Aus der Klinik für Dermatologie, Venerologie und Allergologie
der Medizinischen Fakultät Charité – Universitätsmedizin Berlin

DISSERTATION

Determinants of access to and use of HIV pre-exposure prophylaxis among men who have sex with men in Germany

Determinanten des Zugangs zu und der Nutzung von HIV-Präexpositionsprophylaxe unter Männern, die Sex mit Männern haben, in Deutschland

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AIDS	acquired immunodeficiency syndrome
ART	antiretroviral therapy
CI	confidence interval
DAIG	Deutsche AIDS Gesellschaft
df	degrees of freedom
DSTIG	Deutsche STI Gesellschaft
EEA	European Economic Area
EMA	European Medicines Agency
EMIS	European MSM Internet Survey
EU	European Union
FDA	(US) Food and Drug administration
FTC	emtricitabine
HAART	highly active antiretroviral therapy
HIV	human immunodeficiency virus
incl.	including
IQR	interquartile range
LGBTI+	lesbian, gay, bisexual, transgender, intersex or another gender diverse identity
LHO	local health office (“Gesundheitsamt”)
M	mean
Max	maximum
Mdn	median
Min	minimum
MSM	men who have sex with men
NGC	non-governmental counselling centre (“Beratungsstelle in freier Trägerschaft”)
PrEP	(HIV) pre-exposure prophylaxis
Q1, Q3	first quartile, third quartile
RNA	ribonucleic acid
SD	standard deviation
SE	standard error
STI	sexually transmitted infection
TaSP	treatment as prevention
TDF	tenofovir disoproxil fumarate
US	United States (of America)
VIF	variance inflation factor

Abstract

Background: HIV pre-exposure prophylaxis (PrEP) is highly effective at preventing HIV. However, previous research and a survey of men who have sex with men (MSM) we conducted in 2017/18 point to a substantial gap between the indication for PrEP and its use in Germany. Building on these findings, we conducted two further surveys, one of sexual health counsellors and one of physicians, and also a multi-methods analysis of motivations cited by MSM in the 2017/18 survey for using/considering PrEP. The aim of the surveys was to generate insights to improve PrEP implementation in Germany by exploring determinants of PrEP access and use.

Methods: Using self-developed questionnaires, we collected data from counsellors at non-governmental counselling centres (NGCs) and local health offices (LHOs) in 2018 and HIV-specialists and non-HIV-specialists in 2019. In addition to sociodemographic variables, we gathered information on PrEP knowledge and attitudes to calculate a knowledge score and attitudes score. We also asked about the proportion of consultations in which providers proactively gave PrEP advice to at-risk individuals, and used multiple linear regression to identify independent predictors thereof. We used a qualitative thematic framework to categorise the motivations cited by MSM, and assessed if their frequency differed between respondents using or considering PrEP.

Results: 145 counsellors and 154 physicians completed the surveys. The proportion of proactive PrEP advice was larger in NGCs than LHOs (50.0%, IQR=60.0 vs. 30.0%, IQR=70.0, p=0.003) and among HIV-specialists than non-HIV-specialists (30.0%, IQR=63.40 vs. 0.0%, IQR=11.32, p<0.001). The only independent predictor of this proportion among counsellors and physicians was the knowledge score and not the type of centre in which they worked; among counsellors, the attitudes score was also predictive. The PrEP knowledge/attitudes were better/more positive among NGC counsellors and HIV-specialists than their counterparts. In the MSM survey, 228 questionnaires contained a free-text response. These were in the categories safety/protection (80.2% of participants, incl. general safety; additional protection), mental well-being/quality of life (23.5%, incl. reduced anxiety; better quality of life), condom attitudes (18.9% intent not to use condoms), and expectations about sexuality (14.4%, incl. worry-free/more pleasurable sex). The difference in frequencies of motivations between those using or considering PrEP was not significant.

Conclusions: There is room to improve the PrEP counselling practices of providers in Germany. Targeted training, particularly for counsellors at LHOs and non-HIV-specialists, could improve care, especially in rural areas. Information materials that take a holistic approach emphasising multiple motivations for using PrEP and how these fit into the broader sexual/psychological health of MSM may be more effective than approaches focusing on safety and protection alone.

Zusammenfassung

Hintergrund: Bisherige Studien und eine von uns durchgeführte Befragung von Männern, die Sex mit Männern (MSM) haben, weisen auf eine erhebliche Lücke zwischen der Indikation zur Einnahme der HIV-Präexpositionsprophylaxe (PrEP) und ihrer Nutzung in Deutschland hin. Um Determinanten des Zugangs zu PrEP zu untersuchen, haben wir zwei Umfragen mit Gesundheitsdienstleister:innen, sowie eine Multi-Methoden-Analyse der von MSM genannten Motivationen PrEP zu nutzen (oder nutzen zu wollen) durchgeführt. Ziel der drei Studien war es, Erkenntnisse zur Verbesserung der PrEP-Implementierung in Deutschland zu gewinnen.

Methoden: Mithilfe selbst entwickelter Fragebögen wurden Daten von Berater:innen aus HIV-Beratungsstellen (HBS) und Gesundheitsämtern (GHA) sowie von HIV-Spezialist:innen und anderen Ärzt:innen erhoben. Wir sammelten u.a. Informationen zu PrEP-Wissen und -Einstellungen und berechneten einen Wissens- und Einstellungsscore. Wir fragten nach dem Anteil der Beratungsgespräche, in denen die Gesundheitsdienstleister:innen Risikopersonen initiativ zur PrEP berieten, und führten eine multiple lineare Regressionsanalyse durch, um unabhängige Prädiktoren dieses Anteils zu identifizieren. Zusätzlich entwickelten wir einen qualitativen thematischen Rahmen, um die von MSM genannten Motivationen zu kategorisieren, und bewerteten, ob sich ihre Häufigkeit zwischen den Befragten, die PrEP nutzten oder nutzen wollten, unterschied.

Ergebnisse: 145 Berater:innen und 154 Ärzt:innen beantworteten die Umfragen. Der Anteil initiativer PrEP-Beratung war bei HBS größer als bei GHA (50,0%, IQR=60,0 vs. 30,0%, IQR=70,0, p=0,003) und bei HIV-Spezialist:innen größer als bei anderen Ärzt:innen (30,0%, IQR=63,40 vs. 0,0%, IQR=11,32, p<0,001). Die unabhängigen Prädiktoren dieses Anteils waren der Wissensscore bei Berater:innen und Ärzt:innen sowie zusätzlich der Einstellungsscore bei Berater:innen. Die PrEP-Kenntnisse/-Einstellungen waren bei Berater:innen aus HBS und bei HIV-Spezialist:innen besser/positiver. In der Umfrage von MSM enthielten 228 Fragebögen eine Freitextantwort. Diese fiel in die Kategorien Sicherheit (80,2% der Teilnehmer, u.a. zusätzlicher Schutz), psychisches Wohlbefinden/Lebensqualität (23,5%, u.a. geringere Ängste), die Absicht, keine Kondome zu verwenden (18,9%) und Erwartungen an die Sexualität (14,4%, u.a. sorgenfreier Sex). Der beobachtete Unterschied in der Häufigkeit der Motivationen zwischen denjenigen, die die PrEP bereits nutzten, und denjenigen, die PrEP nutzen wollten, war nicht signifikant.

Schlussfolgerungen: Die PrEP-Beratungspraxis in Deutschland ist verbesserungsbedürftig. Schulungen, insbesondere von Berater:innen in GHA und Ärzt:innen ohne HIV-Schwerpunkt könnten die Versorgung vor allem in ländlichen Gebieten verbessern. Informationsmaterialien, die die vielfältigen Motivationen für die Anwendung der PrEP betonen, könnten effektiver sein als Ansätze, die sich ausschließlich auf die Wirksamkeit der PrEP konzentrieren.

1 Introduction

1.1 Background

In the United States (US) and Europe, men who have sex with men (MSM) remain the population group most strongly affected by HIV, comprising 70% of new HIV diagnoses in the US in 2019 (1) and 53% (where the route of transmission was known) in the European Union (EU) and European Economic Area (EEA) in 2020 (2). For decades, public health programmes aiming to reduce the incidence of sexually transmitted HIV infection focused mostly on behavioural measures, such as promoting the use of condoms in sexually active populations (3) or recommending that members of risk groups limit their number of sex partners (4). A paradigm shift to include biomedical approaches occurred, however, in 2011 when the interim results of the HPTN 052 study conducted by the HIV Prevention Trials Network demonstrated that early treatment with antiretrovirals led to durable prevention of HIV transmission in sero-discordant heterosexual couples (5). This soon led to the widespread adoption of the highly effective approach that came to be known as Treatment as Prevention, or TasP, which involves offering treatment to people living with HIV as early as possible (i.e., independent of CD4 count) to decrease the chance of onward HIV transmission (6, 7). Around this time, the results of the first clinical trials to evaluate the efficacy of a fixed-dose combination of the oral antiretrovirals emtricitabine (FTC) and tenofovir disoproxil fumarate (TDF) as HIV pre-exposure prophylaxis (PrEP) were also published (8, 9), ultimately leading to the approval of this combination for continuous once-daily use in high-risk populations in the US in 2012 and in the EU/EEA in 2016 (10).[1]

Oral PrEP is a type of HIV prevention that involves taking some of the same antiretroviral medications that have been used for many years as a component of highly active antiretroviral therapy (HAART) in people living with HIV. Currently, the only form of PrEP

[1] Since 2016, two additional products have been approved for PrEP, albeit only in the US so far: the fixed-dose combination of FTC and tenofovir alafenamide (TAF), which may have an improved bone and renal safety profile compared to FTC/TDF (11) and was approved by the US Food and Drug Administration (FDA) in October 2019 (12), and long-acting injectable carbotegravir, which after two initiation injections administered one month apart is given every two months thereafter and was approved by the FDA in December 2021 (13). At the time the studies comprising this dissertation were conducted (i.e., late 2017 to late 2019), these forms of PrEP were not approved or available in Germany; therefore, when PrEP is referred to in this synopsis, it is only HIV PrEP using FTC/TDF that is meant, unless otherwise noted. Other forms of PrEP, such as vaginal or rectal microbicides, are under study (14) but do not fall within the scope of this dissertation.

that is approved for use by the European Medicines Agency (EMA) is the fixed-dose combination of the nucleos(t)ide reverse transcriptase inhibitors FTC (200 mg) and TDF (245 mg) (10). As with other components of HAART, it can have side effects and is therefore approved for use as PrEP only in populations at high risk of HIV infection (10). In the German-Austrian Guideline on HIV Pre-exposure Prophylaxis (15), the following groups are cited as examples of such populations:

- "MSM or transgender people who report anal sex without a condom within the past three to six months and/or are likely [to do so] in the next few months and/or [report having had] an STI in the past 12 months"
- "Serodiscordant constellations with a viraemic HIV-positive partner not on antiretroviral therapy (ART), not suppressed on ART, or in the initial phase of ART (i.e., HIV RNA that has not been at least [sic] < 200 RNA copies/ml for 6 months)"
- "People having sex without a condom with partners who are likely to have an undiagnosed HIV infection"
- "Injection drug users not using sterile injection equipment" (15) (author's own translation)

As the present dissertation focuses on the implementation of PrEP in MSM and transgender persons in Germany, references to the use of PrEP should be understood to apply only to this particular context.

PrEP can be taken as one tablet on a continuous, daily basis or, alternatively, on-demand before and after sex (i.e., two tablets 2 to 24 hours before a sexual encounter, one tablet 24 hours after the initial two-pill dose, and one tablet 48 hours after the initial two-pill dose) (16). Although there is evidence for the effectiveness of the latter approach (albeit in MSM only) (17), the EMA has so far approved only the continuous, daily use of PrEP in combination with other safer sex practices (10). There is extensive evidence that daily PrEP is highly efficacious and effective (8, 17-23), and a range of national and international guidelines recommend its use among HIV-negative people who are at substantial risk of HIV infection (15, 16, 24). Moreover, large decreases in the incidence of HIV have been observed among MSM in London (25, 26), San Francisco (27) and Sydney/New South Wales (28) since 2015, and these are thought to be, at least in part, the result of

PrEP use alongside other important prevention strategies, including condom use and TasP (29-32).

There is also extensive evidence on the safety of PrEP. In a systematic review and meta-analysis of the risk of adverse events in 13 randomised trials of PrEP, Pilkington et al. (2018) conclude that there was no significant difference in the risk of grade 3/4 clinical adverse events or serious adverse events between TDF/FTC (or TDF) and the control groups (33). They also found that there was also no significant difference in the risk of specific renal or bone adverse outcomes (33). In the major efficacy and effectiveness trials on PrEP, the most common adverse events were gastrointestinal symptoms such as diarrhoea, nausea, unintentional weight loss and vomiting, as well as joint pain, headache and dizziness, which occurred in fewer than 10% of participants and were usually transient (19, 34, 35).

Importantly for the German context, although PrEP was approved by the EMA in 2016, the German system of statutory health insurance did not begin to cover the costs of the medication and the related laboratory tests and medical supervision ("PrEP care") until September 2019 (36). In the interim, PrEP was available only by means of a private prescription. Until July 2017, the combination of medications in PrEP was still under patent protection and marketed as Truvada® by Gilead Sciences, and a three-month supply (i.e., 90 tablets) cost almost €2500; in August that same year, the first generic versions entered the market but cost at least €1788 (37). In October 2017, however, the cost for the product of one generic producer fell dramatically to €150 for a three-month supply and then in November 2018 to €120 (38). From December 2017, other producers reduced their prices to a comparable level as well (39).

1.2 Unmet health needs – the PrEP gap in Germany

In one of their seminal articles on the subject, Carr and Wolfe (1976) define unmet health care needs "as the differences, if any, between those services judged necessary to deal appropriately with defined health problems and those services actually being received" (40, p. 418). These differences can be seen clearly in the implementation of PrEP, where beyond the results achieved in some larger metropolitan areas, uptake among people who are at substantial risk of HIV acquisition has been slow. Indeed, in 2019, some

224,000 individuals in the US were estimated to have received a PrEP prescription, representing only a fraction of the 1.1 million people calculated based on data from 2015 by researchers at the US Centers for Disease Control and Prevention (CDC) to be eligible for it (32, 41-43). In Europe, data on PrEP uptake and objective measures of unmet need are still scarce. The most comprehensive recent figures available are from a 2019 study that used data from the European MSM Internet Survey (EMIS-2017) (44) to estimate that the gap between self-reported PrEP use and expressed need for PrEP in the EU was 17.4% of MSM, or 500,000 individuals (32, 45). Specifically for Germany, they found a gap of 12.6%, which was lower than the EU average, but not inconsiderable (32, 45). Although this measure of unmet need is based on subjective or expressed need rather than normative need – the latter of which could be defined as satisfying the criteria to be prescribed PrEP according to experts or clinical practice guidelines (45, 46) – it is nevertheless useful because there is evidence of a positive correlation between the willingness of MSM to use PrEP and an increased risk of sexually acquired infection with HIV (45, 47).

Our working group at the Division of Evidence-Based Medicine of the Department of Dermatology, Venereology and Allergy of Charité – Universitätsmedizin Berlin has a longstanding interest in conducting research and developing clinical practice guidelines on topics related to sexual health (see section “Complete list of publications”), and one of its members (RNW) provides sexual health services at the Charité in the form of a weekly STI walk-in clinic. Given the long delay between the regulatory approval of PrEP in the US and Europe (i.e., four years), and between its availability in Germany and the decision of policy and decision makers for its costs to be covered by statutory health insurance (i.e., a further three years), it is perhaps unsurprising that we began to receive anecdotal reports from various project partners and from patients that PrEP was being obtained by MSM through informal channels, such as the internet or from the antiretroviral regimens of friends living with HIV, and used without medical supervision.

To gain a clearer picture of how PrEP was being used and to obtain results that could be shared quickly with policy makers and practitioners in the early days of PrEP implementation in Germany, we designed and, in late 2017/early 2018, conducted the first facility-based paper survey of PrEP use, knowledge and attitudes among MSM in Germany, recruiting almost 500 MSM from non-governmental counselling centres (NGCs; German: “Beratungsstellen in freier Trägerschaft”) and HIV-specialist practices in Berlin (31).

Among other results of this anonymous, cross-sectional survey, we found a substantial amount of unmet need related to PrEP: a total of 12.9% of participants who reported never having used PrEP (who made up 82.3% of the sample) strongly agreed with the statement that they would like to do so (31) – a finding very similar to the 12.6% PrEP gap found for Germany more broadly in the EMIS-2017 survey, as cited above (45). Moreover, 31.7% of non-PrEP-users in our facility-based survey indicated that they had had sex without a condom with multiple partners and/or been diagnosed with an STI over the past six months (31), thus meeting the criteria to be prescribed PrEP according to the German-Austrian PrEP guideline, as well as those of the CDC (which among other differences to the German-Austrian PrEP guideline restricts the period for past diagnosis of an STI to six months) (16).

1.3 State of research

In his early work on access to health care, Anderson points out that “equity of access is best considered in the context of whether people actually in need of medical care receive it or not” (48, p. 5). The existence of a “PrEP gap” in Germany of the magnitude described above would suggest that, according to this definition, equitable access to PrEP has not yet been achieved. Fortunately, the body of evidence on determinants of access to PrEP care has grown substantially since 2012, primarily covering barriers and enablers of a structural, sociocultural or behavioural nature. The barriers among these are many and include the high cost of PrEP/PrEP care and a lack of insurance coverage (e.g., 45, 49-52), as well as difficulties finding providers willing to prescribe PrEP (e.g., 41, 50, 53), but also, among those using or considering PrEP, concerns about side effects (e.g., 41, 51, 52, 54), stigma and discrimination (e.g., 41, 52, 55-57), and low perceived risk of infection (e.g., 41, 58-62) (32). Among providers and policy makers, concerns about increased sexual risk compensation (e.g., 45) may be a relevant barrier (30, 32). Moreover, the results of surveys from the US (63, 64) indicate that knowledge of PrEP may also be limited among physicians (30).

Other behavioural determinants are related to individuals’ motivations to take or consider taking PrEP, or not to do so. Here, it is especially qualitative research that has contributed to the literature on this subject: By exploring the subjective experiences of MSM as they navigate decisions around PrEP, anthropological and ethnographic researchers have used in-depth interviews and focus groups to identify numerous and varied motivations

that call into question the usefulness of purely biomedical approaches to PrEP implementation that de-emphasise psychosocial phenomena (32). In many cases, these motivations derive from powerful affective experiences, including feeling free from decades-long, cyclical anxiety about HIV infection (32, 65-68); feeling empowered and able to make informed choices, in control or autonomous (32, 65, 69); and having less fear and shame about pre-existing high-risk sexual behaviours alongside greater sexual satisfaction and intimacy (32, 70, 71). The qualitative literature also describes motivations that are related to fearing/experiencing stigma related to PrEP, including beliefs that PrEP is only for highly promiscuous people (32, 69, 72); being called a “Truvada whore” (32, 73); encountering stigma among providers, including judgemental behaviour about the use of PrEP (32, 74); or experiencing increased pressure to engage in sex without a condom, whether or not one is taking PrEP (32, 65, 71, 75).

The vast majority of this research, however, derives from the US and, to a lesser extent, from the United Kingdom, Australia and Canada. From the European perspective, this is unfortunate given that the structural and sociodemographic barriers, particularly in the US, are likely to differ considerably from those in health systems in the EU/EEA, including Germany. In early 2017, when we began to develop our facility-based survey of MSM in Berlin, we were able to identify only three, survey-based studies in Germany that focused, at least in part, on the subject (76-78); none of these, however, reported findings explicitly on barriers to, or enablers of, access to PrEP care as results of the surveys themselves. This being said, Spinner et al. (2018) did find that fewer than one third of their respondents who reported taking PrEP said they had received a prescription from a physician (76). This suggests the presence of potential barriers related to finding a physician able to or willing to prescribe PrEP, as well as potential barriers related to cost; it is also roughly in accordance with the results of the EMIS-2017 survey, in which just over half of the men across Europe who had ever taken PrEP had received a prescription for it and only 9% of men without diagnosed HIV reported that someone at a health service in the country they live in had spoken to them about PrEP (44). These findings also suggest that a substantial proportion of MSM using PrEP at the time may have been doing so without medical supervision (44, 76).

Another relevant finding from the EMIS-2017 survey was that 39% of MSM participating in the survey had never heard of PrEP (53% among refugees and asylum seekers), which suggests additional barriers to PrEP access and use in Europe that are probably related

to information and awareness (44). In our facility-based survey of MSM in Berlin, we also found that the PrEP gap might be due, in part, to a lack of information and education on PrEP, including its pros, cons and proper use (31). Among the barriers to PrEP use reported by participants in the Berlin survey who were not using PrEP were worries about side effects, not having a doctor who prescribed it, and a lack of information (31). Moreover, among participants with a history of PrEP use, two of the independent predictors of PrEP use, aside from condomless anal sex with multiple partners, were having a university degree and having friends who were living with HIV. On the provider side, factors related to information and education/training may also play a role in Europe: the results of a survey in 2018 of providers of STI services in the Netherlands suggest a limited knowledge of PrEP and only moderate willingness to prescribe it, particularly among STI specialists (30, 79).

1.4 Scope of this dissertation

Altogether, the evidence available to us in 2017/18 – including from our own, facility-based survey of MSM in Berlin (31) – suggested that informational barriers played a substantial role in contributing to the PrEP gap in Germany. We therefore decided to design and conduct two further anonymous, cross-sectional surveys to gain a clearer picture of PrEP counselling practice, knowledge and attitudes on the side of providers of sexual health services. The first was an online survey in late 2018 of sexual health counsellors at NGCs and local health offices (LHOs; “Gesundheitsämter”) throughout Germany (30), and the second was a hybrid online and paper-based survey in late 2019 of physicians throughout Germany, including HIV-specialists and non-HIV-specialists (29). Additionally, to gain a clearer picture of determinants of PrEP use on the side of health service users, we decided to conduct a separate, multi-methods analysis (32) of the replies to an open-ended, free-text item in our facility-based survey of MSM in Berlin from 2017/18; in this item, we explicitly asked participants who were using or considering PrEP to write what their main motivation was for doing so.

The present dissertation comprises this multi-methods study (32) plus the two studies based on the surveys of counsellors and physicians (29, 30), but it necessarily also interprets their findings in relation to those of the first publication (31) of our four-publication series (29-32) and of the previous literature.

In the following we will refer to our facility-based survey of MSM in Berlin as the “survey of (health) service users” (or “service user survey”), the second survey as the “counsellor survey”, and the third as the “physician survey”. The term “provider surveys” will be used henceforth whenever the counsellor and physician surveys are referred to collectively. Lastly, in this synopsis, we use the term “service user” (i.e., user of health services) as a global term in place of the term “client” used in the counsellor survey and of the terms “patient” or “individual” used in the physician survey.

1.5 Aim and objectives

The overarching aim of all three surveys and the four publications (29-32) generated from them was to identify in an exploratory manner where there was potential to improve the implementation of PrEP and thereby narrow the PrEP gap in Germany, and to generate data and insights that could be used to inform improvement strategies. The two main objectives we set to achieve this aim were (a) to gain a picture in the early days after EMA approval of how PrEP was being used by MSM and transgender people and of how PrEP care was being provided by sexual health counsellors and physicians and (b) to identify and analyse determinants of access to and use of HIV PrEP among MSM and transgender people in Germany.

To achieve the first of these objectives, we asked MSM in the survey of service users about their awareness of PrEP and sources of information about it; their desire to use PrEP and history of PrEP use (including where they obtained it); the anticipated impact of taking PrEP on their use of condoms; their sexual behaviour, HIV risk and STI diagnoses; and other factors alongside a range of sociodemographic variables (31). The quantitative findings related to these survey items are reported in the first (31) of two publications (31, 32) on the service user survey and are not part of this dissertation. Additionally, we coded and categorised the free-text answers to our open-ended question about participants’ main motivation for using or considering PrEP by means of a qualitative thematic framework developed using parallel deductive and inductive approaches by separate researchers. Lastly, in the two provider surveys, we asked participants a number of questions about their counselling behaviour with regard to PrEP, as well as their knowledge of and attitudes towards it, alongside a range of sociodemographic variables (29, 30).

To achieve the second of these objectives (i.e., to identify and analyse determinants of access to and use of HIV PrEP among MSM and transgender people in Germany), we conceptualised access to PrEP care in accordance with the framework developed by Levesque et al. (2013) as "the opportunity to reach and obtain appropriate health care services in situations of perceived need for care" (p. 4) and the use, or utilisation, of PrEP care as "realised access" (p. 4) (80). First, in all three surveys, we operationalised determinants of access to PrEP in line with the model of Levesque et al. (2013) as a range of structural, process and individual-level barriers, as well as facilitators of access related to information and training. Second, we assumed that proactively providing advice on PrEP to people who meet the criteria to be offered PrEP according to the German and Austrian PrEP guideline ("at-risk individuals") represents one way to help narrow the PrEP gap. We therefore operationalised access to PrEP care in our provider surveys as the proportion of consultations in which at-risk individuals were proactively given PrEP advice by providers. We subsequently used multiple linear regression to identify factors that may have influenced this proportion, including knowledge of and attitudes towards PrEP in individuals providers, as well as the barriers mentioned above alongside sociodemographic variables. Third, in our survey of service users, we operationalised access to PrEP as statements about whether individuals had used PrEP at some point in the past or had not but wanted to do so. We then used multiple logistic regression to identify independent predictors of PrEP use and, separately, independent predictors of a desire to use PrEP; the results of this analysis are reported in the first publication on the service user survey (31). Lastly, as part of our later multi-methods investigation of free-text data on motivations from the survey of service users, we assessed whether the frequency of categories of motivation differed in a statistically significant manner (using Fisher's exact test) between respondents who were using or considering PrEP and therefore whether these motivations were related to where MSM were located along a conceptual continuum of care (32). The idea here was that information of this nature might help providers and policy makers develop and distribute targeted information and advice to different groups of at-risk individuals and, in doing so, improve the implementation of PrEP in Germany (32).

2 Methods

2.1 Study design, ethics approval and informed consent

All three surveys were self-administered by the respondents and were cross-sectional. The survey of service users was entirely paper-based, whereas the counsellor survey was entirely online and the physician survey was offered in a hybrid online and paper-based format. The questionnaire for the survey of service users was available in both German and English, whereas the questionnaires for the provider surveys were exclusively in German. Full copies of the questionnaires, respondent information materials, the minimal underlying data sets, and codebooks have been freely available online (open access) and open to public scrutiny as supplementary material since the publication of the study results (29-32).

For the service user survey, data were collected from 1 October 2017 to 2 April 2018; for the counsellor survey from 26 October to 16 December 2018; and for the physician survey from 1 August to 31 October 2019 (29-32). All three surveys were anonymous: we collected no information that would allow us or anyone else to identify the respondents personally. For the online surveys, this also meant that we did not collect any information on IP or email addresses (29, 30). We informed all potential respondents of these points, and of their rights in terms of data protection in accordance with German law in the information materials we provided to them alongside the survey questionnaire (29-32). All three surveys had a cover page or screen that gave a brief description of PrEP and explained the purpose of the survey. Data from the online surveys was transmitted in an encrypted format to the study centre for further analysis (29, 30).

The study protocol for each survey, as well as the information material for respondents and the questionnaires themselves, were approved by the institutional ethics committee of Charité–Universitätsmedizin Berlin (EA1/162/17, 28 September 2017 for the survey of service users and EA1/006/19, 22 February 2019 for both provider surveys) (29-32). Participation in each survey was voluntary, and no monetary incentives were given to the centres or participants to take part (29-32). Respondents to the service user survey provided their physicians with verbal informed consent in English or German before filling in the questionnaire (31, 32). Respondents to the provider surveys gave written informed consent by ticking the box next a statement that they had read the information about the

study and had agreed to take part (29, 30). In the case of the paper version of the physician survey, we assumed consent if the respondent filled in the questionnaire and returned it by fax or mail (29). All participants in the three surveys were 18 years of age or older.

2.2 Settings and eligibility

2.2.1 Counsellor survey

All sexual health counsellors working at an NGC or LHO in Germany were eligible to take part in this survey irrespective of their professional background as long as they provided counselling services on HIV and other STIs (30). We contacted all NGCs that were listed on the website HIV&more, which is a collaboration among the Deutsche AIDS Gesellschaft (DAIG), the Deutsche Gesellschaft für Infektiologie (DGI) and the Deutsche STI Gesellschaft (DSTIG) that provides information on STIs, HIV treatment, PrEP, and post-exposure prophylaxis (PEP), as well as a registry of doctors and counselling centres throughout Germany (30). For each centre in this registry, we also invited an LHO in the same city or district to help ensure comparability; in cases where no LHO was located in a given city or district, we invited an LHO from a city or district of comparable size within the same state as a match (30). Using this approach, a letter of invitation to participate in the survey was sent to a total of 76 centres (i.e., 38 NGCs and 38 LHOs) (30). All invitations were by email, and in these we asked the centres, should they choose to participate, to forward the survey invitation to all counsellors in their organisation who met the eligibility criteria; four weeks after this initial invitation, we sent a reminder email to all centres (30). Lastly, we called all of the invited centres by phone in order to improve participation and gather information on the number of counsellors to whom the survey invitation had been forwarded to be able to estimate the response rate (30). Some of the results of this study have also been published in the context of its first author's (FK) master's thesis (Masterarbeit zur Erlangung des akademischen Grades M.Sc., Management und Qualitätsentwicklung im Gesundheitswesen) (81).

2.2.2 Physician survey

Physicians were eligible to take part in this survey if they were office-based general practitioners, internists, infectious disease specialists, dermato-venereologists or urologists working in Germany (29). We classified participants as HIV-specialists if they reported

working in an HIV-specialty practice and as “non-HIV-specialists” if they reported not doing so (29). In the following two ways, we disseminated a total of 2784 invitations to take part in our study: (i) We obtained the contact details of a random sample of 2200 office-based physicians in the eligible categories from the National Association of Statutory Health Insurance Physicians (Kassenärztliche Bundesvereinigung) and sent them a paper version of our questionnaire by standard mail, which they could return to us in the same manner or by fax; we sent a reminder email with a link to an online version of the questionnaire to the 926 (42%) physicians in this sample for whom an email address was available (29); (ii) We sent an email invitation with a link to the online version of the survey to 253 members of DAIG and 330 members of DSTIG by means of their online mailing lists; we sent a reminder email two weeks after the initial invitation (29). In addition, we distributed flyers to the participants of a Berlin STI conference in September 2019 (29); these contained information on our study and a link to the online version of the survey questionnaire.

2.2.3 Survey of service users

To be eligible to take part in the survey, service users had to be 18 years or age or older, identify as male, report having sex with other men, and have a self-reported HIV status that was negative or unknown (31, 32). We collected data in two types of setting: all four NGCs and six large HIV specialist practices in Berlin: The former are community-based walk-in facilities offering low-barrier services, such as community outreach, anonymous counselling on immigration, legal and health issues for adults and adolescents who identify as lesbian, gay, bisexual, transgender, intersex or another gender diverse identity (LGBTI+), as well as low-priced or free testing for HIV and other STIs (31, 32). Service users are not able to obtain medication or prescriptions from the centres (31, 32). The centres are non-commercial and are funded through donations and by the state government of Berlin. We asked the counsellors to offer participation in the study consecutively to all service users attending the centres for counselling or STI screening (31, 32).

HIV specialist practices in Berlin (and in Germany as a whole) offer generalist and sexual health services to LGBTI+ people regardless of their HIV status and can serve as their family doctors (31, 32). The practices are owned and staffed for the most part by physicians who are certified as HIV-specialists in accordance with the German Quality Assur-

ance Agreement on HIV/AIDS (82), and although consultations usually require an appointment, walk-ins are possible for urgent care (31, 32). Altogether we invited 11 HIV specialist practices from seven districts in Berlin to participate in the study; these were chosen purposively based on their locations across Berlin and our knowledge that they had taken part in previous research projects related to the sexual health of LGBTI+ people (31, 32). We asked the participating physicians to invite each eligible service user in a consecutive manner, regardless of the reason for the consultation (31, 32).

Service users in both settings were asked by the participating counsellors and physicians to fill in the questionnaires in a place of their choosing (e.g., in the waiting rooms or at home) and to return the questionnaires by folding them and putting them into sealed boxes located in the waiting rooms of each centre or practice. Two researchers (RNW and MG) emptied these boxes at regular intervals during the data collection period and provided the participating institutions with new questionnaires as needed.

2.3 Questionnaire development, content and variables

When we developed our suite of three surveys in 2017/18, there were no standardised, validated questionnaires in German available that examined (a) PrEP knowledge, attitudes and counselling practices among providers (29, 30) or (b) knowledge and use of PrEP, or motivations for using or considering it, among MSM (31, 32). All three surveys were therefore developed for the purposes of the three studies. Because of resource limitations (none of the three studies received outside funding) and our desire to generate rapid evidence that might be useful to policy makers in the early days of PrEP implementation in Germany, we chose not to subject the questionnaires to formal validation. The original draft of each questionnaire was tested and discussed among the entire group of core authors, in particular to identify and correct any issues related to the comprehensibility of content and design (29-32).

2.4 Theory and conceptualisation of access to and use of PrEP care

When conceiving of the suite of three surveys, we conceptualised access to PrEP care in accordance with the framework developed by Levesque et al. (2013) as “the opportunity to reach and obtain appropriate health care services in situations of perceived need for care” (p. 4) and the use, or utilisation, of PrEP care as “realised access” (80, p. 4).

Based on their review and synthesis of the published literature on access to health care more broadly, Levesque et al (2013) posit that access results from the interaction of (demand-side) determinants related to the characteristics of individuals, such as their place of residence, economic resources and social status, with (supply-side) determinants related to the characteristics of the services themselves, such as quantity, location of facilities and costs (80). This leads to a framework that consists of five dimensions of accessibility of services and five corresponding dimensions of individuals' abilities to interact with these, as shown in Figure 1.

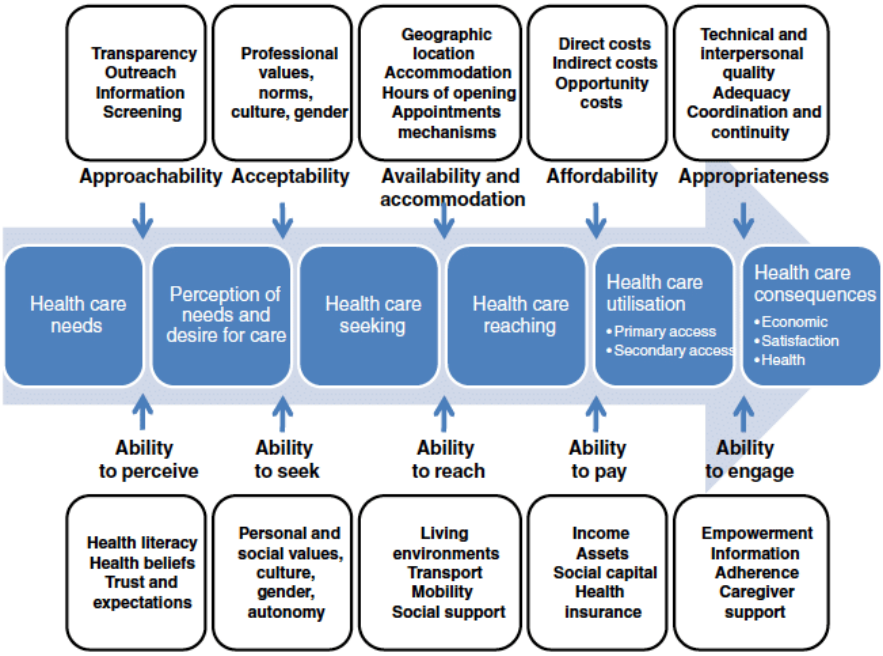

Figure 1: Conceptual framework of access to health care (Levesque et al., 2013) (80)[2]

This conceptual model is useful in the context of PrEP care for two reasons: First, it goes beyond a simplistic but common view of access as predominantly an attribute of services (e.g., their availability and cost) and, instead, takes account of determinants on both the demand and supply sides along the entire process of obtaining care and benefitting from services (80). This fit well with our idea to create a suite of surveys that would look both at the health service user and the provider perspectives. Second, some of the dimensions in the model seemed particularly well suited to the subject of a preventive intervention in

[2] ©2013 Levesque et al.; licensee BioMed Central Ltd, from an Open Access article distributed under the terms of the Creative Commons Attribution License (http://creativecommons.org/licenses/by/2.0)

the area of sexual health, such as PrEP, both intuitively and considering the results of the structured review of the literature we conducted while developing a coding framework to analyse the qualitative data from our user survey study (see section 2.7 “Sample size and qualitative analysis of service user motivations”) (32). For example, while perceiving oneself to be at high risk of acquiring HIV has been described as a factor that may motivate individuals to seek preventive services, there is evidence that such perceptions are often inaccurate and do not align with individuals’ sexual risk behaviour (32, 60-62, 69, 71, 83). This finding fit well with the dimensions “Approachability”/“Ability to perceive” in the conceptual framework by Levesque et al. (2013) (80), which includes determinants on the provider side such as information on available treatments and outreach activities, and determinants on the user side such as health literacy, knowledge about health and beliefs related to health and sickness (80). The dimensions “Acceptability”/“Ability to seek” in this framework also fit the subject of PrEP well because these relate, according to Levesque et al. (2013) to the “challenge of ensuring that care meets the needs of different cultural, socioeconomically disadvantaged and vulnerable populations”, which together with other societal groups (including providers) “may judge appropriateness and quality differently” (80, pp. 5-6).

2.5 Operationalisation of access to and use of PrEP care

In all three survey questionnaires, we operationalised access to and use of PrEP care and the determinants thereof in terms of (a) barriers to access, (b) the proactive provision of PrEP advice to at-risk service users, and (c) facilitators of access, including motivations of service users to use or consider using PrEP, as follows:

(a) Barriers to access: First, in all three surveys, we presented respondents with a list (or, in the case of the service user survey, lists) of factors that might be perceived as barriers for service users to access to PrEP care. In line with the model of Levesque et al. (2013) (80) and their synthesis of the literature on this point (84-86), these factors covered a roughly equal number of structural determinants related to the health system in Germany (e.g., cost of PrEP, availability of physicians who prescribe it), on the one hand, and individual-level determinants (e.g., worries about side effects, motivations for using or considering PrEP, cultural barriers) and process factors (e.g., lack of information, time required for regular visits to doctor) on the other. Some barriers can be seen as a having a combination of aspects, such as a lack of availability of physicians who might

prescribe PrEP (i.e., structural if not enough physicians are available in a given region and process-related if the physicians are available but not willing to prescribe PrEP because they lack information about it – the latter of which also has individual-level dimensions, e.g., attitude towards PrEP).

The following items were presented to participating sexual health counsellors and physicians in the two provider survey questionnaires as potential barriers to health service users initiating PrEP (29, 30):

- Service users' worries about getting infected with other STIs
- The monthly costs of the PrEP medication
- Lack of information about PrEP in service users' native language
- The costs of the laboratory investigations
- Service users' worries about mild or temporary side effects
- Time required for regular visits to the doctor
- Service users' worries about severe or permanent side effects
- Lack of information about PrEP in service-user-friendly language
- Difficulties finding a doctor who prescribes PrEP
- Service users assessing their own risk of getting infected with HIV as too low to take PrEP
- Service users' worries about stigmatization in the peer group
- Cultural barriers for service users

In the physician survey, we additionally asked about the relevance of two factors for physicians: any difficulty identifying PrEP candidates and the time required to management PrEP users (29).

For those who completed the survey online, the items were presented to each respondent in a different, randomly selected order with the aim of reducing question order bias (29, 30). In both provider surveys, we asked respondents to rate the relevance of each of these barriers for (potential) PrEP users on an 11-level, end-verbalised rating scale with numeric markers (0=no relevance, 10=highest relevance) (29, 30). The barriers presented to participating service users can be found in the service user questionnaire under the following items: "Under what circumstances would you use PrEP?" and "What risks do you see for people who use PrEP?" (31). The results for these items in the service user survey are reported in the first publication on the quantitative results of that survey and are not part of this dissertation (31).

(b) Proactive provision of PrEP advice to at-risk service users: The second way that we operationalised access to and use of PrEP care derives from two important findings from the quantitative part of our survey of service users: the need among participating MSM for more information on PrEP, and the difficulty in finding a doctor who would prescribe it (31). We therefore chose to examine a further process/individual-level factor in both of the provider surveys, in the following manner: first we presented participating providers with a brief summary of the recommendation in the German and Austrian PrEP guideline (15) regarding the indication for offering PrEP to HIV-negative MSM and transgender people (which served as our definition of “at-risk individuals”) (29, 30). In this context, we named the guideline as the source of this recommendation and provided a bibliographical reference and link. We then we asked the providers to tell us how many consultations they had with such at-risk individuals during an average month (physicians: calendar quarter) and the proportion of these consultations in which they proactively gave advice on PrEP (29, 30). In the physician survey, we asked for the absolute number of consultations in both cases and calculated the proportion ourselves (29). We subsequently sought to identify independent predictors of the proportion of consultations in which PrEP advice was provided proactively to at-risk individuals, including sociodemographic variables related to the providers and their places of work (NGC vs. LHO; HIV-speciality vs. other practice), and measures of their PrEP-related knowledge and counselling competence, as well as their attitudes towards PrEP (29, 30). This measure therefore covers multiple determinants of access in the dimensions “Approachability” (e.g., screening, information, outreach) and “Acceptability” (e.g., professional values, norms, culture, beliefs) proposed by Levesque et al. (80).

In both provider surveys, we quantified PrEP-related knowledge and counselling competence, as well as PrEP attitudes, by asking providers about their level of agreement with sets of statements about different aspects of knowledge, counselling competence and attitudes; to do so we used fully verbalised, bipolar five-step Likert scales with an ambivalent scale centre (29, 30), as shown in

.

(c) Facilitators of access: In our provider surveys, we chose to focus in our analysis of facilitators on potential information materials for service users and for providers, as well as training for providers. We took this decision based on our early finding from the quantitative part of the survey of service users regarding the importance of information on PrEP.

Table 1: Items used to assess (a) PrEP knowledge and counselling competence and (b) attitudes towards PrEP in both provider surveys

Dimension	Operationalisation	Scores				
Do you agree or disagree with the following statements?		Strongly disagree	Disagree	Neither agree nor disagree	Agree	Strongly agree
(a) PrEP knowledge and counselling competence						
Global assessment	"I am well-informed about PrEP"	0	1	2	3	4
Indications	"I am able to give service users comprehensive advice on whether it makes sense to take PrEP in their respective case"	0	1	2	3	4
Side effects	"I am able to give service users comprehensive advice on the side effects of PrEP"	0	1	2	3	4
Modalities of intake	"I am able to give service users comprehensive advice on the possible modalities of PrEP intake (e.g., continuous vs. on-demand)"	0	1	2	3	4
Investigations	"I am able to give service users comprehensive advice on the medical investigations necessary during the use of PrEP"	0	1	2	3	4
Knowledge score		Summative score with values ranging from 0 to 20				
(b) Attitudes towards PrEP						
Global assessment	"I think that PrEP is an important element of HIV prevention strategies"	0	1	2	3	4
Reliability	"I think that PrEP is a reliable method to protect oneself from HIV"	0	1	2	3	4
Side effects	"I think that PrEP is a method to protect oneself from HIV that has few side effects"	0	1	2	3	4
Availability of better alternatives	"I think that PrEP is unnecessary, because there are better alternatives to protect oneself from HIV"	4	3	2	1	0
Reimbursement of costs	"I think that PrEP should be paid for by statutory health insurance"	0	1	2	3	4
Attitudes score		Summative score with values ranging from 0 to 20				

Notes: Adapted from Kutscha et al. (2020) (30). HIV, human immunodeficiency virus; PrEP, pre-exposure prophylaxis.

We therefore presented providers in both surveys with the following list (29, 30) of tools and asked them to select those which they felt would improve counselling on PrEP or make it more practical:

- A clinical practice guideline that provides a good overview of indications, contraindications and necessary laboratory investigations
- A decision-aid for service users that provides information on PrEP in service-user-friendly language

- A decision-aid for service users that provides information on PrEP in different languages
- Information and training for providers on the management of PrEP (e.g., required examinations)
- Information and training for providers on identifying PrEP candidates
- Information or training on the subject of “Talking with service users about sexuality”
- An app- or SMS-based reminder for PrEP users to promote adherence

This focus also reflected our pragmatic approach to these exploratory surveys insofar as each of the information material and training suggestions represented something that our working group could conceivably develop or contribute to as part of future projects. Again, for those who completed the survey online, the items were presented to each respondent in a different, randomly selected order with the aim of reducing question order bias (29, 30). In the counsellor survey, we additionally asked participants whether training on the subject of PrEP and counselling on PrEP had been offered, whether internal guidelines or procedural instructions for PrEP counselling were available at their counselling centre, and whether they wished to receive training or courses on counselling service users about PrEP (30).In our survey of service users, we included the following open-ended, free-text question in order to explore potential motivational determinants of access to PrEP care and how these might affect individuals’ “ability to seek” (80) appropriate care: “If you are considering or already using PrEP, what is your main motivation for this?” (32). There was space on the questionnaire for respondents to answer with one to two sentences, depending on their handwriting (32). Methodological details related to our multi-methods analysis of the responses to this question and how we distinguished between those considering or using PrEP can be found in the sections 2.7 “Sample size and qualitative analysis of service user motivations” and 2.8 “Quantitative analysis of service user motivations” below.

2.6 Sample size and statistical methods in the provider surveys

Because the provider questionnaires were developed explicitly for the purposes of the two corresponding studies, there were no data available on expected means or variability (29, 30). For the counsellor survey, our aim was to include all NGCs that offered HIV testing and an equal number of matched LHOs (30). For the physician survey, the size of

the random sample (n=2200) was based on feasibility considerations (29). As a result, no sample size calculations were performed in either case (29, 30). We conducted statistical analyses with IBM® SPSS® Statistics version 25 for sample characteristics and bivariate statistics and with Stata SE version 14.2 for multiple linear regression (29, 30).

In the study on the counsellor survey, depending on the data quality, we used descriptive statistics to describe the sample characteristics and the results (30). To quantify the internal consistency of the summative knowledge and attitudes scores we used Cronbach's alpha (30). To quantify associations between variables, we used independent samples t-tests, the Mann-Whitney U test and Pearson's Chi squared tests, depending on the data quality (30). We applied a multiple linear regression using the backward elimination method to identify independent predictors of the proportion of consultations in which participating counsellors proactively gave PrEP advice to at-risk service users (30). We purposefully selected the following variables for the regression model a priori: type of centre (NGC vs. LHO), respondents' gender and years of practical work experience, size of the city or town in which the centre was located, the rate of positive HIV tests, the knowledge score, and the attitudes score (30). The stopping rule for eliminating individual variables was $p<0.2$ (30). We used the variance inflation factor and condition number to verify that there was no multi-collinearity among the predictors or instability of the regression coefficients (30). We excluded missing cases in a listwise manner (30). The level for statistical significance was set at $p=0.05$ (30).

In the study on the physician survey, we used independent t-tests, Pearson's chi squared tests, Mann-Whitney U-tests and Fisher's Exact tests to quantify associations between variables, depending the type of data and their distribution (29). We conducted a multiple linear regression using both backward and forward elimination to identify independent predictors of the proportion of consultations in which participating physicians proactively gave PrEP advice to at-risk service users (29). We purposively selected the following variables for the regression model a priori: HIV specialist status (HIV-specialist vs. non-HIV-specialist), size of the city in which the physician practice was located, practice location in either a western or eastern German state (with eastern states defined as the five new states formed from the territory of former East Germany as part of German reunification in 1990), gender, percentage of positive HIV tests (number of positive tests divided by the total number of service users tested), the knowledge score, and the attitudes score (29). As with the study on the counsellor survey, the stopping rule for eliminating individual

variables was $p<0.2$ (29). We used variance inflation factor, tolerance and condition index to ensure that there was no multi-collinearity among the predictors or instability of the regression coefficients (29). We excluded missing cases in a listwise manner (29). The level for statistical significance was set at $p<0.05$ (29).

For the post-hoc comparisons of the results of the two provider surveys that are reported in this synopsis, whether of descriptive statistics or the multiple regression analysis, no statistical testing was performed as these were not conceived of a priori or designed to be comparable beyond purely descriptive terms.

2.7 Sample size and qualitative analysis of service user motivations

As with the two provider surveys, we did not perform a formal sample size calculation for the survey of service users; instead, based on considerations of feasibility, we strove to collect data from about 500 respondents (32). After defining our analysis units as single motivations within each free-text response, we used a framework analysis method (87) to code each motivation for using or considering PrEP, categorising the data by means of high-level themes (32). In doing so, we took a parallel deductive and inductive approach to develop the coding framework in order to avoid our analysis being driven by pre-existing theoretical interests or analysis-related preconceptions (87, 88): One researcher (RNW) generated a set of categories and subcategories deductively using the findings of a structured search of published frameworks for classifying motivations for PrEP use, whereas a second researcher (MS) generated another set of categories and subcategories in an inductive fashion, starting with a preliminary test coding and analysis of a random subset of 75 of the free-text responses (32). The two researchers then merged these classification schemes through a series of discussions facilitated by a third researcher (MG), who resolved disagreements and inconsistencies with the others by consensus (32).

To identify published frameworks on PrEP, the first researcher (RNW) searched MEDLINE on April 4, 2018, using the search terms “PrEP” and “motivation”, setting the time limit set to five years prior to this date (32). This yielded a total of 61 records, which, after title and abstract screening, were reduced to a total of six records (60, 71, 89-92) to be evaluated as full text (32). Ultimately, the researcher used two of these studies (60, 89) to derive an initial categorisation system for motivations (32).

The second researcher (MS) took the following approach in parallel: to begin, the third researcher (MG) read and re-read all free-text responses in their entirety in order to reach a pragmatic estimate of how many of these would need to be coded before saturation was reached, which in this case was approximately one third of all valid responses (32). He then sent a randomly generated list of 75 responses to the second researcher for the test coding (32). The coding process was conducted in a way that was both open – so that codes were assigned to describe as many perspectives as possible, including particular behaviours, intentions, values, beliefs and emotions (87) – but also circular by looping repeatedly between the codes assigned to the data and the data themselves, and then recoding, considering any emergent categories, and re-categorising (93) as required (32).

The final categories in the merged classification system were “safety/protection against HIV”, “expectations about sexuality”, “mental well-being and quality of life”, “condom attitudes”, and “norms/social perspectives” (32). Table 2 provides an overview of the categories and subcategories of our coding system, and gives definitions for each in addition to references to the relevant literature (32).

Table 2: Overview of final coding framework and categorisation system with definitions (categories and subcategories listed in alphabetical order)

Category	Subcategory
CONDOM ATTITUDES (60) This category comprises two subcategories for coding responses that refer to respondents’ attitudes towards condom use.	**Desire or intent to engage in condomless sex**
	Responses are coded in this subcategory if they refer to the desire or intent to engage in condomless sex. Negative attitudes towards condom use and reporting episodes of condomless intercourse have been described as being associated with the intention to use PrEP (94).
	Difficulties with condom use
	Responses are coded in this subcategory if they mention difficulties with condom use as a motivation to use PrEP (68).
EXPECTATIONS ABOUT SEXUALITY This category comprises two subcategories for coding responses that refer to respondents’ expectations about sexuality while using PrEP.	**Expectations of more pleasureful sex or increased intimacy and closeness (when not using a condom)**
	Responses are coded in this subcategory if they include the expectation of more pleasureful sex, intimacy or closeness as a motivation to use PrEP, irrespective of whether the response refers to using condoms. Believing that condoms reduce intimacy and closeness and/or sexual pleasure is a factor that has been described as associated with the intention to use PrEP (65, 68, 71).
	Expectations of worry-free sex
	Responses are coded in this subcategory if they refer to the expectation of worry-free or less worrisome sex as the motivation for using PrEP (65). In contrast to the subcategory “Reducing anxiety, fear, or worries of being infected with HIV” under the category “Mental well-being and quality of life”, responses here had to mention sex or sexuality explicitly.
MENTAL WELL-BEING AND QUALITY OF LIFE	**Desire for a healthy life**
	Responses are coded in this subcategory if they refer to the general desire to increase health or longevity, or to lead a healthy life.
	Desire to increase quality of life or sexual/personal freedom

This category comprises four subcategories for coding responses that refer to respondents' mental well-being or aspects of general health.	Responses are coded in this subcategory if they refer to the desire to increase quality of life, mental well-being, general health, or sexual or personal freedom as the motivation to use PrEP (65).
	Reducing anxiety, fear, or worries of being infected with HIV
	Responses are coded in this subcategory if they include the desire to reduce anxiety, fear or worries about being infected with HIV (65-68). Unlike the subcategory "expectations of worry-free sex", this subcategory does not include responses that refer explicitly to the act of sex.
	Reducing periods of anticipated regret
	Responses are coded in this subcategory if they included the desire to decrease periods of anticipated regret or worries. The cognitive-based emotion of anticipated regret from engaging in HIV-risk behaviour has been described as an important determinant of the intention to use PrEP (60).
NORMS / SOCIAL PERSPECTIVES This category comprises two subcategories for coding responses that refer either to perceptions of PrEP use as a social norm or that reflect upon PrEP use in terms of social or public health perspectives.	**Perceiving condomless sex / PrEP intake as a social norm**
	Responses are coded in this subcategory if the answer refers to perceptions of PrEP use as a social norm or the need to use PrEP as the only means of personal protection in a social environment that insists on condomless sex (65, 71, 75).
	Prevention altruism (60)
	Responses are coded in this subcategory if the respondent refers to a general public health perspective of reducing the burden of HIV epidemics. General public health concerns have been described as a facilitator of engaging in safer sex practices (95).
SAFETY / PROTECTION AGAINST HIV This category comprises eight subcategories for coding responses that refer to protection against HIV or general safety considerations, as well as more specific aspects of protection or safety for oneself or for others.	**Additional protection against HIV**
	Responses are coded in this subcategory if they reflect the respondent's wish to have additional protection against HIV, or additional safety or security, by using PrEP as a "backup preventive strategy". This has been described in the literature as a specific motivation to use PrEP (89). Safer sex intentions have been shown to be linked with the motivation to use PrEP (94).
	Autonomy and self-empowerment in the protection against HIV
	Responses are coded in this subcategory if they reflect the respondent's wish to protect himself from being infected with HIV using a method of protection that lies within his own responsibility and is not dependent on his partners' reliability or will to use condoms (65, 69).
	Being at self-perceived risk of HIV
	Responses are coded in this subcategory if they reflect the respondent's general perception of being at risk of acquiring HIV due to specific circumstances, such as having sex with many casual partners or being in a relationship with a person living with HIV. Self-perceived risk of acquiring HIV has been described as a factor that may motivate individuals to seek preventive services. Considering oneself as being at risk of HIV infection has been shown to be correlated with self-perceived eligibility for PrEP use (60-62, 69, 71, 83).
	PrEP as an affordable way to protect against HIV
	Responses are coded in this subcategory if they mention the affordability or cost of PrEP as an option to protect oneself from being infected with HIV.
	Protecting partner(s) or relationship(s) from HIV infection
	Responses are coded in this subcategory if they reflect the respondent's wish to protect his (sex) partners' health or well-being or if the answers included relationship-associated aspects. Attitudes towards using PrEP have been shown to be linked with considerations of protecting primary and/or outside partners (68, 94). Concerns for the sexual partners' risk of acquiring HIV and general public health concerns have also been described as a facilitator of engaging in safer sex practices (95).
	Protection against HIV during periods of anticipated increased risk (e.g., recreational drug use, holidays)
	Responses are coded in this subcategory if they reflect the respondent's wish to protect himself from being infected with HIV during specifically defined events (e.g., recreational drug use) or periods (e.g., holidays) that are accompanied by an anticipated increased risk of being infected with HIV. PrEP has been described as an option for situations in which regular patterns of sexual practice

	might be disrupted, such as holidays or in the event of alcohol and/or drug use (62, 89).
	Protection against HIV, prevention of HIV and general safety
	Responses are coded in this subcategory if they reflect the respondent's general wish to protect himself from being infected with HIV, or his generally expressed need for safety, without mentioning specific circumstances or specifying aims beyond (his individual) protection.
	Protection against HIV when not using condoms
	Responses are coded in this subcategory if they reflect the respondent's wish to protect himself from being infected with HIV explicitly without having to use condoms.

Notes: From Gaskins et al. (2021) (32). HIV, human immunodeficiency virus; PrEP, pre-exposure prophylaxis.

After this, two researchers (RNW, MS) used the merged framework to identify, code and classify individual motivations in all of the free-text responses, including those that had been coded in the preliminary test coding (32). Regular meetings of all three researchers took place during this process to discuss potential emerging new categories or subcategories; ultimately, we did not have to make any substantial changes to the framework during this process (32). For information on smaller changes, see Gaskins et al. (2021) (32). Moreover, although the number of responses in the "Norms/social perspectives" category was small we chose to keep it because of the importance placed on it in the qualitative literature (e.g., 65, 71, 75) and our not wanting to follow an overly frequentist approach in our reporting of the qualitative data (32). Overall, there was high agreement between the coding results of the two researchers (Cohen's Kappa=0.837; 95% CI: 0.794-0.880) (32). The third researcher (MG) reviewed all final codes and resolved any disagreements or discrepancies with the other researchers by means of discussion (32).

2.8 Quantitative analysis of service user motivations

We analysed the qualitative data by means of descriptive statistics and Fisher's exact test of independence in order to determine whether there were statistically significant differences (alpha level 0.05) in the frequency of the categories of different PrEP motivations between the subset of the sample reporting PrEP use or a history of PrEP use and the subset reporting that they were considering using PrEP (32).

We classified respondents as considering PrEP use if they reported no current or previous use of PrEP, wrote down a motivation, and did not disagree/strongly disagree with the statement that they would like to use PrEP (32). In the models of the PrEP care continuum that have been developed so far, this group could be situated at any of the steps before that corresponding to PrEP initiation (e.g., "Initiate PrEP" in the model by Newman et al.

(2018) (65), Stage 4b of “Stage 4: PrEP action and initiation” in the model by Parsons et al. (2018) (96), or “Step 7: Initiating PrEP” in the model by Nunn et al. (2017) (97)) (32). We classified respondents as using or having a history of using PrEP if they selected any of the affirmative responses to the corresponding survey item (i.e., “Yes, but not on a regular basis”, “Yes, I regularly use it before and after risky sex (as needed)”, “Yes, I use it continuously”) , wrote down a motivation, and did not disagree or strongly disagree with the statement that they would like to use PrEP (32). This group could be situated roughly in “Stage 5: PrEP maintenance and adherence” of the model by Parsons et al. (2018) or at steps 8 (“Adhere to PrEP”) or 9 (“Retention in PrEP Care”) of the model by Nunn et al. (2017) (32). This being said, people with different PrEP trajectories (i.e., those who had used PrEP in the past but were not necessarily taking it currently) were also part of our analysis sample, so this group would be placed more appropriately between the steps “Initiate PrEP” and “Retention” on the augmented PrEP cascade of Newman et al (2018) (65), with the possibility of being located at the stages “Seasonal or intermittent use” or “Discontinuation” (32).

We used a Bonferroni-corrected alpha level of 0.05, which we divided by the number of compared pairs to take account of multiple testing for post-hoc pairwise comparisons (32). To further ameliorate the problem of multiple testing, we focused in the analysis only on main categories (e.g., “Safety”, “Condom attitudes”) and combinations of main categories (e.g., “Safety & mental well-being”, “Safety & expectations”), and did not include subcategories (e.g., “Difficulties with condom use”, “Desire or intent to engage in condomless sex”). To preserve the richness of our qualitative data in our reporting examples of motivational factors and avoid an overly frequentist approach, we cited, whenever possible, five motivations that we judged to summarise the overall body of motivations in each subcategory best, whether the responses in this subcategory were rare or frequent (32). When fewer or more than five motivations were sufficient or needed in this regard, we cited a different number of responses (32). We conduced our statistical analyses with Stata SE 14.2.

3 Results

3.1 Participation and response rates

3.1.1 Counsellor survey

A total of 179 counsellors at the 76 centres that received an invitation to participate in the study opened the online survey and started to fill out the survey questionnaire (30). Among these counsellors, 145 reported the type of counselling centre at which they worked; this was the first item on the questionnaire and the only one that was mandatory (30). The sample size was therefore 145 counsellors, of whom 56 reported working in an LHO and 89 in an NGC (30). In phone calls with 62 centres, it was possible to obtain information on the number of counsellors to whom the invitation had been forwarded in each centre, which we calculated as a mean of 2.96 (standard deviation (SD)=2.56) in LHOs and 5.58 (SD=5.07) in NGCs (30). In total, five of the invited LHOs chose not to participate in the survey; we therefore estimate that the number of counsellors invited to take part in the study was 98 in LHOs and 212 in NGCs (30). Using these numbers, we calculated a response rate of 57.1% for LHOs and 42.0% for NGCs (30). Overall, 77.9% of the 145 respondents completed the entire questionnaire (30).

3.1.2 Physician survey

Of the 2784 invitations we distributed for the physician survey, we received a total of 161 responses, seven of which we excluded because they did not provide meaningful information (29). The sample included in our analyses therefore consisted of 154 respondents, yielding a response rate of 5.5% (29).

3.1.3 Survey of service users

Each of the four NGCs that existed in Berlin at the time of the survey participated in the study; of the 11 HIV specialist practices invited to take part, six ultimately chose to participate (31, 32). Of the 875 paper questionnaires handed out by these centres and practices, 473 were returned, yielding a response rate of 54.1% (31, 32). We excluded three of these respondents because in the questionnaire they reported that they were living with HIV, leaving 470 questionnaires, of which 259 contained a free-text response to our

question asking respondents what their main motivation was for using or considering PrEP (32). Of these responses, we classified 31 as invalid because the respondents had either disagreed or strongly disagreed with the statement “I would like to take PrEP” (n=30) or responded in the negative to the item asking if they had ever used PrEP but at the same time indicated in their answer to the statement “I would like to take PrEP” that it did not apply to them as they were taking it already (n=1) (32). This yielded a sample of 228 survey questionnaires that contained a valid free-text response for further analysis (32).

3.2 Demographic data

3.2.1 Counsellor survey

The mean age of the 145 respondents to our counsellor survey was 46.03 years (SD=11.67) (30). In total, 76 respondents (52.4%) defined themselves as male, 61 (42.1%) as female, and two (1.4%) as non-binary (30). Ninety-three respondents (64.1%) reported that social work was their primary professional qualification, 15 (10.3%) that they were physicians, 14 (9.7%) that they were psychologists, and four (2.8%) that they were nursing professionals (30). In total, 89 respondents (61.4%) reported that their place of work was in a large city with a population greater than 100,000 and 43 respondents (29.7%) that it was in a major city with a population greater than 1,000,000 (30). A large majority (n=123, 84.8%) reported that their counselling centre was in western Germany or Berlin (30). We found statistically significant associations between the type of centre and gender (χ^2(df: 2, n=139) = 17.40, p<0.001) and primary professional qualification (χ^2(df: 4, n=139) = 19.85, p=0.001) of the respondents, with larger proportions of respondents at LHOs being women and having a primary professional qualification as a physician compared to NGCs, and a larger proportion of respondents at NGCs having a primary professional qualification in psychology. Full demographic data of the sample of sexual health counsellors, including the results of tests for differences according to type of centre, are given in Table 3 (30).

Table 3: Demographic data and contextual characteristics of the sample of sexual health counsellors

Variable	Total sample (N=145)	NGCs (n=89)	LHOs (n=56)	
Age in years (n=139)				**p=0.679†**
Median (IQR)	48.00 (19.00)	47.50 (21.75)	48.00 (17.00)	
Mean (SD)	46.03 (11.67)	45.75 (11.82)	46.51 (11.51)	
Min–max	19–67	23–67	19–62	
Gender (n, %)				**p<0.001§**
Female	61 (42.1%)	27 (30.3%)	34 (60.7%)	
Male	76 (52.4%)	59 (66.3%)	17 (30.4%)	
Non-binary	2 (1.4%)	2 (2.2%)	0 (0%)	
Not specified	6 (4.1%)	1 (1.1%)	5 (8.9%)	
Professional qualification (n, %)				**p=0.001§**
Social work	93 (64.1%)	56 (62.9%)	37 (66.1%)	
Psychology	14 (9.7%)	12 (13.5%)	2 (3.6%)	
Nursing	4 (2.8%)	3 (3.4%)	1 (1.8%)	
Physician	15 (10.3%)	4 (4.5%)	11 (19.6%)	
Other	13 (9.0%)	13 (14.6%)	0 (0%)	
Not specified	6 (4.1%)	1 (1.1%)	5 (8.9%)	
Size of the location (n, %)				**p=0.138§**
Major city (>1,000,000)	43 (29.7%)	28 (31.5%)	15 (26.8%)	
Large city (>100,000)	89 (61.4%)	58 (65.2%)	31 (55.4%)	
City (>10,000)	7 (4.8%)	2 (2.2%)	5 (8.9%)	
Small city (≤10,000)	1 (0.7%)	0 (0%)	1 (1.8%)	
Not specified	5 (3.4%)	1 (1.1%)	4 (7.1%)	
State (n, %)				**p=0.072§**
Baden-Wuerttemberg	20 (13.8%)	17 (19.1%)	3 (5.4%)	
Bavaria	22 (15.2%)	14 (15.7%)	8 (14.3%)	
Berlin	15 (10.3%)	8 (9.0%)	7 (12.5%)	
Brandenburg	9 (6.2%)	6 (6.7%)	3 (5.4%)	
Bremen	1 (0.7%)	1 (1.1%)	0 (0%)	
Hamburg	13 (9.0%)	9 (10.1%)	4 (7.1%)	
Hesse	12 (8.3%)	10 (11.2%)	2 (3.6%)	
Mecklenburg-Western Pomerania	2 (1.4%)	0 (0%)	2 (3.6%)	
Lower Saxony	8 (5.5%)	2 (2.2%)	6 (10.7%)	
North Rhine-Westphalia	22 (15.2%)	14 (15.7%)	8 (14.3%)	
Rhineland-Pfalz	0 (0%)	0 (0%)	0 (0%)	
Saarland	4 (2.8%)	1 (1.1%)	3 (5.4%)	
Saxony	0 (0%)	0 (0%)	0 (0%)	
Saxony-Anhalt	1 (0.7%)	1 (1.1%)	0 (0%)	
Schleswig-Holstein	6 (4.1%)	3 (3.4%)	3 (5.4%)	
Thuringia	0 (0%)	0 (0%)	0 (0%)	
Not specified	10 (6.9%)	3 (3.4%)	7 (12.5%)	
Professional experience in years (n=138)				**p=0.838†**
Median (IQR)	11.50 (18.25)	12.00 (19.75)	11.00 (17.50)	
Mean (SD)	14.19 (10.38)	14.23 (10.63)	14.14 (10.02)	
Min–max	0.5–40	1–40	0.5–31	

Notes: Adapted from Kutscha et al. (2020) (30). IQR, interquartile range; LHO, local health office; Max, maximum; Min, minimum; NGC, non-governmental counselling centre; SD, standard deviation; †From Mann-Whitney U tests of the null hypothesis that the median value of participants from LHOs is equal to that of participants from NGCs (30); §From Pearson's Chi squared tests of the null hypothesis that there is no statistically significant difference between the observed and expected frequencies in each category, by type of counselling centre (30).

3.2.2 Physician survey

Of the 154 respondents to our physician survey, 72 reported that they worked in an HIV-specialty practice ("HIV-specialists") and 79 that they did not ("non-HIV-specialists") (29). Three participants did not give information on the type of practice in which they worked or their medical specialty; we therefore included data from these participants only in the analyses of barriers to and facilitators of PrEP access (29). The mean age of the 154 respondents was 52.22 years (SD=8.98) (29). In total, 97 respondents (63.0%) defined themselves as male and 54 (35.1%) as female (29). Thirty-five (22.7%) reported their specialty as general medicine, 27 (17.5%) as internal medicine, 25 (16.2%) as dermatology, 25 (16.2%) as urology, and 37 (24.0%) as general medicine and internal medicine with an additional qualification for infectious disease (29). In total, 44 respondents (28.6%) reported that their place of work was in a large city with a population greater than 100,000 and 52 respondents (33.8%) that it was in a major city with a population greater than 1,000,000 (29). A larger proportion of physicians (n=46, 29.8%) than counsellors (n=8, 5.5%) reported working in small city or in a city with a population between 10,0000 and 100,000, which was due (a) to our matching approach to inviting LHOs (see section 2.2.1 "Counsellor survey" under 2.2 "Settings and eligibility") and (b) to the large proportion of non-HIV-specialists who reported living in cities of this size (n=40, 50.6%) (29, 30). As in the counsellor survey, however, a large majority (n=123, 79.9%) of physicians reported that their practice was in western Germany or Berlin (29). As with the counsellors, we found statistically significant associations between HIV specialist status and demographic data for gender (χ^2(df=1, n=151) = 6.938, p=0.008) and specialty (χ^2(df: 5, n=151) = 83.379, p<0.001), with the proportion of women among the non-HIV-specialists being almost twice as high as that among HIV-specialists, and (by definition) the number of respondents with an additional qualification for infectious disease being much higher among the HIV-specialists. We also found significant differences between HIV-specialists and non-HIV-specialists with regard to the size of the city (χ^2(df: 3, n=142) = 33.378, p<0.001) and the state (i.e., eastern states vs. western states) (χ^2(df: 1, n=142) = 3.833, p=0.05) in which their practice was located (29), with a larger proportion of HIV-specialists working in larger cities and a smaller proportion working in the eastern states compared to non-HIV-specialists. Full demographic data of the sample of physicians, including tests for differences according to HIV specialist status, are shown in Table 4 (29).

Table 4: Demographic data and contextual characteristics of the sample of physicians

Variable	Total sample (N=154*)	HIV-specialists (n=72)	Non-HIV-specialists (n=79)
Age in years (n=145)			**p=0.180†**
Mean (SD)	52.22 (8.98)	51.20 (8.46)	53.20 (9.39)
Min–max	33–84	34–76	33–84
Gender (n, %)			**p=0.008§**
Female	54 (35.1%)	18 (25.0%)	36 (45.6%)
Male	97 (63.0%)	54 (75.0%)	43 (54.4%)
Not specified	3 (1.9%)	0 (0.0%)	0 (0.0%)
Specialty (n, %)			**p<0.001§**
General Medicine	35 (22.7%)	11 (15.3%)	24 (30.4%)
Internal Medicine	27 (17.5%)	22 (30.6%)	5 (6.3%)
Dermatology	25 (16.2%)	4 (5.6%)	21 (26.6%)
Urology	25 (16.2%)	0 (0.0%)	25 (31.6%)
General Medicine and Internal Medicine with Additional Qualification for Infectious Disease	37 (24.0%)	35 (48.6%)	2 (2.5%)
Not specified	5 (3.4%)	0 (0.0%)	2 (2.5%)
Size of city (n, %)			**p<0.001§**
Metropolis (>1,000,000)	52 (33.8%)	36 (50.0%)	16 (20.3%)
Large city (>100,000)	44 (28.6%)	25 (34.7%)	19 (24.1%)
City (>10,000)	27 (17.5%)	4 (5.6%)	23 (29.1%)
Small city (≤10,000)	19 (12.3%)	2 (2.8%)	17 (21.5%)
Not specified	12 (7.8%)	5 (6.9%)	4 (5.1%)
State (n, %)			**p=0.05#**
Western Germany, including Berlin	**123 (79.9%)**	**62 (86.1%)**	**61 (77.2%)**
Baden-Wuerttemberg	15 (9.7%)	8 (11.1%)	7 (8.9%)
Bavaria	18 (11.7%)	13 (18.1%)	5 (6.3%)
Berlin	26 (16.9%)	14 (19.4%)	12 (15.2%)
Bremen	2 (1.3%)	0 (0%)	2 (2.5%)
Hamburg	5 (3.2%)	4 (5.6%)	1 (1.3%)
Hesse	23 (14.9%)	12 (16.7%)	11 (13.9%)
Lower Saxony	5 (3.2%)	0 (0.0%)	5 (6.3%)
North Rhine-Westphalia	22 (14.3%)	10 (13.9%)	12 (15.2%)
Rhineland-Palatinate	5 (3.2%)	1 (1.4%)	4 (5.1%)
Saarland	2 (1.3%)	0 (0.0%)	2 (2.5%)
Schleswig-Holstein	0 (0.0%)	0 (0.0%)	0 (0.0%)
Eastern Germany, excluding Berlin	**19 (12.3%)**	**5 (6.9%)**	**14 (17.7%)**
Brandenburg	2 (1.3%)	0 (0.0%)	2 (2.5%)
Mecklenburg-Western Pomerania	1 (0.6%)	0 (0.0%)	1 (1.3%)
Saxony	7 (4.5%)	3 (4.2%)	4 (5.1%)
Saxony-Anhalt	5 (3.2%)	0 (0.0%)	5 (6.3%)
Thuringia	4 (2.6%)	2 (2.8%)	2 (2.5%)
Not specified	12 (7.8%)	5 (6.9%)	4 (5.1%)

Notes: Adapted from Sammons et al. (2021) (29). HIV, human immunodeficiency virus; Max, maximum; Min, minimum; SD, standard deviation; *3 respondents who were included in some of the analyses in the physician study did not provide information about their specialist status (HIV-specialists vs. non-HIV-specialists); †From independent samples t-tests of the null hypothesis that the mean value of non-HIV-specialists is equal to that of HIV-specialists (29); §From Pearson's Chi squared tests of the null hypothesis that there is no statistically significant difference between the observed and expected frequencies in each category, according to the HIV specialist status (29); #From Pearson's Chi squared tests of the null hypothesis that there is no statistically significant difference between the observed and expected frequencies in the categories "western German states" vs. "eastern German states" according to HIV specialist status (29).

3.2.3 Survey of service users

Of the 228 respondents who wrote a valid response to our question regarding their main motivation for using or considering PrEP, 65 were using PrEP or had used it at some point in the past, and 163 of were considering PrEP use (32). The mean age of all respondents was 36.4 years (SD=10.8; range: 20-79) (32). Data on their demographics and the sexual risk behaviour are given in Table 5, which also shows these data separately for those who were using PrEP (or had a history of its use) and those who were considering its use; the differences between these two subgroups were small and similar to the mostly analogous subgroups reported in the publication on the quantitative results (31) of the survey (32).

Table 5: Demographic data and sexual risk behaviour of respondents who answered the question about their motivation for using or considering PrEP

	Analysis sample (N=228)	**Participants using PrEP (or with history of its use)** (n=65)	**Participants considering PrEP** (n=163)
Age in years			
Mean (SD)	36.4 (10.8)	33.9 (6.9)	37.3 (11.8)
Min–max	20–79	24–53	20–79
Not stated	9	5	4
Highest degree or level of school (n, %)			
Primary education	0 (0.0%)	0 (0.0%)	0 (0.0%)
Secondary education up to year 10*	21 (9.2%)	3 (4.6%)	18 (11.0%)
Secondary education with apprenticeship	11 (4.8%)	1 (1.5%)	10 (6.1%)
Secondary education to year 12**	41 (18.0%)	7 (10.8%)	34 (20.9%)
University degree	151 (66.2%)	50 (76.9%)	101 (62.0%)
Not stated	4 (1.8%)	4 (6.2%)	0 (0.0%)
Financial situation (n, %)			
Not always have enough money	19 (8.3%)	7 (10.8%)	12 (7.4%)
Enough money	104 (45.6%)	25 (38.5%)	79 (48.5%)
More than enough money	102 (44.7%)	30 (46.2%)	72 (44.2%)
Not stated	3 (1.3%)	3 (4.6%)	0 (0.0%)
Place of residence (n, %)			
Berlin	213 (93.4%)	60 (92.3%)	153 (93.9%)
Other city in Germany	7 (3.1%)	1 (1.5%)	6 (3.7%)
Small town / rural area in Germany	0 (0.0%)	0 (0.0%)	0 (0.0%)
Other country	5 (2.2%)	1 (1.5%)	4 (2.5%)
Not stated	3 (1.3%)	3 (4.6%)	0 (0.0%)
Family origins (n, %)			
Respondent & both parents born in Germany	132 (57.9%)	29 (44.6%)	103 (63.2%)
One parent born outside Germany	17 (7.5%)	7 (10.8%)	10 (6.1%)
Both parents born outside Germany	19 (8.3%)	7 (10.8%)	12 (7.4%)
Respondent born outside Germany	56 (24.6%)	19 (29.2%)	37 (22.7%)
Not stated	4 (1.8%)	3 (4.6%)	1 (0.6%)
Current HIV status (n, %)			
HIV negative	198 (86.8%)	61 (93.8%)	137 (84.0%)

Not sure	24 (10.5%)	0 (0.0%)	24 (14.7%)
Not stated	6 (2.6%)	4 (6.2%)	2 (1.2%)
STI diagnosis in the past six months (n, %)			
No	168 (73.7%)	37 (56.9%)	131 (80.4%)
Yes	57 (25.0%)	25 (38.5%)	32 (19.6%)
Not stated	3 (1.3%)	3 (4.6%)	0 (0.0%)
Role when having anal sex (n, %)			
No anal sex	7 (3.1%)	0 (0.0%)	7 (4.3%)
Bottom only	21 (9.2%)	6 (9.2%)	15 (9.2%)
More bottom than top	60 (26.3%)	15 (23.1%)	45 (27.6%)
Top and bottom (versatile)	58 (25.4%)	19 (29.2%)	39 (23.9%)
More top than bottom	49 (21.5%)	12 (18.5%)	37 (22.7%)
Top only	30 (13.2%)	10 (15.4%)	20 (12.3%)
Not stated	3 (1.3%)	3 (4.6%)	0 (0.0%)
Number of anal sex partners in the past six months (n, %)			
None	14 (6.1%)	0 (0.0%)	14 (8.6%)
1	22 (9.6%)	2 (3.1%)	20 (12.3%)
2 to 5	67 (29.4%)	12 (18.5%)	55 (33.7%)
6 to 10	44 (19.3%)	13 (20.0%)	31 (19.0%)
More than 10	76 (33.3%)	35 (53.8%)	41 (25.2%)
Not stated	5 (2.2%)	3 (4.6%)	2 (1.2%)
Number of anal sex partners without using condom in the past six months (n, %)			
None	62 (27.2%)	6 (9.2%)	56 (34.4%)
1	54 (23.7%)	7 (10.8%)	47 (28.8%)
2 to 5	71 (31.1%)	23 (35.4%)	48 (29.4%)
6 to 10	21 (9.2%)	11 (16.9%)	10 (6.1%)
More than 10	17 (7.5%)	15 (23.1%)	2 (1.2%)
Not stated	3 (1.3%)	3 (4.6%)	0 (0.0%)

Notes: Adapted from Gaskins et al. (2021) (32). HIV, human immunodeficiency virus; Max, maximum; Min, minimum; PrEP, pre-exposure prophylaxis; SD, standard deviation; STI, sexually transmitted infection; *or similar; **for example A levels, high school diploma, German “Abitur”.

Additionally, Table S1 in the supplementary appendix of our publication on the multi-methods study of the service user survey (32) shows a comparison of the demographic data, as well as the sexual risk behaviour, of respondents from our analysis sample and the 104 respondents who indicated they were neutral about PrEP or might be interesting in taking it but did not give a free-text answer to our question about their motivation (32). The comparison suggests that respondents who did not give a free-text response were similar to those who did with regard to age, level of educational attainment and place of residence, but differed in that a substantially greater percentage of them reported being not as financially secure, being uncertain about their HIV status, having never used PrEP and engaging in sexual behaviour that placed them at a lower risk of infection with HIV (32).

3.3 Consultations and PrEP counselling practice of providers

3.3.1 Counsellor survey

Table 6 gives data on the number of consultations and the proportion of consultations in which counsellors proactively gave PrEP advice to at-risk individuals, among other variables reported by the participants. On the average, counsellors had 36.55 (SD=48.23) consultations with MSM and transgender people per month, of which 15.97 (SD=22.17) sessions, or 43.7%, were with at-risk individuals; there were no significant differences in these two variables between NGCs and LHOs (30). With regard to the sample as a whole, the participating counsellors reported that they proactively gave PrEP advice to at-risk individuals in a median of 50.00% (IQR=70.00) consultations (30). The proportion of PrEP advice that the counsellors provided proactively was larger in NGCs (Mdn=50.00%, IQR=60.00) than it was in LHOs (Mdn=30.00%, IQR=70.00), U=1082.0, p=0.003 (30). Another difference between the two types of centre could be seen in the number of HIV tests conducted per month, which was significantly higher in LHOs (Mdn=180.00, IQR=190.00) than in NGCs (Mdn=47.50, IQR=73.75), U=1103.5, p<0.001 (30). There were no significant differences between LHOs and NGCs in terms of the absolute number or relative number of positive HIV tests each month (30).

3.3.2 Physician survey

Table 7 gives data on the number of consultations and the proportion of consultations in which physicians proactively gave PrEP advice to at-risk individuals, among other variables reported by participants. We found significant differences between HIV-specialists and non-HIV-specialists for all of the variables in the table, unlike in the counsellor survey, where we found a significant difference between the centres for the total number of HIV tests per month and the proportion of consultations with at-risk individuals in which counsellors proactively addressed the topic of PrEP (cf. Table 6). On the average, physicians had 162.50 (SD=213.05) consultations with MSM and transgender persons per calendar quarter, of which 71.74 (SD=114.08), or 44.2%, were with at-risk individuals. With regard to the sample as a whole, the participating physicians reported that they proactively gave PrEP advice to at-risk individuals in a median of 15.48% (IQR=50.0) of their consultations with at-risk service users, which

Table 6: Consultations, HIV tests and PrEP counselling practice reported in the counsellor survey

Variable	Total sample	NGCs	LHOs	
Number of consultations with MSM & transgender people per month (n=126)				*p=0.784†*
Median (IQR)	20.00 (35.00)	25.00 (30.00)	20.00 (40.00)	
Mean (SD)	36.55 (48.23)	34.96 (46.03)	39.21 (52.13)	
Min–max	0–330	0–330	0–270	
Number of consultations with at-risk MSM & transgender people per month (n=116)				*p=0.780†*
Median (IQR)	10.00 (10.00)	10.00 (10.00)	10.00 (12.50)	
Mean (SD)	15.97 (22.17)	16.35 (24.23)	15.38 (18.70)	
Min–max	0–170	1–170	0–80	
Overall number of HIV tests per month (n=123)				*p<0.001†*
Median (IQR)	60.00 (175.00)	47.50 (73.75)	180.00 (190.00)	
Mean (SD)	112.69 (109.85)	81.70 (93.87)	162.81 (116.12)	
Min–max	3–400	8–350	3–400	
Number of positive HIV test results per month (n=117)				*p=0.311†*
Median (IQR)	0.00 (1.00)	0.00 (1.00)	1.00 (1.00)	
Mean (SD)	0.67 (0.83)	0.60 (0.78)	0.78 (0.90)	
Min–max	0–4	0–4	0–3	
Proportion of positive HIV tests per month (n=117)				*p=0.373†*
Median (IQR)	0.00% (0.93)	0.00% (1.67)	0.33% (0.65)	
Mean (SD)	0.74% (1.49)	0.99% (1.84)	0.34% (0.38)	
Min–max	0–12.5%	0–12.5%	0–1.25%	
Proportion of consultations with at-risk MSM and transgender people in which counsellors proactively addressed topic of PrEP (n=116)				*p=0.003†*
Median (IQR)	50.00% (70.00)	50.00% (60.00)	30.00% (70.00)	
Mean (SD)	51.98% (34.24)	58.73% (30.98)	41.33% (36.72)	
Min–max	0–100%	10–100%	0–100%	

Notes: Adapted from Kutscha et al. (2020) (30). “at-risk”, meeting the criteria to be offered PrEP according to the German and Austrian PrEP guideline; HIV, human immunodeficiency virus; IQR, interquartile range; LHOs, local health offices; Max, maximum; Min, minimum; MSM, men who have sex with men; NGCs, non-governmental counselling centres; PrEP, (HIV) pre-exposure prophylaxis; SD, standard deviation. †From Mann-Whitney U tests of the null hypothesis that the median value of participants from LHOs is equal to that of participants from NGCs (30).

was substantially lower than the proportion reported by sexual health counsellors (50.00%, IQR=70.00). The proportion of consultations with at-risk service users in which participating physicians proactively gave PrEP advice was significantly higher among HIV-specialists than non-HIV-specialists (Mdn=30.00%, IQR=63.40 vs. 0.00%, IQR=11.32, respectively, U=468.500, p<0.001).

Table 7: Consultations, HIV tests and PrEP counselling practice reported in the physician survey

Variable	Total sample	HIV-specialists	Non-HIV-specialists	
Number of consultations with MSM & transgender people per quarter (n=141)				*p<0.001†*
Median (IQR)	30.00 (345.00)	375.00 (400.00)	5.00 (18.00)	
Mean (SD)	162.50 (213.05)	327.88 (210.47)	16.97 (33.20)	
Q1–Q3	5–350	100–500	2–20	
Number of consultations with at-risk MSM & transgender people per quarter (n=131)				*p<0.001†*
Median (IQR)	17.00 (99.00)	100.00 (170.00)	1.00 (6.00)	
Mean (SD)	71.74 (114.08)	143.60 (132.33)	7.17 (15.33)	
Q1–Q3	1–100	30–200	0–6	
Overall number of HIV tests per quarter (n=145)				*p<0.001†*
Median (IQR)	20.00 (87.00)	80.00 (195.00)	4.0 (17.75)	
Mean (SD)	73.14 (124.03)	139.94 (152.79)	12.50 (23.21)	
Q1–Q3	3–90	30–225	1.00–18.75	
Number of positive HIV test results per quarter (n=143)				*p<0.001†*
Median (IQR)	1.00 (2.00)	2.00 (4.00)	0.00 (1.00)	
Mean (SD)	5.64 (30.46)	11.45 (43.93)	0.51 (1.36)	
Q1–Q3	0–2	1–5	0–1	
Proportion of positive HIV tests per quarter (n=140)				*p<0.001†*
Median (IQR)	1.63% (6.50)	2.83% (8.73)	0.00% (5.00)	
Mean (SD)	6.47% (12.41)	8.02% (10.16)	5.16% (13.96)	
Q1–Q3	0.00–6.50%	1.27–10.00%	0.00–5.00%	
Proportion of consultations with at-risk MSM and transgender people in which physicians themselves proactively address the topic PrEP (n=102)				*p<0.001†*
Median (IQR)	15.48% (50.00)	30.00% (63.50)	0.00% (11.32)	
Mean (SD)	30.20% (35.34)	40.70% (34.21)	16.36% (32.21)	
Q1–Q3	0.00–50.00%	11.50–75.00%	0.00–11.32%	

Notes: Adapted from Sammons et al. (2021) (29). "at-risk", meeting the criteria to be offered PrEP according to the German and Austrian PrEP guideline; HIV, human immunodeficiency virus; IQR, interquartile range; MSM, men who have sex with men; PrEP, (HIV) pre-exposure prophylaxis; Q1, first quartile; Q3, third quartile; SD, standard deviation. †From Mann-Whitney U-tests of the null hypothesis that the median value of HIV-specialists is equal to that of non-HIV-specialists (29).

3.4 Providers' self-assessment of their PrEP knowledge and counselling competence

3.4.1 Counsellor survey

Agreement with the statement in each self-assessed dimension of PrEP knowledge and counselling competence – and thus a positive self-assessment – was more frequent than disagreement, both among respondents from NGCs and from LHOs (30). There was, however, a significant association between the type of centre and the pattern of responses for each of the dimensions (Table 8) (30). Indeed, the differences between the

two types of centre in this regard appeared to be quite substantial: for example, the proportion of respondents from NGCs who agreed or strongly agreed with each statement was always larger than that in LHOs, with the difference ranging from roughly 15 to 40 percentage points depending on the statement (81). Furthermore, the proportion of midpoint responses among respondents from LHOs was (a) particularly large (i.e., 37.2%) for the item on side effects and (b) almost nine times larger than that among respondents from NGCs (i.e., 25.0% vs. 2.9%) in the case of the global self-assessment of PrEP knowledge. Cronbach's alpha for the summative knowledge score was α=0.966 (30). The summative knowledge score was significantly higher for respondents from NGCs (Mdn=18.00, IQR=5.00) than it was for respondents from LHOs (Mdn=14.00, IQR=4.00), U=679.5, p<0.001 (30).

3.4.2 Physician survey

Among physicians there was also a significant association between the category of respondent (i.e., HIV-specialist vs. non-HIV-specialist) and the pattern of responses for each of the dimensions (29). Unlike the counsellor survey, however, agreement with each of the statements about PrEP knowledge and counselling competence was more frequent than disagreement in only one of the two groups of respondents: HIV-specialists. Among non-HIV-specialists, the proportion of those who agreed or strongly agreed with these items was never higher than 27%, with the majority of these physicians disagreeing or strongly disagreeing with each item (range: 62.0-70.5%) (Table 8) (29). In line with these findings, the summative knowledge score was significantly higher for HIV-specialists (Mdn=20.00; IQR=0.00) than it was for non-HIV-specialists (Mdn=4.00; IQR=11.00), U=279.0, p<0.001 (29). Another difference between the results of the counsellor and physician surveys was as follows: although the proportion of HIV-specialists who agreed with each statement about PrEP knowledge and counselling competence was quite similar to that of counsellors at NGCs, the statement about being able to give comprehensive advice to service users about the side effects of PrEP was an exception: whereas 98.3% of HIV-specialists agreed or strongly agreed with the statement (midpoint response: 0%), this was the case for 80.0% of NG counsellors (midpoint response: 14.3%).

Table 8: Providers' self-assessment of their PrEP knowledge and counselling competence

Variable	Total sample counsellors	NGCs	LHOs	Total sample physicians	HIV-specialists	Non-HIV specialists
Global assessment: "I am well-informed about PrEP" (n, %)						
	n=113		*p<0.001*§	n=128		*p<0.001*#
Strongly disagree	1 (0.9%)	1 (1.4%)	0 (0.0%)	31 (24.2%)	1 (1.8%)	30 (42.3%)
Disagree	2 (1.8%)	1 (1.4%)	1 (2.3%)	17 (13.3%)	0 (0.0%)	17 (23.9%)
Neither agree nor disagree	13 (11.5%)	2 (2.9%)	11 (25.0%)	6 (4.7%)	1 (1.8%)	5 (7.0%)
Agree	44 (38.9%)	23 (33.3%)	21 (47.7%)	16 (12.5%)	4 (7.0%)	12 (16.9%)
Strongly agree	53 (46.9%)	42 (60.9%)	11 (25.0%)	58 (45.3%)	51 (89.5%)	7 (9.9%)
Indications: "I am able to give service users comprehensive advice on whether it makes sense to take PrEP in their respective case" (n, %)						
	n=113		*p<0.001*§	n=128		*p<0.001*#
Strongly disagree	1 (0.9%)	1 (1.4%)	0 (0.0%)	23 (18.0%)	1 (1.8%)	22 (31.0%)
Disagree	6 (5.3%)	1 (1.4%)	5 (11.6%)	22 (17.2%)	0 (0.0%)	22 (31.0%)
Neither agree nor disagree	9 (8.0%)	4 (5.7%)	5 (11.6%)	10 (7.8%)	1 (1.8%)	9 (12.7%)
Agree	38 (33.6%)	16 (22.9%)	22 (51,2%)	15 (11.7%)	5 (8.8%)	10 (14.1%)
Strongly agree	59 (52.2%)	48 (68.6%)	11 (25.6%)	58 (45.3%)	50 (87.7%)	8 (11.3%)
Side effects: "I am able to give service users comprehensive advice on the side effects of PrEP" (n, %)						
	n=113		*p<0.001*§	n=128		*p<0.001*#
Strongly disagree	3 (2.7%)	1 (1.4%)	2 (4.7%)	31 (24.2%)	1 (1.8%)	30 (42.3%)
Disagree	11 (9.7%)	3 (4.3%)	8 (18.6%)	19 (14.8%)	0 (0.0%)	19 (26.8%)
Neither agree nor disagree	26 (23.0%)	10 (14.3%)	16 (37.2%)	7 (5.5%)	0 (0.0%)	7 (9.9%)
Agree	37 (32.7%)	26 (37.1%)	11 (25.6%)	11 (8.6%)	3 (5.3%)	8 (11.3%)
Strongly agree	36 (31.9%)	30 (42.9%)	6 (14.0%)	60 (46.9%)	53 (93.0%)	7 (9.9%)
Modalities of intake: "I am able to give service users comprehensive advice on the possible modalities of intake of PrEP (e.g., continuous vs. on-demand)" (n, %)						
	n=113		*p<0.001*§	n=128		*p<0.001*#
Strongly disagree	2 (1.8%)	1 (1.4%)	1 (2.3%)	31 (24.2%)	1 (1.8%)	30 (42.3%)
Disagree	13 (11.5%)	2 (2.9%)	11 (25.6%)	20 (15.6%)	0 (0.0%)	20 (28.2%)
Neither agree nor disagree	8 (7.1%)	5 (7.1%)	3 (7.0%)	5 (3.9%)	1 (1.8%)	4 (5.6%)
Agree	35 (31.0%)	15 (21.4%)	20 (46.5%)	10 (7.8%)	2 (3.5%)	8 (11.3%)
Strongly agree	55 (48.7%)	47 (67.1%)	8 (18.6%)	62 (48.4%)	53 (93.0%)	9 (12.7%)
Investigations: "I am able to give service users comprehensive advice on the medical investigations necessary during the use of PrEP" (n, %)						
	n=113		*p = 0.002*§	n=128		*p<0.001*#
Strongly disagree	3 (2.7%)	1 (1.4%)	2 (4.7%)	29 (22.7%)	1 (1.8%)	28 (39.4%)
Disagree	10 (8.8%)	2 (2.9%)	8 (18.6%)	20 (15.6%)	0 (0.0%)	20 (28.2%)
Neither agree nor disagree	10 (8.8%)	6 (8.6%)	4 (9.3%)	6 (4.7%)	1 (1.8%)	5 (7.0%)
Agree	37 (32.7%)	19 (27.1%)	18 (41.9%)	9 (7.0%)	2 (3.5%)	7 (9.9%)
Strongly agree	53 (46.9%)	42 (60.0%)	11 (25.6%)	64 (50.0%)	53 (93.0%)	11 (15.5%)
Knowledge score (0-20)						
	n=112		*p < 0.001*†	n=128		*p<0.001*†
Median (IQR)	17.00 (6.00)	18.00 (5.00)	14.00 (4.00)	15.00 (17.00)	20.00 (0.00)	4.00 (11.00)
Mean (SD)	15.64 (4.43)	17.10 (3.82)	13.30 (4.38)	11.89 (8.43)	19.23 (2.96)	6.49 (6.76)
Min–max (or phys: Q1-Q3)	0–20	0–20	4–20	3–20	20–20	0–11

Notes: Adapted from Kutscha et al. (2020) (30) and Sammons et al. (2021) (29). IQR, interquartile range; LHOs, local health offices; MSM, men who have sex with men; NGCs, non-governmental counselling centres; phys, physicians; PrEP, (HIV) pre-exposure prophylaxis; Q1, first quartile; Q3, third quartile; SD, standard deviation. §From Pearson's Chi squared tests of the null hypothesis that there is no statistically significant difference between the observed and expected frequencies in each category, by type of counselling centre (30); †From Mann-Whitney U tests of the null hypothesis that the median value of participants from LHOs (or non-HIV-specialists) is equal to that of participants from NGCs (or HIV-specialists) (29, 30); #From Fisher's Exact tests of the null hypothesis that there is no statistically significant difference between the observed and expected frequencies in each category, by physician group (29).

3.5 Providers' self-reported attitudes towards PrEP

3.5.1 Counsellor survey

Agreement with each of the four statements expressing a positive attitude towards PrEP was more frequent than disagreement among respondents from both types of centre (30). For the statement expressing a negative attitude towards PrEP, disagreement was more frequent than agreement, also among respondents from both types of centre (30). As was the case for the statements on PrEP knowledge and counselling competence, there was a significant association between the type of centre and the pattern of responses for each of the attitude-related statements (Table 9) (30). Here, too, the differences between the two types of centre appeared to be quite substantial: the proportion of respondents from NGCs who agreed or strongly agreed with each positive statement (or disagreed or strongly disagreed with the negative statement) was always larger than that in LHOs, with the difference, again, ranging from roughly 15 to 40 percentage points depending on the statement (81). Furthermore, as was the case for PrEP knowledge and counselling competence, the proportion of midpoint responses among respondents from LHOs was particularly large (i.e., 40.9%) for the item on side effects. It was also quite large (i.e., 29.5%) for the item on reimbursement of costs. Cronbach's alpha for the summative attitude score was $\alpha=0.847$ (30). The summative attitude score was, again, significantly higher for respondents from NGCs (Mdn=18.00, IQR=4.00) than it was for respondents from LHOs (Mdn=14.00, IQR=6.75), $U=638.5$, $p<0.001$) (30).

3.5.2 Physician survey

Among physicians, there was also a significant association between the category of respondent (i.e., HIV-specialist vs. non-HIV-specialist) and the pattern of responses for each of the attitude-related dimensions (Table 9) (29). As with the counsellors, agreement with each of the four statements expressing a positive attitude towards PrEP was more frequent than disagreement among both categories of respondent – but with one exception: the item on side effects, where 30.9% of non-HIV-specialists agreed or strongly agreed that PrEP is a method to protect oneself from HIV that has few side effects versus 32.4% who disagreed or strongly disagreed (and 36.8% who gave a midpoint response) (29). For the statement expressing a negative attitude towards PrEP, as was the case with the counsellor survey, disagreement was more frequent than agreement both among

HIV-specialists or Non-HIV-specialists (29). Among the latter, the proportion of those who gave a midpoint response to this item, however, was almost twice that of respondents from LHOs who gave a midpoint response (28.1% vs. 15.9%). As with the summative knowledge score reported above, the summative attitudes score was higher among HIV-specialists (Mdn=18.00, IQR=3.00) than among non-HIV-specialists (Mdn=13.00, IQR=5.25), U=588, p<0.001 (29), roughly mirroring the results for counsellors from NGCs and LHOs, respectively.

3.6 Multiple linear regression on the proportion of consultations in which providers proactively gave PrEP advice

We used multiple linear regression to identify independent predictors of the proportion of consultations in which providers proactively gave PrEP advice to at-risk individuals (30). In the study on the counsellor survey, after applying backward elimination with p<0.2 as a stopping rule for excluding variables, we obtained a significant regression equation ($F_{(2, 109)}$=10.50, p<0.001, n=112) with R^2=0.162 (Table 10) in which the only independent predictors that remained were the knowledge score and the attitudes score (30). Using this model, the proportion of consultations in which counsellors proactively gave PrEP advice to at-risk individuals was predicted to increase by 1.7% and by 2.1% for each point increase in the knowledge score and attitudes score, respectively (30). In the study on the physician survey, we applied a method involving both backward elimination and stepwise forward elimination using a stopping rule of p<0.2 for the exclusion or inclusion of each variable (29). In doing so, we obtained a significant regression equation ($F_{(3,79)}$=7.70, p<0.001, n=83) with R^2=0.165 (Table 11) in which the only independent predictors that remained were city size, knowledge score and attitudes score; the only statistically significant predictor, however, was ultimately the knowledge score (29). Using this model, the proportion of consultations in which physicians proactively provided PrEP advice to at-risk individuals was predicted to increase by 1.8% for each point increase in the knowledge score (29).

Table 9: Providers' self-reported attitudes towards PrEP

Variable	Total sample counsellors	NGCs	LHOs	Total sample physicians	HIV-specialists	Non-HIV specialists
Global assessment: "I think that PrEP is an important element of HIV prevention strategies" (n, %)						
	n=114		*p<0.001*§	n=126		*p<0.001*#
Strongly disagree	1 (0.9%)	0 (0.0%)	1 (2.3%)	1 (0.8%)	0 (0.0%)	1 (1.4%)
Disagree	2 (1.8%)	0 (0.0%)	2 (4.5%)	7 (5.6%)	1 (1.8%)	6 (8.7%)
Neither agree nor disagree	11 (9.6%)	3 (4.3%)	8 (18.2%)	10 (7.9%)	1 (1.8%)	9 (13.0%)
Agree	16 (14.0%)	3 (4.3%)	13 (29.5%)	30 (23.8%)	4 (7.0%)	26 (37.7%)
Strongly agree	84 (73.7%)	64 (91.4%)	20 (45.5%)	78 (61.9%)	51 (89.5%)	27 (39.1%)
Reliability: "I think that PrEP is a reliable method to protect oneself from HIV" (n, %)						
	n=114		*p=0.003*§	n=124		*p<0.001*#
Strongly disagree	0 (0.0%)	0 (0.0%)	0 (0.0%)	5 (4.0%)	0 (0.0%)	5 (7.5%)
Disagree	6 (5.3%)	2 (2.9%)	4 (9.1%)	8 (6.5%)	0 (0.0%)	8 (11.9%)
Neither agree nor disagree	7 (6.1%)	2 (2.9%)	5 (11.4%)	19 (15.3%)	4 (7.0%)	15 (22.4%)
Agree	33 (28.9%)	15 (21.4%)	18 (40.9%)	44 (35.5%)	16 (28.1%)	28 (41.8%)
Strongly agree	68 (59.6%)	51 (72.9%)	17 (38.6%)	48 (38.7%)	37 (64.9%)	11 (16.4%)
Side effects: "I think that PrEP is a method to protect oneself from HIV that has few side effects" (n, %)						
	n=114		*p=0.002*§	n=124		*p<0.001*#
Strongly disagree	8 (7.0%)	5 (7.1%)	3 (6.8%)	5 (4.0%)	0 (0.0%)	5 (7.4%)
Disagree	12 (10.5%)	4 (5.7%)	8 (18.2%)	19 (15.3%)	2 (3.6%)	17 (25.0%)
Neither agree nor disagree	32 (28.1%)	14 (20.0%)	18 (40.9%)	36 (29.0%)	11 (19.6%)	25 (36.8%)
Agree	32 (28.1%)	21 (30.0%)	11 (25.0%)	37 (29.8%)	21 (37.5%)	16 (23.5%)
Strongly agree	30 (26.3%)	26 (37.1%)	4 (9.1%)	27 (21.8%)	22 (39.3%)	5 (7.4%)
Better alternatives: "I think PrEP is unnecessary as there are better alternatives to protect oneself from HIV" (n, %)						
	n=114		*p<0.001*§	n=121		*p=0.003*#
Strongly disagree	67 (58.8%)	53 (75.7%)	14 (31.8%)	54 (44.6%)	34 (59.6%)	20 (31.3%)
Disagree	30 (26.3%)	12 (17.1%)	18 (40.9%)	38 (31.4%)	17 (29.8%)	21 (32.8%)
Neither agree nor disagree	11 (9.6%)	4 (5.7%)	7 (15.9%)	23 (19.0%)	5 (8.8%)	18 (28.1%)
Agree	5 (4.4%)	1 (1.4%)	4 (9.1%)	3 (2.5%)	1 (1.8%)	2 (3.1%)
Strongly agree	1 (0.9%)	0 (0.0%)	1 (2.3%)	3 (2.5%)	0 (0.0%)	3 (4.7%)
Reimbursement of costs: "I think that PrEP should be paid for by statutory health insurance" (n, %)						
	n=114		*p<0.001*§	n=124		*p=0.001*#
Strongly disagree	8 (7.0%)	3 (4.3%)	5 (11.4%)	10 (8.1%)	1 (1.8%)	9 (13.4%)
Disagree	9 (7.9%)	3 (4.3%)	6 (13.6%)	15 (12.1%)	3 (5.3%)	12 (17.9%)
Neither agree nor disagree	16 (14.0%)	3 (4.3%)	13 (29.5%)	23 (18.5%)	10 (17.5%)	13 (19.4%)
Agree	22 (19.3%)	13 (18.6%)	9 (20.5%)	25 (20.2%)	9 (15.8%)	16 (23.9%)
Strongly agree	59 (51.8%)	48 (68.6%)	11 (25.0%)	51 (41.1%)	34 (59.6%)	17 (25.4%)
Attitude Score (0-20)						
	n=114		*p<0.001*†	n=118		*p<0.001*†
Median (IQR)	17.50 (5.00)	18.00 (4.00)	14.00 (6.75)	15.50 (5.00)	18.00 (3.00)	13.00 (5.25)
Mean (SD)	15.96 (4.01)	17.46 (3.10)	13.57 (4.16)	14.93 (3.92)	17.29 (2.59)	12.90 (3.78)
Min–max (or phys: Q1-Q3)	4–20	7–20	4–20	13–18	16–19	10–15.25

Notes: Adapted from Kutscha et al. (2020) (30) and Sammons et al. (2021) (29). IQR, interquartile range; LHOs, local health offices; MSM, men who have sex with men; NGCs, non-governmental counselling centres; phys, physicians; PrEP, (HIV) pre-exposure prophylaxis; Q1, first quartile; Q3, third quartile; SD, standard deviation. †From Mann-Whitney U-tests of the null hypothesis that the median value of participants from LHOs (or HIV-specialists) is equal to that of participants from NGCs (or non-HIV-specialists) (29, 30); §From Pearson's Chi squared tests of the null hypothesis that there is no statistically significant difference between the observed and expected frequencies in each category, by type of counselling centre (30); #From Fisher's Exact tests of the null hypothesis stating that there is no statistically significant difference between the observed and expected frequencies in each category, according to physician group (29).

Table 10: Multiple linear regression to predict the proportion of consultations in which counsellors proactively provided PrEP advice to at-risk MSM and transgender people

Predictors	**Coefficient** (robust SE)	**Beta**	***p***	**VIF**
Constant	-8.208 (11.468)		0.476	
Knowledge score[1]	1.692 (0.842)	0.221	0.047	1.26
Attitudes score[2]	2.111 (0.910)	0.250	0.022	1.26

Note: From Kutscha et al. (2020) (30). "at-risk", meeting the criteria to be offered PrEP according to the German and Austrian PrEP guideline; SE, standard error; VIF, variance inflation factor; [1]Scale from 0 to 20 points, with higher scores indicating a more positive self-assessment of knowledge about PrEP and counselling competence (30); [2]Scale from 0 to 20 points, with higher scores indicating a more positive attitude towards PrEP (30).

Table 11: Multiple linear regression to predict the proportion of consultations in which physicians proactively provided PrEP advice to at-risk MSM and transgender people

Predictors	**Coefficient** (robust SE)	**Beta**	***p***	**VIF**
Constant	-32.632 (16.238)		0.048	
Size of the city[1]	6.107 (4.553)	0.170	0.184	1.39
Knowledge score[2]	1.782 (0.585)	0.320	0.003	2.00
Attitudes score[3]	1.851 (1.031)	0.191	0.077	1.57

Note: Adapted from Sammons et al. (2021) (29). "at-risk", meeting the criteria to be offered PrEP according to the German and Austrian PrEP guideline; SE, standard error; VIF, variance inflation factor; [1]Size of the city coded in four categories with 0 indicating more than 1,000,000 inhabitants and 3 indicating fewer than 10,000 inhabitants (29); [2]Scale from 0 to 20 points, with higher scores indicating a more positive self-assessment of knowledge about PrEP and counselling competence (29); [3]Scale from 0 to 20 points, with higher scores indicating a more positive attitude towards PrEP (29).

3.7 Guidelines, training and educational material

In total, 113 participants (77.9%) in the counsellor survey and 121 participants (78.6%) in the physician survey answered the question about which materials or tools they thought would improve counselling on PrEP or make it more practical (29, 30). The most frequent responses in both surveys were a decision aid for service users that provides information on PrEP in user-friendly language (counsellors: 78.8%, n=89; physicians: 71.9%, n=87) or in different languages (counsellors: 78.8%, n=89; physicians: 56.2%, n=68) (29, 30). The next most frequent response in both surveys was a clinical practice guideline that provides a good overview of indications, contraindications and necessary investigations (counsellors: 74.3%, n=84; physicians: 53.7%, n=65) (29, 30).

Less frequently mentioned materials or training were: an app- or text-message-based reminder for PrEP users to promote adherence (counsellors: 58.4%, n=66; physicians:

45.5%, n=65); information and training for providers on the management of PrEP (counsellors: 45.1%, n=51; physicians: 53.7%, n=65); information and training for providers on the identification of PrEP candidates (counsellors: 38.1%, n=43; physicians: 38.8%, n=47), and information and training for providers on talking with service users about sexuality (counsellors: 28.3%, n=32; physicians: 29.8%, n=36).

In the counsellor survey, we additionally asked participants if the organisation at which they worked had in-house PrEP guidelines or standard operating procedures. Slightly fewer than half responded in the affirmative (48.7%, n=55). We also asked if they had already received internal or external training on PrEP and PrEP counselling. Here, an affirmative response was given by a large majority of counsellors (86.0%, n=98). When then asked if they would like to receive further training on PrEP counselling, fewer than half of respondents replied in the affirmative (44.6%, n=50). There were no significant differences between the two types of counselling centre for any of these additional questions.

In contrast, significantly more non-HIV-specialists than HIV-specialists indicated that they wished to receive educational material or training on how to manage PrEP users (61.9% vs. 43.6%, $\chi^2(df=1, n=118) = 3.938$, $p=0.047$) and to identify PrEP candidates (50.8% vs. 25.5%, $\chi^2(df=1, n=118) = 7.926$, $p=0.005$).

3.8 Barriers for potential PrEP users as perceived by participating providers

When counsellors were asked to rate the relevance of barriers for potential PrEP users to initiate PrEP as perceived in their personal counselling experience, they pointed most frequently to service users' worries about getting infected with other sexually transmitted infections (M=5.56, SD=2.73), the monthly cost of the PrEP medication (M=5.33, SD=2.61), and a lack of information about PrEP in the native language of the service user (M=5.10, SD=3.33). The barriers selected least frequently by counsellors were service users underestimating their own risk of acquiring HIV infection (M=4.08, SD=2.70), service user worries about stigmatization in the peer group (M=3.33, SD=2.67), and cultural barriers (M=2.79, SD=2.51). Further results on barriers for service users to initiate PrEP as perceived by participating counsellors are shown in Table 12.

When physicians were asked to rate the relevance of barriers for potential PrEP as perceived in their personal experience, they pointed to service users underestimating their

own risk of acquiring HIV infection (M=7.13, SD=2.47), service users' difficulties in finding a doctor who prescribes PrEP (M=6.09, SD 3.60), and the lack of information about PrEP in the native language of the service user (M=5.59, SD 3.00). The barriers selected least frequently by physicians were service users' worries about severe of permanent side effects (M=4.44, SD=3.19), service users' worried about mild or temporary side effects (M=4.00, SD=2.95) and stigmatization in the service users' peer group (M=3.88, SD=3.00). Further results on barriers for service users as perceived by participating physicians are shown in Table 12.

In both provider surveys, it was notable that the mean values of the items were clustered around the middle point of the 11-point scale. In the counsellor survey, three of the items had a mean value in the middle point between 5.00 and 6.00, seven of the items had a mean value between 4.00 and 5.00, and no items had a mean value above 6.00. In the physician survey, six of the items had a mean value within the middle point, three items between 4.00 and 5.00 and two items above 6.00.

In the physician survey, we additionally asked about the relevance of two barriers for physicians. Here, the time-consuming management of (potential) PrEP users was regarded as a relevant barrier (M=6.09, SD=3.13), but this was less the case with difficulties identifying those who would benefit from PrEP (M=4.32, SD=3.37).

3.9 Motivations of service users to use or consider PrEP

Participants reported motivations ranging in number from one to five, with a mean of 1.38 and a median of 1.0; in particular, among the 228 responses to our question regarding the motivation of participants for using or considering PrEP, we coded 152 as describing one, 66 as describing two, nine as describing three, and one as describing five motivations (32). Free-text responses containing more than one motivation reported these motivations clearly in the form of a list using a comma or other kind of punctuation, the conjunctions "but" or "and", or some combination of these elements (32).

An overview of the various motivation categories and the number of respondents reporting one or multiple motivations exclusively in each (or a combination of) these is given in Table 13. In total, 154 respondents reported a form of safety/protection against HIV as their only motivation (n=121) or as one of multiple motivations (n=33) for using/considering PrEP (32).

Table 12: Barriers for potential PrEP users as perceived by participating counsellors and physicians

Barriers for service users from the counsellor perspective	n	M (SD)	Barriers for service users from the physician perspective	n	M (SD)
Worries about getting infected with other STIs	111	5.56 (2.73)	Service users' assessment of own risk of getting infected with HIV as too low to take PrEP	69	7.13 (2.47)
The monthly costs of the PrEP medication	109	5.33 (2.61)	Difficulties finding a doctor who prescribes PrEP	74	6.09 (3.60)
Lack of information about PrEP in the native language of the service user	110	5.10 (3.33)	Lack of information about PrEP in the native language of the service user	68	5.59 (3.00)
The costs for the laboratory tests	109	4.80 (3.00)	Lack of information about PrEP in service-user-friendly language	68	5.44 (3.10)
Worries about mild or temporary side effects	109	4.64 (2.43)	The monthly costs of the PrEP medication	69	5.30 (3.36)
Time required for regular visits to the doctor	111	4.26 (2.81)	Worries about getting infected with other STIs	71	5.24 (3.14)
Worries about severe or permanent side effects	111	4.21 (2.59)	The costs of the laboratory tests	73	5.26 (3.30)
Lack of information about PrEP in service-user-friendly language	110	4.17 (2.88)	Time required for regular visits to the doctor	66	5.20 (2.99)
Difficulties finding a doctor who prescribes PrEP	112	4.13 (3.64)	Cultural barriers	72	4.96 (3.20)
Service users' assessment of own risk of getting infected with HIV as too low to take PrEP	110	4.08 (2.70)	Worries about severe or permanent side effects	68	4.44 (3.19)
Worries about stigmatization in the peer group	107	3.33 (2.67)	Worries about mild or temporary side effects	67	4.00 (2.95)
Cultural barriers	110	2.79 (2.51)	Worries about stigmatization in the peer group	69	3.88 (3.00)

Notes: Adapted from Kutscha et al. (2020) (30) and Sammons et al. (2021) (29). HIV, human immunodeficiency virus; M, mean; PrEP, (HIV) pre-exposure prophylaxis; SD, standard deviation. Values from Sammons et al. (2021) (29) reported here as means and standard deviations to facilitate comparison with the counsellor survey.

Another 50 reported a form of mental well-being/quality of life as their only motivation (n=23) or as one of multiple motivations (n=27) (32). This was followed by 43 respondents who reported condom attitudes (that is, a desire/intention to engage in sex without a condom) as their only motivation (n=21) or as one of multiple motivations (n=22) (32). Finally, there were 31 respondents who reported some form of expectations regarding sexuality as their only (n=14) or one of multiple motivations (n=17) (32). Two respondents reported

norms/social perspectives as their only motivation for using/considering PrEP (32). Of those respondents reporting two motivations overall, the only combinations of motivations comprising roughly 5% or more of the analysis sample were in the categories safety and mental well-being (12 respondents, 5.3%) and safety and condom attitudes (10 respondents, 4.4%) (32). Between the two subsamples, the difference in frequencies of categories of motivations was not statistically significant (Fisher's exact test, p=0.234); our post hoc pairwise comparison of the frequencies also revealed that none of these differed in a statistically significant fashion between the subsamples when we set the alpha level to 0.003 (that is, 0.05/13) as part of a Bonferroni correction (32).

Table 13: Participants reporting one or more motivations exclusively in a category or combination of categories in the analysis sample, by subgroup (using or considering PrEP)

Category of motivation(s) for using or considering PrEP	**Participants in analysis sample** (N=228)	**Participants using PrEP (or with history of its use)** (n=65)	**Participants considering PrEP use** (n=163)
Safety	121 (53.1%)	30 (46.2%)	91 (55.8%)
Mental well-being	23 (10.1%)	7 (10.8%)	16 (9.8%)
Condom attitudes	21 (9.2%)	4 (6.2%)	17 (10.4%)
Expectations	14 (6.1%)	4 (6.2%)	10 (6.1%)
Norms	2 (0.9%)	1 (1.5%)	1 (0.6%)
TOTAL RESPONDENTS	**181**	**46**	**135**
Safety & mental well-being	12 (5.3%)	4 (6.2%)	8 (4.9%)
Safety & condom attitudes	10 (4.4%)	4 (6.2%)	6 (3.7%)
Safety & expectations	6 (2.6%)	5 (7.7%)	1 (0.6%)
Expectations & mental well-being	6 (2.6%)	3 (4.6%)	3 (1.8%)
Expectations & condom attitudes	4 (1.8%)	1 (1.5%)	3 (1.8%)
Mental well-being & condom attitudes	4 (1.8%)	1 (1.5%)	3 (1.8%)
TOTAL RESPONDENTS	**42**	**18**	**24**
Safety, mental well-being & condom attitudes	4 (1.8%)	1 (1.5%)	3 (1.8%)
Safety, expectations & mental well-being	1 (0.0%)	0 (0.0%)	1 (0.6%)
TOTAL RESPONDENTS	**5**	**1**	**4**

Notes: From Gaskins et al. (2021) (32). PrEP, (HIV) pre-exposure prophylaxis

We also looked at subcategories of motivations to add complexity to the picture through more fine-grained information (see Table 14) (32). In the category of safety, responses predominated that cited general aspects of safety and protection against HIV (mentioned by 40.4% of respondents); these were followed by more specific motivations, such as PrEP functioning as protection in addition to condom use (16.2%), being at risk of infection with HIV (7.5%), or wanting protection against HIV when not using condoms (6.1%)

(32). In total, 9 respondents (0.04%) mentioned safety/protection with regard to protecting others (32). In the category of condom attitudes, 18.0% percent of the respondents explicitly mentioned their desire to engage in sex without a condom as a motivation for using/considering PrEP (32). As a category, expectations about sexuality included as motivations explicit mentions of anxiety-/worry-free sex (8.3%) and sex that was more pleasurable (6.1%) (32). Finally, the category of mental well-being/quality of life included motivations that were related to worries, fear or anxiety about of HIV infection (8.6%), as well as a desire to increase sexual/personal freedom or quality of life (8.3%) (32). Specific examples of the motivations in these categories are given in Table 14 (32). One researcher (MG) translated all answers given in German into English for the table, and the accuracy and appropriateness of these were verified independently by the other authors, with disagreements resolved by consensus (32).

Table 14: Qualitative results for service users' motivations for using or considering PrEP according to category and subcategory, their frequency, and representative examples

CATEGORY: SAFETY / PROTECTION AGAINST HIV		
Subcategory	**Frequency**	**Example motivations**
General safety / Protection against HIV / Prevention of HIV	92/228 (40.4%)	"To protect myself from HIV" "Reduce the chance of HIV infection" "Safety regarding HIV infection" "HIV prophylaxis" "Health protection"
Additional protection against HIV	37/228 (16.2%)	"Additional safety when having sex" "Backup" "I want extra protection in case a condom fails or if I make a bad decision." "To protect myself from HIV if the condom slips off or loses its protection for some other reason" "Protection (double, with condom)"
Being at self-perceived risk of HIV	17/228 (7.5%)	"HIV-infected partner who has just begun therapy" "It has happened in the past, even though I didn't intend to, that I had sex without a condom" "Many casual sex partners from time to time" "Protection, I live in a long-term relationship with an HIV positive guy"
Protection against HIV when not using condoms	14/228 (6.1%)	"To feel safer in case of unprotected sex" "Easy protection when having sex without a condom" "Sex without a condom and hardly any risk of infection" "Protection against HIV without a condom"
Autonomy and self-empowerment	9/228 (3.9%)	"To protect myself more actively and not rely on others, for example regarding a condom" "More autonomy as (I am) more a bottom" "I have more safety and don't have to depend on my partner keeping the condom on" "Because I find it hard to trust people, so as a way to be more careful." "More control"
Protecting partner(s) or relationship(s)	9/228 (3.9%)	"To protect health (mine, of my partner & of my sex partner)" "To protect my opposite" "Protection for me and others" "Greater security in an open relationship" "The knowledge that I can't harm anybody with my actions"

		"My partner has HIV and we're in an open relationship"
Protection against HIV during periods of anticipated increased risk (e.g. recreational drug use, holidays)	5/228 (2.2%)	"To avoid accidents when I'm in environments that may affect my decisions and behaviour. At a party or around the time I go for a party. I am afraid that alcohol consumption or simply condom break may expose me to HIV." "Addition protection during special occasions (e.g., holiday)" "I have more security and don't have to rely on (...) myself, even under the influence of alcohol, insisting on a condom in every situation" "Protection against stupidity when drinking alcohol"
PrEP as an affordable protection against HIV	2/228 (0.0%)	"Protection, low costs" "It seems like an affordable option and viable way to help protect against HIV infection."
CATEGORY: MENTAL WELL-BEING AND QUALITY OF LIFE		
Subcategory	**Frequency**	**Example motivations**
Reducing anxiety, fear or worries of being infected with HIV	17/197 (8.6%)	"Paranoia, fear of getting infected" "Not constantly having to be afraid" "Less anxiety before the next HIV test" "My whole life there's only been sex with a condom and fear of HIV" "To free myself from fear" "Although I'm putting myself at risk of getting an STD, I find the benefits of PrEP overwhelmingly because I no longer have to fear that I'll get HIV"
Desire to increase quality of life or sexual / personal freedom	19/228 (8.3%)	"Peace of mind" "Convenience" "Quality of life" "Not always (….) having to take PEP" "Personal freedom" "Sexual freedom" "A feeling of security" "Uncomplicated sex" "Spontaneous sex (…) also with casual partners" "I'd like to try a few sex partners who I otherwise couldn't (try out) without being on PrEP" "So I can behave more like heterosexuals and not worry every time I choose not to use a condom"
Reducing periods of anticipated regret	8/228 (3.5%)	"The psycho-stress after unprotected sex" "No guilty conscience about unsafe sex" "To not feel regret after unsafe sex" "Less chance for my imagination to run away from me" ("weniger Kopfkino") "To have a better conscience after having unsafe sex"
Desire for a healthy life	7/228 (3.1%)	"To protect (my) health" "To not become ill" "Longer life" "Health" "Stay healthy"
CATEGORY: CONDOM ATTITTUDES		
Subcategory	**Frequency**	**Example motivations**
Desire or intent to engage in condomless sex	41/228 (18.0%)	"I don't like condoms" "Anal sex without a condom" "Unsafe sex" "Unprotected sex" "To have sex without condom with known sexual partners that test for other STDs regularly" "Unprotected sex with partner" "To have riskier sex"
Difficulties with condom use	2/228 (0.9%)	"Protection from HIV because I can't deal with condoms" "Problem with condom when being a top"
CATEGORY: EXPECTATIONS ABOUT SEXUALITY		
Subcategory	**Frequency**	**Example motivations**

Expectations of worry-free sex	19/228 (8.3%)	“It’s a way to feel safer when having sex” “More relaxed approach to sexuality” “Unencumbered Sex” “Sex without fear” “To have riskier sex without fear” “Carefree sex without worrying about HIV infection”
Expectations of more pleasureful sex	14/228 (6.1%)	“More pleasure” “Sex is more intense” “To enjoy sex” “To (…) enjoy sex more” “Intense feeling during sex” “More sensuality, more pleasure”
CATEGORY: NORMS / SOCIAL PERSPECTIVES		
Subcategory	**Frequency**	**Example motivations**
Perceiving condom-less sex / PrEP in-take as a social norm	1/228 (0.4%)	“More and more guys are doing bareback sex only”
Desire to eradicate HIV	1/228 (0.4%)	“Eradicating HIV”

Notes: From Gaskins et al. (2021) (32). PrEP, (HIV) pre-exposure prophylaxis; HIV, human immunodeficiency virus; STD, sexually transmitted disease

4 Discussion

From 2018 to 2019 we designed and conducted the first surveys in Germany to assess the knowledge of HIV pre-exposure prophylaxis (PrEP) among sexual health counsellors and physicians, as well their attitudes towards it and the role it plays in their consultations with men who have sex with men (MSM) and transgender people who are interested in, or have indications for, PrEP. We did so in response to the findings of an earlier survey of MSM in Berlin that we designed and conducted in 2017/18, and which, among other findings, helped confirm the presence in Germany of a substantial amount of unmet need with regard to PrEP, or a “PrEP gap”. We also conducted a separate multi-methods analysis of free-text data from this survey of MSM in order to gain a clearer picture of the factors affecting PrEP access and use on the side of health service users.

The chief aim of the entire suite of three surveys was to identify in an exploratory manner where there was potential to improve the implementation of PrEP, and to generate data and insights that could be used to inform improvement strategies and thereby narrow the PrEP gap in Germany. To do so, we set two objectives, namely (a) to gain a picture in the early days after EMA approval of how PrEP was being used by MSM and transgender people and of how PrEP care was being provided by sexual health counsellors and physicians and (b) to identify and analyse determinants of access to and use of HIV PrEP among MSM and transgender people in Germany (29-32).

4.1 Role of providers in addressing the PrEP gap by proactively providing PrEP advice to at-risk individuals

In our facility-based survey of MSM in Berlin from 2017/18, several of our findings suggested that the PrEP gap might be due in part to a lack of information and education on PrEP among health service users, including its pros, cons and proper use (31). Identifying individuals who are at substantial risk of HIV infection and proactively providing them with reliable and evidence-based information on PrEP would therefore seem like one way to help address unmet needs in this area of preventive care (29, 30). Clearly, sexual health counsellors and physicians in Germany, thanks to the low-barrier and comprehensive services they provide (cf. Blümel et al., 2020 (98), p. 140ff. and 150ff.), could play a key role in this regard. Indeed, one of findings from our provider surveys underscores the potential of this role: regardless of type of centre or practice at which they worked, sexual

health counsellors at local health offices (LHOs) and non-governmental counselling centres (NGCs), as well as HIV-specialists and non-HIV-specialists, reported having a substantial number of consultations with MSM and transgender people who met the criteria for taking PrEP. Indeed, the proportion of consultations with at-risk individuals was almost identical in the two surveys: 43.7% among counsellors and 44.2% among physicians. This suggests that providers in all four settings can play an important part in reaching people who are at increased risk of infection with HIV and help them make informed decisions about their sexual health, including how PrEP might play a role (30).

Counsellors at NGCs and LHOs also reported that they proactively gave advice on PrEP during these consultations, and they gave positive self-assessments of their own knowledge, counselling skills and attitudes towards PrEP, albeit to varying degrees (30). Indeed, self-assessed knowledge of PrEP was greater and self-assessed attitudes towards PrEP were more positive among counsellors from NGCs than among those from LHOs (30). This is perhaps not surprising given that NGCs evolved from self-help organisations within the LGBTI+ community and have mostly MSM as their clients (30, 99), whereas the LHOs have traditionally served the general population and selected risk groups, such as sex workers (30, 100). Importantly, however, the only independent predictors of the proportion of consultations in which they proactively provided PrEP advice to at-risk MSM and transgender people – our main outcome measure in the provider surveys – were the knowledge and attitudes of the individual counsellors, regardless of the organisation in which they were employed (30).

Among physicians, the findings of our survey were very similar for the knowledge and attitude domains and for our main outcome measure. Here, too, the differences between the two categories of doctors were not surprising: HIV-specialists in Germany are required to complete special training and obtain certification according to the German Quality Assurance Agreement on HIV/AIDS and generally work in HIV-specialist practices (29, 82). However, similar to our finding for sexual health counsellors, the only independent predictor of the proportion of consultations in which doctors proactively provided PrEP advice to at-risk individuals was the knowledge score, regardless of whether they were HIV-specialists or non-HIV-specialists (29).

Overall, these results suggest that the differences we observed between the different categories of providers in terms of their PrEP counselling practices can be explained primarily by different levels of knowledge and counselling skills on the part of individual physicians and sexual health counsellors, and in the case of the latter, also their attitudes towards PrEP (29, 30). This evidence of knowledge and attitudes as important determinants of access to PrEP, in turn, suggests that educational and information-based interventions, such as further training for providers and materials or tools that improve knowledge of and facilitate counselling on PrEP, could improve the implementation of PrEP by increasing the proportion of at-risk service users who are given PrEP advice, helping them make informed decisions about the potential role of PrEP in their broader, individual HIV prevention strategies (29, 30).

In addition to barriers related to information, another frequently selected barrier in both provider surveys and the service user survey was the monthly costs of PrEP medication; however, this can be explained by the fact that at the time of our surveys, these costs were still high and not yet covered by statutory health insurance in Germany. It is therefore likely that this particular structural barrier to PrEP access no longer plays a substantial role (30).

4.2 Educational and information-based interventions among providers – opportunities and caveats

Another important similarity between the two groups of providers was that counsellors and physicians both strongly favoured information materials and tools for service users when asked to select examples of resources that they felt would improve PrEP counselling (29, 30). This suggests that they perceived a lack of information among MSM and transgender people as an important determinant of access to PrEP (29, 30), thus corroborating the finding from our earlier survey of MSM (30). Indeed, several of the barriers to initiating PrEP that were rated by our providers as most relevant are related to information among health service users, namely: incorrect self-assessments of HIV risk, concerns about other sexually transmitted infections, and the lack of information about PrEP in the service users' native languages. Two of the most commonly selected tools to address these barriers in both provider surveys were decision aids for service users that provide information about PrEP in service-user-friendly language and in service users' first languages (29, 30). Importantly, this finding suggests that there may be deficits in PrEP

counselling for migrants, their descendants, refugees and asylum seekers – a point that warrants further research, particularly in light of evidence that these groups often receive suboptimal health care in Germany (101-103).

Importantly, the emphasis placed by respondents in both provider surveys on service-user-focused information materials also suggests that initiatives to improve the knowledge of and attitudes towards PrEP among providers might encounter a lack of interest or even resistance. Indeed, fewer than half of the counsellors reported that they themselves would find information or training on managing PrEP or identifying PrEP candidates to be useful, and only slightly more than a quarter indicated that they would like to receive information or training on speaking with service users about their sexuality (30). The results for physicians were almost identical, with the exception of the proportion of those who reported that information or training on PrEP management would be helpful was just above 50% (29). While this should be considered as a caveat when deciding on the appropriateness and content of training initiatives (30), it is also conceivable that busy doctors and counsellors felt that provider-focused training or materials would not be helpful because they simply did not have time for them. There is ample evidence in the literature that office-based physicians and their staff in Germany are facing increased workloads and work-related stress (104-107) in a health system that has been increasingly geared towards efficiency (cf. (98), p. 193ff, 237ff). Moreover, participants in our physician survey reported that the time-consuming management of (potential) PrEP users was a relevant barrier for service users to initiate PrEP (29). Bearing this possibility in mind, policy and decision makers seeking to improve PrEP implementation through provider-focused training or information materials may wish to find ways to help providers fit these into their busy schedules, such as the online training programmes mentioned previously (29), but also, in the case of self-employed physicians, novel strategies such as funding short periods of educational leave (similar to the *Bildungsurlaub* available to salaried employees in Germany) accompanied by the possibility to identify and employ substitute staff quickly and unbureaucratically.

4.3 Targeting training and information materials to specific categories of providers

Other findings from the provider surveys may be useful in targeting training and information materials to specific categories of providers, with the aim of using health resources

more efficiently while simultaneously improving equity in access to PrEP care, particularly in rural areas in Germany. In the case of sexual health counsellors, our results suggest that targeting counsellors at LHOs could be helpful in two ways. First, at a median of 30.0%, the proportion of consultations in which counsellors from LHOs proactively gave PrEP advice to at-risk MSM and transgender people was considerably lower than the 50.0% reported by counsellors from NGCs (30). Focusing on LHOs when designing training programmes or information materials for sexual health counsellors might therefore address a larger deficit in PrEP care provision and, in doing so, represent the most efficient use of resources. Second, access to PrEP advice (as well as to HIV/STI tests and sexual health advice more generally) in rural areas of Germany, and particularly in eastern Germany, can often be obtained only from LHOs considering that most NGCs are located in larger urban areas (30, 108). Given our sampling strategy, which involved matching an LHO to each participating NGC, this imbalance in provision is well reflected in our sample, with over 90% of respondents indicating that their employer was located in a large or major city (30). While our findings can therefore not be generalised to LHOs in rural areas, it would seem reasonable – based on the results of other studies showing urban-rural discrepancies in health services and outcomes in Germany (109-111) – to assume that the proportion of proactive PrEP advice given to at-risk service users in rural settings is either the same or smaller than that seen in our sample of urban LHOs. Thus, in the absence of further (much needed) research on this topic, focusing on LHOs when designing training programmes or information materials for counsellors might not only be efficient but could also represent a way to help bridge the urban-rural gap in the provision of PrEP care (29, 30).

In the case of physicians, there are also at least two ways in which training might be targeted to improve PrEP implementation. First, the difference in the proportion of consultations in which HIV-specialists proactively provided PrEP advice to at-risk service users compared to that provided by non-HIV-specialists was similarly large to that seen between our two categories of sexual health counsellors (29). Here then, too, focusing on non-HIV-specialists when designing training or information materials for doctors might represent the most efficient use of health resources. In this regard, it is encouraging that 61.9% of non-HIV-specialists in our sample reported that they wished to receive training or information materials on managing PrEP users (29). Second, adjusting the current training requirements that non-HIV-specialists must fulfil to be able to bill statutory health

insurers for the provision of PrEP care might also go some way to addressing the urban-rural divide in the provision of PrEP services in Germany (29). The vast majority of HIV-specialists in Germany work in practices located in larger cities (29, 112), and as we note in our physician survey paper, “any opportunity to increase the number of non-HIV-specialists who can give advice on PrEP and prescribe PrEP to patients at risk of acquiring HIV in conformity with the relevant guidelines should therefore be explored” ((29), p. 11). While attitudes toward PrEP were more negative and especially knowledge of it was lower among non-HIV-specialists than among HIV-specialists in our sample, the results for these domains were considerably more heterogeneous among the non-HIV-specialists (29). This suggests that, for at least some of these doctors, the need for additional training on PrEP care might be minimal (29). Health policy makers in Germany may therefore wish to consider providing this subgroup of doctors, especially if they are located in rural areas, with ways to achieve certification that are less burdensome than the current framework, which requires them, for example, to complete a 16-hour internship in an HIV care facility and prove that they have been present in consultations with at least 15 people who are either living with HIV/AIDS or contemplating or using PrEP (29, 82). Here, too, online training programmes are a solution that we suggest in the publication on this survey (29), and this would seem even more feasible now given the adjustments made in the health sector and broader society in Germany to facilitate online medical consultations (113), as well as teaching and training (114, 115), in the wake of the COVID-19 pandemic.

4.4 Tailoring and choice of content for training and information materials

4.4.1 Concerns about the side effects of PrEP

Concerns about the side effects of PrEP were common in all three of our surveys. In our survey of MSM from 2017/18, 43.6% of respondents cited mild or temporary side effects and 19.8% cited severe or permanent side effects as a risk of using PrEP (31). Moreover, among those who had never used PrEP (n=387), 47.3% reported that they would use PrEP if they had fewer worries about side effects (31). Although a large proportion of NGC counsellors and HIV-specialists agreed or strongly agreed that they would be able to give comprehensive advice on the side effects of PrEP, and also that PrEP is a method to protect oneself from HIV that has few side effects, this was not the case for counsellors from LHOs or non-HIV-specialists (29, 30). Among counsellors from LHOs, the proportion

of those who gave a midpoint response was particularly large compared to the other survey items: 37.2% in the case of the knowledge item on side effects and 40.9% in the case of the attitudes item on side effects (30). The picture among non-HIV-specialists was similar but more negative: 69.1% of this group disagreed or strongly disagreed that they would be able to give comprehensive advice on side effects, and 32.4% disagreed or strongly disagreed with the item about PrEP being a method to protect oneself from HIV that has few side effects (with a further 36.8% giving a midpoint response).

Particularly if we interpret the midpoint responses as an indication of uncertainty about the topic rather than neutrality or indifference (among other possible interpretations) (116, 117), these findings would suggest that information materials or training and education on PrEP, both for health service users and for providers, need to tackle the issue of side effects in a direct and transparent manner to improve the implementation of PrEP in Germany. Information and training materials, as well as future updates of the German and Austrian PrEP guideline, may wish to present safety data from the major efficacy and effectiveness trials transparently and in a way that can help inform the shared decision making process of health service users and providers. Another possibility might to develop a health service user (“patient”) guideline on PrEP, in which the evidence-based recommendations of the German and Austrian PrEP guideline and also the safety information from the major clinical trials are translated into service-user-friendly language, similar to those being developed (in part by our working group, particularly by RNW) as part of a long-standing patient-guideline initiative of the Leitlinienprogramm Onkologie for the clinical practice guidelines on anal cancer and actinic keratosis/squamous cell carcinoma (118, 119). It is possible that concerns about side effects will play a lesser role in the future with the advent of PrEP with FTC/TAF and long-acting injectable carbotegravir, neither of which, however, were approved for use by the EMA at the time of writing.

4.4.2 Knowledge vs. attitudes of providers

One potentially important difference between the two groups of providers was that, among physicians, the attitude score was not an independent predictor of their PrEP counselling practice. If this finding can be replicated in further research, a useful approach to tailoring provider training and information materials might therefore be to focus more on knowledge aspects when developing training and information materials for physicians

and more on a combination of knowledge aspects and attitudes for sexual health counsellors. One possible explanation for this finding may be that physicians, by virtue of their medical education and training, are more likely, on the average, than sexual health counsellors to act based on the indication at hand even if their attitude towards a particular intervention is ambivalent or negative. To our best knowledge, however, no research has been conducted to date comparing sexual health counsellors and physicians in this regard, and exploring this hypothesis in our own data by comparing different categories of sexual health counsellors (e.g., with medical vs. non-medical backgrounds) would not have been feasible due to small sample sizes and our desire to avoid post hoc analysis. This being said, the percentage of consultations in which PrEP advice was provided proactively by physicians in our sample, at a median of 15.5%, was very low – and, indeed, lower than the 50.0% reported by sexual health counsellors – which would speak against this hypothesis.

4.4.3 Holistic vs. biomedical approaches to PrEP implementation

One of the main findings of our multi-methods analysis of qualitative data from our facility-based survey of MSM may also be helpful when choosing content for provider training and information materials on PrEP care for providers or service users, but potentially also for future updates of the German and Austrian PrEP guideline (32). Although we asked in our survey item only about participants' main motivation for using or considering PrEP, more than 30% of respondents nevertheless wrote more than one motivation in the free-text field (32). While these multiple motivations frequently fell into the same category, it was possible even within a category as apparently straightforward as "safety and protection" to identify a wide range of subcategories (e.g., protection during periods of anticipated increased risk, self-perceptions of being at high risk, and additional protection against HIV while using condoms) (32). As we note in the publication reporting these results, this suggests that a biomedical approach to PrEP counselling that aims to increase the uptake up PrEP "by focusing exclusively on its effectiveness in preventing HIV is unlikely to be as successful as a holistic approach that focuses simultaneously on multiple motivating factors, particularly those related to mental health and quality of life" – the last two topics being the second most frequently cited category of motivations among our respondents after that of safety and protection, another of the main findings of our multi-methods study ((32), p. 16).

Policy makers designing training programmes for providers on the management of PrEP, as well information materials for providers and service users, may therefore wish to emphasise the importance of such a holistic approach, as might future updates of the German and Austrian PrEP guideline. The findings of a recent systematic review by Pinto et a. (2018) corroborate our findings in this regard, identifying the need for interventions that target multiple socioecological domains to facilitate better navigation of health services and referrals to mental health and supportive care (32, 52). The breadth of motivations found in our user survey is also in concordance with that found by Lacombe-Duncan et al. (2021), who in their qualitative interviews with MSM in Toronto, Canada, found that the navigation of sexual health and risk practices was complicated by a range of sometimes contradictory individual, interpersonal, organisation and structural factors (32, 75).

4.4.4 Importance of mental well-being and quality of life in PrEP care

The finding from our user survey that mental well-being and quality of life were important motivations for our respondents to use or consider PrEP suggests that it might be wise for providers to focus more on these potential benefits of PrEP when deciding whether it is appropriate for a given individual, and somewhat less on concerns about increased sexual risk compensation and increase STI incidence (32). This is especially the case given that the evidence on the latter is still mixed (32, 120-122), whereas that on depression, self-harm and suicide among sexual minorities worldwide is very clear and shows these to be alarmingly common (32, 123-125). This message could be conveyed to providers in provider training or information materials, or be given greater emphasis in a future update of the German and Austrian PrEP guideline. It could also frame the design and choice of content for information materials for service users. Regarding service users, although we did not identify statistically significant differences in the frequency of motivations between those who were contemplating or considering PrEP that might inform how such information materials could be tailored to those at different stages of the PrEP care continuum, there was some indication that in individuals who had initiated PrEP, categories of benefits beyond safety and protection might have become more readily apparent, such as expectations around sexuality or mental well-being combined with safety concerns (

Table 13) (32). If this hypothesis can be confirmed in future research, information materials for service users could be tailored to these different groups and potentially increase PrEP uptake among those for whom PrEP is indicated and appropriate.

4.4.5 German and Austrian PrEP guideline and its implementation

Clinical practice guidelines can be important sources of information for providers, helping them improve processes and quality of care (126), and in this regard our provider surveys generated potentially useful information on the implementation of the current German and Austrian PrEP guideline. First, as noted above, the participating counsellors and physicians indicated that they proactively provided PrEP advice only in a median of 50.0% and 15.5% of consultations with at-risk service users, respectively (29, 30), suggesting that the implementation of the guideline can be improved (29, 30). Second, when asked which items on a list of information materials would improve their counselling on PrEP, a large proportion of respondents in both provider surveys (counsellors: 74.3%, n=84; physicians: 53.7%, n=65) selected the item for a clinical practice guideline that provides a good overview of indications, contraindications and necessary investigations – even though a German and Austrian PrEP guideline already existed at the time our surveys were conducted (29, 30). Given that we presented all survey participants with a definition of at-risk MSM that stems from the guideline – and that we named and referenced the guideline in doing so – it seems reasonable to interpret this finding as a potential critique that the guideline might not present the necessary information or word its recommendations in a clear enough manner (29, 30). This may be due to the wording of the indication for PrEP in the guideline, which uses multiple operators (“und/oder” and “bzw.”) in the same sentence and imprecisely defined periods of time (“3-6 months”, “next few months”) (30): “MSM or transgender people who report anal sex without a condom within the past three to six months and/or (“und/oder”) are likely [to do so] in the next few months and/or (“bzw.”) [report having had] an STI in the past 12 months” (author’s own translation) (German: “MSM oder Transgender-Personen mit der Angabe von analem Sex ohne Kondom innerhalb der letzten 3-6 Monate und/oder voraussichtlich in den nächsten Monaten bzw. einer STI in den letzten 12 Monaten”) (15). This supposition is strengthened by our finding that only very few providers felt that training on identifying candidates for PrEP would be helpful.

This being said, it is also conceivable that providers found the indication for PrEP given in the guideline to be too broad compared to, for example, the corresponding CDC guideline, which restricts the period for past diagnosis of an STI to six months and exclusively to bacterial STIs (16, 30). This could be an explanation for the surprisingly low proportion of consultations in which physicians, in particular, pro-actively gave PrEP advice to at-risk MSM and transgender people according to the German and Australian guideline definition (29, 30, 81). Another explanation for the limited implementation of the guideline, at least as observed in the counsellor survey, could be that it had only been available since June 2018, or for four months before our data collection began for the survey (30); this explanation is somewhat less plausible, however, for the physician survey, which we conducted one year later.

4.5 Strengths and limitations of the studies

Beyond their cross-sectional design and observational nature, and the obvious caveats that these entail, all three studies have important limitations that must be considered when interpreting their findings, and some of these point to possible avenues for further research.

A first limitation of all three studies and which pertains to the external validity of our findings is the potential for selection bias. Providers and service users with either excellent or no knowledge of PrEP may have been more enthusiastic about the topic and thus more likely to take part in the survey, as may have also been the case with providers and service users with very positive or very negative attitudes towards PrEP (29, 30). With regard to our service user survey, it should be pointed out that facility-based sampling itself introduces a potential selection bias as well (31, 127-129). While a strength of our sample of MSM is its broad age range (18-79 years), it probably represents the subsection of the MSM community in Berlin that is well integrated in the health system and keen to seek information from LGBTI+ counselling centres and HIV-specialist practices (31). This might be an explanation for the high percentage of service users with university degrees and the low percentage who reported their parents having been born in the countries with the historically largest flows of migration to Berlin (31). Thus, it is important to acknowledge that our sample probably does not include a representative number of lower income MSM categories who are facing cultural barriers to access (and might therefore have the strongest need for information and, indeed, for PrEP advice) (31). Moreover, it is probable that

some of the doctors at the participating centres did not, as we had requested, invite all eligible service users to participate in the survey, possibly leading to service users being more likely to have taken part if they asked about PrEP themselves (31). Although the extent of this potential bias in our surveys could not be quantified using the data at our disposal, it is noteworthy that the response rates of 42.0% for NGCs and 57.1% for LHOs in the counsellor survey (30), as well as 54.1% for MSM in the service user survey were relatively good for studies of this nature (31, 32, 130). Although good response rates cannot ensure that estimates are unbiased, they do mean that there is less opportunity for selection bias to happen (30). With regard to our physician survey and its low response rate, it is reasonable to assume that physicians who were more ambivalent about or had only moderately good knowledge of PrEP were less likely to participate and, as a result, should be focused on more strongly in future research on this topic (29). Overall, however, the low response rate to the physician survey means that our findings are likely not representative of the broader populations of HIV-specialists and non-HIV-specialists in Germany and cannot be readily generalized to them (29).

A second limitation, which is related to the representativeness of our sample in the counsellor survey, is that only a few counselling centres from eastern Germany took part (30). Access to HIV tests and sexual health advice in rural areas of Germany, and especially in the east, is often only available through the LHOs; in contrast, large cities like Berlin and Hamburg have more NGCs (30, 108). Thus, the regional distribution of the respondents to our survey at least reflects the status quo with respect to sexual health services in Germany (30, 108). Similar caveats must be borne in mind when interpreting the results of our service user survey. Although we tried to recruit a number of HIV specialist practices in former East Berlin, only one of these decided to take part in the study, and it was very centrally located and might not have many service users from the outskirts of the eastern part of the city, where, for example, a larger number of people with a family history of migration from the former Soviet Union and Vietnam live (31, 131). This being said, many of the sociodemographic characteristics of the MSM in our sample are similar to those of participants in previous, online surveys of MSM in Germany (31, 76, 132). Moreover, the mean age of our respondents and the percentage of those reporting that they or their parents were born outside Germany were similar to data recorded by the participating sexual health counselling centres in 2016 as part of their routine data collection (mean age: 34.2 years; 52.2% born themselves or with parents born outside Germany)

(30, 31, 133). Lastly, when interpreting our results, it must be borne in mind that the findings of our multi-methods analysis and the larger quantitative survey of which it is a part (31) are specific to MSM in Berlin and therefore limited in their generalisability for this reason as well; however, they can provide a useful comparison to the situation in cities with populations of MSM with (roughly) similar demographics, such as in Paris, London, New York, San Francisco or Sydney, where the implementation of PrEP is well underway (31, 32).

A third potential limitation of all three studies and one which might affect the internal validity of our results is social desirability bias, a common limitation of survey-based studies (32, 134-138). In our survey of service users, it is likely that some respondents reported their motivation for using or considering PrEP to be safety because they sought to project a favourable image of themselves and thought that doing so would improve their likelihood of being prescribed PrEP (despite having been informed that the survey was anonymous) (32). However, we did not find any significant differences between the motivations reported by respondents who had a history of PrEP use and those who were considering it, and respondents who had already taken PrEP will presumably would have had fewer concerns about obtaining a new prescription (32). Additionally, if socially desirable motivations had been an important determinant of respondents' answers, it seems reasonable to assume that the number of responses focusing on protecting others or the public health would have been higher (32). With regard to the two provider surveys, one might expect that the reported proportion of consultations in which providers proactively gave PrEP advice to at-risk individuals would be especially susceptible to social desirability bias; however, in the case of both surveys, and in particular the physician survey, this proportion was surprisingly low. We therefore conclude this particular form of bias is probably not something that affected the internal validity of our studies in any substantial way.

A fourth limitation of our studies was our decision, for pragmatic reasons, to develop our questionnaires from scratch and not use validated constructs to elicit self-assessments of knowledge and attitudes (29-32). Moreover, we did not use a score or scales that assessed specifically defined levels of competence or skills (30). There is abundant evidence in the literature that there is often a discrepancy between the knowledge and skills reported by respondents and their actual knowledge and skills (e.g., Gordon (1991) (139) and the systematic review by Davis et al. (2006) (140)) (29, 30). Additionally, there are, to our knowledge, no studies that have compared the quality of PrEP counselling and

advice to the knowledge of or attitudes towards PrEP among providers (30). In both provider surveys, however, there was a significant association between the knowledge score and the attitudes score, on one hand, and the proportion of consultations in which PrEP advice was proactively given to at-risk individuals, on the other, and this provides at least some evidence that our knowledge and attitudes scores may indeed be a valid representation of those two concepts (30). This is also supported by the good internal consistency of the scores in the counsellor survey (30). Another point to mention in this regard is the clustering of ratings of the relevance of the barriers in both provider surveys around the mid-point on the 11-point Likert scale. Although we presented items in the online surveys to each participant in a different order to reduce response order bias, it is possible that the number of barriers presented was too large or that we presented them too late in the survey, and survey fatigue led the respondents to select replies mostly in the middle. It is also conceivable, however, that the clustering of ratings is a sign that we did not select the most relevant barriers, despite our drawing upon the results of a structured search of the literature. To address this potential weakness, we focused on the top and bottom ratings in our reporting of the results.

A fifth limitation to both of our provider surveys is the fact that we did not explore barriers to access that were related to race, ethnicity or migration history (29). Although a lack of information materials in service users' first language was reported as a potential barrier by providers, barriers related to race or migration history, for instance with regard to discrimination, were not part of our data collection or analysis (29). The findings of studies from the US (141, 142) suggest that there are large differences in access to PrEP among individuals of colour and white service users (29). Considering that the incidence of HIV in Germany is high among migrants and we have little data on whether the infections have taken place abroad or within the country (29, 143), future researchers may wish to examine structural discrimination that might impede access to appropriate PrEP care among these individuals (29). Moreover, the sexual orientation of participating providers was not examined in either of the provider surveys (29); however, it may have a role in their counselling practices, as well as in the choice among physicians about whether to specialize in caring for patients living with HIV and for LGBTI+ individuals more generally (29). In particular, we felt that respondents might consider this question to be too invasive of their privacy, and were keen not to include an item that might reduce the response rate unnecessarily. Lastly, we did not specifically include questions about other populations at

high risk of HIV infection (e.g., intravenous drug users or sex workers) in our survey, also to keep the questionnaire as short and feasible as possible in order to increase the participation rate (29).

A sixth limitation is related to the fact that we grouped MSM and transgender people in our provider surveys for pragmatic reasons related, in particular, to the length of the survey questionnaire (29, 30). Distinguishing between them would have made it possible to obtain data on the barriers faced specifically by transgender service users who wished to start PrEP (29); not doing so means that information may have been lost or recorded inaccurately (30). Our assessment of counselling practices in both provider survey may have yielded different results if we had had separate questions for each of these groups (29, 30). In particular, for transgender people, other barriers to accessing health care may be relevant than those that are important for MSM; for example finding a trans-competent provider was found to be an especially relevant barrier to accessing PrEP (30, 144). In our survey of service users, we did not exclude transgender MSM from taking part, but we also did not explicitly instruct participating centres to include this group, nor did we measure how many transgender MSM may have participated (31, 32). To obtain meaningful data on transgender MSM's motivations for using/considering PrEP we would have had to have used other sampling strategies, but this would have gone beyond the scope of our study (31, 32).

A further set of limitations pertains only to our multi-methods analysis of data from the service user survey. The first is related to the survey being paper-based and having only limited space for a free-text response (32). As a result, we were not able to follow a crucial avenue of qualitative enquiry: in-depth follow-up questions that lead from the general to the specific (cf. (145), p. 264ff); without doing so, it is impossible to distinguish between the more superficial and deeper motivations for using or considering PrEP (32). Future researchers in this area may therefore wish to explore our findings through in-depth qualitative interviews (32) or focus groups to gain further and deeper insights into the topic. A second limitation specific to our multi-methods analysis is related to our coding framework: Although this was developed and applied independently and in a systematic fashion by three researchers, any set of qualitative codes and categories will always necessarily be arbitrary to a certain extent (32). This represents a potential source of measurement error in our multi-methods analysis, which sought to identify associations between motivations and individuals' place on a given PrEP-care continuum. Although we aimed to

address this limitation by testing the assumption of independence of observations in broader, larger categories (rather than our subcategories), it is possible that a different coding system would have led to different findings (32). Third, due to limited space on our paper-based survey questionnaire, we did not ask participants to name motivations for *not* using or *not* considering PrEP; such information would have added an interesting perspective to the study, allowing us to explore other steps along the various examples of the PrEP care continuum, as well as approaches to promoting alternative or additional prevention strategies (32). Lastly, respondents who reported being neutral about or potentially interested in taking PrEP but who did not write a response to our open question may have had motivations that differed from those who provided a response (32). Indeed, our informal comparison of these two groups (see Table S1 in the supplementary appendix of our publication (32) on the multi-methods study of the service user survey) suggests that these respondents may have been less interested in PrEP because their self-perceived risk of infection with HIV was lower due to their sexual risk behaviour (e.g., fewer anal sex partners and more condom use) (32).

5 Conclusions

Men who have sex with men (MSM) remain the population group most strongly affected by HIV in Europe. HIV pre-exposure prophylaxis (PrEP) is a safe and highly effective way to prevent HIV and is recommended in multiple national and international guidelines in combination with other safer sex practices for individuals at high risk of HIV infection. The results of previous research, including a facility-based survey of MSM in Berlin we conducted in 2017/18, suggest, however, that there is a substantial gap between the number of people with an indication to use PrEP and of those actually using it. To explore possibilities to narrow this gap, we developed and conducted two additional surveys, which were the first in Germany to assess PrEP-related knowledge, attitudes and counselling practices among sexual health counsellors and physicians. We also conducted a separate, multi-methods analysis of motivations cited by MSM for using or considering PrEP in our facility-based survey to explore motivations for PrEP use on the side of health service users.

The results of the two provider surveys should be regarded as baseline findings soon after the German and Austrian Guideline on HIV Pre-exposure prophylaxis was published in June 2018 (30) and around the time that the costs of PrEP and the associated costs of medical supervision were included in the catalogue of services covered by statutory health insurance in Germany in September 2019. We found that there is substantial room for improvement in providers' counselling practices when these are evaluated in terms of the proportion of consultations in which providers proactively gave advice on PrEP to people at high risk of HIV infection; such advice may help narrow the PrEP gap by empowering at-risk individuals to make informed decisions about their health (30). Moreover, we identified substantial differences between counsellors from non-governmental counselling centres (NGCs) and local health offices (LHOs), and even greater differences between HIV-specialists and non-HIV-specialists, in this regard, as well as in terms of their knowledge of PrEP and their attitudes towards it. Our multiple regression analysis revealed, however, that the type of centre at which providers worked did not independently predict the proportion of consultations in which providers proactively gave PrEP advice, but rather only their knowledge of PrEP and, in the case of counsellors, also their attitudes towards it.

Targeted training, particularly for counsellors at LHOs and non-HIV-specialists, might therefore be able to improve care, especially in rural areas and eastern Germany (29, 30). This might require, however, creative ways to support health care providers find time and energy for training, many of whom are increasingly reporting issues with work overload and burnout. Additionally, the attitudes towards PrEP and especially knowledge of it were more heterogeneous among non-HIV-specialists than HIV-specialists, which would suggest that at least some of the former might require little training on this topic (29). Policy makers might therefore wish to consider furnishing non-HIV-specialists who fit this description with possibilities to demonstrate and certify their skills (i.e., so that that they are permitted to bill for PrEP-related services) that are less burdensome than those currently in place, especially if their practice is located in a rural area (29).

Lastly, many of the participants in our survey of MSM reported several motivations for using or considering PrEP, and their replies were heterogeneous overall. This finding suggest that providers or decision makers who are seeking, where appropriate, to improve the implementation of PrEP by focusing exclusively on its effectiveness in preventing HIV and the aspect of safety are unlikely to be as successful as those who take a holistic approach focusing on multiple motivating factors, particularly those related to mental health and quality of life (32). These results may help in the design of educational and information materials for health service users and providers alike, with the aim of improving PrEP implementation in parallel to other strategies of HIV prevention and support more generally for the psychological and sexual health and well-being of MSM and transgender people (32).

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Statutory declaration

“I, Matthew Gaskins, by personally signing this document in lieu of an oath, hereby affirm that I prepared the submitted dissertation on the topic ‘Determinants of access to and use of HIV pre-exposure prophylaxis among men who have sex with men in Germany / Determinanten des Zugangs zu und der Nutzung von HIV-Präexpositionsprophylaxe unter Männern, die Sex mit Männern haben, in Deutschland’, independently and without the support of third parties, and that I used no other sources and aids than those stated.

All parts which are based on the publications or presentations of other authors, either in letter or in spirit, are specified as such in accordance with the citing guidelines. The sections on methodology (in particular regarding practical work, laboratory regulations, statistical processing) and results (in particular regarding figures, charts and tables) are exclusively my responsibility.

Furthermore, I declare that I have correctly marked all of the data, the analyses, and the conclusions generated from data obtained in collaboration with other persons, and that I have correctly marked my own contribution and the contributions of other persons (cf. declaration of contribution). I have correctly marked all texts or parts of texts that were generated in collaboration with other persons.

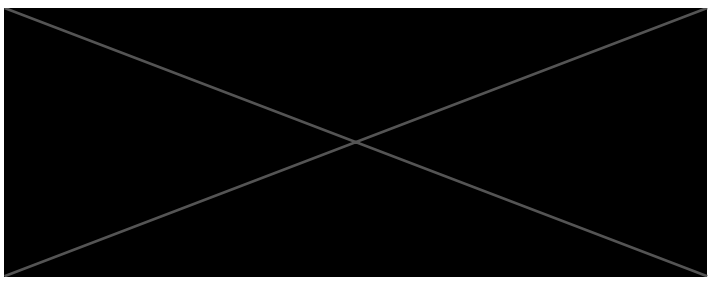
My contributions to any publications to this dissertation correspond to those stated in the below joint declaration made together with the supervisor. All publications created within the scope of the dissertation comply with the guidelines of the ICMJE (International Committee of Medical Journal Editors; http://www.icmje.org) on authorship. In addition, I declare that I shall comply with the regulations of Charité – Universitätsmedizin Berlin on ensuring good scientific practice.

I declare that I have not yet submitted this dissertation in identical or similar form to another Faculty.

The significance of this statutory declaration and the consequences of a false statutory declaration under criminal law (Sections 156, 161 of the German Criminal Code) are known to me.”

22 August 2022

Date



Declaration of doctoral candidate's contribution to the publications

Matthew Gaskins made the following contributions to the three publications listed below:

Publication 1 (first authorship): ***Matthew Gaskins***, Mary Katherine Sammons, Frank Kutscha, Alexander Nast, Ricardo Niklas Werner. Factors that motivate men who have sex with men in Berlin, Germany, to use or consider using HIV pre-exposure prophylaxis – A multi-methods analysis of data from a multicentre survey. PLoS One. 2021;16(11):e0260168. doi: 10.1371/journal.pone.0260168.

- Wrote all sections of the first version of the manuscript that was submitted, taking into account feedback from co-authors.
- Rewrote and revised all sections of the subsequent versions of the manuscript that were submitted, taking account of feedback from co-authors and journal reviewers and editors.
- Responded to and, where appropriate, implemented all comments from journal reviewers and editors.
- Created and revised all tables in the publication (i.e., Tables 1-4 and S1 Table in Supporting Information), taking account of feedback from co-authors and journal reviewers and editors.
- Developed the initial idea for the study and conceived of its design together with RNW (details described on pp. 4-5 of publication; more details in Introduction to the Manteltext, particularly p. 6).
- Developed the methodology and coding framework (Table 1) in consultation with co-authors, and led in conducting the qualitative part of the study, in particular suggesting and developing the approach to using deductive and inductive coding processes in parallel to reach a merged coding framework (described in detail in section "Qualitative data analysis" on pp. 6-7 of publication).
- Conceived of, developed and conducted the quantitative part of the multi-methods aspect of this study, specifically (a) the decision to assess whether the frequency of motivations differed significantly between respondents using or considering PrEP , and whether any such difference found might be used to locate respondents along different conceptual models of the PrEP care continuum (p. 9 of publication),

and (b) the decision to test the null hypothesis that there was no difference between the two groups using Fisher's exact test, and to use broad categories (as opposed to our subcategories) in doing so (described in detail in section "Quantitative data analysis" on pp. 9-10 of publication; broad catergories shown in Table 3).

- Supported RNW as he led in the drafting and administration of the ethics application, and as he led in the drafting and application for approval of the data protection concept (ethics application described on p. 5 under "Materials and methods / Study design, ethics approval and informed consent").
- Jointly drafted with RNW the portion of the survey questionnaire relevant to this study and the overall survey questionnaire (survey questionnaire is available as supplementary material on the PloS One website and has been submitted alongside the primary data as part of this dissertation).
- Interpreted results of qualitative and quantitative analyses together with the co-authors (see Discussion section, pp. 15-18, and Conclusion, p. 18 of publication).
- Supported RNW as he led in project coordination and administration, including in his role in coordinating, and equipping participating counselling centres and practices (some details in "Sampling methods, participants and settings", pp. 5-6 with additional details given in Manteltext, section 2.2 "Settings and eligibility" / 2.2.3 "Survey of service users").

Publication 2: Mary Katherine Sammons, ***Matthew Gaskins***, Frank Kutscha, Alexander Nast, Ricardo Niklas Werner. HIV Pre-exposure Prophylaxis (PrEP): Knowledge, attitudes and counselling practices among physicians in Germany – A cross-sectional survey. PLoS One. 2021;16(4):e0250895. doi: 10.1371/journal.pone.0250895.

Contributions in detail: *Matthew Gaskins*

- Developed the initial idea for the study together with RNW and FK (details described on pp. 2-3 (last two paragraphs of Introduction of publication)).
- Supported MS as she led in the conception and development of the study design, study protocol and study methodology (detail in section Materials and methods pp. 3-4).

- Supported MS in preparing an initial draft of the survey questionnaire; revised this draft and prepared the final draft of the questionnaire along with co-authors (survey questionnaire is available as supplementary material on the PloS One website and has been submitted alongside the primary data as part of this dissertation).
- Provided advice to MS as she led in the formal analysis, statistical analysis, and interpretation of the study data in terms of descriptive and bivariate statistics; in doing so, helped create Tables 1-5.
- Interpreted the results from the formal analysis and other study data with respect to the multiple regression models (multiple regression modelling, p. 5 and p. 7, with the results shown in Table 6).
- Supported MS in preparing the first publication version of the manuscript.
- Revised subsequent publication versions together with RNW and MS.
- Discussed with RNW, MS and the other co-authors the comments and content-related and other required revisions during the peer review process; drafted and revised parts of the replies to the journal editors and reviewers.

Publication 3: Frank Kutscha, ***Matthew Gaskins***, Mary Katherine Sammons, Alexander Nast, Ricardo Niklas Werner. HIV Pre-Exposure Prophylaxis (PrEP) Counseling in Germany: Knowledge, Attitudes and Practice in Non-governmental and in Public HIV and STI Testing and Counseling Centers. Front Public Health. 2020;8:298,1-13. doi: 10.3389/fpubh.2020.00298.

- Developed the initial idea for the study together with RNW and FK (details described on p. 2, last two paragraphs of Introduction of publication; more details in Introduction to the Manteltext, particularly p. 6).
- Supported FK in conceptualization and development of the study design, study protocol, and study methodology (details on pp. 2-4 of publication); helped create Table 1 (operationalisation of knowledge and counselling competence and attitudes towards PrEP) together with co-authors.
- Supported FK in preparing initial draft of the survey questionnaire along with other co-authors, and revised final draft of questionnaire alongside RNW (survey questionnaire is available as supplementary material on the Frontiers in Public Health

website and has been submitted alongside the primary data as part of this dissertation).

- Assisted FK as he led in the formal analysis, statistical evaluation and the interpretation of the study data in relation to his master's thesis (descriptive and bivariate statistics, see pp. 4-7); in doing so, helped create Tables 2 and 3.
- Conducted formal analysis, statistical evaluation and the interpretation of the study data in relation to the evaluations included exclusively in this publication (multiple regression modelling, pp. 6-7, with the results shown in Table 4) together with RNW and FK.
- Supported FK in the preparation of the first publication version of the manuscript.
- Revised subsequent publication versions prepared by FK along with other co-authors.
- Discussed with FK and RNW and the other co-authors the comments and content-related and other required revisions during the peer review process.

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Publication 1 (print copy)

Publication 1 (first authorship): ***Matthew Gaskins***, Mary Katherine Sammons, Frank Kutscha, Alexander Nast, Ricardo Niklas Werner. Factors that motivate men who have sex with men in Berlin, Germany, to use or consider using HIV pre-exposure prophylaxis – A multi-methods analysis of data from a multicentre survey. PLoS One. 2021;16(11):e0260168. doi:10.1371/journal.pone.0260168. (submitted 28 May 2021)

Excerpt from Journal Summary List (see next page)

Journal Data Filtered By: **Selected JCR Year: 2019** Selected Editions: SCIE,SSCI
Selected Categories: **"MULTIDISCIPLINARY SCIENCES"** Selected Category Scheme: WoS
Gesamtanzahl: 71 Journale

Rank	Full Journal Title	Total Cites	Journal Impact Factor	Eigenfactor Score
1	NATURE	767,209	42.778	1.216730
2	SCIENCE	699,842	41.845	1.022660
3	National Science Review	2,775	16.693	0.009760
4	Science Advances	36,380	13.116	0.172060
5	Nature Human Behaviour	2,457	12.282	0.014190
6	Nature Communications	312,599	12.121	1.259510
7	Science Bulletin	5,172	9.511	0.014150
8	PROCEEDINGS OF THE NATIONAL ACADEMY OF SCIENCES OF THE UNITED STATES OF AMERICA	676,425	9.412	0.931890
9	Journal of Advanced Research	3,564	6.992	0.005470
10	GigaScience	4,068	5.993	0.016410
11	Scientific Data	5,761	5.541	0.028720
12	Research Synthesis Methods	2,572	5.299	0.006440
13	ANNALS OF THE NEW YORK ACADEMY OF SCIENCES	45,596	4.728	0.026370
14	FRACTALS-COMPLEX GEOMETRY PATTERNS AND SCALING IN NATURE AND SOCIETY	2,156	4.536	0.002210
15	iScience	1,410	4.447	0.004140
16	GLOBAL CHALLENGES	481	4.306	0.001440
17	Scientific Reports	386,848	3.998	1.231180
18	JOURNAL OF KING SAUD UNIVERSITY SCIENCE	1,640	3.819	0.002020
19	Journal of the Royal Society Interface	13,762	3.748	0.027670

Rank	Full Journal Title	Total Cites	Journal Impact Factor	Eigenfactor Score
20	Frontiers in Bioengineering and Biotechnology	2,770	3.644	0.007650
21	NPJ Microgravity	346	3.380	0.001210
22	PHILOSOPHICAL TRANSACTIONS OF THE ROYAL SOCIETY A-MATHEMATICAL PHYSICAL AND ENGINEERING SCIENCES	20,609	3.275	0.027840
23	PROCEEDINGS OF THE JAPAN ACADEMY SERIES B-PHYSICAL AND BIOLOGICAL SCIENCES	1,669	3.000	0.001980
24	Advanced Theory and Simulations	432	2.951	0.000700
25	SCIENCE AND ENGINEERING ETHICS	2,129	2.787	0.003760
26	PROCEEDINGS OF THE ROYAL SOCIETY A-MATHEMATICAL PHYSICAL AND ENGINEERING SCIENCES	19,218	2.741	0.018450
27	PLoS One	688,763	2.740	1.388860
28	Royal Society Open Science	7,222	2.647	0.027340
29	Symmetry-Basel	4,888	2.645	0.005390
30	INTERNATIONAL JOURNAL OF BIFURCATION AND CHAOS	7,115	2.469	0.007090
31	COMPLEXITY	4,413	2.462	0.007160
32	PeerJ	17,984	2.379	0.062850
33	MIT Technology Review	871	2.357	0.001810
34	Science of Nature	673	2.090	0.002400
35	SCIENCE PROGRESS	499	1.906	0.000340
36	SOUTH AFRICAN JOURNAL OF SCIENCE	2,631	1.866	0.001800
37	Journal of Taibah University for Science	1,126	1.863	0.001470
38	Journal of Radiation Research and Applied Sciences	1,127	1.804	0.002280

Selected JCR Year: 2019; Selected Categories: "MULTIDISCIPLINARY SCIENCES"

PLOS ONE

RESEARCH ARTICLE

Factors that motivate men who have sex with men in Berlin, Germany, to use or consider using HIV pre-exposure prophylaxis—A multi-methods analysis of data from a multicentre survey

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Abstract

Background

While our knowledge of what motivates men who have sex with men (MSM) to use HIV pre-exposure prophylaxis (PrEP) has grown in recent years, quantitative survey-based studies have not asked MSM explicitly to name their motivations. We did so using a qualitative open-ended question and aimed to categorise the responses and explore whether these were related to where MSM were located along a conceptual continuum of PrEP care.

Methods

In a multicentre survey examining knowledge and use of PrEP among MSM in Berlin, Germany, we additionally asked an open-ended question about motivations for using or considering PrEP. Data were collected from 10/2017-04/2018. One researcher developed a thematic framework deductively from the literature and another did so inductively from the free-text data, and a merged framework was used to code responses independently. We used Fisher's exact test to assess whether the frequency of motivations differed significantly between respondents using or considering PrEP.

Results

Of 875 questionnaires, 473 were returned and 228 contained a free-text response. Motivations in the following categories were reported: (1) Safety/protection against HIV (80.2% of participants, including general safety; additional protection to condoms), (2) Mental well-being and quality of life (23.5%, including reduced anxiety; better quality of life), (3) Condom attitudes (18.9% intent not to use condoms), (4) Expectations about sexuality (14.4%, including worry-free sex or more pleasurable sex, with explicit mention of sex or sexuality),

Data Availability Statement: All relevant data are within the paper and its Supporting Information files.

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(5) Norms/social perspectives (0.8%). The difference in frequencies of motivations between those using or considering PrEP was not statistically significant.

Conclusions

Safety and protection against HIV, particularly having additional protection if condoms fail, were the most common motivations for using or considering PrEP, followed by mental well-being and quality of life. Many respondents reported several motivations, and responses overall were heterogeneous. This suggests that approaches to increase PrEP uptake that focus exclusively on its effectiveness in preventing HIV are unlikely to be as successful as a holistic approach that emphasises multiple motivations and how these fit into the broader sexual and psychological health of MSM.

Introduction

Men who have sex with men (MSM) continue to be the population most affected by HIV in the United States (US) and Europe, comprising 69% of new HIV diagnoses in the US [1] and 52% of new diagnoses (where the route of transmission was known) in the European Union (EU)/European Economic Area in 2018 [2]. An important and still relatively new tool to prevent HIV is pre-exposure prophylaxis (PrEP) with emtricitabine/tenofovir disoproxil fumarate, which was approved for once-daily use in at-risk populations in the US in 2012 and in the EU in 2016. However, despite evidence of its high efficacy and safety [3–17], uptake among those at high risk of HIV acquisition has been slow. As of late 2019, approximately 224,000 people in the US were estimated to have received a prescription for PrEP, representing only a small proportion of the 1.1 million individuals estimated by researchers at the US Centers for Disease Control and Prevention (CDC) to have indications for it based on data from 2015 [18–20]. This is unfortunate given that the substantial declines in HIV incidence among MSM in London [21], San Francisco [22] and New South Wales, Australia [23], observed in the past several years are thought to be due, at least in part, to PrEP alongside other crucial prevention strategies such as treatment as prevention (TasP) and the continued promotion of condom use. In Berlin, the decline in HIV incidence among MSM has been smaller [24], and affordable PrEP has been accessible through formal channels in Germany only since autumn 2017.

In Europe, where health policy makers and payers in many countries are still debating whether and how best to integrate PrEP into their publicly funded health systems and broader HIV prevention strategies [25–28], data on PrEP uptake are sparse. The most recent and comprehensive figures are from a 2019 study using data from the European MSM Internet Survey (EMIS-2017) to estimate the gap between self-reported PrEP use and expressed need for PrEP in the EU. Using this definition, the authors found that an estimated 17.4% of MSM, or 500,000 individuals, in the EU who were very likely to use PrEP were not able to access it [29]. At 12.6%, the PrEP gap for Germany in 2019 was smaller than the EU average [29], but not inconsiderable, and was similar to a finding of the first facility-based paper survey of PrEP use among MSM (N = 470) in Berlin in 2017/18, of which the current study is a part: in the survey, 12.9% of participants who reported never having used PrEP (who comprised 82.3% of the sample) strongly agreed with the statement that they would like to do so [30]. The most frequently reported barriers to PrEP use by these participants were worries about adverse effects, cost, not

having a doctor who prescribes it, and, despite a high awareness of PrEP, a lack of information on its pros, cons and proper use [30].

To improve the implementation of PrEP, a range of authors over the past decade have proposed and refined several models of a continuum or "cascade" of PrEP care [31–37]. Most of the earlier models are largely based on a biomedical approach that assumes HIV prevention is the main priority in a person's sexual decision-making and therefore evaluate this decision-making chiefly in terms of risk [38] and in a linear fashion. For example, the model proposed by Nunn et al. (2017) comprises nine steps ranging from identifying individuals at the highest risk of HIV to an end goal of retaining individuals in PrEP care [33]. In contrast, one of the more recent iterations of the PrEP care continuum, developed by Newman et al. (2018), follows a more holistic notion of personhood rooted in the results of their own qualitative analysis and the extensive anthropological and ethnographic literature on HIV prevention [37]. Their model considers the psychological, interpersonal, social and community phenomena that affect PrEP use and non-use, resulting in an augmented PrEP cascade that incorporates alternative decision-making, pathways (such as those with the end goal of intermittent use or discontinuation), and psychosocial impacts [37]. Regardless of the epistemological roots and approaches of these different models, however, what all of them share is that each stage in the proposed cascade represents a potential point of intervention to improve PrEP implementation among those for whom PrEP is a desired and viable option [32, 33]. At the same time, each of these steps is characterised by unique but overlapping sets of barriers and enablers that must be considered if we are to understand more fully how and why individuals move from one step to another–an understanding that is crucial to developing interventions to improve the implementation of PrEP, and HIV prevention strategies more generally, that are efficient, effective and, ideally, support the broader sexual and psychological health of MSM.

Since 2012, evidence on the structural, sociocultural and behavioural barriers to PrEP implementation has grown considerably. These are manifold and include cost and lack of insurance coverage (e.g., [29, 39–43]), access to providers willing to prescribe PrEP (e.g., [18, 41, 44]), concerns among providers about increased sexual risk compensation (e.g., [29, 39]), but also, among those using or considering PrEP, concerns about side effects (e.g., [18, 39, 42, 43, 45]), stigma and discrimination (e.g., [18, 39, 43, 46–48]), and low perceived risk of infection (e.g., [18, 49–53]). Until recently, one significant gap in the literature was the lack of data on individuals' motivations for taking PrEP. Indeed, in their comprehensive early review of research on the acceptability of PrEP and treatment as prevention (TasP), Young and McDaid (2014) identified motivations for PrEP use and adherence as one of the main areas in which further research was needed in order to identify "when, where and for whom PrEP and TasP would be most appropriate and effective" [45, p. 195].

A number of researchers, particularly in anthropological, ethnographic and other primarily qualitative lines of enquiry, have since stepped up to the plate to examine this topic. By exploring the subjective experiences of MSM in their navigation of PrEP, these authors have identified, mostly through in-depth interviews or in focus groups, numerous and varied motivations for using (or not using) PrEP that call into question the usefulness of biomedical approaches to PrEP implementation that de-emphasise psychosocial phenomena. In many cases, the motivations identified in these studies have stemmed from powerful affective experiences, such as being freed from sometimes decades-long, often cyclical anxiety about HIV infection [37, 38, 54, 55]; feeling empowered, able to make one's own informed choices, in control or autonomous [37, 56]; and feeling less fear and shame in relation to pre-existing high-risk sexual behaviours alongside greater sexual satisfaction and intimacy [57, 58]. The qualitative literature also reports motivations related to fearing or experiencing PrEP-related stigma, such as beliefs that PrEP is only for those who are highly promiscuous [56, 59]; being labelled a

"Truvada whore" (or similar) in lesbian, gay, bisexual, transgender, intersex and other gender diverse (LGBTI+) media, or by peers or even friends [60]; encountering provider-level stigma, including judgemental behaviour about the decision to use PrEP [35]; or experiencing, as a PrEP user or non-user, increased pressure to engage in condomless anal intercourse [37, 58, 61].

Among the studies that have explored motivations using survey-based quantitative methods, many have approached the subject in an indirect fashion using, for instance, correlation or regression analysis to identify factors associated with PrEP use, non-use, willingness to use PrEP or PrEP acceptability. A recent example is an analysis of data from a national, online, open-prospective observational study among MSM in Australia by Keen et al. (2020), who found that PrEP use was independently associated with lower levels of HIV anxiety among PrEP-eligible men [54]. Another example is the correlation between lower perceived HIV risk and PrEP non-use or PrEP discontinuation, which has been reported in large number of studies to date (e.g., [31, 51–53, 56, 58]). Furthermore, in a cross-sectional study of 164 HIV-negative MSM in HIV seroconcordant negative primary partnerships who were not taking PrEP, Gamarel et al. (2015) found that age, education and intimacy motivations for condomless sex were associated with PrEP adoption intensions in a multivariate model based on data elicited using interview-administered survey questions and assessment scales. Clearly, all of these factors can be interpreted as motivations for considering or using PrEP, but in none of the examples mentioned above did the survey participants actually describe them as such. Indeed, among this latter stream of the quantitative literature, we were unable to identify any surveys that explicitly asked MSM to name or describe their motivations for taking PrEP, whether by providing them with a list of pre-specified motivations or the possibility of writing a free-text response.

While in-depth qualitative interviews and focus groups are probably the ideal way to explore the complex affective phenomena in this area of enquiry, there are several possible methodological advantages to eliciting such qualitative information using a self-administered survey tool: positioning an open-ended question amidst many closed questions might invite quick, spontaneous responses, and being open-ended it would, moreover, not be influenced by pre-specified categories or subjects (as would be the case with multiple choice items and/or the use of Likert scales) [62, 63]. Also, compared to data from a qualitative interview, the responses to such a question are more amenable to being coded and then analysed using a frequentist approach, and correlations with responses to the closed questions in the survey can be explored. The results can subsequently be reflected against those of previous, more in-depth qualitative research, with the aim of confirming, refuting, complicating or contextualising these. Moreover, whereas some previous work on different models of the PrEP care continuum has located participants of various cohorts along the respective cascade, to our knowledge no studies to date have attempted to identify whether the motivations of participants at one location in a PrEP care continuum might differ significantly from those at another location in the continuum. Lastly, it should also be noted that the focus of much of the qualitative and quantitative research on PrEP motivations to date has been on the US context, as well as on Australia, Canada and the United Kingdom. Perhaps not surprisingly given the four-year lag in the approval of PrEP in the EU/EEA [64], data from this region are minimal in comparison, and Germany is no exception in this regard.

To help fill this gap in the literature, we conducted a multicentre, paper-based survey in late 2017/early 2018 of almost 500 MSM in Berlin with a self-reported negative or unknown HIV serostatus. In it, we explored participants' knowledge and use of HIV pre-exposure prophylaxis using mostly closed questions. The results of this part of the survey are reported elsewhere [30]. The survey also had an open-ended question in which we explicitly asked participants

who were using or considering PrEP to write what their main motivation was for doing so. In the current paper, we present the results of a multi-methods analysis of participants' free-text responses to this question. Our primary aim was to identify, describe and categorise the motivations of MSM in Berlin to use or consider using PrEP. Additionally, drawing upon results from the quantitative part of the survey, we sought to explore whether motivations differed between participants who had already started taking PrEP and those who were still considering it. Such information could help clinicians, sexual health counsellors and policy makers develop and distribute targeted information and advice to individuals at several steps of the PrEP care continuum and thereby improve the implementation of PrEP in Germany and beyond.

Materials and methods

Study design, ethics approval and informed consent

We used an anonymous, self-administered, paper-based questionnaire, available in German and English, to conduct a multicentre, cross-sectional survey of MSM in Berlin. The local institutional ethics committee at Charité–Universitätsmedizin Berlin approved the study protocol, the format and content of the questionnaire, and the information cover sheet for participants (EA1/162/17; 28/09/2017). All participants gave informed verbal consent to their physician or sexual health counsellor in English or in German before filling in the questionnaire. Participation was voluntary, and neither the centres nor the participants received any incentives to take part. The survey period was from 1 October 2017 to 2 April 2018. The questionnaires and information cover sheet can be accessed in full, in both English and German, in the publication of the quantitative study results by Werner et al. (2018) [30].

Sampling methods, participants and settings

To be eligible, participants had to identify as male, be aged 18 years or older, report having sex with men, and have a self-reported negative or unknown HIV status. We collected data from a range of settings, namely all four non-municipal counselling and testing centres for the sexual health of LGBTI+ people, as well as six large HIV specialist practices in Berlin. The former are non-commercial walk-in centres funded by the state government of Berlin and through private donations. They offer a range of low-barrier services, including community outreach and anonymous counselling on legal, immigration and health issues for LGBTI+ adults and adolescents, as well as affordable testing for STIs, including HIV. They are not permitted by law to prescribe medication. All clients attending the walk-in centres for STI screening or counselling were offered participation in the study by the centre staff.

HIV specialist practices in Germany offer a full range of generalist and sexual health services to LGBTI+ people regardless of whether they are living with HIV, and indeed can serve as the designated GP/family doctors for these individuals. The practices are owned and staffed by physicians, and consultations usually require an appointment, but walk-ins are possible. In total, 11 such practices from seven districts in Berlin were invited to participate in the study. We chose these purposively based on their geographic spread across Berlin and our awareness that they had been willing to take part in previous research projects related to HIV and other STIs. In these practices, we asked doctors to include every eligible patient, irrespective of the reason for the consultation, in a consecutive manner.

During the data collection period (1 October 2017 to 2 April 2018), PrEP was available in Germany only by means of a private prescription, which could be written by any licensed doctor. About half way through this period, the price of a month's supply of generic PrEP in Germany fell from approximately 600 euros to as low as 50 euros [30]. The relevant guideline for identifying at-risk patients and prescribing PrEP is the German and Austrian Guideline on

HIV pre-exposure prophylaxis [65], but its recommendations are not binding. The German system of statutory health insurance began to cover the costs associated with PrEP in September 2019.

All of the HIV and STI testing and counselling centres in Berlin (n = 4) participated in the study, as did six of the 11 HIV specialist practices we had invited. Of the 875 questionnaires distributed by the participating centres, 473 were returned (response rate 54.1%). Three participants were excluded because they reported in the questionnaire that they were living with HIV. Of the remaining 470 questionnaires, 259 contained a free-text response to the question about participants' main motivation for using PrEP or considering its use. Thirty one of these responses were considered invalid because the participants had disagreed/strongly disagreed with the statement "I would like to take PrEP" (n = 30) or because they responded "no" to the question whether they had ever used PrEP but had indicated in their response to the statement "I would like to take PrEP" that it was not applicable to them because they were already taking it (n = 1). This resulted in a sample of 228 questionnaires with a valid free-text response for analysis.

Questionnaire format and content

The questionnaire was two pages in length and consisted mostly of closed, multiple-choice questions on participants' knowledge and use of HIV pre-exposure prophylaxis, as well as demographic data and information on their sexual behaviour and HIV risk. Additionally, the survey had the following open-ended question: "If you are considering or already using PrEP, what is your main motivation for this?" The question gave space for responses of one to two sentences. A cover page gave a brief description of PrEP and explained the purpose of the survey.

Qualitative data analysis

We defined our units of analysis as the individual motivations for using or considering PrEP rather than the free-text response as a whole. We applied a framework analysis approach to code each motivation, using high-level themes to categorise the data [66]. To help ensure that the analysis was not driven primarily by our theoretical interests and analytic preconceptions, we took a combined deductive and inductive approach to developing the coding framework [66, 67]: One researcher (RNW) created a set of categories and subcategories deductively based on the findings of a structured search of the literature for existing frameworks and models for characterising motivations for PrEP use, whereas a second researcher (MS) created a separate set of categories and subcategories inductively based on a pilot coding and analysis of a randomly selected subset of 75 free-text responses. These two classification systems were subsequently merged by the two researchers through discussion, with discrepancies and disagreements resolved by consensus in a series of meetings facilitated by a third researcher (MG).

The first researcher (RNW), who created a set of categories and subcategories deductively, took the following approach: To identify studies or reviews reporting a classification system or listing categories of motivations to use PrEP, he searched MEDLINE on 4 April 2018 using the search terms "motivation" and "PrEP", with time limits set to the five years before this date. Categories identified in the literature were noted without further assessment of the quality of the studies. The search yielded 61 records whose abstracts and titles were screened for eligibility, yielding six records to be evaluated in full text [51, 58, 68–71]. Two of these studies were used to derive an initial categorisation system for motivations: Dubov et al. (2018) reviewed factors associated with PrEP uptake and categorised these factors along the Information-Motivation-Behavioural Skills model [51]. Their construct of motivation comprised four domains,

each of which is attributed various further subdomains. Frankis et al. (2016) analysed qualitative data from in-depth interviews to deduce motivations for potential PrEP use, including situations of increased need for protection from acquiring HIV [68].

The second researcher (MS), who developed a set of categories and subcategories inductively, took the following approach: first, the third researcher (MG) familiarised himself with the entire qualitative dataset by reading and re-reading all free-text responses to make a pragmatic assessment of the number of these that would need to be coded before saturation was reached (i.e., roughly one third of all valid responses). Subsequently, a list of randomly generated numbers was appended to the qualitative dataset, and the responses numbered between one and 75 were sent to the second researcher for pilot coding. Coding was undertaken in a manner that was both open (i.e., with codes being assigned to describe as many perspectives as possible, such as particular behaviours, intentions, values, beliefs and emotions) [66] and circular (i.e. looping or cycling repeatedly between the qualitative codes assigned to the data and the data itself, and recoding, considering emergent categories, and recategorising as needed) [72].

After the two classification systems had been merged, the final categories comprised: safety/protection against HIV, expectations about sexuality, mental well-being and quality of life, condom attitudes, and norms/social perspectives. Table 1 gives an overview of the categories

Table 1. Overview of final coding framework and categorisation system with definitions (categories and subcategories listed in alphabetical order).

Category	Subcategory
CONDOM ATTITUDES [51]	**Desire or intent to engage in condomless sex**
This category comprises two subcategories for coding responses that refer to respondents' attitudes towards condom use.	Responses are coded in this subcategory if they refer to the desire or intent to engage in condomless sex. Negative attitudes towards condom use and reporting episodes of condomless intercourse have been described as being associated with the intention to use PrEP [73].
	Difficulties with condom use
	Responses are coded in this subcategory if they mention difficulties with condom use as a motivation to use PrEP [55].
EXPECTATIONS ABOUT SEXUALITY	**Expectations of more pleasureful sex or increased intimacy and closeness (when not using a condom)**
This category comprises two subcategories for coding responses that refer to respondents' expectations about sexuality while using PrEP.	Responses are coded in this subcategory if they include the expectation of more pleasureful sex, intimacy or closeness as a motivation to use PrEP, irrespective of whether the response refers to using condoms. Believing that condoms reduce intimacy and closeness and/or sexual pleasure is a factor that has been described as associated with the intention to use PrEP [37, 55, 58].
	Expectations of worry-free sex
	Responses are coded in this subcategory if they refer to the expectation of worry-free or less worrisome sex as the motivation for using PrEP [37]. In contrast to the subcategory "Reducing anxiety, fear, or worries of being infected with HIV" under the category "Mental well-being and quality of life", responses here had to mention sex or sexuality explicitly.
MENTAL WELL-BEING AND QUALITY OF LIFE	**Desire for a healthy life**
	Responses are coded in this subcategory if they refer to the general desire to increase health or longevity, or to lead a healthy life.
This category comprises four subcategories for coding responses that refer to respondents' mental well-being or aspects of general health.	**Desire to increase quality of life or sexual/personal freedom**
	Responses are coded in this subcategory if they refer to the desire to increase quality of life, mental well-being, general health, or sexual or personal freedom as the motivation to use PrEP [37].
	Reducing anxiety, fear, or worries of being infected with HIV
	Responses are coded in this subcategory if they include the desire to reduce anxiety, fear or worries about being infected with HIV [37, 38, 54, 55]. Unlike the subcategory "expectations of worry-free sex", this subcategory does not include responses that refer explicitly to the act of sex.
	Reducing periods of anticipated regret
	Responses are coded in this subcategory if they included the desire to decrease periods of anticipated regret or worries. The cognitive-based emotion of anticipated regret from engaging in HIV-risk behaviour has been described as an important determinant of the intention to use PrEP [51].
NORMS / SOCIAL PERSPECTIVES	**Perceiving condomless sex / PrEP intake as a social norm**
This category comprises two subcategories for coding responses that refer either to perceptions of PrEP use as a social norm or that reflect upon PrEP use in terms of social or public health perspectives.	Responses are coded in this subcategory if the answer refers to perceptions of PrEP use as a social norm or the need to use PrEP as the only means of personal protection in a social environment that insists on condomless sex [37, 58, 61].
	Prevention altruism [51]
	Responses are coded in this subcategory if the respondent refers to a general public health perspective of reducing the burden of HIV epidemics. General public health concerns have been described as a facilitator of engaging in safer sex practices [74].

(*Continued*)

Table 1. (Continued)

Category	Subcategory
SAFETY/PROTECTION AGAINST HIV	**Additional protection against HIV**
This category comprises eight subcategories for coding responses that refer to protection against HIV or general safety considerations, as well as more specific aspects of protection or safety for oneself or for others.	Responses are coded in this subcategory if they reflect the respondent's wish to have additional protection against HIV, or additional safety or security, by using PrEP as a "backup preventive strategy". This has been described in the literature as a specific motivation to use PrEP [68]. Safer sex intentions have been shown to be linked with the motivation to use PrEP [73].
	Autonomy and self-empowerment in the protection against HIV
	Responses are coded in this subcategory if they reflect the respondent's wish to protect himself from being infected with HIV using a method of protection that lies within his own responsibility and is not dependent on his partners' reliability or will to use condoms [37, 56].
	Being at self-perceived risk of HIV
	Responses are coded in this subcategory if they reflect the respondent's general perception of being at risk of acquiring HIV due to specific circumstances, such as having sex with many casual partners or being in a relationship with a person living with HIV. Self-perceived risk of acquiring HIV has been described as a factor that may motivate individuals to seek preventive services. Considering oneself as being at risk of HIV infection has been shown to be correlated with self-perceived eligibility for PrEP use [31, 51–53, 56, 58].
	PrEP as an affordable way to protect against HIV
	Responses are coded in this subcategory if they mention the affordability or cost of PrEP as an option to protect oneself from being infected with HIV.
	Protecting partner(s) or relationship(s) from HIV infection
	Responses are coded in this subcategory if they reflect the respondent's wish to protect his (sex) partners' health or well-being or if the answers included relationship-associated aspects. Attitudes towards using PrEP have been shown to be linked with considerations of protecting primary and/or outside partners [55, 73]. Concerns for the sexual partners' risk of acquiring HIV and general public health concerns have also been described as a facilitator of engaging in safer sex practices [74].
	Protection against HIV during periods of anticipated increased risk (e.g., recreational drug use, holidays)
	Responses are coded in this subcategory if they reflect the respondent's wish to protect himself from being infected with HIV during specifically defined events (e.g., recreational drug use) or periods (e.g., holidays) that are accompanied by an anticipated increased risk of being infected with HIV. PrEP has been described as an option for situations in which regular patterns of sexual practice might be disrupted, such as holidays or in the event of alcohol and/or drug use [53, 68].
	Protection against HIV, prevention of HIV and general safety
	Responses are coded in this subcategory if they reflect the respondent's general wish to protect himself from being infected with HIV, or his generally expressed need for safety, without mentioning specific circumstances or specifying aims beyond (his individual) protection.
	Protection against HIV when not using condoms
	Responses are coded in this subcategory if they reflect the respondent's wish to protect himself from being infected with HIV explicitly without having to use condoms.

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and subcategories in our coding system, providing definitions for each, as well as references to the pertinent literature.

Two researchers (RNW, MS) subsequently used this framework independently to identify, code and classify individual motivations in each free-text response (including the 75 responses used in the pilot coding). Meetings among all three researchers were held at regular intervals

during the coding and classification process to discuss potential emerging new categories or subcategories during the coding. Ultimately, no substantial changes to the framework were needed during this process, although we did clarify the definition for the subcategory "Expectations of worry free-sex" to require, in contrast to the subcategory "Reducing anxiety, fear, or worries of being infected with HIV", the explicit mention of sex or sexuality. Moreover, a subcategory "Desire to increase quality of life or sexual freedom" was broadened to include "sexual/personal freedom". Furthermore, even though the number of responses in the category "Norms / social perspectives" was minimal, we decided to retain it because of its prominence as a finding in the qualitative literature (e.g., [37, 58, 61]) and our desire not to take an overly frequentist approach to reporting the qualitative data. Lastly, while preparing the manuscript we decided to use the term "quality of life" instead of "general health" to describe the category "Mental health and quality of life" because we felt the term better captured the nature of the responses we had assigned to various subgroups in this category.

There was a high degree of agreement between the coding results of the two researchers (Cohen's Kappa = 0.837, 95% CI: 0.794–0.880). The third researcher (MG) reviewed all disagreements and resolved these with the other researchers through discussion.

Quantitative data analysis

No formal sample size calculations were performed for the survey. Based on feasibility considerations, we aimed at collecting data from approximately 500 participants. Data were analysed using descriptive statistics and Fisher's exact test of independence to assess whether the frequency of motivations for PrEP, by category, differed in a statistically significant manner (alpha level 0.05) between the subset of the sample that reported using PrEP or having a history of its use and the subset that reported considering PrEP.

In our data set, we classified respondents who indicated no previous PrEP use, reported a motivation, and did not disagree or strongly disagree with the statement that they would like to use PrEP as considering PrEP use. Within all of the models of the PrEP care continuum developed to date, this group could be located at any of the steps before the step corresponding to PrEP initiation (e.g., "Initiate PrEP" in the model by Newman et al. (2018) [37], Stage 4b of "Stage 4: PrEP action and initiation" in the model by Parsons et al. (2018) [34], or "Step 7: Initiating PrEP" in the model by Nunn et al. (2017) [33]). Respondents who reported that they were currently using PrEP or had used it in the past (i.e. "Yes, but not on a regular basis", "Yes, I regularly use it before and after risk sex (as needed)", "Yes, I use it continuously"), reported a motivation, and did not disagree or strongly disagree with the statement that they would like to use PrEP were classified as using PrEP or having a history of its use. This group could be located, roughly, in "Stage 5: PrEP maintenance and adherence" of the model by Parsons et al. (2018) or at steps 8 ("Adhere to PrEP") or 9 ("Retention in PrEP Care") of the model by Nunn et al. (2017). However, because we included people with different PrEP trajectories (i.e., those who had used PrEP in the past but were not necessarily taking it at present), they would be more appropriately placed between the steps "Initiate PrEP" and "Retention", with the possibility of being located at the stages "Seasonal or intermittent use" or "Discontinuation" on the augmented PrEP cascade of Newman et al (2018) [37].

For any post-hoc pairwise comparisons, we applied a Bonferroni-corrected alpha level of 0.05 divided by the number of compared pairs to account for multiple testing. To avoid a purely frequentist approach and preserve the richness of our qualitative data when reporting examples of motivational factors given in response to the open question, we chose to cite whenever possible five motivations that summarised the overall body of motivations in each subcategory, whether responses in this subcategory were frequent or rare. In cases where fewer

or more than five motivations were sufficient or needed for this purpose, a different number of responses is cited. Statistical analyses were performed using Stata SE version 14.2.

Results

Demographic data, sexual behaviour and HIV risk of analysis sample

Among the 228 respondents who gave a valid free-text response to our question about motivation, 65 were using PrEP or had used it at some point in the past, and 163 were considering it. Their mean age was 36.4 years (SD 10.8, range 20–79). Table 2 shows these and other

Table 2. Demographic data and sexual risk behaviour of participants who answered the question about their motivation for using or considering PrEP.

	Analysis sample	Participants using PrEP (or with history of its use)	Participants considering PrEP use
	N = 228	N = 65	N = 163
Age			
Mean (SD) in years	36.4 (10.8)	33.9 (6.9)	37.3 (11.8)
Min-max in years	20–79	24–53	20–79
Not stated	9	5	4
Highest degree or level of school (N, %)			
Primary education	0 (0.0%)	0 (0.0%)	0 (0.0%)
Secondary education up to year 10*	21 (9.2%)	3 (4.6%)	18 (11.0%)
Secondary educ. with apprenticeship	11 (4.8%)	1 (1.5%)	10 (6.1%)
Secondary education up to year 12**	41 (18.0%)	7 (10.8%)	34 (20.9%)
University degree	151 (66.2%)	50 (76.9%)	101 (62.0%)
Not stated	4 (1.8%)	4 (6.2%)	0(0.0%)
Financial situation (N, %)			
Not always have enough money	19 (8.3%)	7 (10.8%)	12 (7.4%)
Enough money	104 (45.6%)	25 (38.5%)	79 (48.5%)
More than enough money	102 (44.7%)	30 (46.2%)	72 (44.2%)
Not stated	3 (1.3%)	3 (4.6%)	0 (0.0%)
Place of residence (N, %)			
Berlin	213 (93.4%)	60 (92.3%)	153 (93.9%)
Other city in Germany	7 (3.1%)	1 (1.5%)	6 (3.7%)
Small town / rural area in Germany	0 (0.0%)	0 (0.0%)	0 (0.0%)
Other country	5 (2.2%)	1 (1.5%)	4 (2.5%)
Not stated	3 (1.3%)	3 (4.6%)	0 (0.0%)
Family origins (N, %)			
Participant & both parents born in Germany	132 (57.9%)	29 (44.6%)	103 (63.2%)
One parent born outside Germany	17 (7.5%)	7 (10.8%)	10 (6.1%)
Both parents born outside Germany	19 (8.3%)	7 (10.8%)	12 (7.4%)
Participant born outside Germany	56 (24.6%)	19 (29.2%)	37 (22.7%)
Not stated	4 (1.8%)	3 (4.6%)	1 (0.6%)
Current HIV status (N, %)			
HIV negative	198 (86.8%)	61 (93.8%)	137 (84.0%)
Not sure	24 (10.5%)	0 (0.0%)	24 (14.7%)
Not stated	6 (2.6%)	4 (6.2%)	2 (1.2%)
STI diagnosis in the past six months (N, %)			
No	168 (73.7%)	37 (56.9%)	131 (80.4%)
Yes	57 (25.0%)	25 (38.5%)	32 (19.6%)

(*Continued*)

Table 2. (Continued)

		Analysis sample	Participants using PrEP (or with history of its use)	Participants considering PrEP use
		N = 228	N = 65	N = 163
	Not stated	3 (1.3%)	3 (4.6%)	0 (0.0%)
Role when having anal sex (N, %)				
	No anal sex	7 (3.1%)	0 (0.0%)	7 (4.3%)
	Bottom only	21 (9.2%)	6 (9.2%)	15 (9.2%)
	More bottom than top	60 (26.3%)	15 (23.1%)	45 (27.6%)
	Top and bottom (versatile)	58 (25.4%)	19 (29.2%)	39 (23.9%)
	More top than bottom	49 (21.5%)	12 (18.5%)	37 (22.7%)
	Top only	30 (13.2%)	10 (15.4%)	20 (12.3%)
	Not stated	3 (1.3%)	3 (4.6%)	0 (0.0%)
Number of anal sex partners in the past six months (N, %)				
	None	14 (6.1%)	0 (0.0%)	14 (8.6%)
	1	22 (9.6%)	2 (3.1%)	20 (12.3%)
	2 to 5	67 (29.4%)	12 (18.5%)	55 (33.7%)
	6 to 10	44 (19.3%)	13 (20.0%)	31 (19.0%)
	More than 10	76 (33.3%)	35 (53.8%)	41 (25.2%)
	Not stated	5 (2.2%)	3 (4.6%)	2(1.2%)
Number of anal sex partners without using condom in the past six months (N, %)				
	None	62 (27.2%)	6 (9.2%)	56 (34.4%)
	1	54 (23.7%)	7 (10.8%)	47 (28.8%)
	2 to 5	71 (31.1%)	23 (35.4%)	48 (29.4%)
	6 to 10	21 (9.2%)	11 (16.9%)	10 (6.1%)
	More than 10	17 (7.5%)	15 (23.1%)	2 (1.2%)
	Not stated	3 (1.3%)	3 (4.6%)	0 (0.0%)

STI, sexually transmitted infection

*or similar

**for example A levels, high school diploma, German "Abitur".

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demographic and sexual risk behaviour data for these respondents (analysis sample), as well as separately for those who were using PrEP (or had a history of its use) and those who were considering it. Differences between these latter two subgroups were minor and similar to the roughly analogous subgroups reported in the publication on the quantitative results of the survey [30].

See S1 Table for a comparison of the demographic data and sexual risk behaviour of participants in our analysis sample and respondents who indicated that they were neutral about or might be interesting in taking PrEP but did not provide a free-text answer to the question about their motivation (n = 104). The latter group was very similar to our analysis sample in terms of age, educational attainment and place of residence, but was different to it insofar as a substantially larger proportion of respondents were less financially secure, were unsure about their HIV status, had never used PrEP and reported engaging in sexual behaviour that put them at lower risk of HIV infection.

Motivations of the participants

The number of motivations cited by participants ranged from one to five (mean: 1.38, median: 1.0). More specifically, of the 228 responses to the question about participants' motivation for

Table 3. Participants reporting one or more motivations exclusively in a category or combination of categories in the analysis sample, by subgroup (using or considering PrEP).

Category of motivation(s) for using or considering PrEP	Participants in analysis sample	Participants using PrEP (or with history of its use)	Participants considering PrEP use
	N = 228	**N = 65**	**N = 163**
Safety	121 (53.1%)	30 (46.2%)	91 (55.8%)
Mental well-being	23 (10.1%)	7 (10.8%)	16 (9.8%)
Condom attitudes	21 (9.2%)	4 (6.2%)	17 (10.4%)
Expectations	14 (6.1%)	4 (6.2%)	10 (6.1%)
Norms	2 (0.9%)	1 (1.5%)	1 (0.6%)
TOTAL RESPONDENTS	**181**	**46**	**135**
Safety & mental well-being	12 (5.3%)	4 (6.2%)	8 (4.9%)
Safety & condom attitudes	10 (4.4%)	4 (6.2%)	6 (3.7%)
Safety & expectation	6 (2.6%)	5 (7.7%)	1 (0.6%)
Expectations & mental well-being	6 (2.6%)	3 (4.6%)	3 (1.8%)
Expectations & condom attitudes	4 (1.8%)	1 (1.5%)	3 (1.8%)
Mental well-being & condom attitudes	4 (1.8%)	1 (1.5%)	3 (1.8%)
TOTAL RESPONDENTS	**42**	**18**	**24**
Safety, mental well-being & condom attit.	4 (1.8%)	1 (1.5%)	3 (1.8%)
Safety, expectations & mental well-being	1 (0.0%)	0 (0.0%)	1 (0.6%)
TOTAL RESPONDENTS	**5**	**1**	**4**

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using or considering PrEP, we coded 152 as describing one motivation, 66 as describing two motivations, 9 as describing three motivations, and 1 as describing five motivations. All free-text responses that contained multiple motivations reported these clearly as part of a list using the conjunctions "and" or "but", a comma or other form of punctuation, or some combination of these.

Table 3 gives an overview of the different categories of motivations and the number of respondents who reported one or more motivations exclusively in each category (or combination of categories). Of the 228 respondents, 154 reported some form of safety and protection against HIV as either their only motivation (n = 121) or one of their motivations (n = 33) for using or considering PrEP. This was followed by 50 respondents who reported some form of mental well-being and quality of life as either their only motivation (n = 23) or one of their motivations (n = 27). A total of 43 respondents reported condom attitudes (i.e., a desire or intention to engage in condomless sex) as either their only motivation (n = 21) or one of their motivations (n = 22). Lastly, 31 respondents reported some form of expectations about sexuality as either their only (n = 14) or one of their motivations (n = 17). Only two respondents reported norms and social perspectives as their only motivation for using or considering PrEP. Among those respondents who reported two motivations in total, the only combinations of motivations that comprised at least approximately 5% of the analysis sample were in the categories safety and mental well-being (12 respondents, 5.3%) and safety and condom attitudes (10 respondents, 4.4%). The difference in the frequencies between the two subsamples was not statistically significant (Fisher's exact test, p = 0.234). A post hoc pairwise comparison of the frequencies also revealed that none of them differed in a statistically significant manner between the groups when the alpha level was set to 0.003 (i.e., 0.05/13).

Looking at the subcategories of motivations adds more granular information and complexity to this picture. In the safety category, responses citing general aspects of safety and

protection against HIV predominated (mentioned by 40.4% of respondents), but were followed by more specific motivations, such as PrEP serving as additional protection above and beyond condom use (16.2%), being at risk of HIV infection (7.5%), or seeking protection against HIV when not using condoms (6.1%). Nine respondents (0.04%) mentioned safety or protection in relation to protecting others as opposed to themselves. In the condom attitudes category, 18.0% percent of respondents explicitly mentioned a desire to engage in condomless sex as a motivation for using or considering PrEP. Expectations about sexuality, as a category, included explicit mentions of anxiety- or worry-free sex (8.3%) and of more pleasurable sex (6.1%) as motivations. Lastly, the category of mental well-being and quality of life included motivations related to reducing anxiety, fear or worries of being infected with HIV (8.6%) and a desire to increase quality of life or sexual and personal freedom (8.3%). Table 4 gives

Table 4. Qualitative results: Survey respondents' motivations for using or considering PrEP according to category and subcategory, their frequency, and representative examples.

CATEGORY: SAFETY/PROTECTION AGAINST HIV		
Subcategory	**Frequency**	**Example motivations**
General safety/Protection against HIV/Prevention of HIV	92/228 (40.4%)	"To protect myself from HIV"
		"Reduce the chance of HIV infection"
		"Safety regarding HIV infection"
		"HIV prophylaxis"
		"Health protection"
Additional protection against HIV	37/228 (16.2%)	"Additional safety when having sex"
		"Backup"
		"I want extra protection in case a condom fails or if I make a bad decision."
		"To protect myself from HIV if the condom slips off or loses its protection for some other reason"
		"Protection (double, with condom)"
Being at self-perceived risk of HIV	17/228 (7.5%)	"HIV-infected partner who has just begun therapy"
		"It has happened in the past, even though I didn't intend to, that I had sex without a condom"
		"Many casual sex partners from time to time"
		"Protection, I live in a long-term relationship with an HIV positive guy"
Protection against HIV when not using condoms	14/228 (6.1%)	"To feel safer in case of unprotected sex"
		"Easy protection when having sex without a condom"
		"Sex without a condom and hardly any risk of infection"
		"Protection against HIV without a condom"
Autonomy and self-empowerment	9/228 (3.9%)	"To protect myself more actively and not rely on others, for example regarding a condom"
		"More autonomy as (I am) more a bottom"
		"I have more safety and don't have to depend on my partner keeping the condom on"
		"Because I find it hard to trust people, so as a way to be more careful."
		"More control"
Protecting partner(s) or relationship(s)	9/228 (3.9%)	"To protect health (mine, of my partner & of my sex partner)"
		"To protect my opposite"
		"Protection for me and others"
		"Greater security in an open relationship"
		"The knowledge that I can't harm anybody with my actions"
		"My partner has HIV and we're in an open relationship"
Protection against HIV during periods of anticipated increased risk (e.g. recreational drug use, holidays)	5/228 (2.2%)	"To avoid accidents when I'm in environments that may affect my decisions and behaviour. At a party or around the time I go for a party. I am afraid that alcohol consumption or simply condom break may expose me to HIV."
		"Addition protection during special occasions (e.g., holiday)"
		"I have more security and don't have to rely on (. . .) myself, even under the influence of alcohol, insisting on a condom in every situation"
		"Protection against stupidity when drinking alcohol"
PrEP as an affordable protection against HIV	2/228 (0.0%)	"Protection, low costs"
		"It seems like an affordable option and viable way to help protect against HIV infection."
CATEGORY: MENTAL WELL-BEING AND QUALITY OF LIFE		
Subcategory	**Frequency**	**Example motivations**

(*Continued*)

Table 4. (Continued)

Reducing anxiety, fear or worries of being infected with HIV	17/197 (8.6%)	"Paranoia, fear of getting infected"
		"Not constantly having to be afraid"
		"Less anxiety before the next HIV test"
		"My whole life there's only been sex with a condom and fear of HIV"
		"To free myself from fear"
		"Although I'm putting myself at risk of getting an STD, I find the benefits of PrEP overwhelmingly because I no longer have to fear that I'll get HIV"
Desire to increase quality of life or sexual / personal freedom	19/228 (8.3%)	"Peace of mind"
		"Convenience"
		"Quality of life"
		"Not always (. . .) having to take PEP"
		"Personal freedom"
		"Sexual freedom"
		"A feeling of security"
		"Uncomplicated sex"
		"Spontaneous sex (. . .) also with casual partners"
		"I'd like to try a few sex partners who I otherwise couldn't (try out) without being on PrEP"
		"So I can behave more like heterosexuals and not worry every time I choose not to use a condom"
Reducing periods of anticipated regret	8/228 (3.5%)	"The psycho-stress after unprotected sex"
		"No guilty conscience about unsafe sex"
		"To not feel regret after unsafe sex"
		"Less chance for my imagination to run away from me" ("weniger Kopfkino")
		"To have a better conscience after having unsafe sex"
Desire for a healthy life	7/228 (3.1%)	"To protect (my) health"
		"To not become ill"
		"Longer life"
		"Health"
		"Stay healthy"
CATEGORY: CONDOM ATTITTUDES		
Subcategory	**Frequency**	**Example motivations**
Desire or intent to engage in condomless sex	41/228 (18.0%)	"I don't like condoms"
		"Anal sex without a condom"
		"Unsafe sex"
		"Unprotected sex"
		"To have sex without condom with known sexual partners that test for other STDs regularly"
		"Unprotected sex with partner"
		"To have riskier sex"
Difficulties with condom use	2/228 (0.9%)	"Protection from HIV because I can't deal with condoms"
		"Problem with condom when being a top"
CATEGORY: EXPECTATIONS ABOUT SEXUALITY		
Subcategory	**Frequency**	**Example motivations**
Expectations of worry-free sex	19/228 (8.3%)	"It's a way to feel safer when having sex"
		"More relaxed approach to sexuality"
		"Unencumbered Sex"
		"Sex without fear"
		"To have riskier sex without fear"
		"Carefree sex without worrying about HIV infection"
Expectations of more pleasureful sex	14/228 (6.1%)	"More pleasure"
		"Sex is more intense"
		"To enjoy sex"
		"To (. . .) enjoy sex more"
		"Intense feeling during sex"
		"More sensuality, more pleasure"
CATEGORY: NORMS / SOCIAL PERSPECTIVES		
Subcategory	**Frequency**	**Example motivations**
Perceiving condomless sex/PrEP intake as a social norm	1/228 (0.4%)	"More and more guys are doing bareback sex only"
Desire to eradicate HIV	1/228 (0.4%)	"Eradicating HIV"

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examples of the motivations ordered along these categories; responses in German were translated into English for presentation in the table by one researcher (MG) and checked independently by the remaining authors, with disagreements resolved by consensus.

Discussion

Our study is the first multicentre, paper-based survey to ask MSM in Berlin explicitly to name their motivations for using or considering HIV PrEP. By a large margin, most respondents who answered the question cited some form of safety and protection against HIV as their only motivation or one of their motivations in this regard. Most frequently in this category, respondents mentioned being motivated by the idea of having additional protection in case of condom failure (e.g., "To protect myself from HIV if the condom slips off or loses its protection for some other reason", "Additional safety when having sex"). Even though some 18% of respondents in our analysis sample explicitly mentioned a desire or intent to engage in condomless sex as a motivation for using or considering PrEP, these findings about safety and protection should reassure payers and practitioners who might be focusing disproportionately on the subject of sexual risk compensation, i.e., an increase in sexual behaviours that could put those who engage in them at a higher risk of infection with HIV and other STIs [75–80]. Indeed, the second most frequently cited category of motivations among our respondents after that of safety and protection was that of mental well-being and quality of life. Given the alarming frequency of suicide, depression and self-harm among sexual minorities, for which there is an abundance of evidence worldwide (e.g., [81–83]), our results suggest that it might be wise to attach greater weight to these beneficial effects of PrEP when deciding on its appropriateness for a given patient–and perhaps somewhat less weight than hitherto to the understandable but still largely theoretical concern of increased sexual risk compensation and STI incidence, for which the evidence is mixed [84–86].

This latter finding resonates with the results of qualitative studies that have engaged with this area of enquiry, challenging the predominant biomedical approach to PrEP implementation. With regard to motivations such as those to reduce HIV anxiety, improve self-efficacy, be able to make one's own informed choices, and feel less fear and shame, for example, our respondents wrote short but powerful responses about "not constantly having to be afraid," living a "whole life" in which "there's only been sex with a condom and fear of HIV", wanting to "try a few sex partners who I otherwise couldn't without being on PrEP", and no longer having to "feel regret" or have "psycho-stress" after having "unprotected" or "unsafe" sex. Examining such phenomena, and affective experiences more generally, is crucial because these have been shown to have a profound impact on the sexual and psychological well-being of MSM (e.g., [35, 37, 38, 57, 59, 60]). Moreover, these motivations are also tied to ongoing decision-making about PrEP that is based on sexual risk and relationship trajectories that have been shown to be varied and dynamic [37].

This idea of moving beyond a circumscribed biomedical approach to PrEP implementation is supported by a further, and somewhat unexpected, result from our study: Even though our survey item asked only for respondents' main motivation for using or considering PrEP, one third (76/228) of our respondents nevertheless reported more than one motivation. Although these multiple motivations often fell into the same category (most frequently into that of safety and protection), it is important to bear in mind that even in a category as seemingly one-dimensional as "safety and protection", a broad range of subcategories could be identified, including protection during periods of anticipated increased risk, self-perceptions of being at high risk, and additional protection against HIV while using a condom. Moreover, some 20% (47/228) of respondents reported motivations in more than one category. Altogether, this

suggests that approaches to PrEP counselling that seeks, where appropriate, to increase the uptake of PrEP by focusing exclusively on its effectiveness in preventing HIV is unlikely to be as successful as a holistic approach that focuses simultaneously on multiple motivating factors, particularly those related to mental health and quality of life. While this may be something that any good doctor, sexual health counsellor or social worker would do, the results of our study might nevertheless be useful as a reminder of the breadth of motivations that can influence the decision to use PrEP and encourage practitioners to seek to identify multiple (and, indeed, even apparently contradictory) factors in individual patients. This may also aid decisions to inform patients about other preventive strategies, and to provide support with broader sexual and psychological health issues, as part of a more holistic approach.

The idea of taking a more holistic approach to PrEP implementation has been the focus of several recent publications. Lacombe-Duncan et al. (2021) drew on qualitative data from in-depth, semi-structured interviews with 29 MSM recruited purposively in 2015/16 in a community setting in Toronto, Canada, to identify and explore gaps in PrEP implementation that might be amenable to social work intervention [61]. Among other results, they found that MSMs' navigation of sexual health and risk practices was made complex by a range of sometimes contradictory factors encompassing the individual, interpersonal, organisational and structural levels. This aligns very much with the breadth of motivations reported in our survey, as well as the reporting of multiple motivations by individual respondents. Lacombe-Duncan et al. (2021) make clear that addressing such factors and, more specifically, the social determinants of health and psychosocial issues that affect PrEP engagement solely in terms of HIV infection risk and a binary decision about PrEP uptake would be wholly inadequate to support individuals with informed decision making [61]. A recently published systematic review by Pinto et al. (2018) corroborates these and, in part, our findings, and identifies the need for a range of multilevel interventions targeting multiple socioecological domains, such as interventions to help people navigate health care systems and improve referrals to mental health and supportive services, as well as provider-level interventions such as increased training and education about PrEP [43]. In their scoping review of PrEP service delivery and programming, Hillis et al. (2020) also identify a range of potentially useful multidisciplinary and innovative PrEP care pathways; however, they make the important additional point that PrEP provision in a health system actually creates new opportunities for MSM to access health services to which they might not otherwise have availed themselves, such as sexual health care, testing, treatment, counselling and STI testing and psychological support [87].

A further aim of our study was to determine whether motivations differed between individuals at two different locations on a conceptual continuum of PrEP care: those who were using it or had used it at some point in the past and those who were contemplating or considering its use. Contrary to our expectations, we were unable to identify statistically significant differences in motivations between the groups that might inform targeted approaches to increase uptake or improve adherence. From a qualitative research perspective, however, it is of value to point out that some of the differences appeared substantial and would be worthy of further investigation, ideally applying methods and a study design that would allow for quantitative hypothesis testing as well as in-depth qualitative questioning of findings. In particular, it appears that participants considering PrEP may have been more likely to cite safety as their only motivation whereas motivations in combination with the category of safety played a greater role among those using PrEP or with a history of its use. While this may be due to social desirability bias in survey research, it is conceivable that once individuals have initiated PrEP, other categories of benefits–for example related to expectations around sexuality or mental well-being–may become more readily apparent to them. Interestingly, the comprehensive review of the literature undertaken by Young et al. (2013) before the wide rollout of PrEP found that willingness

to take PrEP (the closest construct to motivations that they examined) was associated with younger age, unprotected anal intercourse with casual partners and increased risk perceptions; on the other side, anxieties around medical side effects of PrEP were commonly reported in the included studies as barriers. Psychosocial correlates of willingness, such as reduced anxiety about HIV infection or an increase in self-efficacy, do not appear to have been reported as frequently in this pre-rollout phase, however. While this may simply be an artefact of the biomedical approach to these questions taken by many of the studies included in their review, it might also support the hypothesis that these positive aspects of PrEP only become more readily apparent after PrEP use has been initiated.

Some of our findings were surprising. Attitudes towards using PrEP have been shown in the literature to be linked to considerations of protecting primary and/or outside partners [73], and concerns for sexual partners' risk of acquiring HIV and the public health have also been described as a facilitator of engaging in safer sex practices [74]. In our study, however, among the high number of respondents who reported some form of safety or protection against HIV as their only motivation or as one of their motivations (n = 154), only a few (n = 9) cited protecting their partners or relationships as a relevant motivational factor. One reason for this may be that a requirement for initiating PrEP, unlike using a condom, is that an individual gets tested for HIV. Knowing with greater certainty that they were not infected with HIV may have led them to focus more on the protective effects of PrEP for themselves rather than the thought of preventing onward transmission. Regardless, given the evidence that individuals are more averse to risk when their decisions affect others [74, 88, 89], focusing on risks to others to convince people to engage in beneficial public health behaviours remains an important part of public health messaging and initiatives. Moreover, the literature [37, 80, 90, 91] and anecdotal reports from the centres that took part in our study suggest that, increasingly, PrEP use is becoming a social norm and many individuals feel pressured to use PrEP in a social environment that insists on sex without condoms. Surprisingly, however, only one participant in our study mentioned this as a motivation for using or considering PrEP ("More and more guys are doing bareback sex only"). The reasons for this result are unclear, but may be related to an already long established culture of unprotected sex in subgroups of the gay population in large cities like Berlin, or to the fact that, at the time of our survey, PrEP had only just become available through formal channels in Germany. Regardless, the topic warrants further research, particularly of a qualitative nature.

An important strength of our survey is that we asked participants explicitly about their motivation for considering or using PrEP rather than interpreting various factors correlated with PrEP contemplation or PrEP use as motivations. Another strength is its facility-based, multicentre design and paper format, which may have avoided or ameliorated some of the disadvantages of online surveys, such as self-selection bias and multiple responses from the same individuals. Nevertheless, our study also has a number of substantial limitations beyond its cross-sectional, observational design and the obvious caveats that this entails. First, the results of survey-based studies are subject to social desirability bias [92–96]. It is probable that some of our respondents indicated that their motivation for taking PrEP was safety because they wanted to project a favourable image of themselves or, despite the anonymous nature of the survey, they thought doing so would ensure continued good care from their physician or make it more likely they would obtain a prescription for PrEP. However, we found no statistically significant differences between the motivations reported by respondents who had a history of PrEP use and those who were considering it. Presumably individuals who had already taken PrEP before will have had fewer concerns about gaining access to the medication. Moreover, if reporting socially desirable motivations had been a strong force behind respondents' answers, one might have expected, from both subgroups, a larger number of responses focusing on the

protection of others or the public health more generally. Second, although our coding framework was developed and implemented in a systematic manner by three independent researchers, any set of codes and categories will always, to a certain extent, be arbitrary. We attempted to address this point by testing the assumption of independence of observations in larger and broader categories (as opposed to our subcategories), but it is possible that a different system of coding would yield different results. Third, due to our study being based on a paper survey with limited space for a free-text response, we were unable to pursue an important avenue of qualitative enquiry, namely in-depth follow-up questions leading from the general to the specific. Without this, it is impossible to know what the more superficial but also the deeper motivations for using or considering PrEP might be. In-depth interviews exploring our findings in future projects might bring more clarity. Fourth, respondents to our survey who indicated that they were neutral about or might be interested in taking PrEP but did not respond to our open question may have had different motivations than those who did provide a response. Our informal comparison of these two groups (see S1 Table) suggests that these individuals may have been less interested in PrEP because their self-perceived risk of HIV infection was lower due to their sexual risk behaviour (e.g., fewer anal sex partners and more condom use). Moreover, the findings of our study and the larger quantitative survey of which it is a part [30] are specific to MSM in Berlin and therefore limited in their generalisability. Nevertheless, they can provide a helpful comparison to the situation in cities with roughly similar populations of MSM such as London, San Francisco, Paris or New York, where the implementation of PrEP is already well underway. Fifth, because of space limitations in our paper-based survey we did not ask for explicit motivations for not using PrEP. Doing so would have added an interesting dimension to the study and allowed us to explore additional steps along the PrEP care continuum and approaches to promoting alternative prevention strategies. Sixth, although we did not exclude transgender MSM from taking part in our survey, we did not explicitly instruct participating centres to include or exclude this group. Anyone who identified as male (cis or trans) and reported having sex with other MSM could take part. Other sampling strategies could have been used to obtain meaningful data on transgender MSM's motivations for using or considering PrEP but would have gone beyond the scope of our study.

Conclusion

As part of a broader multicentre survey of MSM in Berlin, Germany, we additionally asked participants in an open-ended question about their main motivation for using or considering the use of PrEP. While the focus of their responses lay on safety, the range of motivations was broad and could be grouped into five main categories, listed in descending order of frequency: safety and protection again HIV, mental well-being and quality of life, a desire or an intention to engage in sex without a condom, expectations about sexuality, and norms and social perspectives. There were no statistically significant differences in motivations between participants who were using PrEP already versus those who were considering its use. Many respondents reported several motivations, and responses overall were heterogeneous. This suggests that health professionals seeking, where appropriate, to increase PrEP uptake by focusing exclusively on its effectiveness in preventing HIV is unlikely to be as successful as a holistic approach that focuses on multiple motivating factors, particularly those related to mental health and quality of life. These results may inform health providers' approach to PrEP education and prescribing, as well as the design of information campaigns and other interventions to increase PrEP uptake alongside other strategies of HIV prevention and support for the broader sexual and psychological health of MSM.

Supporting information

S1 Table. Demographic data and sexual risk behaviour of participants in analysis sample and participants who were neutral about or potentially interested in taking PrEP but who did not answer the question about their main motivation.
(DOCX)

S1 Dataset. Minimal underlying data set and codebook. Age of respondents has been removed to ensure patient anonymity.
(XLSX)

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Publication 2 (print copy)

Publication 2: Mary Katherine Sammons, ***Matthew Gaskins***, Frank Kutscha, Alexander Nast, Ricardo Niklas Werner. HIV Pre-exposure Prophylaxis (PrEP): Knowledge, attitudes and counselling practices among physicians in Germany – A cross-sectional survey. PLoS One. 2021;16(4):e0250895. doi:10.1371/journal.pone.0250895. (submitted 25 January 2021)

Excerpt from Journal Summary List (see next page)

Journal Data Filtered By: **Selected JCR Year: 2019** Selected Editions: SCIE,SSCI
Selected Categories: **"MULTIDISCIPLINARY SCIENCES"** Selected Category Scheme: WoS
Gesamtanzahl: 71 Journale

Rank	Full Journal Title	Total Cites	Journal Impact Factor	Eigenfactor Score
1	NATURE	767,209	42.778	1.216730
2	SCIENCE	699,842	41.845	1.022660
3	National Science Review	2,775	16.693	0.009760
4	Science Advances	36,380	13.116	0.172060
5	Nature Human Behaviour	2,457	12.282	0.014190
6	Nature Communications	312,599	12.121	1.259510
7	Science Bulletin	5,172	9.511	0.014150
8	PROCEEDINGS OF THE NATIONAL ACADEMY OF SCIENCES OF THE UNITED STATES OF AMERICA	676,425	9.412	0.931890
9	Journal of Advanced Research	3,564	6.992	0.005470
10	GigaScience	4,068	5.993	0.016410
11	Scientific Data	5,761	5.541	0.028720
12	Research Synthesis Methods	2,572	5.299	0.006440
13	ANNALS OF THE NEW YORK ACADEMY OF SCIENCES	45,596	4.728	0.026370
14	FRACTALS-COMPLEX GEOMETRY PATTERNS AND SCALING IN NATURE AND SOCIETY	2,156	4.536	0.002210
15	iScience	1,410	4.447	0.004140
16	GLOBAL CHALLENGES	481	4.306	0.001440
17	Scientific Reports	386,848	3.998	1.231180
18	JOURNAL OF KING SAUD UNIVERSITY SCIENCE	1,640	3.819	0.002020
19	Journal of the Royal Society Interface	13,762	3.748	0.027670

Rank	Full Journal Title	Total Cites	Journal Impact Factor	Eigenfactor Score
20	Frontiers in Bioengineering and Biotechnology	2,770	3.644	0.007650
21	NPJ Microgravity	346	3.380	0.001210
22	PHILOSOPHICAL TRANSACTIONS OF THE ROYAL SOCIETY A-MATHEMATICAL PHYSICAL AND ENGINEERING SCIENCES	20,609	3.275	0.027840
23	PROCEEDINGS OF THE JAPAN ACADEMY SERIES B-PHYSICAL AND BIOLOGICAL SCIENCES	1,669	3.000	0.001980
24	Advanced Theory and Simulations	432	2.951	0.000700
25	SCIENCE AND ENGINEERING ETHICS	2,129	2.787	0.003760
26	PROCEEDINGS OF THE ROYAL SOCIETY A-MATHEMATICAL PHYSICAL AND ENGINEERING SCIENCES	19,218	2.741	0.018450
27	PLoS One	688,763	2.740	1.388860
28	Royal Society Open Science	7,222	2.647	0.027340
29	Symmetry-Basel	4,888	2.645	0.005390
30	INTERNATIONAL JOURNAL OF BIFURCATION AND CHAOS	7,115	2.469	0.007090
31	COMPLEXITY	4,413	2.462	0.007160
32	PeerJ	17,984	2.379	0.062850
33	MIT Technology Review	871	2.357	0.001810
34	Science of Nature	673	2.090	0.002400
35	SCIENCE PROGRESS	499	1.906	0.000340
36	SOUTH AFRICAN JOURNAL OF SCIENCE	2,631	1.866	0.001800
37	Journal of Taibah University for Science	1,126	1.863	0.001470
38	Journal of Radiation Research and Applied Sciences	1,127	1.804	0.002280

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RESEARCH ARTICLE

HIV Pre-exposure Prophylaxis (PrEP): Knowledge, attitudes and counseling practices among physicians in Germany – A cross-sectional survey

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Abstract

Background

German statutory health insurance began covering the costs associated with HIV PrEP in September 2019; however, to bill for PrEP services, physicians in Germany must either be certified as HIV-specialists according to a nationwide quality assurance agreement, or, if they are non-HIV-specialists, have completed substantial further training in HIV/PrEP care. Given the insufficient implementation of PrEP, the aim of our study was to explore the potential to increase the number of non-HIV-specialists providing PrEP-related services.

Methods

We conducted an anonymous survey among a random sample of internists, general practitioners, dermatologists and urologists throughout Germany using a self-developed questionnaire. We calculated a knowledge score and an attitudes score from individual items in these two domains. Both scores ranged from 0–20, with high values representing good knowledge or positive attitudes. We also asked participants about the proportion of PrEP advice they provided proactively to men who have sex with men (MSM) and trans-persons who met the criteria to be offered PrEP.

Results

154 physicians completed the questionnaire. Self-assessed knowledge among HIV-specialists was greater than among non-HIV-specialists [*Median* knowledge score: 20.0 (*IQR* = 0.0) vs. 4.0 (*IQR* = 11.0), $p<0.001$]. Likewise, attitudes towards PrEP were more positive among HIV-specialists than non-HIV-specialists [*Median* attitudes score: 18.0 (*IQR* = 3.0) vs. 13.0 (*IQR* = 5.25), $p<0.001$]. The proportion of proactive advice on PrEP provided to at-risk MSM and trans-persons by HIV-specialists [*Median*: 30.0% (*IQR* = 63.5%)] was higher than that provided by non-HIV-specialists [*Median*: 0.0% (*IQR* = 11.3%), $p<0.001$].

underlying data set and codebook (Supporting file S3). Age of respondents, postal code, state and qualitative data have been removed to ensure anonymity.

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However, the results of our multiple regression suggest the only independent predictor of proactive PrEP advice was the knowledge score, and not whether physicians were HIV-specialists or non-HIV-specialists.

Conclusions

These findings point to opportunities to improve PrEP implementation in individuals at risk of acquiring HIV. Targeted training, particularly for non-HIV-specialists, and the provision of patient-centered information material could help improve care, especially in rural areas.

Introduction

HIV pre-exposure prophylaxis (PrEP) consisting of tenofovir disoproxil fumarate and emtricitabine has been approved for HIV prevention in the United States since 2012 and in the European Union since 2016. Its high effectiveness and safety have been demonstrated in several randomized controlled trials [1–4], and observational studies in a number of metropolitan regions have shown dramatic reductions in the incidence of HIV infections, especially in men who have sex with men (MSM), in recent years–a substantial proportion of which is likely due to PrEP [5–10].

Despite these developments, the uptake of PrEP among those at high risk of HIV acquisition has been slow. By 2019 approximately 224,000 people in the US were estimated to have received a prescription for PrEP, representing only a small fraction of the 1.1 million individuals calculated by researchers at the US Centers for Disease Control and Prevention (CDC) to have an indication for it [11–13]. In Europe, a 2019 study based on data from the European MSM Internet Survey found that an estimated 17.4% of MSM, or 500,000 individuals, in the EU who were very likely to use PrEP were not able to access it [14]. Improving the uptake of PrEP therefore remains a key public health priority.

The German system of statutory health insurance began covering the costs associated with HIV pre-exposure prophylaxis (PrEP) in September 2019. In order to be able to bill for PrEP-related appointments and testing costs, however, physicians in Germany must either be certified according to the German Quality Assurance Agreement on HIV/AIDS as HIV specialists or, if they are non-HIV specialists and belong to certain specialties (e.g., internal and general medicine, dermatology and urology), have completed further training on HIV and PrEP [15]. The training consists of taking part in a 16-hour internship in an outpatient or inpatient HIV care facility and being present during consultations with at least 15 persons who are either living with HIV/AIDS or considering or taking PrEP. In addition, proof of participation in further training courses on the topic must be provided [15]. Because many physicians in Germany work in regions that do not have an outpatient or inpatient HIV treatment facility, the certification requirements represent a substantial barrier to providing PrEP care. This could potentially lead to gaps in treatment, particularly in smaller towns and rural areas, where HIV specialist centers are rare [16].

Given the insufficient implementation of PrEP in populations at risk of acquiring HIV in Germany [17, 18] and beyond, the aim of our study was to explore the potential to increase the number of non-HIV-specialists prescribing PrEP by reducing the barriers to their completing further training. We therefore sought to examine and compare, among HIV-specialists and non-HIV-specialists, self-assessed knowledge and attitudes towards PrEP, as well as the proportion of PrEP advice provided proactively to men who have sex with men (MSM) and trans

persons who met the criteria to be offered PrEP according to the German and Austrian PrEP guideline ("at-risk patients"). Such information could be useful for identifying opportunities to improve PrEP implementation in individuals at risk of acquiring HIV, particularly those in regions underserved by HIV-specialists.

Materials and methods

Study design

We conducted a survey among office-based general practitioners, internists, infectious disease specialists, dermato-venereologists and urologists in Germany. Data was collected from August to October 2019. The study was approved by the institutional ethics board of Charité —Universitätsmedizin Berlin (EA1/006/19). Participation was voluntary and no incentives were provided. All participants were older than 18 years. Participants in the online survey provided their written informed consent by ticking the box next to a statement that they had read the study information and agreed to participate in the study. For participants who completed the paper version of the survey, we assumed consent if they returned their questionnaire by fax or mail.

Setting and participants

Physicians in the abovementioned groups in Germany were eligible to participate in the survey. We classified participants as HIV-specialists if they indicated that they worked in an HIV-specialty practice, and as non-HIV-specialists if they indicated that they did not to work in such a practice. HIV specialist practices in Berlin are owned and staffed primarily by doctors certified as HIV-specialists according to the German Quality Assurance Agreement on HIV/AIDS, and visiting these practices usually requires an appointment. They provide a range of generalist and sexual health care to LGBTI+ people whether or not these individuals are living with HIV.

We used various strategies to recruit participants: (1) We requested the contact details of a random sample of 2,200 office-based physicians in the eligible specialties from the National Association of Statutory Health Insurance Physicians (Kassenärztliche Bundesvereinigung, KBV). We mailed these physicians a paper version of our questionnaire, which could be returned to us by fax or mail. A reminder email with a link to an online version of the questionnaire was sent to the 926 (42%) physicians in this sample for whom we had an email address; (2) An invitation to participate in the survey, containing a link to the online version of the questionnaire, was sent to 253 members of the German AIDS Society (Deutsche AIDS Gesellschaft, DAIG) and to 330 members of the German STI Society (Deutsche STI Gesellschaft, DSTIG) via their online mailing lists. A reminder email was sent two weeks after the initial invitation; (3) Additionally, we placed flyers advertising our study at a Berlin STI conference in September 2019. All online surveys were completely anonymous, with neither IP addresses nor email addresses recorded.

Variables and measurements

A standardized German-language questionnaire exploring PrEP knowledge, attitudes and counselling practices among physicians in Germany was not available. We therefore developed the questionnaire for the purposes of the present study (S1 and S2 Files). The original draft questionnaire (MS) was tested and discussed (RW, MG, FK) to identify and solve any problems concerning the comprehensibility of the content and design, and to ensure alignment with a related questionnaire we developed to explore PrEP knowledge, attitudes and counselling practices among non-governmental counselling centres and local health offices in Germany. The results of this latter study are published elsewhere [19].

Demographic data included medical specialty, whether the practice had been certified according to the Quality Assurance Agreement on HIV/AIDS, age, gender and languages spoken. The first three numbers of the practice zip codes were recorded to determine in which of Germany's 16 states the practice was located. To obtain contextual information about the practice, we asked how many (a) HIV tests had been performed, (b) HIV infections diagnosed and (c) MSM and transgender patients seen within an average calendar quarter (3 months).

After providing a brief summary of the recommendations of the German and Austrian guideline [20] on the indications for offering PrEP to HIV-negative MSM and transgender persons (which served as our definition of "at-risk patients"), we asked participants to indicate the number of patients they saw during an average quarter who fulfilled these criteria and the number of these patients who were provided with advice on PrEP proactively by the physician. Self-assessed knowledge about PrEP and self-reported attitudes towards PrEP were quantified as described in our previous study [19]. This comprised the calculation of a summative knowledge score and a summative attitudes score from five individual knowledge and attitude items, respectively. The total scores ranged from 0 and 20, with high values representing good knowledge or positive attitudes toward PrEP, respectively. Furthermore, we presented a list of various aspects that might be perceived as barriers to patients initiating PrEP and asked participants to rate the relevance of each of these aspects on an 11-level rating scale. This included barriers for the patients as assessed in the previous study [19], as well as additional barriers for physicians. Lastly, we asked participants which training or information materials would help them with PrEP advice and prescriptions [19].

Sample size and statistical methods

The questionnaire was developed for the purposes of this study, and no data were available on expected means or variability. Therefore, no sample size calculation was performed and the size of the random sample (n = 2,200) was based on feasibility considerations. Statistical analyses were performed using IBM® SPSS® Statistics version 25 (sample characteristics and bivariate statistics) and STATA SE version 14.2 (linear regression). Independent t-tests, Mann-Whitney U-tests, Pearson's chi squared tests and Fisher's Exact tests were used to quantify associations between variables, depending on the distribution and type of data.

We performed a multiple linear regression using both backward and forward elimination to identify predictors of the proportion of proactive advice on PrEP that had been provided during appointments with at-risk patients. The following variables for the regression model were purposefully selected a priori: HIV specialist status (HIV-specialists vs. non-HIV-specialists), size of the city in which the physician's practice was located, location in either a western or eastern German state (with eastern states being defined as any of the five new states formed from the territory of former East Germany as part of German reunification in 1990), gender, percentage of positive HIV tests (number of positive tests/total number of patients tested), knowledge score and attitudes score. The stopping rule for eliminating individual variables in the logistic regression was $p<0.2$. Variance inflation factor (VIF) statistics, tolerance and condition index were used to ensure that there was no multi-collinearity of the predictors or instability of the regression coefficients. Missing cases were excluded in a listwise fashion. The level for statistical significance was set at $p<0.05$.

Results

Demographic data

We received a total of 161 responses, of which we excluded seven because they did not provide meaningful information. The sample included in our analyses therefore consisted of 154

respondents, 72 of whom indicated that they worked in an HIV-specialty practice and 79 of whom indicated that they did not work in such a practice ("non-HIV-specialists"). Three participants did not provide information about their HIV specialist status or medical specialty; data from these participants were included only in the analyses of barriers to the prescription of PrEP and of helpful materials and training. Demographic data of the sample, including tests for differences according to HIV specialist status, are shown in *Table 1*. Statistically significant associations between HIV specialist status and demographic data were found for gender ($\chi^2(df = 1, n = 151) = 6.938$, $p = 0.008$), specialty ($\chi^2(df = 5, n = 151) = 83.379$, $p<0.001$), size of the city in which the practice was located ($\chi^2(df = 3, n = 142) = 33.378$, $p<0.001$), and the state in which the practice was located (i.e., eastern states vs. western states) ($\chi^2(df = 1, n = 142) = 3.833$, $p = 0.05$).

Physician appointments with at-risk patients and HIV testing practice

Table 2 depicts data on the number of (a) appointments with MSM and trans persons overall, (b) appointments with MSM and trans persons who met the criteria to be offered PrEP according to the German and Austrian guideline ("at-risk patients"), (c) the overall number of HIV tests and (d) the number and proportion of positive HIV tests per quarter as indicated by the respondents. For all of the mentioned variables, we found statistically significant differences between HIV-specialists and non-HIV-specialists.

Independent of their HIV specialist status, the respondents indicated that in a median of 15.5% of their appointments with at-risk patients, they proactively provided advice on PrEP (*Table 3*). The proportion of appointments with at-risk patients in which the physician provided proactive advice on PrEP was significantly higher among HIV-specialists than it was among non-HIV-specialists: HIV-specialists indicated that they proactively provided advice on PrEP in a median of 30.0% of their contacts with at-risk patients, whereas non-HIV-specialists indicated that they proactively provided advice on PrEP in a median of 0.0% of their contacts, $U = 468.500$, $p<0.001$.

Self-assessment of PrEP knowledge and advising competence

For each of the self-assessed dimensions of knowledge and competence, the participants in our survey tended to agree with the relevant statements in the questionnaire if they were HIV-specialists, whereas they tended to disagree with these statements if they were non-HIV-specialists. These differences were found to be statistically significant (*Table 4*). Correspondingly, the summative knowledge score was higher for HIV-specialists (*Median* = 20.0, *IQR* = 0.0) than it was for non-HIV-specialists (*Median* = 4.0, *IQR* = 11.0), $U = 279.0$, $p<0.001$.

Attitudes towards PrEP

Regarding attitudes towards PrEP, we found that HIV-specialists agreed with all of the statements expressing a positive attitude and disagreed with the statement expressing a negative attitude more often than the non-HIV-specialists (*Table 5*). As with the summative knowledge score reported above, the summative attitudes score was higher among HIV-specialists (*Median* = 18.0, *IQR* = 3.0) than among non-HIV-specialists (*Median* = 13.0, *IQR* = 5.25), $U = 588$, $p<0.001$.

Multiple linear regression on the proportion of proactive PrEP advice

To determine independent factors that predicted the proportion of PrEP advice provided proactively by physicians to at-risk patients, we developed a multiple linear regression model. Applying both a backward elimination and a stepwise forward elimination method (both with a stopping rule of $p<0.2$ for the exclusion or inclusion of each variable), the same regression

Table 1. Demographic data and contextual characteristics of the sample.

Variable		Total sample		HIV specialist status			
				HIV-specialists		Non-HIV-specialists	
N		154*		72		79	
Age in years (n = 145)							$p = 0.180^{\dagger}$
	Mean (*SD*)	52.22	(8.98)	51.20	(8.46)	53.20	(9.39)
	Min; *Max*	33–84		34–76		33–84	
Gender (***n***, **%**)							$p = 0.008^{\$}$
	Female	54	(35.1%)	18	(25.0%)	36	(45.6%)
	Male	97	(63.0%)	54	(75.0%)	43	(54.4%)
	Not specified	3	(1.9%)	0	(0.0%)	0	(0.0%)
Specialty (***n***, **%**)							$p < 0.001^{\$}$
	General Medicine	35	(22.7%)	11	(15.3%)	24	(30.4%)
	Internal Medicine	27	(17.5%)	22	(30.6%)	5	(6.3%)
	Dermatology	25	(16.2%)	4	(5.6%)	21	(26.6%)
	Urology	25	(16.2%)	0	(0.0%)	25	(31.6%)
	General Medicine and Internal Medicine with Additional Qualification for Infectious Disease	37	(24.0%)	35	(48.6%)	2	(2.5%)
	Not specified	5	(3.4%)	0	(0.0%)	2	(2.5%)
Size of city (***n***, **%**)							$p < 0.001^{\$}$
	Metropolis (>1,000,000)	52	(33.8%)	36	(50.0%)	16	(20.3%)
	Large city (>100,000)	44	(28.6%)	25	(34.7%)	19	(24.1%)
	City (>10,000)	27	(17.5%)	4	(5.6%)	23	(29.1%)
	Small city (≤ 10,000)	19	(12.3%)	2	(2.8%)	17	(21.5%)
	Not specified	12	(7.8%)	5	(6.9%)	4	(5.1%)
State (***n***, **%**)							$p = 0.05^{\#}$
	Western German states, including Berlin	**123**	**(79.9%)**	**62**	**(86.1%)**	**61**	**(77.2%)**
	Baden-Wuerttemberg	15	(9.7%)	8	(11.1%)	7	(8.9%)
	Bavaria	18	(11.7%)	13	(18.1%)	5	(6.3%)
	Berlin	26	(16.9%)	14	(19.4%)	12	(15.2%)
	Bremen	2	(1.3%)	0	(0%)	2	(2.5%)
	Hamburg	5	(3.2%)	4	(5.6%)	1	(1.3%)
	Hesse	23	(14.9%)	12	(16.7%)	11	(13.9%)
	Lower Saxony	5	(3.2%)	0	(0.0%)	5	(6.3%)
	North Rhine-Westphalia	22	(14.3%)	10	(13.9%)	12	(15.2%)
	Rhineland-Palatinate	5	(3.2%)	1	(1.4%)	4	(5.1%)
	Saarland	2	(1.3%)	0	(0.0%)	2	(2.5%)
	Schleswig-Holstein	0	(0.0%)	0	(0.0%)	0	(0.0%)
	Eastern German states, excluding Berlin	**19**	**(12.3%)**	**5**	**(6.9%)**	**14**	**(17.7%)**
	Brandenburg	2	(1.3%)	0	(0.0%)	2	(2.5%)
	Mecklenburg-Western Pomerania	1	(0.6%)	0	(0.0%)	1	(1.3%)
	Saxony	7	(4.5%)	3	(4.2%)	4	(5.1%)
	Saxony-Anhalt	5	(3.2%)	0	(0.0%)	5	(6.3%)
	Thuringia	4	(2.6%)	2	(2.8%)	2	(2.5%)
	Not specified	12	(7.8%)	5	(6.9%)	4	(5.1%)

Max, maximum; *Min*, minimum; *SD*, standard deviation;

*3 patients who were included in some of the analyses in the present study did not provide information about their specialist status (HIV-specialists vs. non-HIV-specialists);

†From independent samples t-tests of the null hypothesis that the mean value of non-HIV-specialists is equal to that of HIV specialists;

$From Pearson's Chi squared tests of the null hypothesis that there is no statistically significant difference between the observed and expected frequencies in each category, according to the HIV specialist status;

#From Pearson's Chi squared tests of the null hypothesis that there is no statistically significant difference between the observed and expected frequencies in the categories "western German states" vs. "eastern German states", according to the HIV specialist status.

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Table 2. Number of appointments with different categories of patients and HIV-tests per calendar quarter.

				HIV specialist status			
Variable		**Total sample**		**HIV-specialists**		**Non-HIV-specialists**	
Number of overall appointments with MSM and trans persons per quarter (n = 141)							$p < 0.001^{\dagger}$
	Median (IQR)	30.0	(345.0)	375.0	(400.0)	5.0	(18.0)
	Mean (*SD*)	162.50	(213.05)	327.88	(210.47)	16.97	(33.20)
	Q1 –*Q3*	5.0–350.0		100.0–500.0		2.0–20.0	
Number of appointments with MSM and trans persons who met the criteria to be offered PrEP according to the German and Austrian guideline (at-risk clients) per quarter (n = 131)							$p < 0.001^{\dagger}$
	Median (IQR)	17.0	(99.0)	100.0	(170.0)	1.0	(6.0)
	Mean (*SD*)	71.74	(114.08)	143.60	(132.33)	7.17	(15.33)
	Q1 –*Q3*	1.0–100.0		30.0–200.0		0.0–6.0	
Overall number of HIV tests per quarter (n = 145)							$p < 0.001^{\dagger}$
	Median (IQR)	20.0	(87.0)	80.0	(195.0)	4.0	(17.7)
	Mean (*SD*)	73.14	(124.03)	139.94	(152.79)	12.50	(23.21)
	Q1 –*Q3*	3.0–90.0		30.0–225.0		1.0–18.7	
Number of positive HIV test results per quarter (n = 143)							$p < 0.001^{\dagger}$
	Median (IQR)	1.0	(2.0)	2.0	(4.0)	0.0	(1.0)
	Mean (*SD*)	5.64	(30.46)	11.45	(43.93)	0.51	(1.36)
	Q1 –*Q3*	0.0–2.0		1.0–5.0		0.0–1.0	
Proportion of positive HIV test results among overall number of HIV tests per quarter (n = 140)							$p < 0.001^{\dagger}$
	Median (IQR)	1.63%	(6.50%)	2.83%	(8.73%)	0.00%	(5.00%)
	Mean (*SD*)	6.47%	(12.41%)	8.02%	(10.16%)	5.16%	(13.96%)
	Q1 –*Q3*	0.00%-6.50%		1.27%-10.00%		0.00%-5.00%	

IQR, interquartile range; *Q1*, first quartile; *Q3*, third quartile;

†From Mann-Whitney U-tests of the null hypothesis that the median value of HIV specialists is equal to that of non HIV specialists.

https://doi.org/10.1371/journal.pone.0250895.t002

equation was found ($F(3,79) = 7.70$, $p<0.001$, $n = 83$), with $R^2 = 0.165$ (*Table 6*). Only the city size, knowledge score and attitudes score remained in the model; ultimately, however, the only statistically significant predictor was the knowledge score.

Educational materials and barriers

In total, 121 participants answered the question about which materials or tools they thought would increase the practicability of their PrEP counselling and prescriptions. Patient decision

Table 3. Advice on PrEP during appointments with MSM and trans persons who met the criteria to be offered PrEP according to the German and Austrian guideline (at-risk patients).

				HIV specialist status			
Variable		**Total sample**		**HIV-specialists**		**Non-HIV-specialists**	
Proportion of appointments with 'at-risk' MSM and trans persons in which physicians themselves proactively address the topic PrEP (n = 102)							$p < 0.001^{\dagger}$
	Median (IQR)	15.48%	(50.0%)	30.00%	(63.50%)	0.00%	(11.32%)
	Mean (SD)	30.20%	(35.34%)	40.70%	(34.21%)	16.36%	(32.21%)
	Q1 –*Q3*	0.00% - 50.00%		11.50% - 75.00%		0.00% - 11.32%	

IQR, interquartile range; *Q1*, first quartile; *Q3*, third quartile; *SD*, standard deviation;

†From Mann-Whitney U-tests of the null hypothesis that the median value of HIV-specialists is equal to that of non-HIV-specialists.

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Table 4. Self-assessment of knowledge and counselling competence.

Variable		Total sample		HIV specialist status			
				HIV-specialists		Non-HIV-specialists	
Global assessment: "I am well-informed about PrEP" (n, %), $n = 128$							$p < 0.001^{\dagger}$
	Strongly disagree	31	(24.2%)	1	(1.8%)	30	(42.3%)
	Disagree	17	(13.3%)	0	(0.0%)	17	(23.9%)
	Neither agree nor disagree	6	(4.7%)	1	(1.8%)	5	(7.0%)
	Agree	16	(12.5%)	4	(7.0%)	12	(16.9%)
	Strongly agree	58	(45.3%)	51	(89.5%)	7	(9.9%)
Indications: "I am able to comprehensively give patients advice on whether it makes sense to take PrEP in their respective case" (n, %), $n = 128$							$p < 0.001^{\dagger}$
	Strongly disagree	23	(18.0%)	1	(1.8%)	22	(31.0%)
	Disagree	22	(17.2%)	0	(0.0%)	22	(31.0%)
	Neither agree nor disagree	10	(7.8%)	1	(1.8%)	9	(12.7%)
	Agree	15	(11.7%)	5	(8.8%)	10	(14.1%)
	Strongly agree	58	(45.3%)	50	(87.7%)	8	(11.3%)
Adverse effects: "I am able to comprehensively give patients advice on the adverse effects of PrEP" (n, %), $n = 128$							$p < 0.001^{\dagger}$
	Strongly disagree	31	(24.2%)	1	(1.8%)	30	(42.3%)
	Disagree	19	(14.8%)	0	(0.0%)	19	(26.8%)
	Neither agree nor disagree	7	(5.5%)	0	(0.0%)	7	(9.9%)
	Agree	11	(8.6%)	3	(5.3%)	8	(11.3%)
	Strongly agree	60	(46.9%)	53	(93.0%)	7	(9.9%)
Modalities of intake: "I am able to comprehensively give patients advice on the possible modalities of intake of PrEP (e.g., continuous vs. on-demand)" (n, %), $n = 128$							$p < 0.001^{\dagger}$
	Strongly disagree	31	(24.2%)	1	(1.8%)	30	(42.3%)
	Disagree	20	(15.6%)	0	(0.0%)	20	(28.2%)
	Neither agree nor disagree	5	(3.9%)	1	(1.8%)	4	(5.6%)
	Agree	10	(7.8%)	2	(3.5%)	8	(11.3%)
	Strongly agree	62	(48.4%)	53	(93.0%)	9	(12.7%)
Investigations: "I am able to comprehensively give patients advice on the medical investigations necessary during the use of PrEP" (n, %), $n = 128$							$p < 0.001^{\dagger}$
	Strongly disagree	29	(22.7%)	1	(1.8%)	28	(39.4%)
	Disagree	20	(15.6%)	0	(0.0%)	20	(28.2%)
	Neither agree nor disagree	6	(4.7%)	1	(1.8%)	5	(7.0%)
	Agree	9	(7.0%)	2	(3.5%)	7	(9.9%)
	Strongly agree	64	(50.0%)	53	(93.0%)	11	(15.5%)
Knowledge score (0–20), $n = 128$							$p < 0.001^{\#}$
	Median (*IQR*)	15.0	(17.0)	20.0	(0.0)	4.0	(11.0)
	Mean (*SD*)	11.89	(8.43)	19.23	(2.96)	6.49	(6.76)
	Q1 –*Q3*	3.0–20.0		20.0–20.0		0.0–11.0	

Max, maximum; *Min*, minimum; *IQR*, interquartile range; *Q1*, first quartile; *Q3*, third quartile;

[†]From Fisher's Exact tests of the null hypothesis that there is no statistically significant difference between the observed and expected frequencies in each category, by physician group.

[#]From Mann-Whitney U-tests of the null hypothesis that the median value of HIV-specialists is equal to that of non-HIV-specialists.

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aids that present information on PrEP in patient-friendly language (71.9%, $n = 87$) and in different languages (56.2%, $n = 68$) were chosen most frequently. About half of the respondents (53.7%, $n = 65$) indicated that a national guideline containing a clear presentation of indications, contraindications and laboratory investigations would be helpful. Whereas about half of

Table 5. Attitudes towards PrEP.

Variable		Total sample		HIV specialist status			
				HIV-specialists		Non-HIV-specialists	
Global assessment: "I think that PrEP is an important element of HIV prevention strategies" (n, %), *n* = 126							$p < 0.001^{\$}$
	Strongly disagree	1	(0.8%)	0	(0.0%)	1	(1.4%)
	Disagree	7	(5.6%)	1	(1.8%)	6	(8.7%)
	Neither agree nor disagree	10	(7.9%)	1	(1.8%)	9	(13.0%)
	Agree	30	(23.8%)	4	(7.0%)	26	(37.7%)
	Strongly agree	78	(61.9%)	51	(89.5%)	27	(39.1%)
Reliability: "I think that PrEP is a reliable method to protect oneself from HIV" (n, %), *n* = 124							$p < 0.001^{\$}$
	Strongly disagree	5	(4.0%)	0	(0.0%)	5	(7.5%)
	Disagree	8	(6.5%)	0	(0.0%)	8	(11.9%)
	Neither agree nor disagree	19	(15.3%)	4	(7.0%)	15	(22.4%)
	Agree	44	(35.5%)	16	(28.1%)	28	(41.8%)
	Strongly agree	48	(38.7%)	37	(64.9%)	11	(16.4%)
Adverse effects: "I think that PrEP is a method to protect oneself from HIV that has few side effects" (n, %), *n* = 124							$p < 0.001^{\$}$
	Strongly disagree	5	(4.0%)	0	(0.0%)	5	(7.4%)
	Disagree	19	(15.3%)	2	(3.6%)	17	(25.0%)
	Neither agree nor disagree	36	(29.0%)	11	(19.6%)	25	(36.8%)
	Agree	37	(29.8%)	21	(37.5%)	16	(23.5%)
	Strongly agree	27	(21.8%)	22	(39.3%)	5	(7.4%)
Availability of better alternatives: "I think that PrEP is unnecessary, because there are better alternatives to protect oneself from HIV" (n, %), *n* = 121							$p = 0.003^{\$}$
	Strongly disagree	54	(44.6%)	34	(59.6%)	20	(31.3%)
	Disagree	38	(31.4%)	17	(29.8%)	21	(32.8%)
	Neither agree nor disagree	23	(19.0%)	5	(8.8%)	18	(28.1%)
	Agree	3	(2.5%)	1	(1.8%)	2	(3.1%)
	Strongly agree	3	(2.5%)	0	(0.0%)	3	(4.7%)
Reimbursement of costs: "I think that PrEP should be paid for by the statutory health insurance" (n, %), *n* = 124							$p = 0.001^{\$}$
	Strongly disagree	10	(8.1%)	1	(1.8%)	9	(13.4%)
	Disagree	15	(12.1%)	3	(5.3%)	12	(17.9%)
	Neither agree nor disagree	23	(18.5%)	10	(17.5%)	13	(19.4%)
	Agree	25	(20.2%)	9	(15.8%)	16	(23.9%)
	Strongly agree	51	(41.1%)	34	(59.6%)	17	(25.4%)
Attitude Score (0–20), *n* = 118							$p < 0.001^{\dagger}$
	Median (*IQR*)	15.5	(5.0)	18.0	(3.0)	13.0	(5.25)
	Mean (*SD*)	14.93	(3.92)	17.29	(2.59)	12.90	(3.78)
	Q1 –*Q3*	13.0–18.0		16.0–19.0		10.0–15.25	

IQR, interquartile range; *Q1*, first quartile; *Q3*, third quartile;

†From Mann-Whitney U-tests of the null hypothesis that the median value of HIV-specialists is equal to that of non-HIV-specialists

$^{\$}$From Fisher's Exact tests of the null hypothesis stating that there is no statistically significant difference between the observed and expected frequencies in each category, according to physician group.

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the respondents (53.7%, *n* = 65) indicated that educational material or training on the management of PrEP would be useful for their practice, fewer indicated that educational material or training on identifying PrEP candidates (38.8%, *n* = 47) or on talking with patients about sex (29.8%, *n* = 36) would be helpful. However, significantly more non-HIV-specialists than HIV-specialists indicated that they wished to receive educational material or training on how to

Table 6. Multiple linear regression to predict the proportion of PrEP advice provided proactively to MSM and trans persons who meet the criteria be offered PrEP according to the German and Austrian guideline (at-risk patients).

Predictors	Coefficient (*Robust SE*)		Beta	*p*	*VIF*
Constant	-32.632	(16.238)		0.048	
Size of the city [1]	6,107	(4.553)	0.170	0.184	1.39
Knowledge score[2]	1,782	(0.585)	0.320	0.003	2.00
Attitudes score[3]	1.851	(1.031)	0.191	0.077	1.57

SE, standard error; *VIF*, variance inflation factor; [1] Size of the city coded in 4 categories with 0 indicating more than 1,000,000 inhabitants and 3 indicating less than 10,000 inhabitants [2] Scale from 0 to 20 points, with higher scores indicating a more positive self-assessment of knowledge about PrEP and counselling competence; [3] Scale from 0 to 20 points, with higher scores indicating a more positive attitude towards PrEP.

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manage PrEP users (61.9% vs. 43.6%, $\chi^2(df = 1, n = 118) = 3.938$, $p = 0.047$) and to identify PrEP candidates (50.8% vs. 25.5%, $\chi^2(df = 1, n = 118) = 7.926$, $p = 0.005$). Less than half of the respondents (45.5%, $n = 55$) indicated that an app- or text-message-based reminder service for patients would be useful to increase the adherence of PrEP users.

When respondents were asked to rate the relevance of barriers for patients to initiate PrEP, they rated the following as the most relevant: patients underestimating their own risk of acquiring HIV infection (*Median* = 8.00, *IQR* = 4.0), difficulties in finding a doctor to prescribe PrEP (*Median* = 8.00, *IQR* = *5.5*) and the time required for regular visits to the doctor (*Median* = 7.0, *IQR* = 6.0). Further results on perceived barriers to PrEP initiation and their relevance for patients are shown in ***Table 7***. Among the barriers for physicians, respondents indicated that time-consuming management of PrEP patients was a relevant barrier (*Median* = 7.0, *IQR* = 4.0), but that difficulties identifying those who would benefit from PrEP were less relevant (*Median* = 3.0, *IQR* = 6.0).

Discussion

Our study is the first of its kind to assess physicians' knowledge of HIV PrEP, their attitudes towards it, and their counseling practices in consultations with patients across Germany who are interested in or have indications for PrEP. Given the large gap, in the EU and beyond, between individuals who are interested in using PrEP but are unable to access it, we aimed to explore with our survey whether there might be potential to increase the number of non-HIV-

Table 7. Barriers for patients to initiate PrEP as perceived by participating physicians.

	n	*Median* (*IQR*)	
Assessment of the own risk of getting infected with HIV as too low to take PrEP	69	8.0	(4.0)
Difficulties finding a doctor who prescribes PrEP	74	8.0	(5.5)
Time required for regular visits to the doctor	66	6.0	(6.0)
The monthly costs of the PrEP medication	69	6.0	(6.0)
Lack of information about PrEP in patient-friendly language	68	5.0	(5.0)
Lack of information about PrEP in the native language of the client	68	5.0	(5.0)
Worries about getting infected with other STIs	71	5.0	(5.0)
Cultural barriers	72	5.0	(6.0)
The costs of the laboratory tests	73	5.0	(6.0)
Worries about severe or permanent side effects	68	4.0	(5.0)
Worries about mild or temporary side effects	67	3.0	(4.0)
Worries about stigmatization in the peer group	69	3.0	(5.0)

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specialists providing PrEP-related services in Germany by reducing the barriers to their completing further training and thus being able to bill for these services.

It is therefore highly relevant that participants in our survey rated "difficulties in finding a doctor who prescribes PrEP" as one of the most important barriers for patients to initiate chemoprophylaxis. The lack of HIV-specialists in rural areas is well-reflected in our study, with more than 80% of HIV-specialists who responded to our survey indicating that they were located in cities with more than 100,000 and 50% indicating that they were located in cities with more than 1 million inhabitants. Conversely, more than 50% of the non-HIV-specialists participating in our study reported that they were located in cities with fewer than 100,000 inhabitants. Any opportunity to increase the number of non-HIV-specialists who can give advice on PrEP and prescribe PrEP to patients at risk of acquiring HIV in conformity with the relevant guidelines should therefore be explored. The same can be said of the gap between the western and eastern German states more generally, where a decades-long tradition of large HIV-specialty practices and community-based counselling centers in the west contrasts with a lack of such facilities and institutions in the east.

As expected, our results suggest that HIV-specialists have greater knowledge and counseling competence related to PrEP, as well as more positive attitudes towards it, than do non-HIV-specialists. Unsurprisingly, a greater proportion of patients who had an indication for PrEP were proactively given advice on it by the HIV-specialists. This being said, attitudes towards PrEP and particularly knowledge of it were much more heterogeneous among our participating non-HIV-specialists than was the case among HIV-specialists, which suggests that at least some of the non-HIV-specialists in our sample might require little or no training on PrEP care. Indeed, the results of our multiple linear regression suggest that knowledge of PrEP was the only statistically significant predictor of the proportion of indicated patients who were proactively given advice and counseling on PrEP by participating physicians. It might therefore be wise for policymakers and other actors in the German health system to consider providing non-HIV-specialists who fit this description, particularly if they are in a rural location, with ways to demonstrate and certify their skills that are less onerous than those at present. At the same time, our data strongly suggest that there is indeed a need to provide training on PrEP to a very large percentage of non-HIV-specialists. On average, this group of respondents had less knowledge and poorer counseling skills with regard to PrEP care, as well as attitudes towards PrEP that were more negative than those reported by HIV-specialists. Non-HIV-specialists in our sample also reported providing pro-active counseling on PrEP to a much smaller proportion of individuals who had an indication for it than did HIV-specialists.

Even if non-HIV-specialists do actively refer patients to PrEP-certified physicians, this still requires them to be able to identify patients with an indication for PrEP and proactively discuss the topic. If the gap between rural and urban areas in Germany (and elsewhere) is to be narrowed in this regard, it will be essential to improve training to these physicians, but to do so in a way that takes better account of the local health infrastructure and geographical barriers, such as long distances to the nearest HIV specialty practices. Online training modules or telemedicine visits are just two options. Certainly, efforts in this direction would be welcomed by the participants in our sample, particularly by the non-HIV-specialists, about 62% of whom indicated that they wished to receive training or information materials on managing PrEP patients. Such training could be augmented by providing the participating physicians with information materials and decision aids for patients in patient-understandable language and in different languages. Indeed, in our survey, decision aids for patients were reported by participating physicians to be the materials they thought would increase the practicability of their PrEP counselling and prescriptions the most. Doing so would be a low-cost and potentially

efficient and effective way to augment the counseling skills of physicians who do not (yet) feel themselves to be competent enough to advice patients on taking PrEP.

There are some interesting similarities between the results of our survey and those of an earlier survey we conducted among counselors in community-based non-governmental STI/HIV counseling centers and local health offices [19]. In the latter, we also found differences in knowledge and attitude scores between the different organizational contexts, with the counseling centers having higher scores in both domains and a much larger proportion of LGBTI+ clientele compared to the local health offices–mirroring in some respects the gaps between HIV-specialists and non-HIV-specialists observed in the present study. Moreover, it is interesting that in the present study, as in our earlier survey, a substantial percentage of participants indicated that it would be helpful to have a clinical practice guideline that contained a clear presentation of indications, contraindications and necessary laboratory tests for PrEP. Given that a guideline on these subjects has, in fact, already been available since 2018, the substantial percentage of participants reporting a wish for such a guideline suggests that the dissemination and implementation of the guideline have been inadequate or that the guideline does not present the relevant information in a clear enough manner.

Limitations

This study has a number of important limitations beyond its observational, cross-sectional design and the obvious caveats that this entails. First, the rate of response to the survey, at 5.53%, was very low. Such response rates are not uncommon in surveys of office-based health professionals, such as GPs or dermato-venereologists, in Europe [21], and knowing this we took extensive efforts to encourage participation in the survey by offering it in different formats and sending email reminders. Nevertheless, the low response rate means that our results are probably not representative of the broader populations of HIV-specialists and non-HIV-specialists in Germany and cannot be easily generalized to them. Along these lines, selection bias is a second potential limitation of this paper. Physicians with either profound or no knowledge of PrEP, and physicians with strongly positive or strongly negative attitudes towards it, may have been more passionate about the subject and therefore more likely to participate. While it is impossible to quantify this bias, it is reasonable to assume that those who were more ambivalent about PrEP were less likely to participate and should therefore be targeted more strongly in any future research of this nature. A third limitation of our study was our use of a self-developed questionnaire that, for pragmatic reasons, did not use validated constructs to measure knowledge and attitudes. There is ample evidence that there often exists a discrepancy between reported knowledge and skills and respondents' actual knowledge and skills [22]. A fourth important limitations is our grouping of MSM and transgender patients for pragmatic purposes, particularly related to the length of the study questionnaire. Differentiating between these two groups would have allowed us to obtain meaningful data on the barriers faced by transgender patients wishing to initiate PrEP, but would have gone beyond the scope of our study. Furthermore, we did not specifically include other populations at risk of acquiring HIV, such as intravenous drug users or sex workers, in our survey in order to increase the participation rate by keeping the questionnaire as short and feasible as possible.

A fifth limitation is our decision not to explore race- or migration-related barriers to PrEP initiation. While a lack of language-relevant materials was listed as a potential barrier and materials in various languages were thought to be helpful by physicians, migrant-specific or race-specific barriers, for example related to discrimination, were not examined. Studies from the US suggest that there are large discrepancies between Black, Indigenous Patients of Color (BIPOC) and white patients with regard to PrEP and antiretroviral uptake [23, 24]. Data on

this subject are sparse, but the discrepancies are likely to be considerable [25]. Given that a substantial proportion of new HIV cases in Germany is among migrants and it is unclear whether the infections have occurred abroad or within Germany [10], it will be crucial in future research to examine structural discriminatory practices that might hamper these individuals' access to appropriate PrEP care. Lastly, the sexual orientation of respondents was not examined in this questionnaire; however, it may play a role in counseling practices, as well as in the choice of whether to specialize in the care of patients living with HIV and of LGBTI + individuals more generally.

Conclusions

The findings of this study on HIV-specialists' and non-HIV-specialists' knowledge of PrEP, their attitudes towards it, and their PrEP counseling practices in Germany point to opportunities to improve PrEP implementation in individuals at risk of acquiring HIV. The large gap between the two groups of physicians with regard to knowledge about and attitudes towards PrEP could be addressed, in part, by providing physicians with patient-centered information material. Online training modules or telemedicine visits may also represent more accessible training options, particularly in rural areas, where few HIV specialists are available. Furthermore, the existing guideline on PrEP should be re-evaluated in terms of its dissemination, implementation and ease of use.

Supporting information

S1 File. Survey questionnaire (Original German version). Original German online version of the questionnaire used in the present survey.
(PDF)

S2 File. Survey questionnaire (English translation). English translation of the online version of the questionnaire used in the present survey. Please note that the present translation has been undertaken for the publication only).
(PDF)

S3 File. Minimal underlying data set and codebook. Age of respondents, postal code, state and qualitative data have been removed to ensure anonymity.
(XLSX)

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Publication 3 (print copy)

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Excerpt from Journal Summary List (see next page)

Journal Data Filtered By: **Selected JCR Year: 2018** Selected Editions: SCIE,SSCI
Selected Categories: **"PUBLIC, ENVIRONMENTAL and OCCUPATIONAL HEALTH"** Selected Category Scheme: WoS
Gesamtanzahl: 285 Journale

Rank	Full Journal Title	Total Cites	Journal Impact Factor	Eigenfactor Score
1	Lancet Global Health	6,109	15.873	0.034250
2	MMWR-MORBIDITY AND MORTALITY WEEKLY REPORT	26,534	14.874	0.098040
3	Lancet Public Health	799	11.600	0.003770
4	Annual Review of Public Health	6,769	10.776	0.011700
5	Analytic Methods in Accident Research	669	9.333	0.002420
6	ENVIRONMENTAL HEALTH PERSPECTIVES	42,165	8.049	0.039510
7	INTERNATIONAL JOURNAL OF EPIDEMIOLOGY	23,097	7.339	0.050810
8	BULLETIN OF THE WORLD HEALTH ORGANIZATION	15,736	6.818	0.018090
9	EUROPEAN JOURNAL OF EPIDEMIOLOGY	7,785	6.529	0.016950
10	EPIDEMIOLOGIC REVIEWS	3,477	6.455	0.003470
11	JOURNAL OF TOXICOLOGY AND ENVIRONMENTAL HEALTH-PART B-CRITICAL REVIEWS	1,753	6.436	0.001470
12	TOBACCO CONTROL	8,343	6.221	0.019190
13	AMERICAN JOURNAL OF PUBLIC HEALTH	39,861	5.381	0.065480
14	Journal of Occupational Health Psychology	4,093	5.128	0.005410
15	CANCER EPIDEMIOLOGY BIOMARKERS & PREVENTION	19,542	5.057	0.031380
16	ENVIRONMENTAL RESEARCH	16,339	5.026	0.025480
17	PALLIATIVE MEDICINE	5,682	4.956	0.009860
18	Travel Medicine and Infectious Disease	1,576	4.868	0.004660
19	EPIDEMIOLOGY	13,114	4.719	0.019010
20	INDOOR AIR	4,851	4.710	0.005620

Rank	Full Journal Title	Total Cites	Journal Impact Factor	Eigenfactor Score
21	JOURNAL OF CLINICAL EPIDEMIOLOGY	27,514	4.650	0.029080
22	AMERICAN JOURNAL OF EPIDEMIOLOGY	37,816	4.473	0.039390
23	Environmental Health	5,272	4.430	0.010550
24	Evolution Medicine and Public Health	373	4.400	0.001570
25	INTERNATIONAL JOURNAL OF HYGIENE AND ENVIRONMENTAL HEALTH	4,852	4.379	0.007830
26	JOURNAL OF TRAVEL MEDICINE	2,229	4.155	0.003410
27	JOURNAL OF ADOLESCENT HEALTH	15,535	3.957	0.029260
28	JOURNAL OF EPIDEMIOLOGY AND COMMUNITY HEALTH	14,305	3.872	0.017690
29	MEDICAL CARE	20,250	3.795	0.021130
30	NICOTINE & TOBACCO RESEARCH	9,737	3.786	0.023650
31	Current Pollution Reports	281	3.762	0.000670
32	AIDS PATIENT CARE AND STDS	3,526	3.742	0.006900
33	JOURNAL OF HOSPITAL INFECTION	7,963	3.704	0.010250
34	OCCUPATIONAL AND ENVIRONMENTAL MEDICINE	8,820	3.556	0.009890
35	DRUG SAFETY	5,301	3.526	0.006980
36	SCANDINAVIAN JOURNAL OF WORK ENVIRONMENT & HEALTH	5,026	3.491	0.005010
37	PREVENTIVE MEDICINE	16,004	3.449	0.029820
38	LGBT Health	764	3.307	0.003720
39	ENVIRONMENTAL GEOCHEMISTRY AND HEALTH	3,494	3.252	0.003310
40	Antimicrobial Resistance and Infection Control	1,294	3.224	0.004910
41	HEALTH & PLACE	6,327	3.202	0.009880
42	Clinical Epidemiology	2,684	3.178	0.010800

Selected JCR Year: 2018; Selected Categories: "PUBLIC, ENVIRONMENTAL and OCCUPATIONAL HEALTH"

Rank	Full Journal Title	Total Cites	Journal Impact Factor	Eigenfactor Score
43	SOCIAL SCIENCE & MEDICINE	44,305	3.087	0.050860
44	Journal of Global Health	1,027	3.079	0.004580
45	JOURNAL OF EPIDEMIOLOGY	2,988	3.078	0.005650
46	ACCIDENT ANALYSIS AND PREVENTION	17,335	3.058	0.019280
47	Perspectives in Public Health	632	3.033	0.001400
48	Journal of Exposure Science and Environmental Epidemiology	3,713	3.025	0.004690
49	INJURY PREVENTION	3,461	2.987	0.005600
50	Population Health Metrics	1,419	2.953	0.003930
51	AIDS AND BEHAVIOR	9,705	2.908	0.025060
52	PHARMACOEPIDEMIOLOGY AND DRUG SAFETY	6,452	2.870	0.013260
53	International Journal of Health Geographics	2,432	2.862	0.003150
54	INFECTION CONTROL AND HOSPITAL EPIDEMIOLOGY	9,857	2.856	0.018120
55	PREVENTION SCIENCE	3,888	2.851	0.007740
56	HEALTH EXPECTATIONS	3,199	2.847	0.007740
57	PATIENT EDUCATION AND COUNSELING	12,891	2.821	0.016760
58	Health Reports	1,328	2.768	0.001630
59	Critical Public Health	1,234	2.742	0.002420
60	Research in Social & Administrative Pharmacy	1,895	2.719	0.003790
61	Conflict and Health	619	2.696	0.002390
62	NEUROEPIDEMIOLOGY	3,266	2.689	0.004980
63	Administration and Policy in Mental Health and Mental Health Services Research	2,888	2.681	0.005000
64	PAEDIATRIC AND PERINATAL EPIDEMIOLOGY	3,240	2.681	0.004580

Selected JCR Year: 2018; Selected Categories: "PUBLIC, ENVIRONMENTAL and OCCUPATIONAL HEALTH"

Rank	Full Journal Title	Total Cites	Journal Impact Factor	Eigenfactor Score
65	ETHNICITY & HEALTH	1,303	2.671	0.002260
66	JOURNAL OF TOXICOLOGY AND ENVIRONMENTAL HEALTH-PART A-CURRENT ISSUES	4,186	2.649	0.003340
67	AMERICAN JOURNAL OF HEALTH PROMOTION	3,378	2.636	0.003920
68	Cancer Epidemiology	3,124	2.619	0.008820
69	Journal of Occupational Medicine and Toxicology	920	2.591	0.001290
70	Journal of Transport & Health	962	2.583	0.002270
71	BMC PUBLIC HEALTH	36,306	2.567	0.084820
72	RISK ANALYSIS	9,136	2.564	0.008140
73	Prehospital Emergency Care	2,408	2.557	0.005070
74	Globalization and Health	1,872	2.554	0.005490
75	ANNALS OF EPIDEMIOLOGY	6,620	2.550	0.010200
76	PUBLIC HEALTH NUTRITION	12,956	2.526	0.019040
77	QUALITY OF LIFE RESEARCH	13,192	2.488	0.019050
78	Journal of Infection and Public Health	1,449	2.487	0.003810
79	International Journal for Equity in Health	3,319	2.473	0.009790
80	JOURNAL OF RURAL HEALTH	1,729	2.471	0.002630
81	International Journal of Environmental Research and Public Health	20,692	2.468	0.046780
82	TROPICAL MEDICINE & INTERNATIONAL HEALTH	7,938	2.423	0.012810
83	JOURNAL OF HEALTH AND SOCIAL BEHAVIOR	8,700	2.419	0.003640
84	JOURNAL OF SAFETY RESEARCH	3,508	2.401	0.004110
85	PSYCHOLOGY & HEALTH	5,140	2.401	0.005150
86	International Journal of Public Health	2,917	2.373	0.006840

Selected JCR Year: 2018; Selected Categories: "PUBLIC, ENVIRONMENTAL and OCCUPATIONAL HEALTH"

Rank	Full Journal Title	Total Cites	Journal Impact Factor	Eigenfactor Score
87	International Journal of Transgenderism	752	2.345	0.000950
88	Journal of Developmental Origins of Health and Disease	987	2.340	0.003070
89	AMERICAN JOURNAL OF TROPICAL MEDICINE AND HYGIENE	21,980	2.315	0.030050
100	TRANSACTIONS OF THE ROYAL SOCIETY OF TROPICAL MEDICINE AND HYGIENE	8,448	2.307	0.006050
101	CANCER CAUSES & CONTROL	7,646	2.300	0.011010
102	Reproductive Health	2,813	2.295	0.008970
103	COMMUNITY DENTISTRY AND ORAL EPIDEMIOLOGY	4,609	2.278	0.003440
104	PSYCHIATRIC SERVICES	10,947	2.253	0.015610
105	ANNALS OF OCCUPATIONAL HYGIENE	2,990	2.241	0.002630
106	Translational Behavioral Medicine	1,285	2.237	0.003970
107	EUROPEAN JOURNAL OF PUBLIC HEALTH	6,287	2.234	0.014130
108	HEALTH EDUCATION & BEHAVIOR	3,987	2.190	0.004990
109	Economics & Human Biology	1,555	2.183	0.003000
110	ANNALI DELL ISTITUTO SUPERIORE DI SANITA	1,035	2.172	0.001350
111	JOURNAL OF URBAN HEALTH-BULLETIN OF THE NEW YORK ACADEMY OF MEDICINE	3,864	2.154	0.005900
112	Journal of Racial and Ethnic Health Disparities	771	2.147	0.002360
113	JOURNAL OF MEDICAL SCREENING	1,251	2.125	0.002110
114	REPRODUCTIVE HEALTH MATTERS	1,505	2.119	0.002040
115	AIDS CARE-PSYCHOLOGICAL AND SOCIO-MEDICAL ASPECTS OF AIDS/HIV	6,484	2.105	0.012510
116	Journal of Physical Activity & Health	4,407	2.079	0.008350
117	STUDIES IN FAMILY PLANNING	1,786	2.075	0.002550

Selected JCR Year: 2018; Selected Categories: "PUBLIC, ENVIRONMENTAL and OCCUPATIONAL HEALTH"

Rank	Full Journal Title	Total Cites	Journal Impact Factor	Eigenfactor Score
118	EPIDEMIOLOGY AND INFECTION	9,191	2.047	0.017140
119	PUBLIC HEALTH REPORTS	5,705	2.039	0.008230
120	Preventing Chronic Disease	4,726	2.038	0.013630
121	Annals of Global Health	702	2.037	0.002600
122	Frontiers in Public Health	2,430	2.031	0.008610
123	INTERNATIONAL ARCHIVES OF OCCUPATIONAL AND ENVIRONMENTAL HEALTH	4,098	2.025	0.004430
124	JOURNAL OF WOMENS HEALTH	5,283	2.009	0.009660
125	AMERICAN JOURNAL OF INFECTION CONTROL	7,923	1.971	0.015330
126	Pathogens and Global Health	826	1.969	0.002810
127	REVISTA DE SAUDE PUBLICA	4,507	1.968	0.005250
128	WOMENS HEALTH ISSUES	2,157	1.957	0.005380
129	Global Public Health	1,598	1.943	0.004210
130	VECTOR-BORNE AND ZOONOTIC DISEASES	3,686	1.939	0.005990
131	BIOMEDICAL AND ENVIRONMENTAL SCIENCES	2,130	1.917	0.002660
132	HEALTH PROMOTION INTERNATIONAL	3,296	1.913	0.003800
133	AUSTRALIAN AND NEW ZEALAND JOURNAL OF PUBLIC HEALTH	3,308	1.911	0.004520
134	DIABETES EDUCATOR	2,148	1.910	0.002630
135	Health Security	277	1.910	0.001100
136	AMERICAN JOURNAL OF INDUSTRIAL MEDICINE	5,681	1.902	0.006010
137	Tobacco Induced Diseases	526	1.889	0.001410
138	Health Promotion and Chronic Disease Prevention in Canada-Research Policy and Practice	230	1.870	0.000710
139	AIDS EDUCATION AND PREVENTION	1,758	1.854	0.002330

Selected JCR Year: 2018; Selected Categories: "PUBLIC, ENVIRONMENTAL and OCCUPATIONAL HEALTH"

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HIV Pre-Exposure Prophylaxis (PrEP) Counseling in Germany: Knowledge, Attitudes and Practice in Non-governmental and in Public HIV and STI Testing and Counseling Centers

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Background: Providers of sexual health services play an important role in counseling persons at risk of acquiring HIV. The aim of the present study was to investigate the knowledge of and attitudes toward HIV pre-exposure prophylaxis (PrEP) among counselors in non-governmental counseling centers ("NG counseling centers") and in counseling centers of the local health authorities ("local health offices") in Germany and to determine the extent to which PrEP plays a role in their current counseling practice.

Methods: An anonymous cross-sectional study using an online questionnaire was conducted among counselors from sexual health centers across Germany. All NG counseling centers in Germany offering HIV testing were asked to participate. For each NG counseling center, a local health office in the same city was also invited. A "knowledge score" and an "attitudes score" were calculated from single items on various relevant aspects. The association of these scores with the proportion of PrEP advice provided proactively in sessions with men who have sex with men (MSM) and trans persons who met the German and Austrian guideline criteria for being offered PrEP ('at-risk clients') was quantified.

Results: From Oct. to Dec. 2018, 145 counselors completed the survey. Both self-assessed knowledge of PrEP and attitudes toward PrEP were greater or more positive among counselors from NG counseling centers compared with counselors from local health offices [*Median* knowledge score (range 0-20): 18.0 (*IQR* = 5.0) vs. 14.0 (*IQR* = 4.0), $p<0.001$; *median* attitudes score (range 0-20): 18.0 (*IQR* = 4.0) vs. 14.0 (*IQR* = 6.8), $p<0.001$]. The proportion of PrEP advice provided proactively in sessions with at-risk clients was larger in counseling centers than in local health offices [50.0% (*IQR* = 60.0) vs. 30.0% (*IQR* = 70.0); $p = 0.003$]. The results of the multiple linear regression model indicate that knowledge and attitudes of the individual counselors,

but not the type of center in which they worked, were independent predictors of the proportion of proactive advice on PrEP.

Conclusions: There is room for improvement in the current PrEP counseling practice of sexual health services in Germany. The findings of the present study suggest opportunities to improve the implementation of PrEP as part of a comprehensive HIV prevention strategy.

Keywords: HIV pre-exposure prophylaxis, PrEP, counseling, public health, HIV prevention, health services research

INTRODUCTION

In 2018, an estimated 2,400 new infections with HIV, primarily in men who have sex with men (MSM), occurred in Germany (1) and the prevention of HIV remains a major public health concern (2). Public health strategies to prevent sexually transmitted HIV infection have traditionally focused on behavioral interventions such as supporting condom use in sexually active populations. However, apart from the effects of early diagnosis and treatment of HIV infections, the latter of which is highly effective at preventing the transmission of HIV (3–5), a relatively new form of biomedical HIV prevention, namely HIV pre-exposure prophylaxis (PrEP), and its broad implementation in populations at risk has likely contributed to declining HIV incidence rates in some major cities such as San Francisco, London, and Sydney (6–8). The efficacy and safety of PrEP in MSM and trans persons has been shown in various randomized controlled studies (9–13) and cohort studies (14–17). International and national guidelines recommend the use of PrEP for HIV-negative people at substantial risk of acquiring HIV (18–20). According to the German and Austrian guideline published in May 2018, PrEP should be offered to HIV-negative adult MSM and trans persons who had a sexually transmitted infection (STI) in the past 12 months or who report having had and/or having the intent to practice condom-less anal sex (19). The cost of PrEP has been covered by the public health insurance in Germany only since September 2019.

In the US, the uptake of PrEP has been influenced largely by different, primarily socioeconomic and individual information-related factors (21–27). For the German context, few data on PrEP use are available. A survey among MSM in Berlin identified a substantial gap between the indication to use PrEP and actual PrEP use: almost a quarter of the non-PrEP-using participants reported sexual behavior that put them at risk of acquiring HIV (28). Results from a survey among users of a dating platform for MSM in 2018 suggest that PrEP use among MSM in Germany is less common compared with some other western European countries (29). Access to information about PrEP has been shown to be an important barrier to the initiation of PrEP (28). However, surveys from the US suggest that knowledge of PrEP may also be limited among physicians (30, 31). A survey among Dutch providers of STI and HIV services showed a moderate willingness to prescribe PrEP and limited knowledge of PrEP, especially among STI specialists (32). The provision of PrEP-related training for physicians has been discussed as a factor that could improve the implementation of PrEP (30, 31).

In Germany, HIV testing and counseling on HIV prevention is provided primarily by specialist physicians working in office-based practices and by sexual health services such as HIV and STI testing and counseling centers. The latter are either non-governmental, community-based counseling centers ("NG counseling centers") or public sexual health services of the local health authorities ("local health offices"). Both types of counseling centers offer low-threshold, anonymous HIV and STI testing and counseling and play an important role in the dissemination of information on HIV and strategies to prevent infections (2, 33). To date, no data have been available on PrEP-related counseling competence, knowledge, and attitudes among counselors working at either type of organization.

With the present study, we aimed to investigate the extent to which PrEP plays a role in the counselors' counseling practice, as well as the factors influencing the proportion of proactive PrEP advice they provide to clients at risk of sexually acquired HIV. Furthermore, the relevance of different barriers for potential PrEP users to initiate PrEP as perceived by the counselors was evaluated. With this knowledge we aimed to identify barriers to and facilitators of PrEP implementation and opportunities to improve PrEP implementation among MSM and trans persons in Germany. This study comprised part of the master's thesis of the first author (FK).

METHODS

Study Design

For this cross-sectional study, an online survey was conducted among counselors working in non-governmental, community-based counseling centers ("NG counseling centers") or in counseling centers of the local health authorities ("local health offices"). The anonymous, self-administered questionnaire was available online from October to December 2018. The study protocol was approved by the local ethics committee of Charité – Universitätsmedizin Berlin (EA1/006/19) and informed consent was obtained from all participants.

Setting and Eligibility

Counselors from NG counseling centers and local health offices were eligible to participate if they worked in the field of counseling clients on HIV and other STIs, regardless of their primary professional qualification. All NG counseling centers offering HIV testing and counseling listed by the comprehensive, publicly available register provided by "HIV and more" (34) were asked to participate. In order to ensure the comparability of

TABLE 1 | Dimensions and their operationalisation used to assess **(A)** knowledge and counseling competence and **(B)** attitudes toward PrEP.

Dimension		Operationalisation and scores				
Do you agree or disagree with the following statements?		***Strongly disagree***	***Disagree***	***Neither agree nor disagree***	***Agree***	***Strongly agree***
(A) Knowledge and counseling competence						
Global assessment	"I am well-informed about PrEP"	0	1	2	3	4
Indications	"I am able to comprehensively give clients advice on whether it makes sense to take PrEP in their respective case"	0	1	2	3	4
Adverse effects	"I am able to comprehensively give clients advice on the adverse effects of PrEP"	0	1	2	3	4
Modalities of intake	"I am able to comprehensively give clients advice on the possible modalities of intake of PrEP (e.g., continuous vs. on-demand)"	0	1	2	3	4
Investigations	"I am able to comprehensively give clients advice on the medical investigations necessary during the use of PrEP"	0	1	2	3	4
'Knowledge score'		Summative score with values ranging from 0 to 20				
(B) Attitudes toward PrEP						
Global assessment	"I think that PrEP is an important element of HIV prevention strategies"	0	1	2	3	4
Reliability	"I think that PrEP is a reliable method to protect oneself from HIV"	0	1	2	3	4
Adverse effects	"I think that PrEP is a method to protect oneself from HIV that has few side effects"	0	1	2	3	4
Availability of better alternatives	"I think that PrEP is unnecessary, because there are better alternatives to protect oneself from HIV"	4	3	2	1	0
Reimbursement of costs	"I think that PrEP should be paid for by the statutory health insurance"	0	1	2	3	4
'Attitudes score'		Summative score with values ranging from 0 to 20				

NG counseling centers with the participating local health offices, a local health office in the same or in a comparable city was invited for each NG counseling center. The selected centers were contacted by email and requested to forward the survey invitation to all eligible counselors within their organization. A reminder email was sent three to four weeks after the initial invitation. Additionally, all centers were contacted by telephone to enhance the participation rate. This telephone call also served to obtain information on the number of counselors to whom the invitation email had been forwarded in each organization.

Questionnaire and Variables

A standardized German-language questionnaire exploring knowledge of and attitudes toward PrEP among counselors and their counseling practice on PrEP is not available; the questionnaire was therefore developed for the purpose of the present study. The original draft questionnaire (FK) was tested and discussed (RW, MG, MS, AN) to identify and correct errors concerning spelling, expression and grammar as well as problems concerning the comprehensibility of the content and design. The questionnaire covered the following topics:

- Socio-demographic data and information about the type of center
- Counseling sessions and counseling practice regarding PrEP
- Self-assessed PrEP-related knowledge and self-reported attitudes
- Need for information or training materials to improve PrEP counseling
- Perceived barriers for potential users to initiate PrEP.

After providing informed consent and answering the initial question on the type of center (NG counseling center vs. local health office), participants could, if they so desired, leave any number of questions unanswered. The participants were provided with a brief summary on the efficacy and safety of PrEP, and with information about the recommendations of the German and Austrian guideline on the indications for offering PrEP.

Socio-demographic data comprised gender, age, primary professional qualification and work experience in counseling on sexual health issues. Furthermore, contextual information on the counseling center was obtained, including which of the 16 states in Germany the organization was located and size of the city, the number of HIV tests provided per month and the number of these that were positive. In addition, the total number of personal counseling sessions with MSM and trans persons per month and the number of sessions with MSM and trans persons who met the criteria to be counseled on PrEP according to the German and Austrian guideline ("at-risk clients"), was obtained. Regarding counseling practice, participants were asked to indicate the proportion of counseling sessions with these at-risk-clients (a) in which the topic PrEP had been addressed by the clients themselves and (b) in which the counselors themselves had proactively addressed the topic.

PrEP-related knowledge and counseling competence and the attitudes toward PrEP were quantified using a self-assessment in terms of agreement with statements about various aspects relevant in this context (**Table 1**). Fully verbalized bipolar

five-step Likert scales with an ambivalent scale center were provided to quantify the agreement with these statements. The items were presented randomly to each participant in a different order. Since the evaluation of individual Likert-scaled variables is considered less reliable compared to a summative multi-item scale (35), a summative "knowledge score" and "attitudes score" were calculated from the five individual knowledge and attitudes variables. The total scores assume values between 0 and 20, with high values representing good knowledge and counseling competence, or positive attitudes toward PrEP, respectively.

Furthermore, the participants were asked whether training was offered and whether inhouse guidelines or standard operating procedures on PrEP counseling were available in their organization. In addition, participants could indicate whether they wished to receive training or information material on PrEP counseling. A multiple-choice list was offered to assess tools or training that could be helpful to improve their counseling work or enhance practicability. To assess potential barriers to PrEP initiation, various aspects were presented, and participants were asked to rate the relevance of these potential barriers on an eleven-level, end-verbalized rating scale with numeric markers (0 = no relevance to 10 = highest relevance) according to their counseling experience. Again, the items were presented to each participant in randomized order.

Sample Size and Statistical Methods

Since the questionnaire was expressly designed for the purpose of this study, no data on expected means and variability were available. The aim was to include all NG counseling centers offering HIV testing and a corresponding number of matched local health offices. Therefore, no sample size calculation was performed. Statistical analyses were conducted with IBM® SPSS® Statistics version 25 (sample characteristics and bivariate statistics) and with STATA SE version 14.2 (multiple linear regression). To describe the sample characteristics and the results, descriptive statistics were used depending on the data quality. The internal consistency of the summative knowledge and attitudes scores was quantified with Crohnbach's alpha. To quantify associations between variables, independent samples *t*-tests, the Mann-Whitney *U* test and Pearson's Chi squared tests were used, depending on the data quality. A multiple linear regression, using the backward elimination method, was modeled to identify predictors of the proportion of proactive advice on PrEP in sessions with at-risk clients. The following variables for this regression model were purposefully selected a priori: type of center (NG counseling center vs. local health office), gender and years of practical work experience of the participant, size of the city, rate of positive HIV tests, knowledge score, and attitudes score. The stopping rule for the elimination of individual variables in the multiple linear regression was $p < 0.2$. Variance inflation factor (VIF) statistics and condition number were used to verify that there was no multi-collinearity of the predictors and instability of the regression coefficients, respectively. Missing cases were excluded in a listwise fashion. The level for statistical significance was set at $p = 0.05$.

RESULTS

Recruitment, Participation, and Response Rate

The letter of invitation to participate in the survey was sent to a total of 76 centers (38 NG counseling centers and 38 local health offices). Overall, 179 counselors opened the survey and began to fill it in. Of these, 145 provided information on the type of counseling center at which they worked (NG vs. local health office), which was the initial and only compulsory questionnaire item. Thus, the sample size was 145, of which 56 indicated working in a local health center and 89 in an NG counseling center. The number of counselors to whom the invitation was forwarded within each invited center could be obtained from phone calls with 62 centers and was $M = 2.96$ ($SD = 2.56$) in local health offices and $M = 5.58$ ($SD = 5.07$) in NG counseling centers. Five of the selected local health offices did not participate in the survey. Based on this information, the estimated number of counselors invited to participate in the survey was 98 for local health offices and 212 for NG counseling centers. Using these estimates, the response rate was 57.1% for local health offices and 42.0% for NG counseling centers. Of the 145 participants, 77.9% completed the questionnaire in its entirety.

Demographic Data

Demographic data of the sample are shown in **Table 2**. The mean age of the participants was 46.0 years ($SD = 11.7$). 76 participants (52.4%) defined themselves as male, 61 (42.1%) as female, and two (1.4%) as gender non-binary. The majority ($n = 93$, 64.1%) indicated that their primary professional qualification was social work; a further 15 (10.3%) indicated that they were physicians, 14 (9.7%) that they were psychologists and four (2.8%) that they were nursing professionals. A large majority of the participants indicated that their counseling center was located in a large city with more than 100,000 inhabitants ($n = 89$, 61.4%) or in a major city with more than 1,000,000 inhabitants ($n = 43$, 29.7%). The vast majority ($n = 123$, 84.8%) indicated that their organization was located in one of the old German states (western Germany) or the city state of Berlin. Statistically significant associations between type of center and demographic data were seen for gender ($\chi^2_{(df = 2,\ n = 139)} = 17{,}40$, $p < 0.001$) and primary professional qualification ($\chi^2_{(df=4, n = 139)} = 19{,}85$, $p = 0.001$), see **Table 2**.

Counseling Sessions and Practice

Table 3 depicts data on the number of counseling sessions and HIV tests reported by the participants. Counselors averaged 36.6 counseling sessions with MSM and trans persons per month ($SD = 48.2$) and 16.0 sessions with MSM and trans persons who met the criteria to be offered PrEP according to the recommendations of the German and Austrian guideline on PrEP (at-risk clients) ($SD = 22.2$). No significant differences were seen with regard to these two variables between NG counseling centers and local health offices. However, counselors from local health offices reported a higher number of HIV tests per month ($Mdn = 180$, $IQR = 190$) than did participants from NG counseling centers ($Mdn = 47.5$, $IQR = 73.8$), $U = 1103.5$,

TABLE 2 | Demographic data and contextual characteristics of the sample.

Variable	Total sample		Type of center				
			Local health offices		NG counseling centers		
N	145		56		89		
Age in years ($n = 139$)							$p = 0.679^{\dagger}$
Mdn (*IQR*)	48.00	(19.00)	48.00	(17.00)	47.50	(21.75)	
M (*SD*)	46.03	(11.67)	46.51	(11.51)	45.75	(11.82)	
Min; *Max*	19-67	19-62	23-67				
Gender (*n*, %)							$p < 0.001^{\S}$
Female	61	(42.1%)	34	(60.7%)	27	(30.3%)	
Male	76	(52.4%)	17	(30.4%)	59	(66.3%)	
Non-binary	2	(1.4%)	0	(0%)	2	(2.2%)	
Not specified	6	(4.1%)	5	(8.9%)	1	(1.1%)	
Professional qualification (*n*, %)							$p = 0.001^{\S}$
Social work	93	(64.1%)	37	(66.1%)	56	(62.9%)	
Psychology	14	(9.7%)	2	(3.6%)	12	(13.5%)	
Nursing	4	(2.8%)	1	(1.8%)	3	(3.4%)	
Physician	15	(10.3%)	11	(19.6%)	4	(4.5%)	
Other	13	(9.0%)	0	(0%)	13	(14.6%)	
Not specified	6	(4.1%)	5	(8.9%)	1	(1.1%)	
Size of the location (*n*, %)							$p = 0.138^{\S}$
Major city (>1,000,000)	43	(29.7%)	15	(26.8%)	28	(31.5%)	
Large city (>100,000)	89	(61.4%)	31	(55.4%)	58	(65.2%)	
City (>10,000)	7	(4.8%)	5	(8.9%)	2	(2.2%)	
Small city (≤ 10,000)	1	(0.7%)	1	(1.8%)	0	(0%)	
Not specified	5	(3.4%)	4	(7.1%)	1	(1.1%)	
Federal state (*n*, %)							$p = 0.072^{\S}$
Baden-Wuerttemberg	20	(13.8%)	3	(5.4%)	17	(19.1%)	
Bavaria	22	(15.2%)	8	(14.3%)	14	(15.7%)	
Berlin	15	(10.3%)	7	(12.5%)	8	(9.0%)	
Brandenburg	9	(6.2%)	3	(5.4%)	6	(6.7%)	
Bremen	1	(0.7%)	0	(0%)	1	(1.1%)	
Hamburg	13	(9.0%)	4	(7.1%)	9	(10.1%)	
Hesse	12	(8.3%)	2	(3.6%)	10	(11.2%)	
Mecklenburg-Western Pomerania	2	(1.4%)	2	(3.6%)	0	(0%)	
Lower Saxony	8	(5.5%)	6	(10.7%)	2	(2.2%)	
North Rhine-Westphalia	22	(15.2%)	8	(14.3%)	14	(15.7%)	
Rheinland-Pfalz	0	(0%)	0	(0%)	0	(0%)	
Saarland	4	(2.8%)	3	(5.4%)	1	(1.1%)	
Saxony	0	(0%)	0	(0%)	0	(0%)	
Saxony-Anhalt	1	(0.7%)	0	(0%)	1	(1.1%)	
Schleswig-Holstein	6	(4.1%)	3	(5.4%)	3	(3.4%)	
Thuringia	0	(0%)	0	(0%)	0	(0%)	
Not specified	10	(6.9%)	7	(12.5%)	3	(3.4%)	
Professional experience in years (n = 138)							$p = 0.838^{\dagger}$
Mdn (*IQR*)	11.50	(18.25)	11.00	(17.50)	12.00	(19.75)	
M (*SD*)	14.19	(10.38)	14.14	(10.02)	14.23	(10.63)	
Min; *Max*	0.5-40		0.5-31		1-40		

IQR, inter quartile range; M, mean; Max, maximum; Mdn, median; Min, minimum; SD, standard deviation. †*From Mann-Whitney U tests of the null hypothesis that the median value of participants from local health offices is equal to that of participants from NG counseling centers.* §*From Pearson's Chi squared tests of the null hypothesis that there is no statistically significant difference between the observed and expected frequencies in each category, by type of counseling center.*

TABLE 3 | Counseling sessions and HIV-tests.

Variable	Total sample		Type of center				
			Local health office		NG counseling center		
Number of overall counseling sessions with MSM and trans persons per month ($n = 126$)							$p = 0.784^{\dagger}$
Mdn (*IQR*)	20.00	(35.00)	20.00	(40.00)	25.00	(30.00)	
M (*SD*)	36.55	(48.23)	39.21	(52.13)	34.96	(46.03)	
Min; *Max*	0-330		0-270		0-330		
Number of sessions with MSM and trans persons who met the criteria to be offered PrEP according to the German and Austrian guideline (at-risk clients) ($n = 116$)							$p = 0.780^{\dagger}$
Mdn (*IQR*)	10.00	(10.00)	10.00	(12.50)	10.00	(10.00)	
M (*SD*)	15.97	(22.17)	15.38	(18.70)	16.35	(24.23)	
Min; *Max*	0-170		0-80		1-170		
Overall number of HIV tests per month ($n = 123$)							$p < 0.001^{\dagger}$
Mdn (*IQR*)	60.00	(175.00)	180.00	(190.00)	47.50	(73.75)	
M (*SD*)	112.69	(109.85)	162.81	(116.12)	81.70	(93.87)	
Min; *Max*	3-400		3-400		8-350		
Number of positive HIV test results per month ($n = 117$)							$p = 0.311^{\dagger}$
Mdn (*IQR*)	0.00	(1.00)	1.00	(1.00)	0.00	(1.00)	
M (*SD*)	0.67	(0.83)	0.78	(0.90)	0.60	(0.78)	
Min; *Max*	0-4		0-3		0-4		
Proportion of positive HIV test results among overall number of HIV tests ($n = 117$)							$p = 0.373^{\dagger}$
Mdn (*IQR*)	0.00%	(0.93)	0.33%	(0.65)	0.00%	(1.67)	
M (*SD*)	0.74%	(1.49)	0.34%	(0.38)	0.99%	(1.84)	
Min; *Max*	0-12.5%		0-1.25%		0-12.5%		

IQR, inter quartile range; M, mean; Max, maximum; Mdn, median; Min, minimum; SD, standard deviation. †*From Mann-Whitney U tests of the null hypothesis that the median value of participants from local health offices is equal to that of participants from NG counseling centers.*

$p < 0.001$. No significant differences between the two types of centers were seen with respect to the absolute or the relative number of positive HIV tests per month.

Taking into account the entire sample, the participating counselors indicated on average that in 26.1% of counseling sessions with at-risk clients, the clients themselves had addressed the topic of PrEP ($SD = 22.0$). The proportion of PrEP advice provided proactively by the counselors was indicated to be 52.0% on average ($SD = 34.2$). The proportion of clients addressing the topic of PrEP themselves was larger in NG counseling centers ($Mdn = 30.0\%$, $IQR = 40.0$) than in local health offices ($Mdn = 10.0\%$, $IQR = 10.0$), $U = 877.0$, $p < 0.001$. Similarly, the proportion of PrEP advice provided proactively by the counselors was larger in NG counseling centers ($Mdn = 50.0\%$, $IQR = 60.0$) than in local health offices ($Mdn = 30.0\%$, $IQR = 70.0$), $U = 1082.0$, $p = 0.003$. The data are shown in **Table 4**.

Self-Assessment of Knowledge and Counseling Competence

For each of the self-assessed dimensions of knowledge and counseling competence, agreement (and hence a positive self-assessment of knowledge and counseling skills regarding PrEP) was more frequent than indifference or disagreement with the respective statements. However, there was a statistically significant association between the type of center and the agreement for each of the aspects assessed (**Table 5**). For the summative "knowledge score," Crohnbach's alpha was $\alpha = 0.966$. The knowledge score was significantly higher for counselors from NG counseling centers ($Mdn = 18.0$, $IQR = 5.0$) than for counselors from local health offices ($Mdn = 14.0$, $IQR = 4.0$), $U = 679.5$, $p < 0.001$.

Attitudes Toward PrEP

As with the knowledge and counseling competence aspects presented above, agreement with the dimensions assessed for attitudes toward PrEP was more frequent than indifference or disagreement with the four statements expressing positive attitudes toward PrEP. For the statement expressing a negative attitude, disagreement was more frequent than indifference or agreement. Again, for each of the aspects assessed, significant associations between the type of center and agreement were found (**Table 6**). For the summative "attitudes score," Crohnbach's alpha was $\alpha = 0.847$. The attitudes score was significantly higher for counselors from NG counseling centers ($Mdn = 18.0$, $IQR = 4.0$) than for counselors from local health offices ($Mdn = 14.0$, $IQR = 6.8$), $U = 638.5$, $p < 0.001$.

Multiple Linear Regression on the Proportion of Proactive PrEP Advice

A multiple linear regression was modeled to predict the proportion of PrEP advice provided proactively by the counselors to at-risk clients. Applying backward elimination with $p < 0.2$ as

TABLE 4 | Counseling practice in counseling sessions with MSM and trans persons who met the criteria to be offered PrEP according to the German and Austrian guideline (at-risk clients).

Variable	Total sample		Type of center				
			Local health office		NG counseling center		
Proportion of sessions with 'at-risk' MSM and trans persons in which the topic PrEP is addressed by the clients themselves ($n = 115$)							$p < 0.001^{\dagger}$
Mdn (*IQR*)	20.00%	(30.00)	10.00%	(10.00)	30.00%	(40.00)	
M (*SD*)	26.09%	(21.95)	16.36%	(15.86)	32.11%	(23.11)	
Min; *Max*	0-100%		0-80%		0-100%		
Proportion of sessions with 'at-risk' MSM and trans persons in which the counselors themselves proactively address the topic PrEP ($n = 116$)							$p = 0.003^{\dagger}$
Mdn (*IQR*)	50.00%	(70.00)	30.00%	(70.00)	50.00%	(60.00)	
M (*SD*)	51.98%	(34.24)	41.33%	(36.72)	58.73%	(30.98)	
Min; *Max*	0-100%		0-100%		10-100%		

IQR, inter quartile range; M, mean; Max, maximum; Mdn, median; Min, minimum; SD, standard deviation. †From Mann-Whitney U tests of the null hypothesis that the median value of participants from local health offices is equal to that of participants from NG counseling centers.

a stopping rule for the exclusion of each variable, a significant regression equation was found ($F_{(2,109)} = 10.50$, $p < 0.001$, $n = 112$), with $R^2 = 0.162$ (**Table 7**). The only independent predictors that remained in the model were the knowledge and the attitudes score. Participants' predicted proportion of proactive PrEP advice in sessions with at-risk clients was equal to$-8.208 + 1.692$ (knowledge score) $+ 2.111$ (attitudes score), where knowledge score and attitudes score are coded on scales from 0 to 20 points, with higher scores indicating a more positive self-assessment of knowledge about PrEP and more positive attitudes toward PrEP, respectively, and the proportion of proactive advice on PrEP is coded on a scale from 0 to 100%. The proportion of proactive PrEP advice provided to at-risk clients increased by 1.7% and by 2.1% for each point increase on the knowledge score and on the attitudes score scales, respectively.

Guidelines, Training and Educational Material

Slightly fewer than half of the participants (48.7%, $n = 55$) indicated that their respective organization had in-house PrEP guidelines or standard operating procedures, but a large majority indicated that training on PrEP advice had been offered to them (86.0%, $n = 98$). Fewer than half of the participants indicated that they wished to receive further training on PrEP counseling (44.6%, $n = 50$). Counselors from NG counseling centers indicated having been offered training on PrEP advice more frequently (90.0%, $n = 63$) than counselors from local health offices (79.5%, $n = 35$), but this difference was not statistically significant ($\chi^2_{(df=1,n=114)} = 2{,}447$, $p = 0.118$). Regarding the availability of in-house guidelines and the wish for further training on PrEP no significant differences by type of center were seen, likewise. Asked which of the listed information materials or trainings would improve their counseling practice, decision aids for the clients that present information on PrEP in client-friendly language and in different languages were chosen most frequently (both 78.8%, $n = 89$), followed by a clinical practice guideline that provides a good overview of indications, contraindications and necessary investigations (74.3%, $n = 84$). Less frequently mentioned materials or training were: an app- or SMS-based reminder for PrEP users to promote adherence (58.4%, $n = 66$), information and training for counselors on the management of PrEP (45.1%, $n = 51$), information and training for counselors on the identification of PrEP candidates (38.1%, $n = 43$), and information and training for counselors on talking with clients about sexuality (28.3%, $n = 32$).

Asked to rate the relevance of barriers for potential users to initiate PrEP as perceived in their personal counseling practice, participants pointed to worries about getting infected with other sexually transmitted infections ($M = 5.56$, $SD = 2.73$), the monthly cost of the PrEP medication ($M = 5.33$, $SD = 2.61$), and a lack of information about PrEP in the native language of the client ($M = 5.10$, $SD = 3.33$). Further results on perceived barriers to initiate PrEP are shown in **Table 8**.

DISCUSSION

This is the first survey to assess knowledge, attitudes and counseling practice regarding PrEP among counselors from HIV and STI testing and counseling centers in Germany. Given that targeted counseling of persons at increased risk of acquiring HIV can help them take an informed decision about their personal HIV prevention strategy, counseling centers can play a key role in improving the implementation of PrEP. Providing persons at risk of HIV infection with reliable information on PrEP is an essential prerequisite for improving PrEP implementation in Germany. For this study, we focused on MSM and trans persons who met the criteria to be offered PrEP according to the guideline currently applicable in Germany, and the proportion of PrEP advice proactively provided to this group was one of the key outcomes evaluated within our study.

Regardless of whether they were employed in NG counseling centers or local health offices, participants in the survey indicated that they indeed had counseling sessions with these "at-risk clients" and that they proactively provided PrEP advice in sessions with this group of clients, albeit to varying degrees. The majority of the participating counselors had a positive self-assessment of their knowledge and counseling skills as well as

TABLE 5 | Self-assessment of knowledge and counseling competence.

Variable	Total sample		Type of center				
			Local health office		NG counseling center		
Global assessment: "I am well-informed about PrEP" (*n*, %), *n* = 113							$p < 0.001^{\S}$
Strongly disagree	1	(0.9%)	0	(0.0%)	1	(1.4%)	
Disagree	2	(1.8%)	1	(2.3%)	1	(1.4%)	
Neither agree nor disagree	13	(11.5%)	11	(25.0%)	2	(2.9%)	
Agree	44	(38.9%)	21	(47.7%)	23	(33.3%)	
Strongly agree	53	(46.9%)	11	(25.0%)	42	(60.9%)	
Indications: "I am able to comprehensively give clients advice on whether it makes sense to take PrEP in their respective case" (*n*, %), *n* = 113							$p < 0.001^{\S}$
Strongly disagree	1	(0.9%)	0	(0.0%)	1	(1.4%)	
Disagree	6	(5.3%)	5	(11.6%)	1	(1.4%)	
Neither agree nor disagree	9	(8.0%)	5	(11.6%)	4	(5.7%)	
Agree	38	(33.6%)	22	(51,2%)	16	(22.9%)	
Strongly agree	59	(52.2%)	11	(25.6%)	48	(68.6%)	
Adverse effects: "I am able to comprehensively give clients advice on the adverse effects of PrEP" (*n*, %), *n* = 113							$p < 0.001^{\S}$
Strongly disagree	3	(2.7%)	2	(4.7%)	1	(1.4%)	
Disagree	11	(9.7%)	8	(18.6%)	3	(4.3%)	
Neither agree nor disagree	26	(23.0%)	16	(37.2%)	10	(14.3%)	
Agree	37	(32.7%)	11	(25.6%)	26	(37.1%)	
Strongly agree	36	(31.9%)	6	(14.0%)	30	(42.9%)	
Modalities of intake: "I am able to comprehensively give clients advice on the possible modalities of intake of PrEP (e.g., continuous vs. on-demand)" (*n*, %), *n* = 113							$p < 0.001^{\S}$
Strongly disagree	2	(1.8%)	1	(2.3%)	1	(1.4%)	
Disagree	13	(11.5%)	11	(25.6%)	2	(2.9%)	
Neither agree nor disagree	8	(7.1%)	3	(7.0%)	5	(7.1%)	
Agree	35	(31.0%)	20	(46.5%)	15	(21.4%)	
Strongly agree	55	(48.7%)	8	(18.6%)	47	(67.1%)	
Investigations: "I am able to comprehensively give clients advice on the medical investigations necessary during the use of PrEP" (*n*, %), *n* = 113							$p = 0.002^{\S}$
Strongly disagree	3	(2.7%)	2	(4.7%)	1	(1.4%)	
Disagree	10	(8.8%)	8	(18.6%)	2	(2.9%)	
Neither agree nor disagree	10	(8.8%)	4	(9.3%)	6	(8.6%)	
Agree	37	(32.7%)	18	(41.9%)	19	(27.1%)	
Strongly agree	53	(46.9%)	11	(25.6%)	42	(60.0%)	
Knowledge score (0-20), *n* = 112							$p < 0.001^{\dagger}$
Mdn (*IQR*)	17.00	(6.00)	14.00	(4.00)	18.00	(5.00)	
M (*SD*)	15.64	(4.43)	13.30	(4.38)	17.10	(3.82)	
Min; *Max*	0-20		4-20		0-20		

IQR, inter quartile range; M, mean; Max, maximum; Mdn, median; Min, minimum; SD, standard deviation. †*From Mann-Whitney U tests of the null hypothesis that the median value of participants from local health offices is equal to that of participants from NG counseling centers.* §*From Pearson's Chi squared tests of the null hypothesis that there is no statistically significant difference between the observed and expected frequencies in each category, by type of counseling center.*

positive attitudes toward PrEP. However, significant differences were found between counselors from NG counseling centers and local health offices: the self-assessment indicated that the former had greater knowledge and counseling skills and more positive attitudes toward PrEP. Furthermore, the proportion of PrEP advice provided proactively in sessions with at-risk clients was larger among counselors from NG counseling centers than among counselors from local health offices.

The differences found between NG counseling centers and local health offices may be attributable to a different basic orientation and organizational policy: whereas NG counseling centers arose from community-based self-help organizations, the local health offices have long focused on advice on HIV and STIs for the overall population and selected risk groups such as sex workers. Whereas the majority of clients in NG counseling centers are MSM (36), this client group only constitutes a minority of the clients in local health offices (37). In the multiple linear regression, however, knowledge of and attitudes toward PrEP remained the only independent predictive factors for the proportion of PrEP advice provided proactively in sessions with

TABLE 6 | Attitudes toward PrEP.

Variable	Total sample		Type of center				
			Local health office		NG counseling center		
Global assessment: "I think that PrEP is an important element of HIV prevention strategies" (*n*, %), *n* = 114							$p < 0.001$[§]
Strongly disagree	1	(0.9%)	1	(2.3%)	0	(0.0%)	
Disagree	2	(1.8%)	2	(4.5%)	0	(0.0%)	
Neither agree nor disagree	11	(9.6%)	8	(18.2%)	3	(4.3%)	
Agree	16	(14.0%)	13	(29.5%)	3	(4.3%)	
Strongly agree	84	(73.7%)	20	(45.5%)	64	(91.4%)	
Reliability: "I think that PrEP is a reliable method to protect oneself from HIV" (*n*, %), *n* = 114							$p = 0.003$[§]
Strongly disagree	0	(0.0%)	0	(0.0%)	0	(0.0%)	
Disagree	6	(5.3%)	4	(9.1%)	2	(2.9%)	
Neither agree nor disagree	7	(6.1%)	5	(11.4%)	2	(2.9%)	
Agree	33	(28.9%)	18	(40.9%)	15	(21.4%)	
Strongly agree	68	(59.6%)	17	(38.6%)	51	(72.9%)	
Adverse effects: "I think that PrEP is a method to protect oneself from HIV that has few side effects" (*n*, %), *n* = 114							$p = 0.002$[§]
Strongly disagree	8	(7.0%)	3	(6.8%)	5	(7.1%)	
Disagree	12	(10.5%)	8	(18.2%)	4	(5.7%)	
Neither agree nor disagree	32	(28.1%)	18	(40.9%)	14	(20.0%)	
Agree	32	(28.1%)	11	(25.0%)	21	(30.0%)	
Strongly agree	30	(26.3%)	4	(9.1%)	26	(37.1%)	
Availability of better alternatives: "I think that PrEP is unnecessary, because there are better alternatives to protect oneself from HIV" (*n*, %), *n* = 114							$p < 0.001$[§]
Strongly disagree	67	(58.8%)	14	(31.8%)	53	(75.7%)	
Disagree	30	(26.3%)	18	(40.9%)	12	(17.1%)	
Neither agree nor disagree	11	(9.6%)	7	(15.9%)	4	(5.7%)	
Agree	5	(4.4%)	4	(9.1%)	1	(1.4%)	
Strongly agree	1	(0.9%)	1	(2.3%)	0	(0.0%)	
Reimbursement of costs: "I think that PrEP should be paid for by the statutory health insurance" (*n*, %), *n* = 114							$p < 0.001$[§]
Strongly disagree	8	(7.0%)	5	(11.4%)	3	(4.3%)	
Disagree	9	(7.9%)	6	(13.6%)	3	(4.3%)	
Neither agree nor disagree	16	(14.0%)	13	(29.5%)	3	(4.3%)	
Agree	22	(19.3%)	9	(20.5%)	13	(18.6%)	
Strongly agree	59	(51.8%)	11	(25.0%)	48	(68.6%)	
Attitudes score (0-20) (*n* = 114)							$p < 0.001$[†]
Mdn (*IQR*)	17.50	(5.00)	14.00	(6.75)	18.00	(4.00)	
M (*SD*)	15.96	(4.01)	13.57	(4.16)	17.46	(3.10)	
Min; *Max*	4-20		4-20		7-20		

IQR, inter quartile range; M, mean; Max, maximum; Mdn, median; Min, minimum; SD, standard deviation. [†]*From Mann-Whitney U tests of the null hypothesis that the median value of participants from local health offices is equal to that of participants from NG counseling centers.* [§]*From Pearson's Chi squared tests of the null hypothesis that there is no statistically significant difference between the observed and expected frequencies in each category, by type of counseling center.*

at-risk clients. This implies that the differences between the two types of centers are mainly explained by different knowledge and counseling skills and attitudes toward PrEP on the side of the individual counselors working in the respective centers. This finding points at the importance of training for the counselors and of supplying material that facilitates counseling on PrEP.

Overall, the counselors participating in the survey indicated that they proactively provided PrEP advice in a mean of 52.0% of sessions with at-risk clients, and it must therefore be assumed that the implementation of the current German and Austrian PrEP guideline has been incomplete so far. This assumption is supported by the fact that, despite of their existence, almost three quarters of the participants indicated that a guideline with a clear presentation of indications, contraindications and necessary laboratory investigations would help to improve PrEP consultations. The wording of the indication for recommending PrEP to MSM and trans persons ("MSM or trans persons who report having had anal sex without condom within the past 3-6 months and/or probably having anal sex without condom in the next months, or who had an STI in the last 12 months,

TABLE 7 | Multiple linear regression to predict the proportion of PrEP advice provided proactively to MSM and trans persons who meet the criteria be offered PrEP according to the German and Austrian guideline (at-risk clients).

Predictors	Coefficient (Robust SE)		Beta	*p*	VIF
Constant	−8.208	(11.468)		0.476	
Knowledge score[1]	1.692	(0.842)	0.221	0.047	1.26
Attitudes score[2]	2.111	(0.910)	0.250	0.022	1.26

SE, standard error; VIF, variance inflation factor. [1]Scale from 0 to 20 points, with higher scores indicating a more positive self-assessment of knowledge about PrEP and counseling competence. [2]Scale from 0 to 20 points, with higher scores indicating a more positive attitudes toward PrEP.

TABLE 8 | Relevance of barriers to PrEP use.

	n	M (SD)		Min-Max
Worries about getting infected with other STIs	111	5.56	(2.73)	0-10
The monthly costs for the PrEP medication	109	5.33	(2.61)	0-10
Lack of information about PrEP in the native language of the client	110	5.10	(3.33)	0-10
The costs for the laboratory investigations	109	4.80	(3.00)	0-10
Worries about mild or temporary side effects	109	4.64	(2.43)	0-10
Time required for regular visits to the doctor	111	4.26	(2.81)	0-10
Worries about severe or permanent side effects	111	4.21	(2.59)	0-10
Lack of information about PrEP in client-friendly language	110	4.17	(2.88)	0-10
Difficulties finding a doctor who prescribes PrEP	112	4.13	(3.64)	0-10
Assessment of the own risk of getting infected with HIV as too low to take PrEP	110	4.08	(2.70)	0-10
Worries about stigmatization in the peer group	107	3.33	(2.67)	0-10
Cultural barriers	110	2.79	(2.51)	0-10

M, mean; Max, maximum; Min, minimum; SD, standard deviation.

respectively," English translation by the authors of the present paper) in the German and Austrian guideline (19) is ambiguous due to the use of unclear operators ("and/or," "respectively") and imprecisely defined time periods ("3-6 months", "next months"). This may be a factor that limits the implementation of the guideline recommendations. The survey revealed that fewer than half of the centers had in-house guidelines or standard operating procedures for PrEP counseling. No information was collected on the content of these in-house guidelines, and it remains unclear whether they contain indications for PrEP advice that deviate from the German and Austrian guidelines. For the purpose of this study, the recommendations of the German and Austrian guideline on HIV pre-exposure prophylaxis were used to define at-risk clients. Whereas one indication to offer PrEP to MSM and trans persons according to the German and Austrian Guideline is a history of an STI in the past 12 months (19), the CDC guidelines on PrEP, for instance, restrict this aspect to the past six months and exclusively to bacterial STIs (18). A narrower definition of the indication to recommend PrEP to MSM and trans people might have led to a higher proportion of proactive PrEP advice in counseling sessions with these clients. It must also be taken into account that the German and Austrian guideline on PrEP has only been available since June 2018, and thus for approximately four months before the data collection for this survey began. This relatively short period of time is probably the most important reason for the incomplete implementation of the guideline recommendations in current counseling practice and for the limited awareness of the guideline found in this survey.

Nonetheless, the incomplete implementation of the current guideline recommendations and the limited awareness of their existence indicate that there is a need and potential for improving and harmonizing counseling on PrEP in counseling centers, particularly when targeting at-risk populations. Bearing this in mind, it is interesting that the counselors who took part in the survey selected mainly client-directed tools as resources that would help to improve PrEP counseling. Among the most frequently selected tools were (1) decision aids for clients that provide information about PrEP in client-friendly or (2) in the client's first language, and (3) an app- or SMS-based reminder system for PrEP users to promote their adherence. In contrast, information or training for counselors was less frequently selected as being helpful for their counseling practice. In line with these results, fewer than half of the participants indicated that they would like to receive training or courses on PrEP counseling. This must be taken into account when deciding on measures to improve targeted counseling on PrEP among counselors in sexual health services.

The focus on client-directed information material and tools when selecting resources that would improve counseling on PrEP reflects that lack of information on the side of potential PrEP users is perceived as one of the most important barriers to initiating PrEP. This barrier can be addressed through the availability of easily understandable information material for clients and especially populations at risk of acquiring HIV. Concerns about sexually transmitted infections, the cost of PrEP medication and follow-up examinations, the lack of information about PrEP in the clients' first languages and worries about mild or temporary side effects were among the barriers for potential PrEP users rated as particularly relevant by the counselors who participated in this survey. This corresponds well with the barriers to taking PrEP found in the Berlin survey among MSM (28). However, aspects such as the costs of PrEP medication and corresponding accompanying examinations as barriers to initiating PrEP are structural barriers. With a law passed in July 2019, the cost of PrEP and necessary laboratory investigations has been covered by public health insurance in Germany since September 2019, which renders this barrier obsolete. Stigmatization of PrEP users by their peers or in their social environments was rated by the counselors as the least relevant barrier, although the aspect of stigmatization was repeatedly mentioned in the free text fields and also in the international literature (38).

Limitations

These insights into PrEP-related knowledge, counseling skills, attitudes, and counseling practice among counselors working in HIV testing and counseling centers can be used to identify and develop strategies for improving PrEP implementation in at-risk

populations. However, there is a number of important limitations to consider when interpreting the results:

Firstly, the questionnaire used in this study was not formally validated before it was used as a survey instrument. PrEP-related knowledge and counseling skills were self-assessed by the participants. We did not present a score that assessed specifically defined levels of competence or skills. It is therefore unclear whether the respective score validly represents the actual knowledge and counseling skills. A systematic review showed that there may be relevant discrepancies between self-assessed knowledge and actual knowledge (39). In addition, no empirical data are available on the question of whether the actual quality of counseling on PrEP is determined primarily by the knowledge of the counselors. However, the fact that there was a significant association between the knowledge score and the attitudes score on one hand, and the proportion of proactive PrEP advice in sessions with at-risk clients on the other, indicate that the knowledge and attitudes scores may be a valid representation of the respective concepts. This is also supported by the good internal consistency of the scores.

Secondly, for pragmatic reasons, the risk groups of "MSM" and "trans persons" were grouped together in the survey. As a result, information may have been lost or recorded inaccurately. The assessment of the counseling practice could lead to different findings if the questions had specifically related to the respective populations separately. Especially with regard to the efficacy and safety of PrEP, far more data are available for MSM than for trans persons (9–12, 14–17, 39). At the same time, for trans persons, other access barriers to health care may be relevant than for MSM—for example, for trans persons, finding a competent physician was described as a particularly relevant barrier to accessing PrEP (40). Furthermore, the sexual orientation of the counselors was not assessed in the survey, although this may have a relevant impact on the PrEP counseling practice and explain differences in this regard between counseling centers and health authorities as an additional variable. We also did not include the primary professional qualification of the counselors in our multiple regression model, as this was not one of the variables that we had chosen a priori, which were limited in number to avoid overfitting.

A third limitation, which pertains to the validity of our findings may be the presence of selection bias. Counselors with little knowledge of or negative attitudes toward PrEP may have been less likely to participate in the survey than counselors with more positive attitudes and/or better knowledge. The extent of such a bias cannot be quantified. In this context, it is worth pointing out that the response rates of 42 and 57% for NG counseling centers and local health offices, respectively, were comparatively high for a survey of this nature. For example, surveys on PrEP among physicians in the USA and the Netherlands had response rates of 23.5 and 39%, respectively (30, 32). While high response rates cannot guarantee unbiased estimates, they do provide less opportunity for selection bias to occur. However, the sample size of the present study is relatively small, also limiting the generalisability of our findings. A further limitation of the representativeness is that only few counseling centers from the new German states (former East Germany) took part in the survey. It must be taken into account that access to HIV tests and advice in rural regions and particularly in the new German states is often only supplied by the local health authorities and only in a small number of NG counseling centers. In contrast, large cities such as Berlin and Hamburg have a higher number of NG counseling centers (34). The regional distribution of the participants in the survey therefore reflects the current situation with respect to sexual health services.

Conclusions

The results of this first survey assessing PrEP-related knowledge, attitudes, and counseling practice among counselors from HIV and STI testing and counseling centers in Germany should be interpreted as baseline data shortly after publication of the German and Austrian guidelines on PrEP. The survey revealed that PrEP counseling in these centers is currently heterogeneous and that the knowledge of and attitudes toward PrEP vary substantially among counselors. In particular, substantial differences were found between counselors from NG counseling centers and the local health offices. Due to the rapid developments in the field of PrEP services in Germany, re-evaluating counseling practice after the guideline recommendations have been available for a longer period and some time after the inclusion of PrEP in the benefits catalog of the public health insurance will probably yield useful findings. In the meantime, concepts that increase the awareness of the guideline recommendations among counselors in the HIV and STI counseling and testing centers in Germany should be developed and implemented. For the comprehensive and successful implementation of HIV prevention strategies with the goal of empowering at-risk populations to take informed decisions, targeted and proactive PrEP advice is a key element. In this regard, there is room for improvement, and both NG counseling centers and the public health authorities should undertake measures to optimize their counselors' knowledge and counseling skills. Bearing in mind that the desire for further training on PrEP counseling was expressed by fewer than half of the counselors who took part in the survey, these measures may focus on decreasing the barriers identified for potential PrEP users, for example by developing and testing resources and tools such as decision-aids for potential PrEP users in client-friendly language and in different languages. Both potential PrEP users and counselors should be included in this process in order to ensure good acceptance and implementation of the tools that are developed.

DATA AVAILABILITY STATEMENT

All datasets generated for this study are included in the article/**Supplementary Material**.

ETHICS STATEMENT

The study protocol was reviewed and approved by Ethikkommission der Charité-Universitätsmedizin Berlin.

The participants provided their informed consent to participate in this study.

AUTHOR CONTRIBUTIONS

FK developed the study design and drafted the questionnaire, which was discussed and finalized by FK, RW, MG, MS, and AN. FK led the data collection. FK, MG, and RW conducted the statistical analyses and supported interpretation of results. FK wrote the first draft of the manuscript. All authors provided considerable editing, revisions and content review of the initial manuscript draft, and approved the final draft of the manuscript.

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SUPPLEMENTARY MATERIAL

The Supplementary Material for this article can be found online at: https://www.frontiersin.org/articles/10.3389/fpubh.2020.00298/full#supplementary-material

Data Sheet S1 | Survey questionnaire (English translation, please note that the questionnaire was only available in German language and the present translation has been undertaken for the publication only).

Data Sheet S2 | Survey questionnaire (original German version).

Table S1 | Minimal underlying data set (Please note that gender, age and years of professional experience of the respondents as well as federal state of the counseling center and qualitative data have been removed to ensure the anonymity of the respondents).

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Conflict of Interest: The authors declare that the research was conducted in the absence of any commercial or financial relationships that could be construed as a potential conflict of interest.

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