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“Belt and braces approach; added benefit and...extra reassurance”: A Multi-Stakeholder Examination of the Challenges to Effective Provision of Pre-Exposure Prophylaxis (PrEP) for HIV Prevention Among Men Who Have Sex with Men (MSM) in Northern and Central England

Abstract

Pre-exposure prophylaxis (PrEP) involves HIV negative individuals taking antiretroviral drugs to reduce the probability of infection if exposed and is available through the IMPACT trial in England. This study aimed to explore MSM and service provider (SP) perspectives on provision and accessibility of PrEP in Northern and Central England. 20 MSM and 25 SP from four Northern cities and one city in the West Midlands region were recruited for semi-structured interviews (December 2018 to October 2019). Interviews were analysed using Interpretative Phenomenological Analysis. Three key themes emerged: ‘Self-sourcing PrEP’; ‘Service delivery learnings’; and ‘Impact of using PrEP’. Problems with equity of access and accessibility were noted, and recommendations for the future of PrEP programming and equitable service delivery were also presented. The study highlighted divergence in PrEP service experience from patients and providers, with results informing policy, practice and professional training.

Keywords

Pre-exposure prophylaxis; HIV prevention; Sexual health; MSM; Service delivery

Word count

2,997 words

Introduction

The United Kingdom (UK) has a concentrated human immunodeficiency virus (HIV) epidemic, with an estimated 103,800 people aged over 15 years living with HIV (O'Halloran et al., 2019). Globally, antiretroviral treatment (ART) alone cannot reduce the epidemic (Stover et al., 2016). UNAIDS (2016) estimated that three million people worldwide were eligible for pre-exposure prophylaxis (PrEP), an evidence-based biomedical HIV prevention intervention involving HIV negative individuals taking ARTs¹ to reduce the probability of infection (Davies, 2016). Generally prescribed daily, an alternative is event-based dosing regimen² (Molina et al., 2015). PrEP is positioned within a series of HIV prevention measures, including condom use, testing, counselling and HIV treatment as prevention (Ford et al., 2014; Nugroho, Erasmus, Zomer, Wu, & Richardus, 2017).

The World Health Organization (2015; 2016; WHO) and UNAIDS are prioritising PrEP implementation for populations at the greatest risk of HIV, as when adherence is high, it is effective among men who have sex with men (MSM) (McCormack, 2016; Trager et al., 2018), serodiscordant heterosexual couples (Baeten, Donnell, & Ndase, 2012), and people who inject drugs (PWID) (Choopanya, Martin, & Suntharasamai, 2013). Globally, MSM have 19-fold greater odds of acquiring HIV compared to the general population (Freeborn and Portillo, 2018). Although a decrease in diagnoses among MSM has been observed, UK HIV transmission is still occurring with 2,250 new MSM diagnoses in 2018 (O'Halloran, et al., 2019). Hence, PrEP is an integral prevention tool among MSM to mitigate the risk of HIV acquisition (Trager, et al., 2018; UNAIDS, 2014).

¹ Tenofovir disoproxil fumarate (TDF) and emtricitabine (FTC)

² Minimum of one pill 24 hours before and one 24 hours after sex

Initially, research studied the safety and efficacy of PrEP (Desai et al., 2016; McCormack et al., 2016) and knowledge, awareness and willingness to use (Eaton et al., 2014; Grov, Whitfield, Rendina, Ventuneac, & Parsons, 2015; Holloway et al., 2017; Klevens et al., 2018), ahead of implementation and demonstration trials, including the IMPACT trial in England (NHS England, 2017; PrEP IMPACT Trial, 2020). In August 2020, of the 79 countries where PrEP is available, 48 were conducting implementation or demonstration trials; 38 indicated PrEP in HIV prevention guidelines; and 27 were at national level roll-out (PrEP Watch, 2020). Although PrEP is now commissioned in England, significant obstacles remain (Hillis, Germain, Hope, McVeigh, & Van Hout, 2020). Aside from numerous reviews on optimum programming and service delivery (Amico and Bekker, 2019; Hillis, et al., 2020; Sullivan and Siegler, 2018; Vanhamel et al., 2020), there is a paucity of qualitative research examining those taking and providing PrEP, and experiences of services available in England. This study builds upon the existing evidence-base, providing insight into the nuances, obstacles and holistic perspective of PrEP service provision. The findings will inform how PrEP can be embedded into existing HIV prevention programmes to ensure a streamlined integration into wider sexual health provision.

Materials and methods

Theoretical framework

MSM and service provider (SP) perspectives on provision and accessibility of PrEP were examined using an Interpretative Phenomenological Analysis (IPA). IPA has an idiographic focus and is a dynamic process, offering insights into how a given person, in a given context, makes sense of a phenomenon. IPA is a dynamic process with the researcher actively making sense and offering insights into a given person in a specific context (Smith, 2009).

Participant selection

The intensity of IPA in giving each participant complete appreciation requires small sample sizes (Pietkiewicz and Smith, 2012; Smith, Flowers, & Larkin, 2009). A similar study recruiting a sample of only 18 SP in America (Calabrese et al., 2016). In IPA the sample is selected purposively with varying degrees of homogeneity. Participants were unknown to the interviewers. MSM participants were recruited from community health and support services, approached by service level staff who acted as gatekeepers. Posters at service sites and relevant social media pages were also used. At the end of interviews, interviewees were asked to refer potential participants to the study team. This was capped at two participants per MSM to avoid over representation from one particular social network. For SP recruitment, key personnel were emailed and recruited in person during Liverpool John Moores University staff visits to the community health and support services as well as through National Health Service (NHS) research departments. Recruitment was conducted between December 2018 and October 2019, across Liverpool, Manchester, Sheffield, Leeds and Birmingham, resulting in a purposive sample of 20 MSM and 25 SP. Informed consent (written and verbal) was sought prior to interview.

Setting and data collection

IPA uses semi-structured interviews to achieve an immersive understanding and desired outcomes (Pietkiewicz and Smith, 2012). AH (female, research assistant), JG (female, researcher), MH (male, research assistant) and MCVH (female, lead investigator) conducted the one-to-one interviews over the phone, via Skype or in person. Interviews lasted up to 90 minutes. Referral information was provided where required, and both participants and data were anonymised.

An interview guide was generated based on a scoping review of extant PrEP international literature (Hillis, et al., 2020). The semi-structured interview guide was piloted within the research team and adapted throughout data collection when necessary. Open questions, with prompts, were used to explore experiences. Topics included participants' experiences of PrEP (eligibility, compliance, access, sourcing and knowledge sources); sexually transmitted infections (STIs), HIV and hepatitis testing patterns; sexual risk behaviours; barriers to access; and complexities around PrEP service provision. Using purposive sampling measures, the MSM sample included those intending to use, or currently on PrEP (either through the IMPACT trial or from self-sourcing). SPs included LGBT and HIV community outreach workers, nurses, clinicians and other health professionals. Recruitment and data collection ended with data saturation, when no new information was obtained from participants (Tong, Sainsbury, & Craig, 2007). No interviews were repeated, and no field notes were taken. All interviews were audio-recorded and transcribed. No participants requested to review their transcription, and none were asked to provide feedback on findings.

Data analysis

Data management and analysis was conducted in QSR-NVivo v12. In using IPA, the analysis was iterative and inductive, generating codes from the data to understand the participant claims in relation to the researcher's interpretation of those claims. Preliminary coding was conducted by AH (for MSM transcriptions) and JG (for SP transcriptions). Triangulation of the codes was conducted through discussions with the research team. AH and JG catalogued the agreed codes into subordinate themes and grouped into broader superordinate themes, with constant comparison and iteration, and presented with quotes from the narratives. Findings from the triangulation process (Erzberger and Prein, 1997; Farmer, Robinson, Elliott, & Eyles, 2006; Foster, 1997), was presented in an individual graph

identifying the code frequency by each group under superordinate themes (see Figures 1,2 and 4).

For complete Consolidate Criteria for Reporting Qualitative Studies (COREQ) checklist, see Table 1. Ethical approval was received from LJMU Research Ethics Committee and the NHS.

Results

Three key themes emerged: '*Self-sourcing PrEP*'; '*IMPACT trial: service delivery learnings*'; and '*Impact of using PrEP*'. The participant profiles are illustrated in Table 2. Table 3 details each theme with subordinate themes.

[Table 2 and Table 3 near here]

Of the 20 MSM interviewed, 50% (n=10) were on the IMPACT trial, 5% (n=1) was self-sourcing, and 45% (n=9) were not on PrEP at the time of the interview. Four MSM were unable to gain a place on the trial and one MSM considered himself low risk to HIV acquisition. Three MSM had historical negative experiences of sexual health clinics and so sourced PrEP online. However, they reported that the websites were hard to follow, and the process was "*convoluted*" (PS15), which led them to distrust PrEP sourced online.

Contrastingly, nearly half of the MSM reported that they decided to take PrEP as it provided an additional form of protection to counter the existing fear of contracting HIV, describing it as the "*belt and braces approach*" (PS16) and an "*added benefit and...extra reassurance*" (PS12) against HIV and STIs for themselves and their partners.

Self-sourcing PrEP

[Figure 1 near here]

Reasons for self-sourcing were discussed by MSM (40%) and SPs (72%). One MSM, and the second youngest in the sample, stated that self-sourcing PrEP “*might be easier, rather than...jumping through the hoops*” (PS18). Three MSM and nine SPs stated that extensive trial waiting lists and NHS ‘referral’ routes led to self-sourcing. Others chose to self-source, namely through *iwantprepnw*, due to avoidance of the NHS (three MSM), concerns of existing stigma across healthcare services (three MSM) and reservations about SPs having insufficient knowledge (three MSM). Interestingly, SPs mentioned that if patients self-sourced, they could still receive full health screening every three months, aligned to current guidelines. However, the private purchase of PrEP raised questions, “*Is it the real deal?*” (SP8). This should be concerning for policy makers as, “*Although the website is a great resource, I would like to know that some sort of governance is in place behind it*” (PS9).

Service delivery learnings

[Figure 2 near here]

Referral

The main referral pathways described by participants were through community organisations, charities, the wider MSM and gay community outreach and LGBTQ+ services, personal social connections, SPs (sexual health clinics, health advisers and PrEP advice clinics), materials distributed at sexual health clinics and self-referrals. Online communication (websites, media and dating apps) instigated interest in, and desensitised people to, sourcing and using PrEP. Services should therefore continue to “*operate with people where they are...It’s an online community these days*” (SP8). This was observed with caution, as although “*sex is intertwined with use of the apps*”, there is a potential issue with “*over-deliver[ing] to certain areas of the community*” as there needs to be “*more access in non-LGBT [and] more mainstream services*” (SP8). Some SPs noted this lack of diversity was also reflected in the IMPACT trial; “[*patients*] *tend to be urban city centre kind of*

higher socioeconomic group, knew about PrEP, knew it was coming, came to the clinic and asked for it” (SP12). Disparity in knowledge and information-seeking behaviour have undoubtedly impacted on referral, with some individuals ill-informed; “*we’re always seeing people who don’t actually know about PrEP even though engaging in very high-risk sex*” (SP11), and some communities such as Black, Asian and Minority Ethnic (BAME) groups left behind. Recommendations for improving referral routes to PrEP included utilising targeted social connections, community organisations, media campaigns, working with MSM communities through outreach services, PrEP advocates, and extending PrEP services to primary care.

Eligibility

Two MSM identified that when one person in a serodiscordant couple achieves a low viral load, they are undetectable and untransmissible, and so would be excluded from the trial. Three MSM admitted to “*stretching the truth a little bit by saying it was condomless sex*” (PS11) in order to meet the criteria. Most SPs identified that unprotected anal sex (UAS) constituted the main eligibility criterion (followed by multiple partners, sexuality, risk level, HIV negative status, ethnicity and chemsex participation). However, by restricting UAS to three months, services are excluding a cohort of potentially high-risk individuals who could be either side of these time parameters. Establishing different criterion was also questioned by SPs, as assessing HIV status varied per site (INSTI test, full blood test, abstaining from sex for a month). SPs also identified gaps in the criteria (social, ethnic, racial), impacting on access. One participant reported that their SP was in disbelief that they were gay, a Muslim and wanted PrEP. The same participant described experiencing “*discrimination [from within] the South Asian community. People aren’t nice about it*” (PS14). Similar scenarios were observed for the BAME community with two SPs describing religion as, “*a challenge*” regarding PrEP (SP11, SP16). SPs were also concerned that those not associated with “*gay*

culture”, for example heterosexual African women, transgender people and sex workers continue to experience HIV-related stigma, limiting access to PrEP.

Location

Several MSM discussed the setting they have and would like to receive their PrEP prescriptions. One described how “*trying to find which clinics actually provide PrEP has been a bit of a minefield*” (PS12). Many reported wanting to “*find somewhere [they’re] comfortable with*”, such as pharmacies, primary care practices, following visits to A&E, or through over-the-counter prescriptions. SPs supported numerous access points for PrEP to meet the varying service user requirements; “*In an ideal world you’d have multiple channels through which people could obtain it*” (SP4). One suggestion was to “*[offer] clinics outside the nine to five working hours*” (SP13). Further proposals included extending PrEP communication in various settings through waiting room television screens.

Resource capacity

Some sites appeared under strain with increased staff workload and inadequate resources, “*They’re expected to deal with [a new thing available, like PrEP] within the current financial envelope*” (SP15). Again, issues varied by site as one MSM stated “*the waitlist is not too long... there [are] appointments available in...reasonable time*” (PS20). Resource constraints meant some participants had difficulty booking their three-month follow-up appointment. One participant described having to “*modify my behaviour because you cannot guarantee that you’ll be able to get to see the doctor...when you go back for your next lot of tablets*” (PS11). SPs were aware of patients accessing A&E to obtain post-exposure prophylaxis for use as PrEP, and that patients were “*seroconverting for HIV...because [they couldn’t] get into clinic*” (SP22).

Service providers

SP roles included checking the patients’ health before administering PrEP, outlining side effects, vaccinations, providing advice and working with vulnerable groups. A further

role involved discussing daily and event-based dosing regimens. One SP highlighted “*there needs...a dialogue around individual needs within PrEP*” (SP1), such as individual risk profiles. Recommendations to aid patients in adhering to the medication included distributing PrEP in a 7-day blister pack, mobile apps and developing a PrEP implant. A community-based SP reported that their department offered an outreach service, “*we go into GP surgeries, opticians, dentists, and we train those healthcare providers on LGBT issues and what barriers are faced by LGBT people*” (SP3).

Service delivery

Lack of privacy in sexual health clinic waiting rooms and stigma from SPs when discussing sexuality, sexual health or PrEP use was evident with some believing that “*[some] equate PrEP with promiscuity [and] immoral[ity]*” (PS1). In contrast, others reported feeling at ease. Suggestions were made for enhanced programming of PrEP including operating a PrEP information helpdesk, waitlist and appointments; informing receptionists of how to handle PrEP-related enquiries; creating PrEP “*support packages*” for health workers outside of sexual health; allowing clinician discretion for prescribing PrEP and extending initial, as well as follow-up, consultations to a minimum of 30 minutes. There was a sentiment that extensive, ongoing training, education and peer training across all levels of primary and secondary care is required to ensure that all access points and associated SP were knowledgeable about PrEP. Figure 3 illustrates the PrEP pathway as reported by participants.

[Figure 3 near here].

Impact of using PrEP

[Figure 4 near here]

Changes in an individual’s sexual behaviour was the main impact for those taking PrEP. Nine MSM and nine service providers reported riskier behaviour when taking PrEP, such as UAS, more frequent chemsex participation and using dating apps displaying a PrEP

status. There was divergence around lack of condom use during casual encounters, and concern around a potential rise in STIs. SPs tended to take the stance that MSM “*are a group who will not use condoms for sex and not having PrEP does not change that*” (SP7). Eleven MSM discussed STIs, five experienced an increase in STIs since taking PrEP, and two recognised that the rise was a consequence of increased UAS. Four MSM reported never having an STI; one reported that he “*was getting STI’s before, and [has] continued to get them since*” (PS17). Two MSM reported becoming safer since taking PrEP, which was validated by three SPs.

Two community workers described how PrEP could be a tool used for “*control and coerciveness*” with partners withholding medication (SP3, SP5). The process for PrEP discontinuation was not reported, though one SP described an MSM returning “*three months’ worth of pills because he decided he was no longer at risk...when actually he [was]*” (SP6).

Discussion

The study has provided a rich understanding of the experiences of PrEP service delivery for MSM in England. Findings underscored the importance of a streamlined care pathway to ensure effective service delivery of PrEP to MSM (Hillis, et al., 2020).

Our study has several limitations. The investigation intentionally focused on urban areas and recruited in Northern and Central England as they are less commonly studied than London and Southern England. Furthermore, although half of all major clinics are based in London, other cities have growing gay and chemsex scenes, most notably Manchester (Gafos et al., 2019). Secondly, the MSM interviewed were aware of, and largely had access to PrEP, indicating they were able to overcome structural barriers. Further research needs to be conducted on harder to reach populations, including BAME, women and transgender communities, as well as those who are not testing or find service engagement difficult

(Witzel, Nutland, & Bourne, 2018). Finally, our MSM participants were largely well educated, white older men; though this probably reflects the demographic of PrEP users in this area.

According to recent modelling, access, referral routes, consultations, adherence and monitoring are key stages in the patient care pathway (Hillis, et al., 2020). Whilst some participants reported lack of access to PrEP through the IMPACT trial, PrEP is now available on the NHS. However, experiences highlighted the need for additional resources to support the demand in the provision of PrEP. Additionally, the negative experiences at sexual health clinics should be addressed through greater education of SPs, whilst addressing the concern of self-sourcing unknown substances online. This is important, as the findings show that PrEP service provision facilitates MSM access to sexual health care, treatment and support that would not be accessed otherwise (Freeborn and Portillo, 2018).

The inequity of access was highlighted by both cohorts. Access was driven by knowledge and peer networks, predominantly by white, middle class and educated groups. Additional stigma was described for BAME communities, indicating the need to provide outreach and information to specific demographics. Targeting those with lower socio-economic status is also warranted, such as through PrEP navigators, by disseminating high-quality, updated messaging tailored to communities, and acting as multi-level touch points to PrEP-related services provided in various settings, encouraging open dialogue between patients and trusted SPs (Lelutiu-Weinberger and Golub, 2016; Sun et al., 2019; Witzel, et al., 2018).

Findings indicated that some non-eligible trial participants '*played the system*' to obtain PrEP, highlighting inequity of access. Eligibility is risk-based, however, many felt that PrEP should be available to all that may benefit from it. Furthermore, the setting and PrEP provision should be regionally reviewed and offered through multiple channels. We

additionally highlight the need to support trust building and enhance communication in order to optimise PrEP cascade and widen availability (Hillis, et al., 2020; Patel et al., 2018). If this is achieved, patients will arguably have greater adherence, increase testing and reduce HIV/STI transmission, allowing resources to be consolidated and the removal of pressure from an overstrained system. More specifically, we found a need for PrEP-specific consultations within sexual health clinics to provide a streamlined service throughout the patient pathway.

Conclusion

The study highlights the complexities in providing optimal PrEP services for MSM given diverse experiences; barriers to uptake; and the need for availability through culturally and ethnically sensitive models. PrEP service delivery should appropriately accord to the needs of low to high-risk groups within the MSM community. Finally, there needs to be a seamless transition from the IMPACT trial to national PrEP provision and access throughout the health service.

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Tables

Table 1. Consolidate Criteria for Reporting Qualitative Studies (COREQ) 32-point checklist

No. Item	Guide questions/description	Section reported in
Domain 1: Research team and reflexivity		
<i>Personal Characteristics</i>		
1. Interviewer/facilitator	Which author/s conducted the interview or focus group?	Methods
2. Credentials	What were the researcher's credentials? E.g. PhD, MD	Author affiliations
3. Occupation	What was their occupation at the time of the study?	Author affiliations
4. Gender	Was the researcher male or female?	Methods
5. Experience and training	What experience or training did the researcher have?	Methods
<i>Relationship with participants</i>		
6. Relationship established	Was a relationship established prior to study commencement?	Methods
7. Participant knowledge of the interviewer	What did the participants know about the researcher? e.g. personal goals, reasons for doing the research	Methods
8. Interviewer characteristics	What characteristics were reported about the interviewer/facilitator? e.g. Bias, assumptions, reasons and interests in the research topic	N/A as IPA used
Domain 2: study design		
<i>Theoretical framework</i>		
9. Methodological orientation and Theory	What methodological orientation was stated to underpin the study? e.g. grounded theory, discourse analysis, ethnography, phenomenology, content analysis	Methods
<i>Participant selection</i>		
10. Sampling	How were participants selected? e.g. purposive, convenience, consecutive, snowball	Methods
11. Method of approach	How were participants approached? e.g. face-to-face, telephone, mail, email	Methods
12. Sample size	How many participants were in the study?	Methods
13. Non-participation	How many people refused to participate or dropped out? Reasons?	N/A as purposive sampling used
<i>Setting</i>		
14. Setting of data collection	Where was the data collected? e.g. home, clinic, workplace	Methods
15. Presence of non-participants	Was anyone else present besides the participants and researchers?	Methods
16. Description of sample	What are the important characteristics of the	Table 2

sample? e.g. demographic data, date

<i>Data collection</i>		
17. Interview guide	Were questions, prompts, guides provided by the authors? Was it pilot tested?	Methods
18. Repeat interviews	Were repeat inter views carried out? If yes, how many?	Methods
19. Audio/visual recording	Did the research use audio or visual recording to collect the data?	Methods
20. Field notes	Were field notes made during and/or after the interview or focus group?	N/A as interviews were recorded
21. Duration	What was the duration of the interviews or focus group?	Methods
22. Data saturation	Was data saturation discussed?	Methods
23. Transcripts returned	Were transcripts returned to participants for comment and/or correction?	Methods
Domain 3: analysis and findings		
<i>Data analysis</i>		
24. Number of data coders	How many data coders coded the data?	Methods
25. Description of the coding tree	Did authors provide a description of the coding tree?	Results and Figures 1,2,3 and 5
26. Derivation of themes	Were themes identified in advance or derived from the data?	Methods
27. Software	What software, if applicable, was used to manage the data?	Methods
28. Participant checking	Did participants provide feedback on the findings?	Methods
<i>Reporting</i>		
29. Quotations presented	Were participant quotations presented to illustrate the themes/findings? Was each quotation identified? e.g. participant number	Results
30. Data and findings consistent	Was there consistency between the data presented and the findings?	Results
31. Clarity of major themes	Were major themes clearly presented in the findings?	Results
32. Clarity of minor themes	Is there a description of diverse cases or discussion of minor themes?	Results

Table 2. Profile of Participants

Profile of Participants		MSM n=20 (%)	Service Providers n=25 (%)
Age range		24-59 years old	
Highest level of education	Secondary level	3 (15)	
	Bachelor's degree	6 (30)	
	Master's degree	3 (15)	
	PhD	4 (20)	
	Unknown	3 (15)	
Location	Manchester	5 (25)	9 (36)
	Birmingham	5 (25)	3 (12)
	Yorkshire	3 (15)	3 (12)
	Liverpool	7 (35)	10 (40)
Workplace	NHS		9 (36)
	Community organisation (CO)		16 (64)
Position	CO manager		4 (16)
	CO worker		7 (28)
	Doctor		10 (40)
	Nurse/Health Advisor		3 (12)
	Unknown		1 (4)
Access to PrEP	IMPACT trial	10 (50)	
	Self-sourcing	1 (5)	
	Not on PrEP	9 (45)	

Table 3. Subordinate Themes

Key Theme	Subordinate Theme
Experiences of self-sourcing PrEP	<ul style="list-style-type: none"> • Reasons for self-sourcing: <ul style="list-style-type: none"> ▪ Cannot access PrEP through IMPACT trial and knowledge of PrEP • Concerns regarding self-sourcing: <ul style="list-style-type: none"> ▪ Cost of purchasing PrEP, drug efficacy and fear of taking unknown substance
Current patient pathway for those accessing PrEP on the IMPACT trial	<ul style="list-style-type: none"> • Accessing the trial <ul style="list-style-type: none"> ▪ Knowledge, referrals, availability of places, eligibility • The consultation and additional elements <ul style="list-style-type: none"> ▪ Regimen, setting, staff, resource capacity • Monitoring, testing and adherence
Impact of using PrEP	<ul style="list-style-type: none"> • Instils confidence • Reduced fear of contracting HIV • Betters sex life • Increase in STI diagnoses • Changes in sexual behaviour