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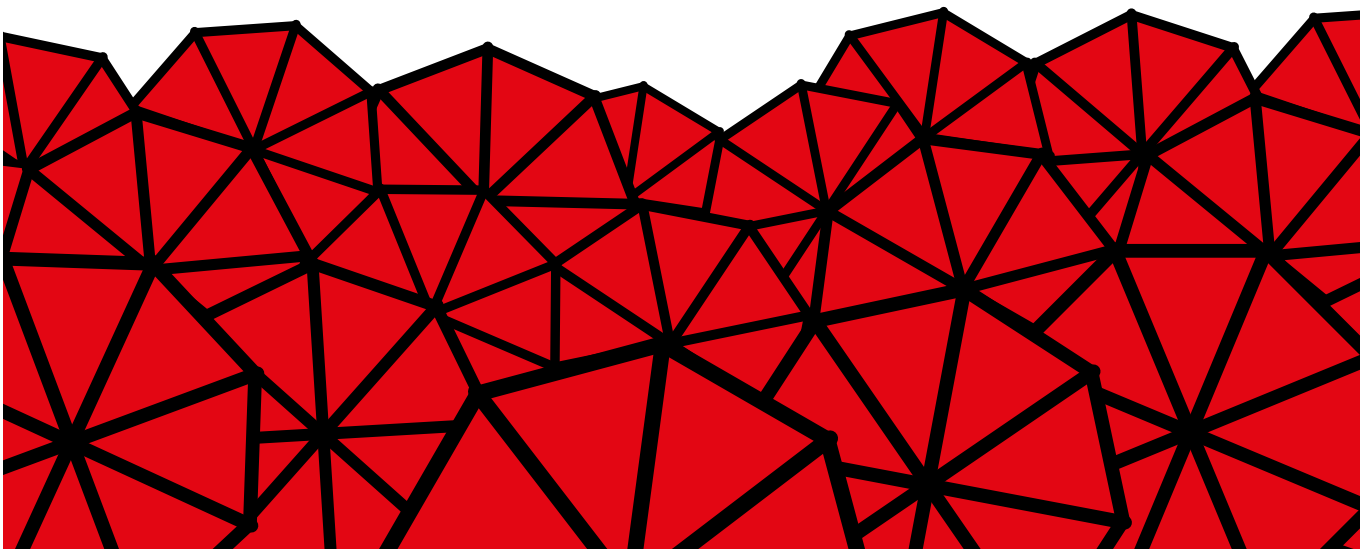
Global Network of Sex Work Projects

Promoting Health and Human Rights

BRIEFING PAPER

PrEP



PrEP

Introduction

With the prevalence of HIV among sex workers being twelve times that of the general population[1], and the World Health Organization (WHO) noting that "Female, male and transgender sex workers are disproportionately affected by HIV"[2], sex worker organisations around the world are at the forefront of HIV prevention efforts. It is therefore important that these organisations are aware of the latest developments in HIV prevention, so they can pass this information on to sex workers in the areas they serve. While HIV prevention efforts among sex workers have traditionally focused on condoms, there is an increasing emphasis on a range of emerging biomedical methods of HIV prevention.

Pre-Exposure Prophylaxis (PrEP) is the use of anti-retroviral HIV medicines (ARVs) by people who do not have HIV to prevent the transmission of HIV. The ARV used for PrEP is currently Truvada®, which consists of 300mg of Tenofovir Disoproxil Fumarate (TDF) and 200mg of Emtricitabine (FTC)[3]. "Prophylaxis" means a treatment given, or action taken, to prevent a disease.

In 2012, WHO recommended that PrEP be made available to sero-discordant couples, regardless of gender, and to men who have sex with men (MSM) and transgender people where an additional form of HIV prevention is needed[4]. In 2014, WHO updated this to say where sero-discordant couples can be identified, and where additional HIV prevention choices are required, PrEP may be considered, and that PrEP is recommended as an additional HIV prevention choice among MSM, within a comprehensive HIV prevention package[5].

In 2014, NSWP consulted with its membership over the use of PrEP and early treatment[6]. This consultation highlighted several concerns in relation to the impact on the health and human rights of sex workers, the impact on already existing and successful prevention programmes among sex workers, the accessibility and sustainability of PrEP among sex worker populations, the stigma that PrEP may exacerbate, and increases in the discrimination sex workers already face. Recommendations in that briefing paper included; ensuring sex workers have access to accurate knowledge and information about PrEP by strengthening the capacity of sex worker organisations to educate their own communities, prioritising research and data collection on the use of PrEP, promoting and expanding sex worker-led HIV testing and treatment services. There was also as a range of other recommendations, including to "engage sex workers in all levels of policy and programmatic discussions relating to PrEP and early treatment as prevention strategies, including sex worker involvement in the design, implementation, and monitoring of these programmes"[7].

1 Joint United Nations Programme on HIV/AIDS (UNAIDS). *The GAP Report*. (Geneva: UNAIDS, 2014), 13. Available from http://www.unaids.org/en/resources/documents/2014/Sexworkers

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

3 Gilead Sciences. *Truvada Prescribing Information*. (Foster City, CA: Gilead, 2016), 1. Available from http://www.gilead.com/~/media/Files/pdfs/medicines/hiv/truvada/truvada_pi.PDF

4 World Health Organization. Guidance on oral pre-exposure prophylaxis (PrEP) for serodiscordant couples, men and transgender women who have sex with men at high risk of HIV: recommendations for use in the context of demonstration projects. Geneva: World Health Organization, 2012). Available from http://apps.who.int/iris/bitstream/10665/75188/1/9789241503884_eng.pdf?ua=1

5 World Health Organization. Policy brief: Consolidated guidelines on HIV prevention, diagnosis, treatment and care for key populations. (Geneva: World Health Organization, 2014). Available from http://apps.who.int/iris/bitstream/10665/128049/1/WHO_HIV_2014.8_eng.pdf?ua=1&ua=1

6 NSWP. *Global Consultation: PrEP and Early Treatment as HIV Prevention Strategies*. (Edinburgh: NSWP, 2014). Available from http://www.nswp.org/sites/nswp.org/files/PrEP%20Global%20Consultation%20final3.pdf

7 Ibid, p 22.

This briefing paper is therefore an update and elaboration of that earlier consultation.

In 2015, WHO amended their briefing to delete references to sero-discordant couples and MSM, changing it to an all-encompassing "people at substantial risk". "Substantial risk" is defined as "HIV incidence greater than 3 per 100 person–years in the absence of PrEP", noting that this has been recorded in some groups of MSM and transgender women, as well as sero-discordant heterosexual couples[8]. Currently, WHO recommends that:

> ***"Oral pre-exposure prophylaxis (PrEP) containing… TDF should be offered as an additional prevention choice for key populations at substantial risk of HIV infection as part of combination HIV prevention approaches"***[9].

WHO also recommends that condoms remain part of prevention efforts.

Sex workers are one of the key populations identified by WHO. Therefore, WHO recommends that PrEP should be available to sex workers as part of a comprehensive HIV prevention package. Nevertheless, WHO also recommends that condoms remain part of prevention efforts:

> ***"The correct and consistent use of condoms with condom-compatible lubricants is recommended for all key populations to prevent sexual transmission of HIV and sexually transmitted infections (STIs)."*** [10]

Organisations supporting sex workers have also noted that, "Sex workers' concerns about PrEP contrast sharply with those expressed by men who have sex with men (MSM) advocates"[11]. Sex worker organisations were noticeably absent from the list of those who drafted the Community Consensus Statement for the AIDS2016 Conference in Durban. This statement urged that PrEP be "offered now to all people at high risk of HIV", while acknowledging that it should be an option, not something that people are pressured into using[12].

The issue of PrEP is therefore of great importance to sex workers around the world, as they may find PrEP being promoted by governments, often at the urging of the scientific community, donor organisations or other treatment activists, without the demand for its introduction coming from sex workers themselves.

This document provides insight into what sex workers think about PrEP and the concerns they have about it, including legal barriers, side effects, and what actions should be taken before consideration of the introduction of PrEP.

8 World Health Organization. *Guideline on when to start antiretroviral therapy and on pre-exposure prophylaxis for HIV*. (Geneva, World Health Organization, 2015). Available from http://apps.who.int/iris/bitstream/10665/186275/1/9789241509565_eng.pdf?ua=1

9 World Health Organization. *Consolidated guidelines on HIV prevention, diagnosis, treatment and care for key populations – 2016 update*. (Geneva: World Health Organization, 2016), xvii. Available from http://www.who.int/hiv/pub/guidelines/keypopulations-2016/en/

10 World Health Organization. *Consolidated guidelines on HIV prevention, diagnosis, treatment and care for key populations – 2016 update*. xvii.

11 Institute of Development Studies. *Rapid Response Briefing: Examining the implications if PrEP as HIV prevention for sex workers*. (Brighton: Institute of Development Studies, 2016). Available from https://opendocs.ids.ac.uk/opendocs/bitstream/handle/123456789/8680/RRB12_rev.pdf?sequence=5

12 Global Advocacy for HIV Prevention, European AIDS Treatment Group, Global Forum on MSM and HIV, Global Network of People Living with HIV, HIV i-Base, International HIV/AIDS Alliance, International Treatment Preparedness Coalition, & NAM. *Community Consensus Statement on Access to HIV Treatment and its Use for Prevention*. Available from http://www.hivt4p.org/wp-content/uploads/2012/12/Community-consensus-statement-English.pdf

Available research on PrEP

The earliest mention of using ARVs to prevent HIV infection was SIMBA, conducted in Rwanda and Uganda. This trial found a reduction in HIV transmission from mother to child when using HIV medications in the first 6 months of breastfeeding[13]. While this looked at the use of ARVs to prevent transmission through breast milk, trials later began examining how well ARVs could be used to prevent HIV infection after exposure (Post-Exposure Prophylaxis – PEP), and later to prevent HIV infection before exposure (Pre-Exposure Prophylaxis – PrEP).

One of the first trials of ARVs for PrEP examined how effective TDF was at preventing HIV transmission among women in Ghana, Cameron, and Nigeria. Both the Nigerian and Cameroonian sites closed before all the planned participants had been recruited or before all participants had adequate follow-up. The Ministry of Health in Cameroon, "suspended study drug distribution in February 2005 primarily in response to concerns about the standard of long-term post-trial care that could be guaranteed to seroconverters", while the site in Nigeria had, "repeated noncompliance with the protocol that was not resolved with staff retraining, enrolment was stopped in March 2005, and the site was closed thereafter." There were 8 seroconversions among the participants, of whom 2 were on TDF, the other 6 on a placebo. As the authors of the study expected more than twice the rate of seroconversion that they observed, they found that the, "overall rate of HIV infection while women were on TDF or placebo in Ghana, Cameroon, and Nigeria was too low to demonstrate a reduction in risk for those assigned to the TDF group." Nevertheless, they concluded that PrEP could be used as a new HIV prevention method when combined with other prevention strategies such as condoms to reduce the number of people who become infected with HIV"[14].

…"overall rate of HIV infection while women were on TDF or placebo in Ghana, Cameroon, and Nigeria was too low to demonstrate a reduction in risk for those assigned to the TDF group."

This was followed by the iPrEx study in 2010. It covered 9 sites in 6 countries, mostly among MSM, with a few transgender women. Half of the participants were given a placebo and the other half were given Truvada®. Although 41% of both the Truvada® and placebo groups reported having paid sex in the 6 months prior to the study, it did not indicate if they were sex workers or clients, or a mix of both. There were 100 seroconversions among participants – 36 among the Truvada® group and 64 among the placebo group. No cases of Truvada® resistance were reported among those who became HIV positive. In particular, iPrEx reported that PrEP was more likely to work if a person continued to take Truvada® as instructed. Incidents of unprotected receptive anal intercourse reduced after enrolment. The authors concluded that the 44% reduction in risk showed that "preexposure prophylaxis with oral FTC–TDF among men and transgender women who have sex with men addressed an important unmet need in public health"[15].

13 Vyankandondera J, Luchters S, Hassink E, Pakker N, Mmiro F, Okong P, Kituuka P, Ndugwa C, Mukanka N, Beretta A, Imperiale Jr. M, Loeliger E, Giuliano M, Lange J. *Reducing risk of HIV-1 transmission from mother to infant through breastfeeding using antiretroviral prophylaxis in infants (SIMBA study)*. 2nd IAS Conference on HIV Pathogenesis and Treatment, Paris, France, 15 July 2003, cited in F. Dabis, R. Becquet, L. Dequae-Merchadou, D.K. Ekouevi, V. Leroy, E. Mouillet, J. Orne-Gliemann, F. Perez, C. Sakarovitch. *PMTCT Intelligence Report*, Vol 3, Issue 8 (August 2003). Available from http://www.who.int/hiv/mtct/HIV_Care_0803.pdf

14 Leigh Peterson, Taylor, D., Roddy, R., Belai, G., Phillips, P., Nanda, K., Grant, R., Clarke, E.E.K., Doh, A.S., Ridzon, R., Jaffe, H.S., Cates, W. "Tenofovir Disoproxil Fumarate for Prevention of HIV Infection in Women: A Phase 2, Double-Blind, Randomized, Placebo-Controlled Trial", *PLOS Clinical Trials*. Available from http://journals.plos.org/plosone/article?id=10.1371%2Fjournal.pctr.0020027

15 Robert M. Grant, Lama, J.R., Anderson, P.L., McMahan, V., Liu, A.Y., Vargas, L., Goicochea, P., Casapía, M., Guanira-Carranza, J.V., Ramirez-Cardich, M.E., Montoya-Herrera, O., Fernández, T., Veloso, V.G., Buchbinder, S.P., Chariyalertsak, S., Schechter, M., Bekker, L-G., Mayer, K.H., Kallás, E.G., Amico, K.R., Mulligan, K., Bushman, L.R., Hance, R.J., Ganoza, C., Defechereux, P., Postle, B., Wang, F., McConnell, J.J., Zheng, J-H., Lee, J., Rooney, J.F., Jaffe, H.S., Martinez, A.I., Burns, D.N., & Glidden, D.V. "Preexposure Chemoprophylaxis for HIV Prevention in Men Who Have Sex with Men", *New England Journal of Medicine*, (2010; 363:2587–2599). Available from http://www.nejm.org/doi/full/10.1056/NEJMoa1011205

The study authors, "could not distinguish the type of anal sex (i.e. receptive or insertive), and therefore were unable to distinguish the risk between the two..."

Subsequent studies showed that PrEP significantly reduces the risk of HIV transmission. The CAPRISA 004 study in South Africa, which used a vaginal gel containing TDF, found that in those who used the gel consistently, HIV incidence was 54% lower than in the placebo arm, indicating the relatively modest 'success' of the gel so long as it was used as directed. Those who used the gel less often had less reduction in HIV incidence[16]. A study of sero-discordant heterosexual couples in Kenya and Uganda which used Truvada®, TDF by itself, and a placebo, found that Truvada® was 25% more effective among men than among women. Furthermore, of the 29 people in the study who became HIV positive, 31% had detectable levels of TDF in their blood, indicating they had been taking the drug. Of those eight people, two "developed HIV-1 with resistance to the study medications: one with TDF-resistant virus … and one with FTC-resistant virus"[17].

In a study completed in Melbourne, Australia, results showed that where HIV incidence is above 2% in MSM subgroups with specific characteristics, and whose last HIV test was negative, Truvada® as PrEP, "is considered cost effective at this incidence and could potentially be used along with other preventive interventions for these individuals in more than half of the population." The study authors, "could not distinguish the type of anal sex (i.e. receptive or insertive), and therefore were unable to distinguish the risk between the two. Furthermore, the number of sex acts was not collected and hence [they] were not able to identify the number and nature i.e. insertive or receptive of condomless anal sex acts. Other risk practices such as group sex and anonymous sex are found to be highly associated with HIV and STI but were not collected in this study". The study was carried out at only one sexual health clinic[18] and prompted, "Melbourne activists [to put] up posters through the [Central Business District] touting PrEP's benefits for those who choose to 'fuck raw'"[19].

However, in February 2016, it was announced that at least one person had become HIV positive despite continued use of Truvada®[20]. Cases of TDF resistance following treatment for HIV also exist. A study from Kenya among 333 study participants taking TDF, of whom 55% were female, found that 18% had detectable viral loads (some with a significantly high viral load), indicating the HIV they had was now resistant to TDF. Of those 59 people, only eight had been on medications other than TDF prior to starting TDF treatment[21].

Membership Consultation

A questionnaire was devised for use in all countries chosen for in-depth consultation with sex workers, and an information sheet from NSWP on Truvada® accompanied the questionnaire. The countries selected by the regional networks were; Canada and Jamaica (North America and Caribbean), Colombia and El Salvador (Latin America), France and Macedonia (Europe), India and Thailand (Asia-Pacific), and Kenya and Zimbabwe (Africa). A global e-consultation using the same questionnaire was also carried out with NSWP member organisations.

16 Quarraisha Abdool Karim, Karim, S.S.A., Frohlich, J.A., Grobler, A.C., Baxter, C., Mansoor, L.E., Kharsany, A.B.M., Sibeko, S., Mlisana., K.P., Omar, Z., Gengiah, T.N., Maarschalk, S., Arulappan, N., Mlotshwa, M., Morris, L., & Taylor, D. "Effectiveness and Safety of Tenofovir Gel, an Antiretroviral Microbicide, for the Prevention of HIV Infection in Women", *Science*, (2010, Sep 3, 329(5996): 1168–1174). Available from http://www.ncbi.nlm.nih.gov/pmc/articles/PMC3001187/

17 Jared M. Baeten, Donnell D, Ndase P, Mugo NR, Campbell JD, Wangisi J, Tappero JW, Bukusi EA, Cohen CR, Katabira E, Ronald A, Tumwesigye E, Were E, Fife KH, Kiarie J, Farquhar C, John-Stewart G, Kakia A, Odoyo J, Mucunguzi A, Nakku-Joloba E, Twesigye R, Ngure K, Apaka C, Tamooh H, Gabona F, Mujugira A, Panteleeff D, Thomas KK, Kidoguchi L, Krows M, Revall J, Morrison S, Haugen H, Emmanuel-Ogier M, Ondrejcek L, Coombs RW, Frenkel L, Hendrix C, Bumpus NN, Bangsberg D, Haberer JE, Stevens WS, Lingappa JR, Celum C. "Antiretroviral Prophylaxis for HIV-1 Prevention among Heterosexual Men and Women", *New England Journal of Medicine*, (2012 Aug 2; 367(5):399–410). Available from http://www.ncbi.nlm.nih.gov/pmc/articles/PMC3770474/

18 King T. Cheung, Fairley C.K., Read T.R.H., Denham I., Fehler G., Bradshaw C.S., Chen, M.Y., & Chow, E.P.F. "HIV Incidence and Predictors of Incident HIV among Men Who Have Sex with Men Attending a Sexual Health Clinic in Melbourne, Australia", *PLoS ONE*, (2016,11(5):e0156160. doi:10.1371/journal.pone.0156160). Available from http://journals.plos.org/plosone/article?id=10.1371%2Fjournal.pone.0156160

19 Nic Holas. "PrEP again dominates day three of HIV/AIDS summit in Brisbane. Here's what happened", *Gay News Network*, (2015, 19 Sep). Available from http://gaynewsnetwork.com.au/checkup/hiv/prep-again-dominates-day-three-of-hiv-aids-summit-in-brisbane-here-s-what-happened-19020.html

20 David C. Knox, Tan, D.H., Harrigan, P.R., Peter L. Anderson, P.L. *HIV-1 Infection with Multiclass Resistance Despite Pre-exposure Prophylaxis (PrEP)*. Conference on Retroviruses and Opportunistic Infections, February 2016. Available from http://www.croiconference.org/sessions/hiv-1-infection-multiclass-resistance-despite-preexposure-prophylaxis-prep

21 Katherine Brooks, Diero, L., DeLong, A., Balamane, M., Reitsma, M., Kemboi, E., Orido, M., Emonyi, W., Coetzer, M., Hogan, J., & Kantor, R. "Treatment failure and drug resistance in HIV-positive patients on tenofovir-based first-line antiretroviral therapy in western Kenya", *Journal of the International AIDS Society*. (2016; 19(1): 20798). Available from http://www.ncbi.nlm.nih.gov/pmc/articles/PMC4882399/

Demographics

There were 379 individuals who took part as focus group members in the country consultations. Several individuals and sex worker organisations replied to the e-consultation.

Most respondents identified as sex workers (97%), with only 3% being representatives of a sex worker-led organisation. 45.2% of those who were recorded worked in multiple venues (street, managed, and/or independent), 33.3% worked independently only, and 19.3% were street workers. Less than 2% stated they only worked in a managed venue or strip club. The majority of those consulted were women, with 18.7% of those recorded identifying as male, and 17.4% identifying as transgender. Only 2.7% reported being ages 18–20, and 9.9% reported being over 40. The majority were aged 21–30 (61.4%), followed by those aged 31–40 (26%). A wide range of sexual orientations were reported, with the majority (56%) stating they were heterosexual. 6.3% identified as lesbian, 18.7% as gay men, and another 18.7% identified as bisexual. Queer and pansexual identities were also stated.

Advocacy for PrEP

Several of the sex worker organisations believed PrEP may be useful, considering the risks associated with sex work. Some had concerns, including; that it may undermine sex worker safety, that clients may pressure sex workers to take PrEP instead of use condoms, and that PrEP will be used as evidence by police against sex workers in the same manner that condoms are. These concerns are the same as those reported in the AIDS2014 Sex Worker Consensus paper[22]. Some sex worker-led organisations and a number of the focus groups believed that PrEP was being advocated for by treatment, HIV and MSM activists. Half of the focus groups believed those in the medical professions were responsible for advocating for PrEP, while some believed that donor agencies were advocating for it. Government agencies, such as Health Ministries, and drug companies manufacturing Truvada® were believed to be advocating for PrEP by some focus groups. Harm reduction activists, scientists, and sex workers seeking to increase protection from HIV were believed to be advocating for PrEP by one country each. Interestingly, two countries, one from Africa and one from the North America and the Caribbean region, believed that those advocating for PrEP were doing so as a means to increase demand for the drug and gain profit. The majority of respondents to both the regional consultancy and the e-consultancy stated that if PrEP were to be introduced for sex workers, it should be through sex worker-led organisations working for sex workers.

…it may undermine sex worker safety, that clients may pressure sex workers to take PrEP instead of use condoms, and that PrEP will be used as evidence by police against sex workers…

22 Sex Worker Pre-conference attendees, AIDS2014. *Sex Worker Pre-conference AIDS 2014 Consensus Statement*, (2014, 19 July), available from http://www.scarletalliance.org.au/library/consensusAIDS2014

Availability of PrEP

PrEP was generally not available or not known to be available by those attending the focus groups. This was the case in most countries, unless part of a trial (Colombia, El Salvador, India, Jamaica, Macedonia, Zimbabwe). It was formally approved in two (Canada and France – to some extent), available through a sex worker clinic in one (Kenya), and available upon payment in another (Thailand). Those in the e-consultation also indicated that PrEP was not generally available in their countries, except for those taking part in trials planned for Australia. One sex worker-led organisation reported that PrEP was available through certain General Practitioners if individuals paid full cost (£460). Another reported PrEP was also available through medical specialists, with continued monitoring, though gay men and transgender women were often stigmatised in this setting.

Both African countries reported that PrEP was only available to those sex workers taking part in trials. Thailand reported that it was available at cost from certain clinics, though the cost varied between THB1020 and THB6000 for a month's supply (£22 to £130), and Canada reported it was available to sex workers off label at a cost of CAN$1000 per month (£575). PrEP was not available, or not readily available, to sex workers in other countries. A number of countries reported that barriers existed to accessing PrEP, even where it was available on trials, as there was often a level of stigma against sex workers, particularly street-based sex workers, within health services. These barriers also existed in a number of countries where PrEP was not readily available. One person from Macedonia reported that PrEP is available there, but only to health-care workers, claiming this was discriminatory.

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Stigma and the resulting discrimination was reported from a number of countries. This has serious effects on the health of sex workers, who may feel discouraged from attending clinics and other health services as a result. It is clear therefore, that this stigma and discrimination must be addressed in clear and concise ways to ensure that health inequalities for sex workers are eliminated, or at least minimised. Focus groups in the regional consultancy, as well as sex worker-led organisations and individuals in the e-consultation, all agreed that this stigma needs to be addressed.

Knowledge of PrEP

Knowledge of PrEP varied considerably, with a regional consultant stating sex workers in one focus group had heard others saying it prevented HIV when taken every day. Others were unaware of PrEP until attending the focus group. Nevertheless, even in countries in which PrEP is approved, regional consultants reported that the majority of sex workers were not familiar with PrEP. This lack of knowledge appears to be systemic in some countries, with the regional consultant for Latin America noting sex workers in that region face a number of challenges in accessing health services, mostly related to discrimination based on gender identity or their work. While the majority of sex workers who took part in the focus groups and in the e-consultation knew what PrEP involved, El Salvador reported that none of those who took part in the focus group had heard of PrEP, while Macedonia reported that 71% of those taking part in the focus groups had no knowledge of PrEP prior to taking part.

Knowledge of trials

Sex workers in Canada and France were aware of the IPERGAY trials, and one of the male sex workers in France reported that a new trial, Prévenir, is about to start in October 2016. Thai sex workers knew of the studies that had been completed there, including one which involved sex workers that was just beginning. Kenyan and Zimbabwean sex workers knew of the trials that had occurred in their countries. It was known that no trials had taken place in Jamaica, but sex workers in the remaining countries (Colombia, El Salvador, India and Macedonia) did not know if any trials had occurred in their countries. One country in the Asia-Pacific region stated that a trial was about to start, while there were various levels of awareness among individuals from another country in the region of a trial about to start there.

Condom use and PrEP

The majority of sex workers consulted believed PrEP would increase demand from clients for unsafe sex, which may lead some sex workers to internalise reasons for risky behaviour. A small number believed that condom use would decrease because of demands from employers, although one focus group thought there would be no change in condom use, as PrEP is recommended to be used in conjunction with condoms. While some of those consulted stated that there would always be a demand for unsafe sex, some believed that condom use would stay the same if PrEP were introduced. Importantly, the focus groups in one country stated condom use was already difficult due to police actions and that it was likely this would extend to PrEP. This would particularly affect transgender people of colour who are sex workers, as they are already heavily stigmatised and oppressed. None of the countries in which focus groups occurred believed that condom use would increase if PrEP were introduced.

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What may be more concerning is that a minority of sex workers in 3 countries stated they would stop using condoms if PrEP became available. Participants in the two African focus groups noted that some sex workers no longer used condoms because of the protection PrEP gives from HIV. This is concerning as Truvada® protects only against HIV, not the other STIs, such as gonorrhoea, chlamydia, and syphilis. Indeed, the majority of sex workers in focus groups in Kenya, Thailand, France, Macedonia, El Salvador, Canada, and Jamaica noted this lack of protection from other STIs as a barrier to the use of PrEP in their countries.

Usefulness of PrEP

While there was hope that the introduction of PrEP would result in peace of mind for some sex workers and that it would result in clients taking more care of their sexual health, as they would have more check-ups if on PrEP, one person was suspicious of the introduction of PrEP, stating that the large pharmaceutical companies would have a lot to gain from it. Some stated that they had concerns about the long term use of PrEP and the side effects that could cause.

Opinions about the usefulness of PrEP varied among respondents, with a participant in the focus group in Kenya noting that it would be useful if there was enough advocacy among key populations to avoid misinformation about Truvada®. Participants in Zimbabwe stated concerns about the misuse or incorrect use of Truvada® if it was readily available. Those attending a focus group in India stated they believed PrEP would be useful, as it provides additional protection from HIV if a condom breaks. In line with CDC and WHO recommendations, PrEP is seen here as being used with condoms as an additional form of protection from HIV, rather than as a substitute for condoms. Some responses thought the benefits were gender specific, with a focus group in Macedonia believing it would be more helpful to male sex workers. Participants in French focus groups believed it would have a negative impact, as it does not protect against other STIs or unwanted pregnancy, and would give more power to clients. Women in the French focus groups said they would not want PrEP as they already have high condom use.

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Side effects

Concerns were raised by a number of focus group members about the side effects of Truvada® and so they have been listed here. Side effects of taking Truvada® vary between individuals, but may include:

<2% OF CASES	>2% OF CASES
◗ Acute kidney failure ◗ Build-up of lactic acid in the body ◗ Liver damage (fatty or enlarged) ◗ Decrease in bone mineral density ◗ Fat redistribution and accumulation	◗ Headache ◗ Abdominal pain ◗ Decrease in weight

◗ Taking Truvada® while you have hepatitis B (HBV) may make your hepatitis worse if you stop taking the medication.

No long term studies of the effects of Truvada® on the body have been completed.

Although liver damage may be fatal, stopping Truvada® use will reverse the damage. Similarly, stopping Truvada® will also reverse other side effects, except for a redistribution in fat, which is permanent. No long term studies of the effects of Truvada® on the body have been completed. Some side effects may be more pronounced the longer Truvada® is taken[23, 24].

Concerns about PrEP

Nearly all focus group participants in all countries, in both the regional and e-consultations, had concerns about the safety of Truvada® and the side effects it caused. Some of these side effects, such as kidney failure or liver damage, could be life threatening. While other side effects such as decreased bone density, as well as common side effects such as nausea, are reversible on stopping medication.[25, 26] Changes in body fat distribution were generally not reversible without further medication or surgery, depending on how long a person has been on Truvada®[27, 28]. The focus group members in India noted some sex workers were uncomfortable about the use of PrEP because of the indicated side effects, as they stated they had no problems ensuring clients wore condoms.

While the majority of respondents believed that PrEP would be useful to sex workers overall – despite misgivings over side effects – participants also said that it would be useful only if used concurrently with condoms. A significant minority in four countries said that PrEP would be a good harm reduction tool in place of condoms, or where condom use may not be possible or practical. Some of these countries already had concerns about condom accessibility, with the feedback from Thailand indicating that access to free condoms had been restricted for female sex workers, meaning they were only able to obtain 10 condoms a month following an HIV and STI test. Nevertheless, focus group members believed there would be a benefit of increased feelings of safety for sex workers who were male or transgender women.

23 Starttruvada.com, *Important Safety Information*. Available from https://start.truvada.com/hcp/important-safety-information#

24 Gilead Sciences. *Truvada Prescribing Information*. (Foster City, CA: Gilead, 2016), 1. Available from http://www.gilead.com/~/media/Files/pdfs/medicines/hiv/truvada/truvada_pi.PDF

25 Gilead (2016), ibid.

26 Alcorn, Keith. Bone density recovers quickly after stopping PrEP. *NAM/AIDSmap*, (24 Feb. 2016). Available from http://www.aidsmap.com/Bone-density-recovers-quickly-after-stopping-PrEP/page/3038620/

27 CATIE. *A Practical Guide to HIV Drug Side Effects: 3. Body Weight and Body Shape Changes*, (2013). Available from http://www.catie.ca/en/practical-guides/hiv-drug-side-effects/3-body-changes#Antiretroviral_drugs

28 AIDSinfo. *Side Effects of HIV Medicines: HIV and Lipodystrophy*, (13 Sep. 2016). Available from https://aidsinfo.nih.gov/education-materials/fact-sheets/22/61/hiv-and-lipodystrophy

Five countries had concerns about the ability of governments or health officials to maintain supplies of Truvada®, or about problems accessing Truvada®, particularly in relation to the cost of the medication. In North America it was noted that CATIE, Canada's source for HIV and Hepatitis C information, hopes PrEP will be made more accessible and covered by health care plans. However, some respondents believed that accessibility problems could be overcome as PrEP became more common.

A number of participants sought greater information about PrEP for sex workers, including sex workers who use drugs, while the majority of focus group members in two countries believed that PrEP should not be available to ensure better negotiation around condoms and safe sex. Focus group members in Colombia noted that PrEP, if made available, should solely remain at the discretion of sex workers, to enable them to be able to negotiate condom usage with clients. There were concerns from two countries about those sex workers who, because of either drug use or criminalisation, had difficulty adhering to a treatment regime.

The majority of focus group participants in three countries had concerns about resistance to PrEP occurring. This included Macedonia, where no trials had occurred, as well as both Kenya and Zimbabwe, where trials have occurred. Kenya is one of the countries where resistance to TDF, a component in Truvada®, has occurred, with at least 59 cases of TDF resistant HIV being recorded[29].

…sex workers' voices must be heard and listened to and sex workers must be involved at all levels and at all times when trials of PrEP are being considered or if PrEP is to be made available.

Focus group members also identified various barriers to the use of PrEP, including a concern that possession of the pills will lead to greater stigma against sex workers. Focus group members in Thailand indicated they believed police would use the presence of Truvada® in the same way they use the presence of condoms to harass sex workers and suggested that "Truvada Blue" would become the "next colour of stigma".

Several other countries identified the criminalisation of sex work as a barrier to the implementation of PrEP, identifying that in their countries police often use condoms as part of a pattern of evidence to prove sex work related charges against a person. Seven of the countries in which focus groups occurred feared that Truvada® may be used against sex workers as evidence of sex work activities.

Sex workers at these focus groups also identified several needs. These included; a need for more research into differing PrEP regimes and how they affect the most vulnerable sex workers and sex workers who use drugs, a need for more education about PrEP for sex workers, and a need for better access to health care for sex workers. Two respondents to the e-consultation identified problems with their health care systems, noting this needed to improve before PrEP was introduced.

One of the main issues raised by those in the focus groups and the e-consultation was the recognition of sex workers' rights and that sex work needs to be decriminalised. In the July 2014 issue of Lancet it was noted that decriminalising sex work could reduce HIV infections by between 33% and 46%[30].

However, the most important requirement from the majority of members of the focus groups in all ten countries was that whatever decision was made in regards to the availability of PrEP among sex workers, sex workers' voices must be heard and listened to and sex workers must be involved at all levels and at all times when trials of PrEP are being considered or if PrEP is to be made available.

29 Brooks, et al, ibid.

30 Kate Shannon, Strathdee, S.A., Goldenberg, S.M., Duff, P., Mwangi, P., Rusakova, M., Reza-Paul, S., Lau, J., Deering, K., Pickles, M.R., Boily, M-C., Global epidemiology of HIV among female sex workers: influence of structural determinants. *Lancet* (22 July 2014, pp13–29), available from http://www.thelancet.com/journals/lancet/article/PIIS0140-6736(14)60931-4/fulltext

Conclusion

While a number of the organisations who took part in this consultation could see a positive effect from the introduction of PrEP, particularly that it may afford sex workers an additional method of protection from HIV, there were also concerns. These concerns are significant, particularly around the side effects of PrEP, especially following long term use, and concerns about condom use. While some believed that condom use would increase or remain the same, most believed that condom use would decrease following the introduction of PrEP, and that this would leave sex workers at risk of other STIs.

Another key message raised in the consultation was the need for more information and education about PrEP. For example, in relation to the minimum time PrEP must be taken before it affords protection, the Centers for Disease Control and Prevention states that, "PrEP reaches maximum protection from HIV for **receptive anal sex** at about **7 days** of daily use. For **all other activities**, including insertive anal sex, vaginal sex, and injection drug use, PrEP reaches maximum protection at about **20 days** of daily use"[31]. As an increase in knowledge around PrEP was indicated by a significant number of the respondents, it is important that sex workers are aware of these time frames, as they would be vulnerable to HIV if they had condomless sex within these.

There are significant concerns that PrEP may be forced upon sex workers against their will, or that, like condoms, PrEP would be used by authorities as evidence against sex workers.

Another concern is how PrEP would be seen by local law enforcement agencies, particularly where sex work is criminalised, or where it may be tightly controlled by a legalised model of sex work regulation. There are significant concerns that PrEP may be forced upon sex workers against their will, or that, like condoms, PrEP would be used by authorities as evidence against sex workers. This could lead to the further stigmatisation and criminalisation of sex workers. It is therefore very important that the legal standing of sex work is considered before PrEP is introduced for sex workers. The statement from the Sex Worker Pre-Conference at AIDS 2014 therefore remains salient:

> ***"Legal Barriers for sex workers are still so significant that unless we resolve those issues first, through the full decriminalisation of sex work, test and treat or treatment as prevention are abstract concepts that have no meaning for sex workers but will divert resources away from approaches that we know work"***[32].

It is also extremely important that prior to any trials involving sex workers and prior to the introduction of PrEP, sex worker voices are heard and listened to.

31 Centres for Disease Control and Prevention. *PrEP.* (2016, 21 July). Available from http://www.cdc.gov/hiv/basics/prep.html. Emphasis in original.

32 Sex Worker Pre-conference attendees, AIDS2014. *Sex Worker Pre-conference AIDS 2014 Consensus Statement*, (2014, 19 July)

Recommendations

- Policy makers must consult with local sex worker-led organisations regarding any planned trials of PrEP, or the planned introduction of PrEP, to ensure that local sex worker organisations are aware of issues surrounding it.
- Local sex worker-led organisations must be provided with the tools with which to educate and inform their community about PrEP, so that their communities can make fully informed decisions before consenting or refusing to take PrEP.
- Sex workers must fully understand and have control and input over all processes. This includes the dissemination of information about PrEP, the side effects, and treatment regime.
- If introduced, PrEP must be voluntary and programmes must be affordable.
- Community-led, participatory research is needed to better understand the structural barriers faced by sex workers in accessing health services within their country of residence.
- Mandatory testing of sex workers for HIV or other STIs must be stopped. As HIV testing is required before taking PrEP, this testing must be voluntary. Any plans to introduce PrEP to a sex worker population against their will would mean that a mandatory testing regime is implemented. Such testing regimes are contrary to the human rights of sex workers.
- Testing, treatment, and assessment of sex workers for PrEP must be confidential and prioritise the needs and well-being of sex workers.
- Sex work must be recognised as work.
- The possession of ARVs, PrEP medication, and condoms must not be used as evidence to convict sex workers.
- The decriminalisation of sex work (including sex workers, clients, third parties, families, partners and friends), in line with recommendations by Amnesty International, UNAIDS, UNDP, WHO and many others must take place, so that the rights of sex workers are upheld and protected.

The Global Network of Sex Work Projects uses a methodology that ensures the grassroots voices of sex workers and sex worker-led organisations are heard. The briefing papers document issues faced by sex workers at local, national, and regional levels while identifying global trends.

The NSWP Secretariat manages the production of briefing papers and conducts consultations among its members to document evidence. To do this, NSWP contracts:

- Global Consultants to undertake desk research, coordinate and collate inputs from Regional Consultants and draft the global briefing papers.
- Regional Consultants to coordinate inputs from National Key Informants and draft regional reports, including case studies.
- National Key Informants, identified by the regional networks, to gather information and document case studies.

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