Report on Public Involvement meetings with PrEP users enrolled in the PROUD study and trans service users from cliniQ, in the draft stages of the World Health Organisation's PrEP Implementation Guidelines

Contents

Summary of Project

cliniQ held a series of public involvement meetings in Central London in June 2015, in order to inform the draft stages of the World Health Organisation's *PrEP Implementation Guidelines.* The meetings included a range of gay/MSM PrEP users who were participating in the PROUD study, and a range of HIV negative trans people who have previously accessed sexual health services at cliniQ. Through the discussions within the groups, cliniQ gathered information which can enable the voices of WHO's key populations to be heard in throughout the PrEP implementation guidelines.

Public Involvement meeting with cliniQ service users

Introduction

cliniQ held a public involvement meeting with nine trans sexual health service users on Thursday 18 June 2015. The group, lasting two hours, was conducted to allow trans people's experiences to feed into the WHO PrEP Implementation Guidelines. The participants provided information in two ways: group discussion and written responses.

The discussion aimed to address the following questions:

1. How to deliver PrEP in order to maximize uptake by people who can most benefit from it?
2. How to mitigate the risk of stigma related to PrEP impacting on uptake and usage?
3. How to promote PrEP in terms of reasonable presentation of effectiveness (efficacy v effectiveness), risks (side-effects) and benefits (protection when at risk)?
4. How to support appropriate usage, which includes sufficient adherence during periods of risk (considering both daily and on-demand options)?
5. How to help people decide if PrEP is right for them at this point in their lives?
6. How to support people to use PrEP, including advice about the challenges of use and ways to communicate use to partners?
7. How to promote behaviour change in the context of PrEP whereby people can conceive PrEP as a way to avoid HIV in their lives, considering specific tactics such as PrEP champions, Grindr ads etc?
8. Are there additional questions that need to be addressed in order to support PrEP delivery to gay, bi-sexual, other MSM, and trans-populations?

Participant Demographics

cliniQ recruited participants from the trans communities to take part in the meetings on the basis that they were over 18 years of age, had accessed cliniQ's holistic and/or sexual health services in the past, were HIV negative, and had sex with men.

Nine people took part in the meeting:

- Four people identified as trans women, or female with a trans history. Two identified as non-binary/genderqueer trans men, two as trans men, and one participant identified as non-binary/genderqueer.
- 6 of the 9 participants had heard of PrEP prior to the meeting, 3 had not.
- 8 participants reported that they would take PrEP if it were available via the NHS, 1 said they would not take PrEP if it were available to them.
- Of the 9 participants, 5 accessed sexual health services either once or twice per year, 2 accessed sexual health services every 3-6 months, 1 stated accessing services yearly or less, and 1 person declined to state.

cliniQ service user perspectives

Due to practice knowledge gained from delivering services at cliniQ, and from anecdotal evidence from services users, we assumed a low baseline level of knowledge concerning PrEP within the trans communities. On this basis, participants were sent a briefing sheet

that provided basic information about PrEP, PrEP usage, and efficacy, including the results of the PROUD study. 3 of the participants reported having not heard of PrEP prior to receiving the briefing sheet.

In order to ensure that participants would be able to adequately contribute to conversations about PrEP implementation, cliniQ provided multimedia materials to create discussion points. The material included:

1. **Video interview with a serodiscordant gay couple, one of whom was a PrEP user**

   Link: https://www.youtube.com/watch?v=gAha5LrBsgE
   The response from participants was unanimously positive, describing the decision for the HIV negative person to take PrEP as "responsible" and "understandable." One member of the group noted that it would provide better protection if the couple were to use PrEP as opposed to misusing condoms. Participants also saw taking PrEP as being analogous to cisgender women being responsible for their own reproductive health by taking contraceptive medication. The group clearly expressed support for PrEP being available to serodiscordant couples of any gender identity.

   One member of the group discussed his experience of previously dating a man who was living with HIV. He described how he would have "seriously considered" taking PrEP at this time, but only with more information being available considering its long-term use.

2. **Video interview with a gay man, describing how his increasingly inconsistent condom use with multiple partners was part of his decision to take PrEP**

   Participants acknowledged that everyone should be able to make informed decisions about how to protect themselves from HIV and other STIs. However, there was some concern within the group that if people are only taking PrEP for specific periods in their lives, or (if in low-to-middle income countries) only when they can afford it, then skills such as negotiation and condom self-efficacy could be lost.

   Members of the group also voiced concerns over the lack of knowledge they had about the long-term effects of Truvada™, and stated that any Implementation Guidance would need to include this type of information.

   The trans men/male identified individuals in the group discussed times where PrEP may have been useful at varying points in their lives. In particular, several participants expressed feelings of having taken increasingly more risks as they adjusted to testosterone therapy, and their increasingly positive relationship to their bodies. Mostly, this was as trans men who were having sex with cisgender MSM via sex finder apps and in sex on premises environments. Most participants agreed that during these periods of transition and sexual exploration, they would have liked to have been afforded the opportunity to take PrEP.

3. **Video interview with a PrEP user who identified as a trans women, discussing stigma, sexuality and describing her use of PrEP as an empowering tool**

   Participants were particularly struck by the stigma that had been described, and suggested Public Health messages need to be clear in the message that taking PrEP is a positive act of self-empowerment and a tool for self-protection. There were some reservations concerning highlighting MSM and trans people as key populations who would benefit from PrEP, as it could increase stigma directed towards those communities. However, there was also an agreement from most participants that PrEP should be targeted to key populations in the first instance.

Several members of the group also noted that if Public Health messages are focused on marketing the virtues of PrEP, and of staying negative, that they must not do so by further stigmatizing people who are living with HIV.

The group also noted that being given a prescription for PrEP should be part of a range of wrap-around services, which would include sexual health information, counselling and regular testing.

Participants were also asked to comment on the following statements:

4. **In the IPREX study, 13% of the participants were classified as trans women (whom either identified as women, or were using feminising hormones). The study found that overall, trans women's use of PrEP was inconsistent and adherence was generally poorer than in men who have sex with men. Anecdotally, there were conversations that suggest this could due to fears of negative interactions between PrEP and hormones. However, there is currently no research into this area and we do not know how the drugs interact with hormones.**
Discuss: consider what information you, as a trans, non-binary or queer person would like to know if you wanted to take PrEP.

   Several of the participants experience multiple disability, and expressed serious concerns about PrEP's interaction with their existing medication, as well as with hormone therapy. One participant asked if PrEP would react with "the 40 odd other pills I take every day?" and asked if disabled people have been represented in any of the PrEP studies. There were concerns about drug interactions, but more significantly the issue is one of inclusion, as once again, people with a disability are being overlooked with regards to sex and STI health needs.

   Several of the participants questioned whether PrEP would affect or interact with their hormone usage, with several people stating that if it were a choice between PrEP and their hormones, they would not take PrEP.

   One participant who said they would not want to take PrEP if it was available on the NHS asked "if all the other drugs I'm taking, including my hormones already have side-effects, why would I want to take more drugs if I'm negative?" However, multiple others agreed that as a trans person, being medicated becomes part of everyday life and they had no issue with taking PrEP if it was unlikely to affect hormone therapy.

   The group agreed that for trans people to make informed decisions about taking PrEP, there needed to be further studies about how PrEP will affect trans bodies.

5. **Adherence: Lots of different studies have reported that PrEP is effective if you take it but not effective if you don't. For gay men, this requires taking a single pill of tenofovir/FTC on at least 4 days every week. Several research groups have suggested that women would need to take PrEP on 6-7 days every week to get the same protection. This is because drug levels are much higher in rectal tissue compared to vaginal tissue.**
Discuss: consider how the above information does or not does not relate to you, your body and your identity

   The participants felt that for information about PrEP to be relevant to trans communities, then any guidelines published by WHO cannot perpetuate the gender

binary. The group felt that existing studies actively excluded trans and queer identities, with one participant asking of the above statement "What does this mean for cisgender women or bi people who have anal sex?"

Other questions re: existing PrEP information included questions from trans men who were unsure of which dosage would be appropriate for them, as MSM who are having vaginal sex with men. Trans women in the group also raised the issue that they may be having vaginal sex, but that there is no information as which level of PrEP would be effective for them either.

Several members of the group agreed that there was no need for the guidelines to use gendered language at all i.e. individuals can be referred to as "people with vaginas, or people with penises" in order to clarify which information is relevant, without excluding trans people.

The group also spoke about where they would access PrEP, and noted the level of safety provided by a trans-lead service, with one participant asserting that they "would trust cliniQ [to prescribe me PrEP], but I would not trust my GP."

One member of the group stated that, as a trans person, they would have wanted to access PrEP during their transition. They described experiencing HIV-related anxiety, and worrying about the ways in which a positive diagnosis could impact on their transition (i.e. hormones and surgery). They explained that as a trans person, they need to be able to present at gender identity clinics as physically and mentally healthy; being HIV positive could seriously affect that for them, and therefore result in withheld gender care services. They stated PrEP would have been an effective safety net to shield against this anxiety.

The group also discussed the experience of gender validation through sex in more detail, and described the risk they feel they are taking as trans people. One participant expressed "I know I should be responsible, but I find it hard when people find me attractive, and I take risks. If I had to take a pill a day for even 10% more safety than I have now, I would do it as I don't trust myself."

The group also discussed how PrEP use would be important for sex workers, and noted several studies which showed the number of trans sex workers to be disproportionate to the number of cisgender sex workers.
See: p194 Handbook of the Sociology of Sexualities, John DeLamater & Rebecca Plant 2015, publishing a paper by A H Devor & K Dominic, citing: 'Transgender Care' by Israel & Tamer, 1997; 'Invisible lives….' Namaste 2000, 'Undoing theory….' Namaste 2009 and Nemoto et al 2014. See also http://ajph.aphapublications.org/doi/abs/10.2105/AJPH.2010.197285

6. In a short written survey, participants were asked if they would take PrEP if it was available to them on the NHS. 8 participants reported that they would take PrEP if it were, 1 said they would not take PrEP if it were available to them. They were also asked if their gender identity would effect this decision. The responses were mixed, with one participant stating their elevated HIV vulnerability as a trans woman would inform their decision to actively take PrEP, and another trans woman expressing that having condomless sex made them feel "normal" and was a gender "confirming" experience. The participant who stated they would not take PrEP suggested it was because "they are already on hormones and T-Blockers and they do not want any more chemicals in their body."

Recommendations

Existing data suggests 49% greater risk of HIV among trans women compared to all adults of reproductive age across 15 countries (van Griensven 2012). Despite this, it is clear from the responses and the discussions that trans communities do not feel represented by the information about PrEP that is currently available.

Trans participants of varying gender identities and morphologies felt that information about "men" and "women" provided by existing studies excluded them, and had the potential to create messages about PrEP usage which are either unclear or not at all applicable to trans people. The group felt that any guidance concerning PrEP usage needed to be able to refer to accurate, inclusive research that could clearly outline the implications of taking PrEP for trans people. If such data and information becomes available, resulting guidelines and public health campaigns would need to be visibly inclusive of trans people, including case studies and visual representations.

The group explored the possibility of integrated sexual health and gender care services, and although there was significant distrust of both general practice and gender care services (as they exist currently), it is clear that there is scope for PrEP to be included as part of gender care. By including PrEP in transitional services, there is the potential to mitigate the additional risks our participants felt they experienced at varying points in their transition journey.

Participant Involvement meeting with PrEP users enrolled in the PROUD study

Introduction

cliniQ held a participant involvement meeting with 11 Gay/bisexual/MSM who were actively taking PrEP, via their participation in the PROUD study on Thursday 25th June, 2015. The meeting, lasting two hours, was conducted to allow MSM PrEP users to feed into the WHO PrEP Implementation Guidelines. The participants provided information via group discussion.

The group discussion aimed to address the following issues:

1. How to deliver PrEP in order to maximise uptake by people who can most benefit from it?
2. How to mitigate the risk of stigma-related to PrEP impacting on uptake and usage?
3. How to promote PrEP in terms of reasonable presentation of effectiveness (efficacy versus effectiveness), risks (side-effects) and benefits (protection when at risk)?
4. How to support appropriate usage, including sufficient adherence, during periods of risk (considering both daily use and on-demand options)?
5. How to help people decide if PrEP is right for them at this point in their lives?
6. How to support people use PrEP, including advice about the challenges of use and ways to communicate use to partners?
7. How to promote behaviour change in the context of PrEP, whereby people can conceive PrEP as a way to avoid HIV in their lives, considering specific tactics (such as PrEP champions, Grindr ads etc)?
8. Are there additional questions that need to be addressed in order to support PrEP delivery to gay, bisexual and MSM populations?

Participant demographics

Participants were recruited via the PROUD study team to take part in the participant involvement meeting. They were UK-based Gay/Bi/MSM, over the age of 18, who were HIV negative and active users of PrEP.

PrEP users perspectives

How to deliver PrEP in order to maximise uptake by people who can most benefit from it?

Participants discussed the very high effectiveness of PrEP demonstrated within the PROUD study, noting that it was likely to have been an effective study based on the level of transmission risk within the participants (which was thought to be high). Most participants noted that they had heard about PrEP and the PROUD study via the sex finder app Grindr, suggesting that to reach MSM who would benefit from PrEP "social media must be engaged."

The participants noted that the PROUD study had reached a particular demographic within MSM (predominantly affluent, gay, white males who were reasonably well-informed about

sexual health) and that specific drives within other groups, particularly those low-income or BAME backgrounds would need to be engaged with specifically, and in different ways.

Participants discussed the possibility of encouraging uptake of PrEP specifically to those whose condom use is already inconsistent, provided it is as part of a comprehensive range of interventions (including sex education, behaviour change counselling etc.). It was also noted that if a range of ways to take PrEP are available, uptake may be easier to encourage.

Within sexual health clinics in the UK, it was suggested that people who have previously accessed PrEP could be offered PrEP when it becomes available, but other methods (including social media, and community outreach) will be needed to reach those who do not access clinics.

How to mitigate the risk of stigma-related to PrEP impacting on uptake and usage?

Several participants expressed that when discussing PrEP use during negotiations of condomless sex, that they had experienced some negative reactions from prospective partners, and described accusations of promiscuity and much enacted stigma around PrEP use. One participant described these experiences to his key worker and felt incredibly supported by the advice he was given: "I realised this was about me taking control of the sex I'm having, and protecting myself at the same time. It can be a very empowering process."

The group agreed that condomless sex needs to be reframed, to include messages of protection when PrEP is being taken. "The term 'barebacking' didn't even exist until HIV came along. We need to rid the feeling of negativity because we are protected." There was a rich discussion about the feelings of guilt attached to advocating condomless sex, but suggested that including examples of how this can be mitigated would be useful.

The group suggested that more open discussion around PrEP would be useful to reduce stigma, and noted there is a feeling that this is beginning to take place. As an example, several people noted that "PrEP user" is becoming a common feature of MSM's profiles on sex finder apps. Useful conversations are also being had online, for example, PrEP facts: https://www.facebook.com/groups/PrEPFacts/#!/groups/PrEPFacts/ and HIV equal: http://www.hivequal.org/hiv-equal-online/trans-men-the-invisible-battle-with-hiv

How to promote PrEP in terms of reasonable presentation of effectiveness (efficacy versus effectiveness), risks (side-effects) and benefits (protection when at risk)?

Effectiveness

One member of the group expressed concerns over efficacy, and times when PrEP may be less effective (suggesting the drug is less effective when the user has diarrhoea), but is still more effective than condoms. There was a discussion around the general public's understanding of clinical trials, and suggestions that information concerning efficacy would need to be presented in more accessible terms, i.e. that PrEP is "as good or better than condoms."

Risks

Some of the group had concerns that some MSM have been using PrEP use to coerce others into having condomless sex which they are not comfortable with; the group felt that as knowledge of PrEP increases, people may be less likely to feel as much discomfort around

condomless sex. Education about PrEP for both health care providers and potential users is necessary to promote this.

Some participants stated that they had witnessed MSM both offline and on sex finder apps claiming to be PrEP users in order to negotiate condomless sex, when they were not taking PrEP.

Benefits

Participants described the benefits of increased HIV prevention as being the "easy sell" of PrEP, but felt that a much harder conversation to have, is if users are finding they are having condomless sex and that "sex without condoms is better"; many of the group agreed they often struggle to comfortably articulate that message. "The benefits are peace of mind, taking control over your own health and other aspects of your life. Feeling better, and the pleasure benefits can often be a hard sell topic, and can be a bit taboo."

One benefit that the majority of the group experienced is a lack of guilt and anxiety concerning sexual encounters they have had since using PrEP. "Condoms make me lose my erection every time I put one on, and every time I had sex [without a condom] I felt guilty. Having been able to take PrEP, I've been able to have sex which doesn't make me feel guilty, or which doesn't make me wake up and rethink all the things I've done, and all the conversations we had... did I ask if he was negative?"

The group agreed that PrEP needs to be described as part of a comprehensive range of options people can choose from, in order to protect themselves from HIV transmission.

How to support appropriate usage, including sufficient adherence, during periods of risk (considering both daily use and on-demand options)?

Participants described the elements of the PROUD study which enabled them to adhere to PrEP use appropriately; this process included a review of usage after one month (to discuss side effects, adherence and to speak to a health advisor); followed-up by check-ups every 3 months.

Participants also discussed timing the need to have a check-up with replenishing their prescriptions, using dosette boxes and keeping "back-ups" in their wallet or cars in case they forget a dose, or spend a short time away from home.

Some participants suggested that peer support could be useful, including "checking in" with people via forums and social networks.

How to help people decide if PrEP is right for them at this point in their lives?

Participants drew comparisons to the contraceptive pill and described how PrEP can be viewed as an additional layer of protection, as opposed to replacing condom use. It was commented that health professionals need to be more aware of what constitutes 'periods of risk' for MSM stating that the end of a relationship may be a time where men find it difficult to return to condom usage, and may take more risks. Clinicians need to be able to understand where risk exists, scenarios where intimacy may be particularly desired, or where condom use is less likely.

How to support people use PrEP, including advice about the challenges of use and ways to communicate use to partners?

The participants discussed boundaries in relationships as they may relate to PrEP usage, and mentioned that PrEP may provide additional protection for those in open-relationships and their partners, as well as individuals with multiple partners, or those having sex outside of their relationships.

The importance of capable culturally aware health advisors was also noted as being highly important in the implementation of PrEP. Participants want to speak to professionals who are sensitive to possible stigma from partners concerning PrEP use. Health Advisors should be able to support individuals to communicate about PrEP to potential partners, as well as encourage people to challenge any stigma they feel about using Truvada.

How to promote behaviour change in the context of PrEP, whereby people can conceive PrEP as a way to avoid HIV in their lives, considering specific tactics (such as PrEP champions, Grindr ads etc)?

The participants highlighted the importance of community-lead initiatives to encourage uptake of PrEP and referenced models which have been used previously, such as peer outreach workers disseminating condoms in clubs, social media campaigns, club advertising, adverts on sex finder apps and the use of 'PrEP champions' to discuss the issue with other MSM.

One participant noted that "PrEP" has been added to the dropdown menu of a popular sex finder app, forcing people to engage with PrEP. It was agreed that this encourages PrEP to become something tangible. It was also mentioned that an online assessment tool for PEP use currently exists, and could be modified and replicated in relation to PrEP and shared on social media.

Are there additional questions that need to be addressed in order to support PrEP delivery to gay, bisexual and MSM populations?

- What happens when people stop taking PrEP? Individuals felt there needed to be information about stopping PrEP i.e. if a person has condomless sex on a Friday, and stops taking the drug on a Sunday, are they still protected?
- What are the dosing recommendations likely to be in the UK? It was felt that daily adherence is easier to manage than intermittent dosing; how can intermittent dosing be supported (reminder apps etc.)?
- Would intermittent dosing or stop/start taking of PrEP increase or effect side-effects?

END NOTES

The public involvement meetings were facilitated by Michelle Ross and Aedan Wolton of cliniQ, with input from Mitzy Gafos on behalf of the PROUD study team. The report was prepared by Aedan Wolton and submitted to WHO and UNAIDS. The meetings were funded by WHO and UNAIDS.