Sex Res Soc Policy (2018) 15:283–289
DOI 10.1007/s13178-017-0278-9

HIV Pre-Exposure Prophylaxis (PrEP) Is Coming to Europe, but Are Gay Men Ready to Accept It? Qualitative Findings from Berlin, Germany

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Published online: 9 March 2017

Abstract In 2016, the European Medicines Agency approved the marketing of Truvada for use as pre-exposure prophylaxis (PrEP) in European Union (EU) member states. As individual countries throughout the EU make decisions about whether to adopt PrEP and fund it via governmental insurance, it is vital to understand key populations' knowledge of and attitudes toward PrEP. In 2015, 20 gay men completed face-to-face audio-recorded interviews, describing their knowledge of and attitudes toward PrEP (mean age 35.9; 35% HIV-positive, 65% HIV-negative). We found that in spite of PrEP not yet having been approved for marketing in Germany, all but one of the participants were aware of PrEP and knew the difference between PrEP and post-exposure prophylaxis (PEP; which *is* approved for use in Germany). By and large, attitudes were favorable about PrEP, especially among HIV-negative participants. Next, there appeared to be an already high demand for PrEP with several participants going to great lengths to gain access to PrEP; two described intentions to obtain PEP for use as PrEP, one was obtaining PrEP via another country (where it was legal), and a fourth participant was discretely distributing PrEP out of his home. Our findings appear to validate anecdotal evidence suggesting high demand for PrEP and that some are already finding ways to obtain it without governmental approval. Our findings suggest that participants were prepared to see the rollout of PrEP in Berlin, pending its approval.

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Keywords Pre-exposure prophylaxis (PrEP) · Gay men · Men who have sex with men · Barebacking · HIV · Berlin · Germany

Introduction

In 2012, the US Food and Drug Administration approved the use of once-daily Truvada (emtricitabine and tenofovir disoproxil) for use as HIV pre-exposure prophylaxis (herein PrEP) (Gilead 2012). Given the ongoing burden of HIV among gay, bisexual, and other men who have sex with men (GBM), the US Centers for Disease Control estimated that as many as one in four GBM in the USA would benefit from the protection PrEP offered (CDC 2014). Meanwhile, the World Health Organization (WHO) recommended that all GBM consider PrEP as part of their comprehensive HIV prevention plan (WHO 2014, 2015).

In the 5 years since PrEP was approved in the USA, several other countries have also approved the use of PrEP (PrEPWatch 2016). To date, these include Norway, Australia, Israel, Canada, Kenya, and South Africa. Meanwhile, the European Union (EU) is in the process of approval—unlike many individual countries, the approval process for medicine in the EU is harmonized via the European Medicines Agency (EMA), which has the authority to evaluate medicines for use across the EU as a whole (European Medicines Agency 2016). In July 2016, the EMA granted marketing authorization of Truvada as PrEP in the EU (Gilead 2016). Following this, in all 28 EU member countries, PrEP must be subject to national regulatory authority approval for required pharmacovigilance materials (PrEP in Europe Initiative 2016), and each country will need to make decisions about price and reimbursement.

To date, the only EU nation in which PrEP is available within the national health system is France (PrEPWatch

2015). In Switzerland, PrEP *can* be prescribed off-label, but it is not reimbursed. As of February 2017, no other European countries have granted regulatory approval—though some are in the beginning stages of rolling out PrEP educational campaigns (e.g., www.wasistprep.de), and several EU member states are currently conducting or have recently completed PrEP trials (AMPrEP in Amsterdam (avac.org/trial/amprep-amsterdam-prep), Be-PrEPared in Belgium (avac.org/trial/be-prepared-antwerp-prep-project)).

In spite of regulatory blockades, anecdotal data suggest that key populations (namely, gay and bisexual men) in Europe (particularly western European countries) are becoming familiar with PrEP and finding ways to gain access. The PrEP in Europe Initiative (2016) indicated that some medical providers in various EU nations have been prescribing off-label use of Truvada as PrEP, in spite of the possibility for legal recourse. Further, they noted that some patients have been "clinic hopping" to obtain 30-day supplies of *post*-exposure prophylaxis (PEP) for use as PrEP and the emergence of underground markets for pill-sharing, smuggling, and ordering generic PrEP online (see prepster.info/buying-prep-online) (PrEP in Europe Initiative 2016).

As information about—and access to—PrEP (whether legal or not) continues to proliferate across Europe, it is essential for researchers and providers to understand key populations' knowledge of and attitudes toward PrEP. Ultimately, these can both play powerful roles in the uptake and adherence of PrEP (Golub et al. 2013). For example, in a UK sample of gay and bisexual men, Jaspal and Daramilas (2016) found that opinions about PrEP were negatively influenced by social stigma. And, in a US national sample of gay and bisexual men, Parsons et al. (2017) found that more than half of the gay and bisexual men who met CDC objective criteria for PrEP were unwilling to consider taking it.

Notably, much of the research on PrEP is based out of the USA (Cohen et al. 2015; Liu et al. 2014)—where it has been approved since 2012—and less is known about attitudes in other areas of the world. US-based studies suggest that familiarity with PrEP has been increasing over time (Grov et al. 2016), from reported ranges of 11% in 2010–2011(Young and McDaid 2014) to 54% in 2014 (Zarwell et al. 2015). Similarly, willingness to start PrEP has varied from 28 to 80% with most studies reporting 50% or higher (Young and McDaid 2014). Anecdotal data suggest that there are multiple barriers to beginning PrEP including stigma attached to using PrEP (Tangmunkongvorakul et al. 2013), fears around side effects, and potential drug resistance to future forms of HIV biomedical prevention (Bauermeister et al. 2013; Golub et al. 2013).

As part of ongoing efforts to document best practices for HIV prevention and care (Grov 2017; Grov et al. 2014), the present study reports on qualitative data gathered from gay men in Berlin, Germany. Similar to men in many other developed nations, gay and bisexual men in Germany have been affected greatly by HIV and AIDS (Kramer et al. 2015; Marcus et al. 2005; Marcus et al. 2006). In 2013, 75% of new HIV diagnoses in Germany were estimated to be as a result of sexual transmission between men (Robert Koch Institut 2014), up from 57% in 2012 (Robert Koch Institut 2013).

Berlin, Germany's capital and largest city, is home to more than 3.5 million individuals and is known for its acceptance of diversity, including its vibrant LGBT community (Beachy 2015; Marcus et al. 2009; Whisnant 2008). It is home to concentrated and visible gay neighborhoods, shops, bars/clubs, and sex/fetish scenes. Berlin's Christopher Street Day is one of the largest LGBT Pride events in Europe (see http://csd-berlin.de/en/), and Berlin is host to Folsom Europe, Europe's largest annual gay and bisexual fetish street fair (see http://folsomeurope.info/). Likewise, the city is known for its vibrant sexual scene and as a popular sex tourism destination (Barnett 2013, November 15)—many bars and clubs, including gay bars and clubs, permit sex in designated areas (i.e., darkrooms) or out in the open (i.e., on the dance floor) (Rodgers 2014).

In 2015, we gathered qualitative interview data from gay men regarding attitudes about HIV prevention and treatment in Berlin (Grov 2017). For the present manuscript, we report on participants' knowledge of and attitudes toward PrEP. As one of Europe's gay cultural capitals, Berlin possesses many similarities to other cities with concentrated gay and bisexual populations. Thus, the findings of this study can provide important lessons not only for the uptake of PrEP in Berlin but also in other cities across Europe and the world that will be adopting PrEP in the years to come.

Method

Data for this study were taken from face-to-face semi-structured qualitative interviews conducted between September and October 2015 with 20 gay men living in Berlin, Germany (Grov 2017). Participants were identified via a variety of sources including referrals from HIV prevention/treatment and LGBT advocacy organizations in Berlin, via advertising for the study in a popular men-for-men sexual networking website, and peer-to-peer referral. Although a targeted sampling framework was not established, it was the lead investigator's objective to interview both HIV-positive and HIV-negative men as well as native and non-native Germans who were living in Berlin. Those interested were asked to contact the lead investigator for more information about the nature and scope of the study. Although we did not calculate a formal response rate (e.g., we do not know how many people saw a flyer), no individuals who contacted the lead investigator later declined to participate in an interview.

All interviews were conducted face-to-face at a location of the participant's choosing. Interviews were conducted in

English, which is spoken commonly throughout Berlin (Morgenpost.de 2010). Language was not a barrier to establishing rapport with participants, conducting interviews, or identifying potential participants. In the event that a participant was unsure of what word or phrase to use in English, they were advised to say it in German and this would be translated later. Interviews were between 30 and 75 min (median 40), and participants were asked about their knowledge of PrEP relative to PEP, their beliefs about who would be an ideal candidate for PrEP, and their personal opinions about PrEP.

Following each interview, the lead investigator kept detailed field notes which were used in the review of transcripts and identification of themes during analyses. Data saturation (i.e., informational redundancy), which "occurs when researchers sense they have seen or heard something so repeatedly that they can anticipate it. [And] Collecting more data is deemed to have no further interpretive value," was reached by the 20th interview, and thus, data collection was concluded (Given 2008).

In order to be eligible, participants had to be at least 18 years of age, able to complete an interview in English, identify as gay or bisexual, identify as male (though ultimately all participants were cisgender male), have lived in Berlin for a minimum of 6 months (shortest duration reported was 2 years), and had prior interaction with HIV prevention or treatment services/outreach in Berlin (broadly defined). Examples of prior interaction included having gone for HIV or STI testing at a state-sponsored or community-based clinic/facility, receiving free condoms/print materials from an organization, or having interacted with prevention outreach educators/workers at a gay bar or other similar locations.

There were no incentives offered. All procedures were approved by the City University of New York Institutional Review Board. Informed consent documents were provided in German and English. Participants were asked not to use their own name in the interviews, and any instances of personally identifiable information were redacted from transcripts.

Analysis Plan

Interviews were transcribed verbatim by a third party, and the lead investigator reviewed all transcripts against the original audio file for accuracy. Although few, any terms and phrases that were in German were translated to English by a native German speaker and verified by a second German speaker.

Following transcription and quality assurance checks, the research team met to discuss themes and develop a coding rubric. Coding staff were then trained to use the codebook and identify text representing codes (Neuendorf 2002; Saldaña 2013). The first author reviewed coded transcriptions for overlap and discrepancies. Any discrepancies were discussed with coding staff, and consensus was reached over the application of a particular code. Using the principals of thematic analysis, the research team reviewed transcriptions and codes for narratives around PrEP. Thematic analysis has shown to be an effective method for evaluating qualitative data of many varieties (Miles and Huberman 1994; Patton 1990). Each theme outlined in the results was endorsed by several participants. Participant names have been changed in all quotes.

Results

Participant ages ranged from 24 to 54, M = 35.9, SD = 8.8. Thirty-five percent of men were HIV-positive and the remainder identified as HIV-negative. Most HIV-positive participants had been living with HIV for at least a decade; however, one reported his diagnosis had been less than 3 months prior to the interview. Duration living in Berlin ranged from as little as 2 years to as much as 41 (i.e., lifetime), M = 13.2, SD = 10.2. In total, 65% of participants said they were born in a European country and half of all participants were born specifically in Germany.

All participants were familiar with PEP and all but one was familiar with PrEP. One HIV-negative participant indicated that he was taking PrEP (accessing via a country in which PrEP was approved, visiting quarterly to obtain a 90-day supply), and another participant indicated he had on occasion borrowed pills from his HIV-positive friends. Although probes around participants' personal use of PEP were not included as part of the interview protocol, two HIV-negative participants voluntarily disclosed that they had prior experience taking PEP and one HIV-positive participant indicated escorting one of his partners to a clinic for PEP after a condom broke during sex.

In total, 19 of 20 participants who knew what PrEP was understood that it came in the form of a pill that reduced the chances of getting HIV if exposed. Nevertheless, not all participants were familiar with the exact dosing schedule (e.g., one pill a day) or its clinical effectiveness (guessing a range of 50–99% effective, with most skewing toward higher values). All told, most were aware that PrEP was highly effective when taken as prescribed. Further, all participants who were familiar with PrEP understood that it did not provide protection against STIs.

Although it was not part of the interview protocol, two participants described that they understood that the active drugs/ingredients used in PEP and PrEP were very similar (PEP treatment includes Truvada plus one more drug, raltegravir (Isentress)), and thus, believed PEP could be used as PrEP if dosing started ahead of when condomless anal sex was anticipated.

> "*PEP and PrEP are almost the same thing, yes? I read that PEP is just PrEP plus one more drug. So, to me, it makes sense that if you started taking PEP* before *a risky event occurred that it would protect you just like PrEP, right? My doctor told me you have to start PEP as soon as possible after risk occurred. So why not start before?*

I feel like sometimes people can anticipate it [risk]. I certainly I can."—Frantz, age 25, HIV-negative (original emphasis)

Later in the interview, both of these participants expressed plans to tell a medical provider that they had been exposed to HIV (when in fact they had not) in an effort to obtain a 30-day supply of PEP with plans to use it as PrEP. One of these participants, who reported prior engagement of condomless sex as a result of substance use, described that he would start taking the PEP ahead of an upcoming big "party weekend" because he was afraid that he might engage in condomless sex as a result of substance use.

"*I have thought about it [using PEP as PrEP] a lot. I mean, I have been taking PEP twice now, so I know I can tolerate the medicine and, clearly, it works as I am still HIV-negative. There is a big [dance] party coming up in [location redacted] that I am going to. I take a lot of drugs, so sometimes I forget if a condom was used or not. That is how I ended up on PEP both times before. I guess it would be better if I see my doctor before the party that way I already have it [PEP] on me. Maybe I can even start to take the pills before the party?*"—Oskar, age 31, HIV-negative

Both HIV-negative and HIV-positive participants described that they had "gay-friendly" doctors who they were out to about having sex with men. Many HIV-negative participants believed that their doctor would prescribe them PrEP (or that they could find a doctor who would prescribe it); however, these participants understood that PrEP was not yet approved for use in Germany, and thus, they would have to pay for it out of pocket, at a very high cost.

"*Finding a gay-friendly doctor is easy here. You just have to ask your friends. It is easy with our insurance system because you can see any doctor you want. People are very open here, so it's okay to talk to your friends about sex and who they see if they get an STD, or something. I remember the first time I saw mine. The first thing he asked was if I engaged in fisting. It surprised me and it was funny, because he used the very polite formal German [as opposed to informal], 'Fisten Sie?' Like he was speaking to his grandmother.*"—Abel, age 29, HIV-negative

"*I mean, I am sure if I asked my doctor that he would write me a prescription for it [PrEP], but there is no way I could get it [from the pharmacy]. You cannot get those drugs if you are HIV-negative. The government insurance would not pay for it. So, I guess you would have to pay out of pocket, and that would be very expensive.*"—Wolfgang, age 49, HIV-negative

All but one of the HIV-negative participants expressed favorable attitudes about PrEP, citing it as "*An effective tool for HIV prevention*," Kort, age 34; "*One more thing we can do to protect ourselves*," Dieter, age 25; and acknowledging that "*Well not everyone uses condoms all the time, so this can protect them [when they do not]*," Tibalt, age 54. One HIV-negative participant—the one who had not yet heard of PrEP—first expressed negative attitudes toward PrEP, but later changed his mind. The excerpt below is from Karl, age 43, HIV-negative.

"*So if a person takes this pill, it can prevent them from getting HIV even if a condom is not used?* [pause] *I don't know about that. Why should the government pay so that someone can engage in irresponsible behavior? There are condoms. That is what people should use.*"—Karl, age 43, HIV-negative

Later in the interview, Karl was asked who he thinks PrEP would be appropriate for.

Karl: "*Well me, of course. I would be the first person in line for it.*"

Interviewer: "*But earlier you said…*"

Karl: "*I know. I know, but if this pill really exists and it can actually prevent HIV, then I would want it for myself. For so long I have been afraid of HIV. This would fix that. Anyone who wants it should be able to get access to it. Of course the government should pay for it, if it works.*"

Karl and other participants indicated that PrEP would reduce the biological risks of contracting HIV while also alleviating psychological anxiety associated with having sex (regardless of whether a condom was used). Participants also explicitly described how PrEP would be essential in a city like Berlin, because of its pre-existing high burden of HIV among gay and bisexual men, where sex is permitted in public spaces and where barebacking (intentionally engaging in sex without a condom) is common.

"*Is it* [PrEP] *necessary for a city like Berlin? Berlin! You know they call it 'BARE-lin?' This is where people come to live out their fantasies, tourists and locals [alike]. It is the most sexually free place in the world. There is a sex club on every corner. People fuck on the dance floor, and you can't always find condoms. Plus, HIV is very high here. [HIV-positive] People come to Berlin because they can get good treatment, but also because there is less stigma.*"—Johann, age 35, HIV-positive (original emphasis)

In contrast to overall positive attitudes toward PrEP among HIV-negative participants, attitudes toward PrEP among HIV-positive participants were mixed. Those expressing positive attitudes echoed sentiments described by HIV-negative participants. Meanwhile, those expressing negative attitudes believed that PrEP would make it too easy for HIV-negative people to engage in condomless sex and that it negated the seriousness of HIV and its historical impact on gay communities.

> "*It [PrEP] will give them [HIV-negative people] license to bareback, you know. HIV is very serious. I have to take medicine every day so that I do not get sick; whereas, they will take it so they can fuck around. It seems a little unfair if you ask me.*"—Luther, age 35, HIV-positive

> "*Young people today. They don't understand HIV, they don't even understand what it is, and they think a pill will cure everything. They have to learn to protect themselves in other ways, to take care of themselves. You can't just give them a pill.*"—Theo, age 36, HIV-positive

Finally, although not part of the interview protocol, one participant disclosed that he was running what could best be described as an underground market for PrEP distribution. Through methods he did not describe during the interview, he said he brought several years' worth of PrEP (in the form of Truvada, not generic) into the country. At the conclusion of the interview, he showed the interviewer the medicine cabinet in his bathroom, which was filled with bottles of PrEP along with rapid at-home HIV test kits (again, obtained through methods that he did not disclose during the interview).

> "*I tell anyone that visits me, 'Go in the bathroom and take what you need. No questions asked,' but I warn all my guests that they should only take Truvada if their test comes back HIV-negative. That's why I keep the [rapid HIV] test kits in there too. And I keep it all in my bathroom so it's completely private. Others won't know if they are using the bathroom or doing something else. This is important if I am throwing a party or entertaining a group of people. People know I have it [PrEP], so sometimes they bring over a friend.*"—John, age 50, HIV-positive

Discussion

In 2016, the EMA approved the marketing of Truvada for use as PrEP in EU member states. As individual countries throughout the EU ultimately make decisions about whether to approve PrEP and pay for it via governmental insurance, it is vital to understand key populations' knowledge of and attitudes toward PrEP. In our study, we found that in spite of PrEP not yet having been approved for marketing in Germany (our data were collected in 2015), all but one of the participants were aware of PrEP and knew the difference between PEP—which is approved for use in Germany—and PrEP. By and large, attitudes were favorable about PrEP, especially among HIV-negative gay participants (i.e., those who would be potential candidates for PrEP). There also appeared to be an already high demand for PrEP with several participants going to great lengths to gain access to PrEP; two described intentions to obtain PEP for use as PrEP, one obtaining PrEP via another country, and a fourth participant discretely distributed PrEP via his home. Thus, our findings appear to validate anecdotal evidence suggesting high demand for PrEP and that some are already finding ways to obtain it without governmental approval (PrEP in Europe Initiative 2016).

The benefits of PrEP in terms of its effectiveness at preventing HIV when taken as prescribed are clear. PrEP may be particularly beneficial for key populations in cities like Berlin, which has permissive attitudes toward sex, including sex in public spaces, barebacking, and chemsex (combining sex with drugs like methamphetamine) (Deimel et al. 2016; McCall et al. 2015), and is a renowned destination for sex tourism (Barnett 2013, November 15; Rodgers 2014). Indeed, this was reaffirmed by the men we interviewed—recognition of pre-existing need for PrEP and recognition of the benefits PrEP would bring for HIV prevention, particularly in Berlin.

But our findings must be understood in light of their limitations. As an industrialized modern city, Berlin is among Europe's "gay capitals" (Lonely Planet 2012, August 8). Much like how the gay liberation movement in the USA ignited following the Stonewall riots in New York City, Germany (and many other countries in Europe) experienced gay liberation movements in tandem (Edsall 2006); however, cultural milieu specific to Germany's history (including WWII through the reunification of East and West Germany in 1990) have shaped LGBT life in Germany in unique ways (Beachy 2015; Whisnant 2008). Thus, our findings regarding high familiarity of and strong demand for PrEP could be unique to Berlin, and it would be important to repeat the study in other cities.

Next, although qualitative methods allow for rich contextualization of participants' experiences, the themes identified for this study were generated from 20 individuals who were willing to participate in a research study. Toward the end of the data collection procedures, saturation of themes was achieved (Badia et al. 2004; Guest et al. 2006; Morse 1995); however, we cannot discount that other data collection methods (e.g., ethnographic field observations, longitudinal procedures) would provide valuable additional information to further inform this study's findings. We also highlight the urgent need for HIV research and prevention that

serves other populations who are disproportionally impacted by HIV, such as transgender women.

To facilitate open and candid responses, participants were told that their interviews were confidential and identifying characteristics about them would be redacted from transcripts (Singer et al. 1995). That being said, face-to-face interviews can result in socially desirable responses. All interviews were in English, which is commonly spoken throughout Berlin; however, conducting interviews in participants' native language might have facilitated more nuanced responses. In addition, although language was not a barrier to enroll participants for this study, not all people in Berlin are fluent in English. Participant's education level was not assessed in the present study, and it may be that the men in this study were well educated, thus greater comprehension of English. Further, those who grew up in former East Germany (including East Berlin), where English was not as emphasized in the educational system, as well at those who may have recently immigrated to Germany from non-Westernized countries including eastern European countries, might be underrepresented in this study. Next, at present, Germany and Berlin are undergoing massive social transformations due to the influx of refugees from war-torn parts of the world (Spiegel Online 2015). It remains unknown how the HIV epidemic may shift once again as a result of the unfolding refugee crisis. Finally, as PrEP is not yet approved for use in Germany (and was not even approved for *marketing* at the time of data collection), we must highlight that some of participant's responses were based on hypothetical scenarios. That is, participants who were interested in PrEP might not have ultimately gone on PrEP where it is actually available.

Conclusion

As part of our efforts to describe ongoing HIV prevention and treatment strategies in Berlin, we collected data on knowledge of and attitudes toward PrEP. The rollout of PrEP is a complex process involving a range of factors including educating those who would benefit from about it, educating providers about how to talk about PrEP with their patients, sustaining affordable methods for patients to obtain PrEP, achieving optimal adherence for those on PrEP, and maintaining retention in the health care system such that PrEP recipients (people who may be otherwise healthy) return for quarterly medical visits to remain on PrEP. There was high interest in PrEP among men in this study; however, it would be important to examine PrEP interest in larger and more generalizable samples, as well as monitoring interest over time.

Acknowledgements This study was supported in part by the Tow Fellowship. A special thanks to the research participants who gave their time and shared their stories, Philip Gussmann, and the research team at the Hunter College Center for HIV/AIDS Educational Studies and Training.

Compliance with Ethical Standards

Conflicts of Interest The authors declare that they have no conflicts of interest.

Research Involving Human Participants All procedures performed in studies involving human participants were in accordance with the ethical standards of the institutional and/or national research committee and with the 1964 Helsinki declaration and its later amendments or comparable ethical standards.

Informed Consent Informed consent was obtained from all individual participants included in the study. Consent documents were available in English and German.

Funding This study was supported in part by the Tow Fellowship.

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