Sex workers' hopes and fears for HIV pre-exposure prophylaxis: recommendations from a UNAIDS consultation meeting

Johannesburg 11–12 November 2013 Wits Reproductive Health and HIV Institute

UNAIDS / JC2634 (English original, July 2014.)

Sex workers' hopes and fears for HIV pre-exposure prophylaxis: recommendations from a UNAIDS consultation meeting

Johannesburg 11–12 November 2013 Wits Reproductive Health and HIV Institute

ACKNOWLEDGEMENTS

This report was facilitated by the excellent quality of the presentations made by the speakers at this meeting. These presentations and the resulting discussion and recommendations were synthesised by Rosalind Coleman. Other participants at the meeting commented and helped refine the text and the thinking it presented. This meeting was organized by Kevin O'Reilly of the HIV Department at the World Health Organization and Peter Godfrey Faussett of the Joint United Nations Programme on HIV/AIDS (UNAIDS) in collaboration with the hosts Wits Reproductive Health and HIV Institute. Generous funding was provided by the Bill and Melinda Gates Foundation under its grant to the WHO number OPP1032248.

TABLE OF CONTENTS

ACRONYMS

AIDS	acquired immunodeficiency syndrome
ASWA	African Sex Worker Alliance
AVAC	Global Advocacy for HIV Prevention (originally AIDS Vaccine Advocacy Coalition)
FEM-PrEP	Pre-exposure Prophylaxis Trial for HIV Prevention among African Women
FTC	emtricitabine
GNP+	The Global Network of People living with HIV
HIV	human immunodeficiency virus
iPrEx	Iniciativa Profilaxis Pre-Exposición - pre-exposure prophylaxis initiative
LVCT	Liverpool VCT, Care and Treatment, now LVCT Health
NSWP	Global Network of Sex Work Projects
PrEP	pre-exposure prophylaxis
SWEAT	Sex Workers Education and Advocacy Taskforce
TDF	tenofovir
UNAIDS	Joint United Nations Programme on HIV/AIDS
VOICE	Vaginal and Oral Interventions to Control the Epidemic
WHO	United Nations World Health Organization

EXECUTIVE SUMMARY AND RECOMMENDATIONS

Background

In 2012 there were an estimated 2.3 million new HIV (human immunodeficiency virus) infections globally. Approaches to prevent new HIV infections have evolved over the past three decades so that combination prevention is now accepted as the key strategy. Combination prevention draws from evidence-based and synergistic biomedical, behavioural and structural interventions and should be proposed in a context of dialogue, education and empowerment. Effective prevention strategies include condom use and behavioural risk reduction, knowledge of HIV serostatus with appropriate antiretroviral therapy, male circumcision, needle and syringe programmes, and treatment of other sexually transmitted infections. Health programme planners can design a package of prevention interventions, guided by the needs and epidemiological characteristics of different priority populations. Individual choice is then possible to achieve optimal and high coverage of HIV prevention.

Recent clinical studies have demonstrated the efficacy of a new prevention method based on antiretroviral medication taken daily by people who are not living with HIV. The medications tested were tenofovir disoproxil fumarate (TDF) alone or with emtricitabine (FTC). This pre-exposure prophylaxis (PrEP), when used consistently, has been shown to reduce the risk of HIV infection by up to 90% among heterosexual people, men who have sex with men, transgender individuals and people who inject drugs. The United States Food and Drug Administration has approved the medication for use as PrEP among adults at high risk for HIV infection, as part of a combination HIV prevention strategy. The Centers for Disease Control and Prevention have recommended the use of PrEP in adults (1), and the World Health Organization (WHO) has issued recommendations for the use of PrEP by men who have sex with men and also in the context of discordant couples (2). The manufacturer of PrEP, Gilead, has submitted an application to license its use in HIV prevention in South Africa and Peru.

PrEP can contribute to the health-seeking strategy of individuals who are at high risk of exposure to HIV and who are not always in a position to keep themselves safe from HIV infection. An extra HIV prevention method under individual control could be an attractive option for key populations, including sex workers, young women in populations with a high incidence of HIV, men who have sex with men, people who inject drugs, and transgender individuals. As part of a series of community consultations, a meeting was held to explore the perceptions and attitudes of sex workers towards PrEP and to consider whether PrEP might feasibly expand HIV prevention choices within the complexity of their world beyond clinical studies. The meeting brought together sex workers from sites in Africa and Asia where introduction of PrEP is being actively considered, representatives of global sex work projects, other people involved in HIV prevention at the national and international level, and funders of HIV prevention research. Participants in group sessions discussed perceptions of PrEP, identified knowledge and information gaps, and considered delivery issues. The content of these discussions is captured in Box 1a and Box 1b. The PrEP research evidence and information requested is covered from page 19.

The PrEP studies of TDF with FTC used the medication Truvada®, manufactured by Gilead.

Box 1 Hopes and fears expressed for PrEP: feedback from five group discussions

Box 1a

Hopes and perceived benefits

- PrEP will be feasible and beneficial in real life with widespread access for all who choose it, including marginalized sex workers and people who need it for short periods of higher infection risk.
- PrEP will lead to increased HIV testing and treatment and strengthened services for other sexually transmitted infections.
- PrEP, like condoms, will empower individual sex workers by giving them more control and choice over their protection.
- Involvement in development, delivery and promotion of PrEP can strengthen the sex worker community.
- PrEP can progress the HIV prevention conversation around health promotion and human rights, reinforced by training of sex workers in legal issues and advocacy.
- One daily pill is easy to take. A gel or depot injection might be even better in the future.
- PrEP might be particularly attractive to younger or new sex workers who have not acquired the skills to negotiate condom use.
- PrEP is useful during condom stock-outs or when choosing to not use condoms, such as with regular partners, for stable discordant couples or when conception is desired.
- PrEP is reassuring in situations when condoms are not used, such as rape or obligation of a third party, or when a condom bursts.
- PrEP can be presented as a public health intervention where there is frequent unsafe sex – consider the cost of not preventing HIV.

Box 1b

Fears and perceived drawbacks

- PrEP could compromise established condom and safe sex behavioural norms.
- The positive PrEP message may mask the fact that it does not prevent pregnancy or other sexually transmitted infections.
- Funding may not be available to maintain PrEP supplies, or funding PrEP may undermine other health services, including antiretroviral therapy.
- Side-effects of PrEP can be worrying.
- PrEP may over-medicalize HIV prevention by reducing it to a single pill.
- PrEP could reduce the community cohesion around HIV by creating division between people living with and not living with HIV.
- Possession of PrEP could be used to identify and stigmatize sex workers. There may be no access to PrEP when sex workers are incarcerated, forcibly displaced, or otherwise denied their legal and human rights.
- Sex workers who migrate for work may not be able to access PrEP.
- Informal or unregulated use of PrEP could undermine its effects.
- PrEP may be sold to or stolen by people of unknown HIV status or who are living with HIV.
- PrEP may be confused with sedatives or drugs of abuse.

RECOMMENDATIONS

RECOMMENDATIONS

The recommendations were made by the groups and refined in open discussion at the meeting and through inputs to this report. A deeper consideration of each recommendation follows this summary.

In general, there is demand from sex workers for complementary tools in addition to condoms to increase their choice of HIV prevention strategies. Within the communities represented at the meeting, the demand for PrEP clearly exists so long as its use is non-coercive, remains the individual's choice, and does not undermine existing services and programmes.

ESTABLISHING COMMUNITY-BASED IMPLEMENTATION OF PrEP

1

Sex workers should be involved in programme planning in ways that are beneficial to individuals and their communities and based on genuine partnerships between all stakeholders.

2

The effective mobilization of sex workers needs to be included in plans for widespread roll-out of PrEP to all sex work communities.

3

The introduction of PrEP should be community-led and decentralized as much as possible, bringing the necessary trained personnel and technology closer to the users.

LINKING PrEP TO COMPREHENSIVE SERVICES

4

PrEP needs to fit within the broader context of improved community and social services for sex workers, strengthened by outreach activities with the legal authorities and other third parties.

5

PrEP should be proposed as part of a combination HIV prevention strategy that includes promotion of the regular use of condoms and lubricant.

6

The introduction of PrEP to sex workers should be integrated within the secure provision of comprehensive sexual health care, including HIV treatment.

STARTING AND SUSTAINING PrEP

7

PrEP is for people who are not living with HIV. Any provision of PrEP has to be linked to appropriate HIV testing services.

8

Individual sex workers should be provided with the information they need to assess their own risk of HIV infection and to choose whether or not to use PrEP.

9

Information on PrEP has to be made available to all populations in appropriate presentations using a variety of media.

MARKETING, FUNDING AND REGULATION OF PrEP

10

Action is needed on PrEP licensing, pricing and national programming to ensure the sustainability of PrEP programmes.

11

The packaging and marketing of PrEP need to be designed to encourage uptake and to avoid confusion with other medications.

12

Widespread monitored access to PrEP is necessary to reduce informal and unregulated use.

Establishing community-based implementation of PrEP

1. Sex workers should be involved in programme planning in ways that are beneficial to individuals and their communities and based on genuine partnerships between all stakeholders

The sex workers wanted to be closely involved in developing any PrEP strategy with their communities. PrEP programme planning needs to meaningfully value sex workers' experience, motivation and know-how, and to recognize the mutual dependency of policy-makers, the research community and this key population. A bidirectional flow of information, expertise and cooperation will improve the fit and effect of any policy or intervention. The presentation of PrEP with its encouraging message of HIV prevention could be an opportunity to reduce the stigma and misconceptions associated with sex work by highlighting safe sex behaviours.

2. The effective mobilization of sex workers needs to be included in plans for widespread roll-out of PrEP to all sex work communities

As demonstrated by several successful collectives, the political organization of sex workers is vital to promote their rights, garner support and fight against discrimination. However, the most vulnerable sex workers, including those without legal documents, working under coercion, or who do not speak the local language, are less likely either to be members of organizations or to be known to local health services; their risk of HIV infection is higher. Financial resources are required for training and outreach by sex workers to introduce PrEP broadly, even to these unseen sex workers. A widely representative community of sex workers will carry greater weight in negotiations for services.

3. The introduction of PrEP should be community-led and decentralized as much as possible, bringing the necessary trained personnel and technology closer to the users

The term "community-led" implies that the people motivating for the introduction of PrEP within sex work communities should be sex workers. Sex workers are too often the secondary partners in the delivery of programmes intended for their benefit. In many countries there has been progress from coercive service delivery, and yet abuse and discrimination from health service providers are still common. Practical methods to move from the situation of sex workers being recipients of services to participating actively in research and prevention programmes for HIV and sexually transmitted infections have been described (3,4). Open communication, exchange of information and suitable power sharing are priority components.

The decentralization of PrEP and other HIV and sexual health services is seen as important for several reasons. Sexual health services with HIV testing and treatment are often difficult for sex workers to access, either because they are geographically far away or due to the stigmatizing attitudes of health-care workers. Bringing services closer to sex workers, and training selected sex workers to manage and participate in associated outreach activities, could address specific local barriers; local ownership of sexual health services would then increase in parallel. This shifting of tasks requires careful regulation, clear lines of support and supervision, and allocated resources. Key considerations include maintaining clinic users' confidentiality, ensuring a secure supply of medication, diagnostic and other materials, and maintaining the security of the premises and the safety of service providers.

Linking PrEP to comprehensive services

4. PrEP needs to fit within the broader context of improved community and social services for sex workers, strengthened by outreach activities with the legal authorities and other third parties

Sex workers' freedom of choice in health-promoting behaviours is influenced by the activities of local authorities. In under-resourced and disadvantaged localities, being moved on or incarcerated by police increases the risk of violence and unsafe sex and reduces access to health services. In some situations, sex workers have succeeded in creating working partnerships with the police and now benefit from their protection. Elsewhere, however, the law enforcement mandate is exceeded, with harassment, violence and rape of sex workers by police. Strengthening sexual health and HIV prevention and treatment activities should be in cooperation with other social services and include raising awareness of sex workers' rights to correct legal and police treatment. Training selected sex workers in legal procedures and advocacy, and sharing experience between sex worker groups, are among the first steps towards building useful relationships with the local authorities.

Securing the access of sex workers to PrEP may also require the approval of brothel owners and other third parties with influence on sex workers. Health workers and sex workers together need to make representations to other interested parties to work towards improved access to sexual health care and HIV prevention.

Sex workers often work away from home. Ensuring their access to health care is a challenge, especially when migration is cross-border. Trained sex worker educators prioritizing the wider sex worker community could disseminate information among migrant and informal sex workers. The choice of whether or not to take PrEP should always remain voluntary for the individual sex worker.

5. PrEP should be proposed as part of a combination HIV prevention strategy that includes promotion of the regular use of condoms and lubricant

Many years of hard work have gone into successfully increasing the use of condoms with lubricant for prevention of HIV and other sexually transmitted infections. The meeting was concerned that the introduction of PrEP could undo these gains and reduce HIV prevention to a single pill. A sex worker taking PrEP will be understood to not be living with HIV and therefore at increased risk of being forced to not use condoms. Alternatively, sex workers may view PrEP as a reason to not use condoms. If the distorted rumour spreads that condoms are no longer required, then all sex workers could be compromised. Because of this, PrEP may not be taken up by sex workers who have already established condom use as routine and non-negotiable and do not want to risk weakening this habit. Support and information about PrEP are required to ensure it complements and strengthens existing HIV prevention behaviours.

Rates of condom use vary both for and between individuals for different reasons, and 100% consistent condom use will never be achieved. The capacity to negotiate condoms is diminished where there is poverty, inexperience, coercion, rape or incarceration. Condoms can burst or slip during intercourse. PrEP has the empowering advantage that the choice to use it rests with the individual sex worker, reducing the risk of HIV infection, although not the possibility of pregnancy or other sexually transmitted infections. Use of condoms may not be an attractive choice with regular partners thought to not be living with HIV, or with a long-term partner living with HIV, especially when conception is desired. In these situations, PrEP can provide important protection from HIV infection.

6. The introduction of PrEP to sex workers should be integrated within the secure provision of comprehensive sexual health care, including HIV treatment

Infection with HIV was not the only health concern for the sex workers in the meeting. They viewed PrEP as only one aspect of their combined health-seeking strategy and emphasized the need for explicit and widespread information on this combined prevention approach. The sex workers felt that PrEP should be introduced as part of a comprehensive strengthening of primary sexual health care that included a secure supply of condoms and lubricants, diagnosis and treatment of other sexually transmitted infections, and voluntary HIV counselling and testing linked to antiretroviral therapy for sex workers found to be living with HIV.

Starting and sustaining PrEP

7. PrEP is for people who are not living with HIV. Any provision of PrEP has to be linked to appropriate HIV testing services

The sex workers at the meeting understood that repeat HIV testing was required to ensure PrEP was not given to a person living with HIV. Attitudes to testing are changing as antiretroviral therapy becomes available; HIV testing was not thought to present a big barrier to PrEP introduction, providing those people found to be living with HIV had good access to antiretroviral therapy. Testing algorithms should be clarified for PrEP to minimize the chances of starting (or continuing) PrEP by a person with recent acute HIV infection who initially tests negative. A proposed approach is to repeat the HIV test within the first month of starting PrEP and thereafter to test quarterly each time a new supply of medication is dispensed.

8. Individual sex workers should be provided with the information they need to assess their own risk of HIV infection and to choose whether or not to use PrEP

PrEP still needs to overcome the hurdles faced by any prophylactic medication, such as the oral contraceptive pill. A healthy person needs to take a chemical compound regularly for prevention rather than for treatment, so the individual has to be sufficiently convinced of their risk of an outcome that they want to avoid, have confidence in the effectiveness and safety of the prophylaxis proposed, and be in a position to use the medication correctly. Acknowledgement of the risk of individual HIV infection depends partly on being well informed and knowing other people living with HIV. It is also influenced strongly by peer norms and the power that comes from being able to reduce the risk. In the same way that sex workers have health concerns beyond HIV, their identity is not limited to their profession. They are also parents, partners, children or siblings, and in these roles their risk of HIV infection may be low. The introduction of PrEP as a new HIV prevention tool can promote the discussion of risk while being proposed as part of the solution.

Having started PrEP, adherence is critical for it to be effective. The nuances of individual motivation that lead to useful adherence are still under investigation. Individual free choice is important: coercion may lead to high uptake but not long-term adherence. Participants in clinical trials with poor adherence to PrEP have described feeling obliged to start PrEP when those proposing it were controlling resources. Participants were also uncomfortable with the idea of a placebo-controlled trial and concerned about the possible side-effects of PrEP. The current and planned PrEP demonstration projects, situated in pre-existing HIV and sexual health programmes, with voluntary participation and no control or placebo research arm, are expected to shed more light on adherence and usage patterns of PrEP.

In places with a high incidence of HIV, young women are particularly at risk of infection, and yet randomized trials showed an association between young women, a high risk of HIV infection and low adherence with PrEP. The meeting felt that younger and new sex workers were the least able to assess their HIV infection risk. Younger sex workers may attract a high client load before they learn how to negotiate condom use or other protective safe sex behaviour. Taking PrEP during this vulnerable time could be an important HIV prevention method while other approaches to reducing risks are learned.

9. Information on PrEP has to be made available to all populations in appropriate presentations using a variety of media

The sex workers at this meeting were actively involved in reproductive and sexual health education and research. They were often in authority in their peer groups, and they were looking for research updates and other information so they could answer questions in their home and work settings (see question boxes). Evidence-based information and education tools about PrEP need to be developed urgently, using different delivery platforms, including street theatre, public art, video, radio and printed media. Collaboration between sex workers, health promotion professionals and creative media professionals will guide the methods, messages and languages used, making the information clear, appropriate and engaging for different populations. Priority audiences include sex workers, their clients and third parties, health-care workers, adolescents and people in authority. Follow-on public health information could use the novelty of PrEP to re-energize the public discussion on the common interest and benefit of sexual health promotion.

Marketing, funding and regulation of PrEP

10. Action is needed on PrEP licensing, pricing and national programming to ensure the sustainability of PrEP programmes

PrEP activities and funding should be integrated with, rather than drain resources from, existing sexual health programmes; they are linked by the same prevention rationale. The sustainability of PrEP within an HIV prevention programme depends on political engagement to secure its permanent place in national health policy, as well as on price negotiations, similar to those for the introduction of antiretroviral therapy. Without public funding, the PrEP programme will not reach its full potential. Generic manufacture, within the country of use where possible, is the desired aim. Bulk buying could reduce the cost to around US$ 90 per year in low-income countries.

PrEP is a major step forward in the choices available to sex workers in situations where the health service is already providing a comprehensive HIV care, treatment and prevention package. In more resource-constrained settings, the policy debate over priorities is ongoing. The cost of PrEP and how it will be funded are major concerns. Mathematical modelling involves many variables, including HIV incidence and HIV infection avoided, the cost of counselling and testing, the price of PrEP, the rate of uptake of PrEP, the length of time used compared with antiretroviral therapy, and service delivery costs. When prioritizing the people most at risk in a population where HIV incidence is high, a PrEP programme can be cost-effective since the monetary costs of preventing HIV in a person are likely to be similar to or less than the costs of treating HIV if it occurs.

11. The packaging and marketing of PrEP need to be designed to encourage uptake and to avoid confusion with other medications

The current oral formulation of TDF with FTC that is taken as PrEP is the same as that used in antiretroviral therapy regimens in some countries. The meeting participants were concerned that this could cause confusion and requested that the formulation, or at least its presentation, be different for PrEP. Any antiretroviral medication intended for prophylaxis needs to be packaged specifically for the prevention programme, and in as compact a form as possible to facilitate discrete storage. Brothel owners, police and other third parties should be shown the PrEP and its presentation so they can recognize it and distinguish it from drugs of abuse and sedatives.

Distinctive packaging and marketing, linked closely with the information activities, will promote PrEP as an empowering individual choice to remain healthy. In some high-incidence communities there is a view developing that HIV infection is inevitable and that antiretroviral therapy is an inoffensive strategy. However, although the life expectancy of people receiving antiretroviral therapy is now close to that of peers not infected with HIV, the quality of life of a person on PrEP may well be higher than that of a person on antiretroviral therapy. Even when the viral load is suppressed, there is still evidence of immune disturbance in people living with HIV. In addition, antiretroviral therapy needs to be taken for life, whereas PrEP can be taken while a sex worker is at high risk of HIV exposure and then stopped later in life, when the risk is judged to be low.

12. Widespread monitored access to PrEP is necessary to reduce informal and unregulated use

Antiretroviral drugs are already sometimes used as PrEP informally and without monitoring, and there is potentially an inverse market for selling PrEP for its antiretroviral properties. Obtaining one or more antiretroviral drugs from a person living with HIV and buying PrEP online are the two strategies most often reported. There are reports of individuals relying on various combinations of this informal, unregulated PrEP, treatment of other sexually transmitted infections, sporadic post-HIV exposure prophylaxis and emergency contraception to maintain their sexual health. In such unregulated settings there is no requirement to test negative for HIV before starting PrEP, and the drugs used may be inappropriate or inactive. These practices are likely to become more common, along with their inherent risks of drug resistance and inefficacy. Rolling out a monitored and properly funded PrEP programme with supporting education programmes could reduce these potential risks.

QUESTIONS RAISED IN GROUP DISCUSSIONS

What is the place of PrEP in HIV prevention programmes?

- PrEP is not a stand-alone intervention.
- PrEP is recommended in combination with condoms, lubricants and other safe sex practices.
- PrEP does not prevent other sexually transmitted infections or pregnancy.
- PrEP is only appropriate for people who are not living with HIV and are at high risk of HIV infection.
- Use of PrEP requires good adherence and regular HIV testing.
- PrEP can be introduced only where there is established patient confidentiality.

How safe is PrEP and what are the side-effects of PrEP?

- Millions of person-years of experience with people living with HIV have shown the drugs used in PrEP to be very safe. However, for a drug to be used as prevention in people not living with HIV, the risk of serious side-effects has to be very low.
- PrEP has not been shown to interact with alcohol. Safe sexual behaviour, however, includes responsible alcohol consumption.
- PrEP should not be taken with high doses of non-steroidal anti-inflammatory medicines such as aspirin.
- The most common side-effects of PrEP are usually short-lived (lasting up to a few weeks) and include diarrhoea, nausea, headache and dizziness.
- There is a very low risk of serious kidney damage when taking PrEP.
- There is rarely some mild bone thinning, not associated with bone fractures.
- PrEP can be taken with or without food.
- Severe acute exacerbations of hepatitis B have been reported rarely in people living with HIV who stop taking TDF with FTC. This is being monitored in people not living with HIV who are receiving PrEP.

Can PrEP be used during pregnancy and breastfeeding?

- The antiretroviral drugs used as PrEP have so far been found to be safe in pregnant women living with HIV and in new-borns, but PrEP has not been researched formally in pregnant or breastfeeding women.
- To monitor foetal outcomes of pregnant women exposed to PrEP, an antiretroviral pregnancy registry has been established.

What is the summary of PrEP research to date?

Four trials have shown daily oral PrEP preventing sexual transmission of HIV. The effect was higher for people who took PrEP consistently:

- iPrEx: PrEP reduced the risk of HIV by 44% in homosexual men and transgender women of black, Asian, Hispanic/Latino and white racial origin. Taking PrEP consistently reduced the risk by more than 90%.
- Partners PrEP: PrEP reduced the risk of HIV by 73% in heterosexual HIV-discordant couples in Kenya and Uganda. Taking PrEP consistently reduced the risk by more than 90%.
- TDF2: PrEP reduced the risk of HIV infection by 63% in heterosexual men and women in Botswana.
- Bangkok Tenofovir Study: PrEP reduced the risk of HIV infection by 49% in people who inject drugs in Thailand. Taking PrEP consistently reduced the risk by 75%. It is not certain how much of this transmission was sexual.
- Two trials – VOICE and FEM-PrEP – have shown no HIV prevention effect for PrEP. This is thought to be due to low or incorrect use of PrEP during the trials.

What is the risk of drug resistance with PrEP and how is this linked to HIV testing?

- PrEP is only for people who are not living with HIV.
- The use of PrEP by a person living with HIV would expose them to the risk of HIV drug resistance. Therefore a person must test negative for HIV before starting PrEP and continue to be tested regularly while using PrEP.
- Treatment of HIV disease consists of at least three antiretroviral drugs to ensure the virus does not become drug resistant. (The virus develops resistance more easily to a single drug than to a combination of drugs.)
- Recommended PrEP regimens contain two antiretroviral drugs, both of which are already important in HIV treatment. The introduction of the prevention of HIV with PrEP should not compromise the effectiveness of these drugs for HIV treatment.
- There is a small chance that a person will test negative for HIV and start PrEP during the acute infection phase (window period). To detect this, the unofficial guidance is that the HIV test needs to be repeated 1 month after starting PrEP and every three months thereafter.

Can PrEP be used periodically during temporarily increased HIV infection risk?

- Periodic PrEP is the planned and monitored use of PrEP during temporary and anticipated periods of increased HIV infection.
- Periodic PrEP with high adherence could be an effective prevention strategy once it has been determined how long PrEP needs to be taken before and after the high-risk period. Adherence to such a regimen depends on the person being able to anticipate discrete periods of unsafe sexual behaviour.
- Periodic PrEP should be used as part of a combination prevention strategy.
- Testing negative for HIV is necessary before each course of periodic PrEP. People choosing to use periodic PrEP may also have an increased risk of HIV infection between their PrEP courses, so a prevention strategy still needs to be defined.
- Research results for periodic PrEP have not been published and its use is not recommended. It is probably already being used informally.
- Periodic PrEP will be more complicated to monitor than full-time consistent PrEP use.
- Periodic PrEP is sometimes referred to as seasonal PrEP. It should be distinguished from intermittent PrEP, sometimes referred to as PrEP on demand, where medication is taken before and after unsafe sex. Intermittent PrEP is currently under research.

CONCLUSION

The interest in PrEP by sex workers is for both the improved protection from HIV infection and the increased choice of individual health promotion strategy. The dynamics of sex work are changeable, and PrEP has the potential to be of long-term benefit in varying and unpredictable situations. The reticence from the meeting to use PrEP came partly from uncertainty about side-effects but also from wariness that the attention given to PrEP might detract from other service amelioration and HIV treatment and prevention efforts. The reaction to this needs to be the establishment of robust, comprehensive and appropriate sexual health services closer to sex worker populations and ready to integrate PrEP. This is work in progress with important financial, procedural and capacity-building implications.

Although HIV incidence is dropping in some countries, the decline is uneven and too slow, with an estimated 2.3 million new HIV infections in 2012. A multifaceted response has matured based on social and behavioural changes, other biomedical interventions such as male medical circumcision, testing for HIV and appropriate access to antiretroviral therapy. Each of these has an important role to play, but their level of uptake and effect are insufficient to reduce HIV incidence to zero. Where individuals are motivated by appreciation of their high risk of HIV infection to seek HIV testing, PrEP can be a cost-effective contribution to reducing HIV incidence. In these populations, PrEP can be immediately useful while safer sexual behaviour, increased HIV testing and antiretroviral therapy-induced suppression of viral loads progress towards their full effect on incidence reduction.

Looking to the future

Future PrEP projects are oriented towards demonstrating the place of PrEP in national health policies. In countries where PrEP is not yet licensed, it is being introduced under open label regulations with close monitoring of people taking the medication. Research is continuing into PrEP on demand and parallel or stepwise PrEP with antiretroviral therapy introduction.

Trials of topical PrEP delivered as a gel or via vaginal rings are also in progress, and injectable/depot formulations of PrEP are in preparation. Networks of researchers, health-care workers and activists are prioritizing the sharing and discussions of results and experiences.

REFERENCES

1. Preexposure prophylaxis for the prevention of HIV infection in the United States – 2014: a clinical practice guideline. Atlanta, GA: Centers for Disease Control and Prevention; 2014 http://www.cdc.gov/hiv/pdf/guidelines/PrEPguidelines2014.pdf

2. Consolidated guidelines on HIV prevention, diagnosis, treatment and care for key populations: recommendations for a health sector response. Geneva: World Health Organization; 2014. In press. http://apps.who.int/iris/bitstream/10665/128049/1/WHO_HIV_2014.8_eng.pdf?ua=1

3. Good participatory practice: guidelines for biomedical HIV prevention trials, 2nd edition. Geneva: Joint United Nations Programme on HIV/AIDS and AVAC; 2011. http://www.unaids.org/en/media/unaids/contentassets/documents/unaidspublication/2011/JC1853_GPP_Guidelines_2011_en.pdf

4. Implementing comprehensive HIV/STI programmes with sex workers: practical approaches from collaborative interventions. Geneva: World Health Organization, United Nations Population Fund, Joint United Nations Programme on HIV/AIDS, Global Network of Sex Work Projects and World Bank; 2013. http://www.who.int/hiv/pub/sti/sex_worker_implementation/swit_intro.pdf

ANNEX 1

Topics covered and their presenters

An overview of safety trials, the current licensing situation for TDF and Truvada, and the rationale behind HIV testing before prescribing PrEP was given by Peter Godfrey-Faussett of the Joint United Nations Programme on HIV/AIDS (UNAIDS) and Kevin O'Reilly of WHO. Helen Rees of the Wits Reproductive Health and HIV Institute provided a comprehensive update on prevention technology. Representatives of the Sex Workers Education & Advocacy Taskforce (SWEAT) and the African Sex Worker Alliance (ASWA), described the realities and practical considerations of HIV prevention for sex workers, and the representative from GNP+ South Africa gave feedback from a consultation with 150 Western Cape sex workers. Cindra Feuer from AVAC presented Good Participatory Practice: guidelines for biomedical HIV prevention trials, and Ruth Morgan Thomas from the Global Network of Sex Work Projects (NSWP) presented Implementing comprehensive HIV/STI programmes with sex workers. Both of these publications and Ruth Morgan Thomas's later report on the global consultation Sex workers' perspectives on HIV & STI prevention and treatment services fed in to the recommendations presented here.

Site reports and descriptions of local conditions for sex workers were presented from India (Kolkata and Mysore), Kenya, South Africa and Zimbabwe.

To close the meeting, Gina Dallabetta representing Salif Sow and the Bill & Melinda Gates Foundation described the Foundation's current activities with oral PrEP and other PrEP delivery modes.

ANNEX 2

List of participants and organisations represented in alphabetical order
PrEP projects and community activists

India

Minati Dutta

Swapna Gayen

Nirmala Ghosh

Smarajit Jana

Protim Ray

Sushena Reza-Paul

Putul Singh

Akram Pasha Anwar

Lakshmi

Jinendra Jain Hubbali Mahaveera

Manjula Ramaiah

Durbar Mahila Samanwaya Committee (Kolkata)

Ashodaya Samithi (Mysore)

Kenya

Phelister Abdalla

Grace Kamau

Nduku Kilonzo

Joshua Kimani

John Mathenge

Peter Michira

Daughtie Ogutu

ASWA

Bar Hostess Empowerment and Support Programme

Global Network of Sex Work Projects

LVCT

Partners PrEP Study site, Thika

Sex Workers Outreach Project

South Africa

Kholi Buthelezi

Nomonde Mihlali Meji

Nyaradzo Mutanha

Helen Rees

Maria Sibanyoni

Francois Venter

GNP+

Sisonke

Wits Reproductive Health and HIV Institute

Zimbabwe

Rumbi Mapfumo

Centre for Sexual Health and HIV/AIDS Research – Zimbabwe

International

Reproductive Health Institute, University of Witwatersrand
Helen Rees (hrees@wrhi.ac.za)

AIDS Control programme, Nigeria
John Idoko (jonidoko@yahoo.com)

Global Network of Sex Work Projects
Ruth Morgan Thomas (ruth.morganthomas@nswp.org)

AVAC USA
Cindra Feuer (cindra@avac.org)

UNAIDS
Alison Crocket (crocketa@unaids.org)
Peter Godfrey-Faussett (godfreyp@unaids.org)
Rosalind Coleman, consultant to UNAIDS (colemanr@unaids.org)

WHO
Kevin O'Reilly (oreillyk@who.int)
Katie Curran (currank@who.int)
Peter Fajans, consultant to WHO (fajansp@gmail.com)

Bill & Melinda Gates Foundation
Gina Dallabetta (gina.dallabetta@gatesfoundation.org)

London School of Hygiene & Tropical Medicine
Robyn Eakle (robyn.eakle@lshtm.ac.uk)

O'Neill Institute – Georgetown University
Sue Kim (sck3@law.georgetown.edu)
John Kraemer (jdk32@georgetown.edu)

Printed on FSC-certified paper