugs. The Guidelines Development Group also stated that issues of criminalization, stigma and discrimination, and violence should be considered during implementation, especially where injection drug use is illegal.

Additional considerations
After reviewing all the available evidence, the Guidelines Development Group concluded that no recommendation should be made on PrEP for people who inject drugs. There was uncertainty regarding the benefits versus harms and about resource utilization and feasibility.

The Guidelines Development Group pointed out that existing acceptable, cost-effective methods of preventing HIV in people who inject drugs (such as NSP, OST) are not implemented in many settings. While the Group acknowledged that further effectiveness and safety studies are unlikely given the positive efficacy shown in the Bangkok trial, the Group considered that further research is needed into the values and preferences of injection drug users and to determine the feasibility of implementing PrEP in the context of these proven prevention strategies. Therefore, the Group concluded, it was premature to make a recommendation, but a recommendation could be reconsidered when further information becomes available.

SEX WORKERS
The existing recommendation to offer daily oral PrEP as an additional HIV prevention choice for the HIV-negative partner in a serodiscordant couple remains relevant for sex workers who are in serodiscordant couple relationships (conditional recommendation, high quality of evidence) (74).
Summary of the Guidelines Development Group discussion and other considerations

In the scoping meeting of October 2013, the External Steering Group decided that the use of PrEP for sex workers should not be considered in this guidelines process as there were no studies of PrEP among sex workers and results from demonstration projects were not yet available. Furthermore, studies relating to the values and preferences of sex workers regarding PrEP were underway, and results were not yet available. This decision was confirmed in the guidelines meeting. The Guidelines Development Group agreed that this question could be considered as a PICO question with subsequent systematic review and GRADE assessments for future guidelines and should be prioritized with a focus on high prevalence settings with good ART access. Additionally, concerns were raised that a recommendation to use PrEP could undermine current comprehensive condom programming efforts, which have high acceptability and uptake in many settings.

TRANSGENDER PEOPLE

Where HIV transmission occurs among transgender women who have sex with men and additional HIV prevention choices for them are needed, daily oral PrEP (specifically the combination of tenofovir and emtricitabine) may be considered as a possible additional intervention (conditional recommendation, high quality of evidence) (74).

Summary of the Guidelines Development Group discussion and other considerations

In the scoping meeting of October 2013, the External Steering Group decided that the conditional recommendation of 2012 should not be reconsidered, as there was no new evidence relating to transgender women, and very few transgender women have been included in PrEP trials to date. This was confirmed in the guidelines meeting, endorsing no change to the 2012 WHO guidelines recommendation for the use of PrEP for transgender people in demonstration projects. The Guidelines Development Group recognized that a systematic review of values and preferences, resource utilization and feasibility had not been conducted in the specific population of transgender women. For this reason the 2012 recommendation would remain valid. The Guidelines Development Group agreed that this question could be considered as a PICO question with subsequent systematic review and GRADE assessments for future guidelines. Additionally, a concern was raised that potential drug interactions may exist between regular use of PrEP and hormone replacement therapy (see Section 4.4.3); any future assessment of PrEP for transgender women will need to consider this issue.

Implementation considerations

Issues of criminalization, stigma and discrimination, and violence should be considered during
implementation.

**Delivery.** It is currently not possible to develop definitive guidance on how best to deliver daily oral PrEP; in many settings demonstration projects are needed (74).

**Demonstration projects.** Countries that introduce oral PrEP should undertake demonstration projects to ascertain the most appropriate user groups and the best delivery approaches (74).

**Further reading**

- Web Annexes 1, 2 and 3.