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An Introduction to Pre-Exposure Prophylaxis (PrEP) for People who Inject Drugs: pros, cons, and concerns

Introduction: what is pre-exposure prophylaxis?

“In 2010 alone an estimated 2.7 million people became newly infected with HIV. Additional safe and effective approaches to HIV prevention are urgently needed.” (WHO 2012: 3)¹

In the context of ongoing high incidence of HIV infections, there has been considerable international focus on producing new HIV prevention initiatives. There has now been widespread discussion regarding ‘pre-exposure prophylaxis’, or simply ‘PrEP’, a relatively new method for preventing HIV infection. PrEP refers to “the daily use of antiretrovirals in HIV-uninfected people to block the acquisition of HIV infection”².

Clinical trials have shown efficacy for PrEP, and subsequent open label extensions have shown PrEP to be safe and effective as a prevention tool. Studies have demonstrated that PrEP can reduce HIV transmission among serodiscordant heterosexual couples (an ongoing sexual relationship where one partner is living with HIV and the other is not), men who have sex with men (MSM), transwomen who have sex with men, and people who inject drugs. People who took pre-exposure prophylaxis every day were significantly less likely to get infected with HIV. In an open label study, involving men and transwomen where participants were offered PrEP at the end of the trial, there was zero new HIV incidence amongst those who took between 4 and 7 doses per week, suggesting that PrEP could be somewhat forgiving with regard to missed doses.³ However, as with antiretroviral therapies more generally, adherence to PrEP should be regarded as critical since “PrEP effectiveness is strongly correlated with daily adherence”. (WHO 2012: 12)⁴

Status of PrEP globally: the CDC and the WHO

PrEP has been approved for use in some countries. Notably, the United States Center for Disease Control (CDC) recommends PrEP for groups at high risk of HIV exposure, including at risk HIV negative men who have sex with men, at risk HIV negative people who inject drugs, as well as persons of any gender in serodiscordant couples. It is recommended by the CDC as an element of a comprehensive set of HIV prevention services, to be accompanied by quarterly monitoring of HIV status, pregnancy status, side effects (which can include nausea, cramping, and long-term effects including kidney problems), medication adherence, and risk behaviours. The CDC note that PrEP delivery for people who inject drugs should be

¹ World Health Organization, 2012, *Guidance On Pre-Exposure Oral 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*, available at http://www.who.int/hiv/pub/guidance_prep/en/ (last accessed 8 September 2014)

² Ibid

³ Grant, R. M. et al, 2014, Results of the iPrEx open-label extension (iPrEx OLE) in men and transgender women who have sex with men: PrEP uptake, sexual practices, and HIV incidence. *Presented at 20th International AIDS Conference, Melbourne Australia, 20-25 July*

⁴ World Health Organization, 2012, *Guidance On Pre-Exposure Oral 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*

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integrated with prevention and clinical care for additional health concerns, which, in this context, include hepatitis B and C infection, abscesses, and overdose.

In 2012, based on the evidence available, the World Health Organisation recommended that countries consider daily oral PrEP as an additional prevention strategy for HIV negative partners in serodiscordant couples as well as men and transwomen who have sex with men.⁵ In discussion of PrEP in the World Health Organisation's 2014 *Consolidated Guidelines on HIV Prevention, Diagnosis, Treatment and Care for Key Populations*, no recommendations were made for people who inject drugs, due in part to concerns raised by community representatives regarding human rights and other issues, detailed below.

What do we know about PrEP for people who inject drugs?

“Although the evidence of effectiveness is strong, it remains unclear how PrEP may best be implemented and scaled up in settings where its use might be most beneficial.” (WHO 2012: 3)⁶

It is unclear to what extent advocating and rolling-out PrEP for people who use drugs would be beneficial, and it could well have detrimental side-effects.

A study conducted among people who inject drugs in Bangkok, Thailand, showed an overall reduction of almost 50% in HIV incidence amongst those who received PrEP.⁷ Though the study (re)demonstrated the efficacy of PrEP, many practical questions relating to the feasibility of advocating and implementing PrEP for people who use drugs are pressing. This is notably in a context of limited empirical data vis-à-vis the effectiveness of PrEP strategies, and intersections with other variables, discussed below.

Is PrEP feasible in the context of global prohibition?

Concerns about PrEP implementation in criminalised communities, such as people who use drugs, have been raised, as have concerns as to the feasibility of PrEP in repressive regimes where people who use drugs are subject to human rights violations, violence, and incarceration, and do not enjoy access to service and healthcare provision and harm reduction initiatives.⁸

Several aspects of PrEP delivery in the abovementioned trial in Thailand, including participant compensation and direct observation of pill-taking, simply may not be practical and realistic for implementation in real-world settings. The adherence to PrEP observed in the Bangkok trial may therefore not be indicative or generalisable. Further studies, including where people who inject drugs are offered PrEP as an open label option, are called for to assess the feasibility and acceptability of PrEP, and to assess real-world demand. The fact that some trials have been terminated due to inability to reach conclusions – arguably due to poor adherence – should certainly flag concern in terms of whether PrEP is a realistic prevention initiative on-the-

⁵ Ibid

⁶ Ibid

⁷ Choopanya, K. et al., 2013, Antiretroviral prophylaxis for HIV infection in injecting drug users in Bangkok, Thailand (the Bangkok Tenofovir Study): a randomized, double-blind, placebo-controlled phase 3 trial. *The Lancet*: doi:10.1016/S0140-6736(13)61127-7

⁸ Wolfe, D., 2013, Beyond the Hype: PrEP for People Who Inject Drugs. *The World Post*, 14th June, available at http://www.huffingtonpost.com/daniel-wolfe/beyond-the-hype-prep-for-_b_3437910.html (last accessed 9 September 2014)

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ground. This is not to say that poor adherence is due to the common, but misleading, assertion that people who use drugs are unreliable and/or non-compliant: harassment, social exclusion, arrest, detention, and incarceration of people who use drugs remain common the world over, and so maintaining adherence to PrEP, as with acquiring and maintaining access to antiretroviral medication for people living with HIV, could well be impossible for many due to the infrastructures of prohibition.

“we should worry about what PrEP might look like in countries like Russia and Thailand, which have demonstrated no willingness to support needle and syringe programs, but great readiness to punish and incarcerate. Pharmaceuticalization of HIV prevention for injecting drug users without corresponding reform in law enforcement and healthcare delivery is in no one's interest, and will result in money wasted, new infections, and lives lost.” (Wolfe 2013)⁹

Sidelining harm reduction and provision of ART to people living with HIV

Concerns have also been raised regarding the conduct of the Bangkok trial, specifically, that sterile injecting equipment – accepted to be the most effective HIV prevention intervention for people who inject drugs – was not provided to participants. Harm reduction works, and it needs to be stressed that initiatives like PrEP cannot sideline well-demonstrated harm reduction programmes. Many states remain opposed to even the most rudimentary harm reduction initiatives and targeted service provision for people who use drugs, and it is concerning that PrEP has been advocated in a context where service provision and healthcare is already lacking: this has already been the case, with Gennady Onishchenko – the Chief Sanitary Inspector of the Russian Federation – noting in 2013 that PrEP would serve as an alternative to methadone opiate substitution, the provision of which is opposed by the Russian government.¹⁰

Additionally, such a focus on PrEP in place of comprehensive harm reduction packages is essentially a focus on an initiative that does not protect against other sexually transmitted or blood-borne infections. PrEP does not impact problems other than HIV associated with sharing injecting equipment, including hepatitis C and B infection, abscesses, or endocarditis¹¹. Other harm reduction interventions, such as needle and syringe programmes, engage with other blood-borne infections in addition to HIV, which is imperative given that hepatitis C is the most prevalent blood-borne infection affecting people who inject drugs. A focus on HIV and on PrEP should not eclipse other harm reduction or other pressing health concerns for people who use drugs.

It should also be remembered that in some states, fewer than 1% of people who inject drugs and who are living with HIV are in receipt of antiretroviral therapy¹² (globally, the figure is estimated to be closer to 4%)¹³.

⁹ Wolfe, D., 2013, Beyond the Hype: PrEP for People Who Inject Drugs. *The World Post*, 14th June, available at http://www.huffingtonpost.com/daniel-wolfe/beyond-the-hype-prep-for-_b_3437910.html (last accessed 9 September 2014)

¹⁰ Россия выделит 500 млн рублей на программу по профилактике ВИЧ в странах СНГ, TACC, 13 June 2013, available at <http://itar-tass.com/obschestvo/610627> (last accessed 30 January 2015)

¹¹ Wolfe, D., 2013, Beyond the Hype: PrEP for People Who Inject Drugs. *The World Post*, 14th June, available at http://www.huffingtonpost.com/daniel-wolfe/beyond-the-hype-prep-for-_b_3437910.html (last accessed 9 September 2014)

¹² Mathers, B. M., et al., 2010, HIV prevention, treatment, and care services for people who inject drugs: a systematic review of global, regional, and national coverage. *The Lancet* 375, 9719:1014-1028

¹³ Recent World Health Organization recommendations advise commencement of ART in adults living with HIV when CD4 cell count falls to 500 cells/mm³ or below; previous recommendations were for 350 CD4 cells/mm³. This means

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Focussing on PrEP, a prophylaxis initiative that involves the distribution of antiretroviral medications to those who have yet to be exposed to HIV, seems highly unrealistic, irresponsible, and unethical where even those who require antiretroviral treatments for their very wellbeing are not receiving them. This is not to say that provision of PrEP is not desirable, given its apparent efficacy as an HIV prevention initiative; rather, it is a word of caution regarding the practicable feasibility of offering PrEP in all settings and contexts at this point. It is imperative to provide *all* well-demonstrated HIV prevention and treatment programmes available.

Moving forward

Though PrEP is a welcome addition to HIV prevention initiatives, INPUD stresses that existing research and empirical data – particularly on the subject of people who use/inject drugs – leaves a lot to be desired. Further demonstrations of PrEP’s effectiveness in various settings and contexts are required. PrEP’s potential to significantly impact HIV incidence amongst people who inject drugs will, in all likelihood, be significantly impeded by repressive legislation and policy the world over, as well as by current failings and shortfalls in healthcare provision. It is also concerning that a focus on PrEP could well come to sideline and jeopardise the provision of harm reduction interventions. INPUD (re)stresses that harm reduction interventions are well-demonstrated in their efficacy and scope, and we are concerned that PrEP could be used as a means with which to excuse a failure to adopt and implement appropriate and fully realised harm reduction.

INPUD and the WHO are systematically reviewing evidence and the opinions, values, and preferences of people who inject drugs, so that they can be taken into consideration in forming policy. One finding from INPUD’s first consultation with people who inject drugs from the Eastern European region, was that people who inject drugs found the idea of PrEP, as conceived, both concerning and unrealistic. This concern was based on the potentially detrimental impact that a prioritisation of PrEP could have on harm reduction programmes, in the context of the currently lamentable access to healthcare for people who inject drugs living with HIV, as discussed in this paper. INPUD is currently preparing a report documenting the findings of two community consultations that have already been held on this topic.

In conclusion, PrEP must not come to eclipse other essential harm reduction interventions. People who use and inject drugs must have the right to choose for themselves which HIV prevention options best suit them. All blood-borne virus prevention and treatment interventions, as well as harm reduction interventions and service and healthcare provision more broadly, need to be available to those who require them.

INPUD urges caution and restraint in engagements with PrEP in a context where, globally, harm reduction and healthcare and service provision for people who use drugs are far from sufficient and comprehensive; INPUD will thus continue to advocate for well-proven harm reduction interventions.

that percentage ART coverage of those defined as requiring treatment is now likely to be even lower.

For more information see:

WHO issues new HIV recommendations calling for earlier treatment. *World Health Organization*, 30 June 2013, available at http://www.who.int/mediacentre/news/releases/2013/new_hiv_recommendations_20130630/en/ (last accessed 30 January 2015)

International Network of People who Use Drugs

INPUD | Unit 2C05 | South Bank Technopark | 90 London Road | London | SE1 6LN | UK

info@inpud.net | www.inpud.net

