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“PrEP is not ready for our community and we are not ready for PrEP”: Pre-Exposure Prophylaxis for HIV for people who inject drugs and limits to the HIV prevention response

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Abstract

Background and aims—Pre-Exposure Prophylaxis for HIV, or ‘PrEP’, is the use of antiretroviral medicines by people who are HIV negative to protect themselves against acquiring HIV. PrEP has shown efficacy for preventing HIV acquisition. Despite the potential, many concerns have been voiced by people who inject drugs (PWID) and their organisations. There is a need to engage with these views and ensure their integration in to policy and strategy. This paper presents PWID views on PrEP to foster the uptake of these opinions into scientific and policy debate around PrEP

Methods—Critical analysis of a report of a community consultation led by the International Network of People who Use Drugs (INPUD).

Results—The INPUD report highlights enthusiasm from PWID for PrEP, but also three main concerns: the feasibility and ethics of PrEP, its potential use as a substitute for other harm reduction strategies and how a focus on PrEP heralds a re-medicalisation of HIV. Each concern relates to evidenced gaps in essential services or opposition to harm reduction and PWID human rights.

Conclusions—People who use drugs have fundamental concerns about the potential impacts of Pre-Exposure Prophylaxis for HIV (PrEP) which reflect a ‘fault line’ in HIV prevention: a predominance of biomedical approaches over community perspectives. Greater community engagement in HIV prevention strategy is needed or we risk continuing to ignore the need for action on the underlying structural drivers and social context of the HIV epidemic.

Introduction

People who inject drugs (PWID) are disproportionately affected by the HIV epidemic in many parts of the world. From the estimated global population of 12.7 million PWID, 2.7 million people are living with HIV (1, 2). The largest numbers of PWID living with HIV are

The full report is available at: <http://www.inpud.net/sites/default/files/INPUD%20PrEP%20-%20Community%20Voices.pdf>

Declarations of competing interest: We have no competing interests.

in Eastern Europe, Southeast and Central Asia and Latin America, with HIV prevalence over 20% in countries such as Ukraine and Russia; epidemics continue to emerge in other settings like Sub-Saharan Africa (2-5). This vulnerability to HIV is matched by a failure to make available evidence-based interventions proven to prevent and treat HIV (6, 7): sterile needle and syringe programmes (NSP), Opioid Substitution Therapies (OST) such as methadone and buprenorphine, and antiretroviral treatment (ART) for PLHIV who inject drugs are all at dismally low levels (6-9). Globally, available estimates suggest just 2 needle/syringes are distributed to each PWID per month, 8% receive OST and 4% of PWID living with HIV receive ART (7). Provision of these interventions varies globally, with coverage often lowest where need is greatest (7). This vulnerability to HIV, and to other co-infections such as Hepatitis C (10), and lack of access to evidenced-based interventions are the result of numerous processes, but hinge on criminalisation and social, political and economic marginalization of PWID (11, 12).

In this context of limited access to long-evidenced interventions, criminalisation and marginalization, we aim to critically explore the potential for Pre-Exposure Prophylaxis for HIV, or PrEP, for PWID (13, 14). We are responding in particular to the publication of a recent report: Pre-Exposure Prophylaxis (PrEP) for People who Inject Drugs: community voices on pros, cons, and concerns by the International Network of People who Use Drugs (INPUD) (15). The report details PWIDs' anticipation of this potentially important intervention. More prominent in the report, however, are a series of concerns. The INPUD report prompts a core question: how should those concerned about protecting human rights and supporting public health (e.g. PWID, activists, community representatives, health care professionals, researchers, policy makers, donors) respond to these concerns about PrEP? We discuss the accounts from PWID documented in the INPUD report in an effort to foster the uptake of these opinions in to scientific and policy debate around PrEP.

The potential for PrEP in preventing HIV transmission

PrEP is the use of ART, commonly used to treat HIV, to prevent HIV infection. A number of trials have explored the safety and clinical efficacy of PrEP amongst high risk groups (14), including men who have sex with men (iPrEx (16), PROUD (17)), heterosexual couples and women (Partners PrEP (18), TDF2 (19), FEM-PrEP (20), VOICE (21)), transgender populations (iPrEx (16)) and PWID (Bangkok Tenofovir study (22)). Whilst drug combinations for PrEP have evolved, the current focus is on a combination of tenofovir and emtricitabine, branded Truvada® and sold by Gilead (Truvada is also a conventional treatment for HIV, forming part of many ART regimens). Studies have indicated PrEP's efficacy in preventing HIV for men who have sex with men (iPrEx, PROUD), but studies with women in sub-Saharan Africa indicate mixed results, which has been attributed to sub-optimal adherence (Fem-PrEP, VOICE).

The one trial that has explored efficacy of tenofovir for preventing HIV amongst PWID in Thailand (Bangkok Tenofovir study) found a reduction in HIV incidence of 48.9% amongst those receiving the intervention (22). The study findings are clouded by controversy over the trial being conducted in the absence of best available preventative options for HIV (i.e., NSP), and a failure to respond to community concerns (23, 24). Even considering the

Bangkok study, the only evidence for efficacy for PrEP for PWID relates to sexual transmission of HIV, with the efficacy of PrEP in preventing HIV acquisition through the sharing of injecting equipment not yet established (24).

The World Health Organisation currently recommends PrEP be considered for HIV prevention amongst all those at substantial risk for HIV, including PWID (25). PrEP is also approved by the US Food and Drug Administration linked to CDC and US Public Health Service guidance (26). Most recently the *Vancouver statement*, signed by leading HIV scientists, advocated for the use of PrEP as part of the strategic use of ARVs (27).

Whilst the focus for considerable enthusiasm, PrEP has also been subject to much opposition. Whilst growing evidence suggests PrEP is proving effective in preventing sexual HIV transmission among MSM (28), is accepted by some populations (29) and cost-effective (30), there are also concerns (31-35) which include potential limits on adherence, drug toxicity, disinhibition and PrEP becoming a ‘party drug’, its cost and links to access, and the ethics of making PrEP available whilst other interventions – such as NSP, OST and ART – are not. In summary: whilst clinical trials point towards the efficacy of PrEP for some groups there are many remaining questions over its feasibility and implementation, especially among PWID.

Beyond isolated studies reporting enthusiasm and caution by PWID (29, 36, 37), there is little understanding of, or attention paid to, the views and perceptions of PWID and their organisations (14). Amidst the controversy of the Bangkok study specifically (22) and more general concerns (38, 39), there have been calls by INPUD for caution and restraint in implementing PrEP (24). Acknowledging the specific needs of PWID, as compared to MSM or other populations, there is a need for more concerted engagement with the views and experiences of the PWID community.

Community concerns

The INPUD consultation on PrEP was a response to concerns over PWID engagement in policy debates. 75 people (30% women) from 33 countries participated in three consultations, and a linked series of interviews. Many respondents highlighted the potential importance of PrEP:

“PrEP is going to have a role to play and that it is going to be a good option for perhaps a lot of people and we should be educating people about it and we should be figuring out how to incorporate it into our programmes and our services.”

(consultation respondent)

Amidst the hope there is also alarm and doubt. The full report warrants reading (see url below), but here we summarise and discuss our interpretation of the respondents’ concerns.

The feasibility and ethics of offering PrEP to PWID when ART coverage is so low

“it seems crazy to start pumping in PrEP before ARVs” (consultation respondent)

A core concern is how efforts to make PrEP available relate to the well documented access gaps for ART for PWID who are living with HIV, as well as major gaps in NSP and OST

coverage (7). Some doubt how it can be done: if HIV treatment isn't readily available for HIV-positive PWID, then how can PrEP be brought to scale among people who are HIV-negative? Some have also expressed ethical concerns about whether those living with HIV should instead be prioritized for treatment (35). Similar concerns about resources relate to a focus on the broader environment of constraint and deeply entrenched structural barriers that limit HIV care access, and how these barriers still need addressing in many contexts (6, 12, 40):

“I don't see why it can't be part of a truly comprehensive universally accessible package of services. But that is not the reality. So given that, it is simply not a priority” (consultation respondent)

Undermining harm reduction

Extending fears on the ethics of funding PrEP is an overlapping concern about how the introduction of PrEP could undermine the urgent advocacy objective of bringing community-based harm reduction programmes to scale. For some, this fear stems from statements by Russian authorities that PrEP is a suitable alternative to OST or NSP.

“One of the concerns is that well.....like.....we've given people PrEP so we don't need to give them access to any other harm reduction support.” (consultation respondent)

More broadly, the injection of drugs is criminalized in many countries, leading to stigma, discrimination and violence(41). Whilst principles of harm reduction are arguably slowly spreading, their application and realization is still tenuous in many contexts (42). In Russia, OST is illegal and there is limited NSP access (6). The example of Russia is a cautionary warning for how enthusiasm for PrEP can serve opposition to evidence based comprehensive harm reduction.

A re-medicalization of HIV prevention

“The 'end of AIDS' rhetoric... is very much predicated on biomedical solutions. I find it alarming because I think it's diverting attention away from the larger determinants of the risk environments and the reasons why particular groups have become key affected populations” (consultation respondent)

It has long been recognized that the response to HIV needs to be comprehensive, multi-sectoral and address the social determinants that drive the epidemic (43). PrEP, in contrast, is being seen by some as part of a broader re-medicalisation of the response to HIV with this happening in a context of limited progress on structural barriers to HIV prevention:

“Biomedical responses are all about individualizing responsibility for HIV transmission... the responsibility is loaded on to the person to prevent transmission, as opposed to governments or communities or organisations or funders” (consultation respondent)

Growing theoretical and empirical insight into the structural drivers of HIV for PWID focus on the need to situate prevention interventions within supportive policy environments to

enable access and address stigma (44, 45). Such environmental interventions or reforms are however only limited in their uptake (46).

PrEP as success and failure?

We consider the concerns raised in the INPUD consultation as more than simply implementation challenges and instead as a fundamental questioning of the potential role for PrEP in HIV prevention for PWID. Years of work to develop PrEP have led to a momentous medical achievement (47) that will save lives and justifies it as a valuable component of a comprehensive HIV prevention response. This is progress welcomed by many PWID, as noted in the INPUD report. And yet, any progress and official enthusiasm for PrEP contrasts with that for the nine components of the essential HIV prevention interventions for PWID (48) where implementation and scale-up is grossly lacking, especially NSP, OST and ART (7). The medical achievement of PrEP serves therefore to highlight the continuing need for the economic, organizational and human resources necessary to implement other evidence-based interventions (49).

It is in this context of slow progress on ensuring harm reduction and HIV prevention, treatment and care access for PWID that the INPUD consultation highlights how PrEP risks failure as well as success: success if delivered in response to PWID consultation and statement of need to allow for adaptation for context and as part of comprehensive HIV prevention, linked to scale-up of other social and structural interventions to allow the necessary range of services for PWID; failure if implemented without attention to other crucial interventions, for how PrEP could inadvertently divert resources, legitimize opposition to, and neglect of, NSP and OST delivery, and not respond to what PWID actually need. PrEP offered in isolation and without consultation could undermine HIV prevention efforts and lead to new infections and lives lost (38).

The fault line in HIV prevention for PWID

The emergence of PrEP and the controversy around it reveals a profound challenge to our collective HIV prevention response. The INPUD consultation demonstrates the need for more concrete and detailed engagement with communities of people who inject drugs and their organisations, consideration of the social and behavioral process and contexts for PrEP implementation (32), and addressing the linked challenge of resourcing other interventions. We consider the relative absence or neglect of these issues as further evidence of a “fault line” in HIV prevention: a dominant regime of biomedicine, with associated institutional and financial resources, which functions to marginalize or exclude community and other forms of knowledge in HIV prevention (50). In this section, we reflect on this fault line and the nature of a biomedical regime that has shaped PrEP and is disengaged from community views and needs. We need careful reflection on this policy agenda. How did such a distance between community views and established institutional priorities arise and will this ‘fault line’ remain, or even widen? And what does this mean for the future of HIV prevention? Our purpose is to draw attention to how our HIV prevention response may continue to prioritise and implement PrEP with little consideration of its broader implications and without the equivalent and necessary resourcing of other interventions. Furthermore, we seek to draw

attention to how by continuing to ignore and understand what communities are saying we risk prioritising the development of biomedical interventions that, whilst efficacious, are rarely brought to scale.

Echoing the INPUD report, the rise of PrEP supports arguments that our current HIV response is continually or increasingly dominated by biomedical assumptions and responses (47, 51, 52), linked to suggestions of a remedicalisation of the response to the HIV epidemic (49, 53). PrEP conforms to the neo-liberal ideal of technical, top-down, individualizing responses (54), and this orientation to particular solutions is manifested in the prioritizing of treatment as prevention, microbicides and vaccines, whilst community-level and structural interventions are neglected. It is not that biomedical interventions, or medicalized responses, are necessarily ‘bad’ of course (55). What is of concern is the potential for biomedical interventions to dominate and limit the potential for true combination HIV prevention.

The predominance of biomedical responses emerges from a broad institutional regime oriented towards biomedical assumptions (56). Disparate groups – governments, researchers, NGOs, think tanks, patients, private sector business – through direct consultation, or with little or no actual contact, can coalesce in purpose around particular beliefs and values (50, 56). This ideology then achieves its influence through its various resources: the control over taxation by governments to allocate towards services and research, the cultural power and financial resources available to universities and research institutions, and then private sector income through sales and profits. The biomedical paradigm is therefore a set of values consistent with a range of institutions and overlapping with access to resources.

The resources for HIV prevention then predominantly focus on biomedical interventions and approaches. Whilst \$1.25 billion is spent on research and development of biomedical HIV prevention, just 1% of this is oriented towards their social and behavioural dimensions (57). Other analysis has shown how as funding for vaccine development has risen, resources for integrated condom programming have decreased (58) and HIV focused civil society organisations globally report declines in funding (59). The most recent manifestation of this pattern is a new set of HIV research priorities from the US National Institutes for Health Office of AIDS Research that focus almost exclusively on cure and treatment efforts (60).

Here the fault line emerges. PWID and their organisations frequently have little or no access to these decision making processes. A counterpoint to the picture presented above is the marginal position in all levels of decision making of PWID and their organisations. Whilst PWID are in some contexts included in, or consulted through, forums and mechanisms such as conferences and workshops, there is little direct influence on specific policy and resource allocation. The refrain ‘nothing about us, without us’ (61) is long held but proving difficult to implement in practice, and so accountable representation is a work in progress. Specific challenges reflect the limits on the structures of community groups, who face challenges of a global funding crisis. A neglect of community agendas, concerns, knowledge and expertise is all the more concerning considering the historical role of PWID in pioneering interventions to respond to HIV (50, 62).

Limits to engagement in decision making is of course in the context of a broader criminalization and persecution of people who use drugs globally (41, 63, 64). The conflation of prioritizing PrEP by institutions such as governments and pharmaceutical companies who are often linked to the active criminalization and persecution of PWID, deprioritizing of other priority interventions, or prioritisation of profits from treatments inaccessible to many generates considerable mistrust. The INPUD report references a mistrust of Gilead in particular; Gilead manufactures Truvada, the principal PrEP formulation, and also the hepatitis C treatment, Sofosbuvir, which it has been argued yields an extremely high profit margin (65). The purported intransigence of Gilead on pricing of Sofosbuvir has been a focus for anger and frustration for many PWID, since the prevalence of HCV among PWID is very high. The INPUD report suggests that this mistrust has been a basis for concerns that efforts to scale up PrEP are driven by similar profit motives.

Prioritising comprehensive HIV prevention

We see these trends in the HIV policy environment as limiting the potential for a comprehensive HIV prevention response that meets the needs and concerns of PWID. We are, of course, not seeking to abandon PrEP, and welcome its development. We do, however, regret a system that has produced PrEP without comparable effort towards, for example, securing full coverage of NSP, OST and ART, or by addressing the stigma faced by PWID by publicly recognizing and enforcing the right to access these services, and holding accountable the governments that deny them.

A search for medicines to cure, treat and prevent HIV for PWID is essential, and yet these need to be integrated within a plurality of perspectives and responses to recognize the social dimensions of the epidemic (54, 66) and how a comprehensive HIV prevention response is needed to address these, and also enable broader action on linked health emergencies for PWID such as Hepatitis C. There are many potential entry points for such strategic integration; one example is how scaled-up OST, contingent in many settings on policy reform, could be a basis for delivering PrEP, in response to how OST facilitates ART engagement (67). A corresponding imperative for unity is around the need for funding to match the need for comprehensive HIV and harm reduction interventions: in 2015 it is estimated that of the \$2.3 billion needed to fund HIV prevention amongst PWID, only \$160 million will be invested, just 7% of the need (68). Finally, action is needed to ensure communities are more effectively engaged in policy debates, strategy development and resource planning. Such actions could include removal of legal obstacles and support to financing for PWID organizing and networking, recognition of the expertise of PWID as well as the need to engage with their experiences, and more than tokenistic involvement in decision making(69).

Conclusion

“Knowing medicine cannot work in isolation and ARVs alone cannot end AIDS, a comprehensive response attentive to underserved groups is urgent”. The Vancouver Statement, July 2015

Whilst the development of PrEP will be an important part of our growing response to HIV (13, 14), we argue that the report from INPUD needs to stimulate careful collective reflection by those concerned to support communities and ensure effective responses to HIV (6, 7). We have discussed the particular challenges to PrEP of its feasibility and ethics, the potential to undermine harm reduction and how it potentially heralds a remedicalisation of HIV. Based on these themes we posit that risk exists for PrEP to be both success and failure for PWID, and ground this divergence in the ‘fault line’ in HIV prevention between a dominant biomedical regime and community voices. While biomedical interventions – like PrEP - are essential, so too is action in the social and political sphere to ensure health systems are accessible, non-discriminatory and adapted to the needs of people who use drugs. If, however, we continue to ignore and misunderstand what communities are saying, we risk continuing to prioritise the development of biomedical interventions that, whilst efficacious, are rarely brought to scale. Advocates for PrEP, harm reduction and HIV prevention in general need to ensure that PrEP for PWID is introduced as part of a comprehensive harm reduction package that includes existing interventions that have been shown efficacious for decades.

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