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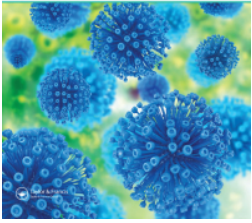
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Consultations for HIV post-exposure prophylaxis before and after health insurance coverage of pre-exposure prophylaxis to a university-based emergency department in Germany

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Background: Potential risk contacts for HIV transmission may lead to presentations to the emergency department (ED) for counseling and initiation of post-exposure prophylaxis (PEP).

Objective: To examine the impact of German health insurance covering pre-exposure prophylaxis (PrEP) following Sept 1st 2019 for certain risk groups on the frequency and reasons for PEP counseling in a university-based ED in Germany.

Methods: In a before-after study design, all persons aged ≥ 18 years who presented for PEP counseling were analyzed retrospectively. We compared characteristics of presentations in the 18 months prior to PrEP coverage on Sept 1st, 2019, with those in the following 18 months.

Results: 154 ED presentations occurred in the first study period, and 155 ED presentations in the second period. Regarding the reasons for ED visits, no statistically significant difference was found [occupational risk contact (18.2 vs. 26.5%, $p=0.081$), sexual risk contact (74.7 vs. 69.0%, $p=0.266$), other non-occupational risk contact (7.1 vs. 4.5%, $p=0.329$)]. For men who have sex with men (MSM), no statistically significant differences were found [38.9 ($n=60$) vs. 35.5% ($n=55$), $p=0.537$]. All persons presenting to the HIV outpatient clinic after ED PEP initiation ($n=60$ vs. $n=52$) tested negative for HIV 3 months later.

Conclusion: In this study, reasons to present for PEP counseling to a university ED showed no change following the implementation of PrEP coverage by health insurances. Therefore, PEP remains an important prevention for HIV transmission and presentations to the ED for PEP counseling may provide an opportunity to educate persons at risk of HIV infection about PrEP, thereby helping to prevent new HIV infections.

KEYWORDS: Emergency department, HIV post-exposure prophylaxis, HIV pre-exposure prophylaxis, HIV prevention, MSM

Introduction

In 2020 2,000 new HIV infections were estimated in Germany. Of these, 1,100 occurred in men who have sex with men (MSM) – while these numbers have been declining, they still represent the largest proportion.¹

Pre-exposure prophylaxis (PrEP) has been recommended by the World Health Organization² as well as

in Germany and the European Union for persons aged 16 years and older at increased risk of HIV infection (e.g. MSM, transgender persons with condomless anal intercourse, partners with uncontrolled HIV, persons who inject drugs with no access to sterile injection materials)^{3,4}. Initially, an obstacle for widespread uptake of PrEP was high monthly prices of around \$2,200 in the United States⁵ and up to €800 in Germany.⁶ However, in October 2017, the initiative of a pharmacy in Cologne, Germany, lowered the price for a monthly dose to €50. Subsequently the number of monthly prescriptions rose from 585 to 6059⁷ over

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the subsequent six months, with many users – especially MSM – paying for the pills out of pocket after obtaining a doctor’s prescription.⁷ Other potential users who did not have this option used other means of acquisition: in addition to online mail order, the medication was purchased abroad or shared with acquaintances.⁸ This led to issues, as there was no medical supervision as well as a lack of supervised HIV testing before and during use of PrEP.

Germany’s healthcare system consists of two tiers: statutory health insurance and private health insurance. Statutory health insurance is mandatory for all citizens and permanent residents regardless of income, while private health insurance requires a certain income level and offers more flexibility and additional benefits. When on September 1st, 2019, German law mandated statutory health insurances to cover the costs of PrEP for eligible users,^{4,9} its accessibility increased tremendously. This coverage also entailed counselling for PrEP and testing for HIV and other sexually transmitted diseases. Private health insurances followed shortly after.

Both the decrease in price as well as the uptake by health insurances led to a steep increase of PrEP users: while exact numbers are unknown since there is no central registry, one publication estimated 1,200 PrEP users in November 2017 increasing to 14,700 in December 2019 shortly after insurance uptake and 15,600–21,601 users in June 2020.¹⁰

In the present study we wanted to determine the impact of health insurances covering PrEP after 09/01/2019 on the frequency of presentations for post-exposure prophylaxis (PEP) counseling following potential risk-contact with HIV in a tertiary-care Emergency Department (ED) as well as describe the characteristics of the preceding risk contacts.

Materials and methods

Study design

All persons aged 18 years or older who presented for PEP counseling from March 2018 through February 2021 at the ED of the University Hospital Düsseldorf were analyzed retrospectively. Two time periods were compared, period 1 (03/01/2018–08/31/2019, 18 months) before and period 2 (09/01/2019–02/28/2021, 18 months) after nationwide health insurance approval of PrEP on 09/01/2019. The study was approved by the Ethical Review Board of the University of Düsseldorf (2021–1499).

Consultations for post-exposure prophylaxis

Our ED serves as a sole provider for all persons seeking PEP in the city of Düsseldorf (pop. 650,000) as

well as its immediate surroundings outside regular working hours (Monday–Friday 08:30–2:30 pm) of infectious disease specialists as well as our university’s own clinic of infectious diseases. Hence, all clients seeking PEP after working hours present here. These ED presentations follow a standard operating procedure (SOP) based on the German-Austrian guideline on HIV post-exposure prophylaxis.¹¹ According to the guideline, following events with a high risk of HIV transmission (contact with blood or body fluids of a patient with known HIV and either a high viral load or unknown treatment status), clients should be recommended to initiate PEP. Following an incident where HIV exposure *may* have occurred with some probability (e.g. unprotected intercourse with a partner belonging to a group with high prevalence of undiagnosed or untreated HIV, e.g. MSM, persons from a country with high prevalence of HIV or persons who inject drugs) PEP should be considered and the clients offered the choice to start PEP. After male-on-female sexual assault, due to insufficient evidence, the guideline recommends an approach of shared-decision-making. The guideline also specifies situations in which PEP is not indicated and should not be administered.

Using the SOP, the treating physician evaluated whether the event leading to presentation at the ED was associated with an increased risk of HIV transmission. In unclear cases, an on-call infectious disease specialist could be contacted by phone. When indicated, and presentation was within 72h of the event, PEP was started immediately with emtricitabine/tenofovir disoproxil 200/245 mg and raltegravir 1200 mg. A blood sample was obtained and analyzed – including a lab screening test for HIV (4th gen – HIV-p24-Ag/Ag) – however, the results were not awaited before initiation of PEP.

The clients received enough PEP doses to last until the next working day, when presentation to the Infectious Diseases Outpatient Clinic of the Department of Gastroenterology, Hepatology and Infectious Diseases was recommended. When proper indication for PEP was confirmed, usually emtricitabine/tenofovir disoproxil 200/245 mg plus raltegravir 2x600mg QD was prescribed.

Client population and index events

Demographic characteristics were recorded for each client. Risk contact was categorized as occupational, sexual, and ‘other’. For sexual risk contacts, we recorded the client’s gender identity, the type (vaginal/anal) of intercourse and if consent had been given. Furthermore, we recorded the partner’s gender and, where documented, HIV-status, origin from a country

with high prevalence of HIV, and if they belonged to a group with high incidence of HIV (MSM, persons who inject drugs) as well as mentions of drug use or sex work.

When PEP was commenced, history was used to determine whether prescription was in accordance with guidelines. If clients presented to the university hospital's own infectious disease outpatient clinic, it was verified whether a full 28-day PEP regime was ultimately prescribed. The result of the initial HIV test was also recorded, as well as the HIV status after repeated testing three months later where available.

Data recruitment

Routinely documented clinical data were extracted from the Patient Data Management System (PDMS, COPRA®, COPRA System GmbH, Berlin, Germany) of the ED and for the Infectious Diseases Outpatient Clinic from the Hospital Information System MEDICO® (Cerner Deutschland GmbH, Itstein, Germany) for all subjects included into the study. Cases were identified by searching medical records for standardized text strings used for documentation in all PEP consultations.

Data analysis and statistics

The collected and anonymized data was analyzed using Microsoft Excel 2016 MSO 32 bit (Microsoft Corp., Redmond, WA, USA). In addition to numbers and percentages, median and interquartile range were used, where appropriate. After verifying normal distribution using the Kolmogorov-Smirnov test, the two groups were further analyzed with respect by using Mann-Whitney-U-test and X^2 -test. Statistical significance was defined as a P value of less than 0.05.

Results

Client characteristics and reasons for ED presentation

There were 309 presentations for PEP counseling during the study period, 154 clients (49.8%) in the first and 155 clients (50.2%) in the second observation period. In both periods, presentations following occupational HIV contact, sexual contact and other non-sexual, non-occupational risk contact did not differ significantly. The epidemiological data of the clients as well as the types of exposures can be found in Table 1.

Presentations after occupational exposure

The number of presentations following occupational exposure, and the amount of PEP regimes prescribed did not differ significantly between both intervals (Table 2).

Presentations after sexual exposure

Men presented significantly more often than women following sexual contact in both observation periods [79.1 ($n=91$) vs. 74.8% ($n=80$), $p=0.4477$]. Most men presented following a same-sex encounter [65.9 ($n=60$) vs. 76.5% ($n=54$), $p=0.1291$]. Table 3 provides information on indications as well as administered PEP regimes.

Characteristics of sex partners, as far as they were known to the clients and documented in patient history, can be found in Table 4.

Among consensual sexual encounters, accidental loss of condom [33.0 ($n=36$) vs. 33.3% ($n=33$), $p=0.9622$] and unprotected sexual contacts [40.4 ($n=44$) vs. 40.4% ($n=40$), $p=1.0$] were equally frequent in both observation periods. Similarly, no statistically significant difference was found between the two study periods regarding presentations after contact with blood or semen [4.3 ($n=5$) vs. 0.9% ($n=1$), $p=0.1166$].

Three MSM presented twice for PEP counseling after sexual exposure, once in each observation period, and eight other MSM had a history of PEP use prior to study onset.

46 clients presented after sexual assault. 19 (group 1 vs. 2: $n=11$ vs. $n=8$) of these assaults occurred after administration of date rape drugs; two entailed removal of the condom by the partner without consent. The distribution of gender of the victims as well as the amount of PEP recommendations and decisions can be found in Figure 1.

Consultations after same-sex sexual encounters between men

We found no difference in the proportion of MSM in each study period [38.9 ($n=60/154$) vs. 35.5% ($n=55/155$), $p=0.537$] nor their age at presentation (31 ± 8 vs. 31 ± 8 years, $p=1.0000$). The number of presentations following an incident with a PEP indication was comparable in both observation periods (88.3 vs. 94.5%, $p=0.242$) and significantly higher than for persons presenting after sexual encounters with a member of the opposite sex (58.2 vs. 55.8%).

For PEP counseling following consensual, unprotected sexual encounters between men – i.e. those which would have been prevented by PrEP use – we found no significant difference in the percentage of recommended PEP regimes (PEP recommended due to high risk for HIV transmission 12.5 vs. 13.2%, $p=0.9135$, choice to initiate PEP due to low risk of HIV transmission (75.0 vs. 81.1%, $p=0.4446$).

Table 1. Epidemiology of clients presenting for PEP counseling.

	Group 1 (n = 154)	Group 2 (n = 155)	p
Age (years), [median (IQR)]	29 (25–36)	29 (25–37)	0,751
Gender			
Male, cisgender [n, (%)]	112 (72,7%)	102 (65,8%)	0,1895
Female, cisgender [n, (%)]	42 (27,3%)	52 (33,5%)	0,2370
Female, transgender [n, (%)]	0 (0,0%)	1 (0,6%)	0,3365
HIV status at presentation			
Negative [n, (%)]	129 (83,8%)	123 (79,3%)	0,3088
Positive [n, (%)]	2 (1,3%)	0 (0,0%)	0,1551
Not determined [n, (%)]	23 (14,9%)	32 (20,6%)	0,1906
Reasons for presentation			
Occupational exposure [n, (%)]	28 (18,2%)	41 (26,5%)	0,081
Sexual exposure [n, (%)]	115 (74,7%)	107 (69,0%)	0,266
Other non-occupational exposure [n, (%)]	11 (7,1%)	7 (4,5%)	0,329

Table 2. Indications of PEP and PEP regimes started following occupational exposure.

PEP indication	Group 1 (n = 28)	Group 2 (n = 41)	p
PEP recommended following incidents with high risk of transmission	19 (67.9%)	21 (51.2%)	0.171
PEP offered to clients following incidents with low risk of transmission	5 (17.9%)	14 (34.1%)	0.142
Not indicated	4 (14.3%)	6 (14.6%)	0.975
Administered PEP	Group 1	Group 2	
Administration in accordance with guideline	22 (78.6%)	27 (65.9%)	0.2568
Declined by clients though indicated	2 (7.1 %)	8 (19.5%)	0.3421
Not administered because not indicated	4 (14.3%)	6 (14.6%)	0.5785

PEP: post-exposure prophylaxis.

Table 3. Indications of PEP and numbers of PEP regimes started following sexual exposure.

PEP indication	Group 1 (n = 115)	Group 2 (n = 107)	p
PEP recommended following incidents with high risk of transmission	10 (8.7%)	9 (8.4%)	0.9365
PEP offered to clients following incidents with low risk of transmission	56 (48.7%)	53 (49.5%)	0.9054
Shared decision making after male-on-female sexual assault	19 (16.5%)	19 (17.8%)	0.7977
Not indicated	30 (26.1%)	26 (24.3%)	0.7582
Administered PEP			
Administration in accordance with guidelines	78 (67.8%)	77 (72.0%)	0.4967
Declined by clients though indicated	9 (7.8%)	4 (3.7%)	0.1943
Started despite lack of indication due to strong client request	3 (2.6%)	1(0.9%)	0.3396
Not administered because not indicated	25 (21.7%)	25 (23.4%)	0.7624

PEP: post-exposure prophylaxis.

Table 4. Characteristics of partners of sexual exposures.

	Group 1 (n = 115)	Group 2 (n = 107)	p
Gender			
Male, cisgender [n, (%)]	82 (71.3%)	75 (70.1%)	0.8447
Female, cisgender [n, (%)]	31 (27%)	28 (26.2%)	0.8930
Male, transgender[n, (%)]	1 (0.9%)	0 (0.0%)	0.3265
Female, transgender[n, (%)]	1 (0.9%)	4 (3.7%)	0.1607
HIV status			
Negative [n, (%)]	10 (8.7%)	6 (5.6%)	0.3732
Negative, PrEP use [n, (%)]	1 (0.9%)	1 (0.9%)	1.0
Positive [n, (%)]	11 (9.6%)	9 (8.4%)	0.7557
Positive, virological controlled HIV infection	3 (2.6%)	3 (2.8%)	0.9269
Unknown [n, (%)]	90 (78.3%)	88 (82.24%)	0.4627
Other characteristics, where known			
Infection with Hepatitis C [n, (%)]	1 (0.9%)	0 (0.0%)	0.3265
Endemic region origin [n, (%)]	10 (8.7%)	9 (8.4%)	0.9365
Possible intravenous drug use [n, (%)]	2 (1.7%)	1 (0.9%)	0.6018
Bisexual man [n, (%)]	0 (0%)	2 (1.9%)	0.1384
Sex worker [n, (%)]	18 (15.7%)	9 (8.4%)	0.0973
Sex at sauna/sex club or sex party [n, (%)]	5 (4.3%)	2 (1.9%)	0.3101

PrEP: pre-exposure prophylaxis.

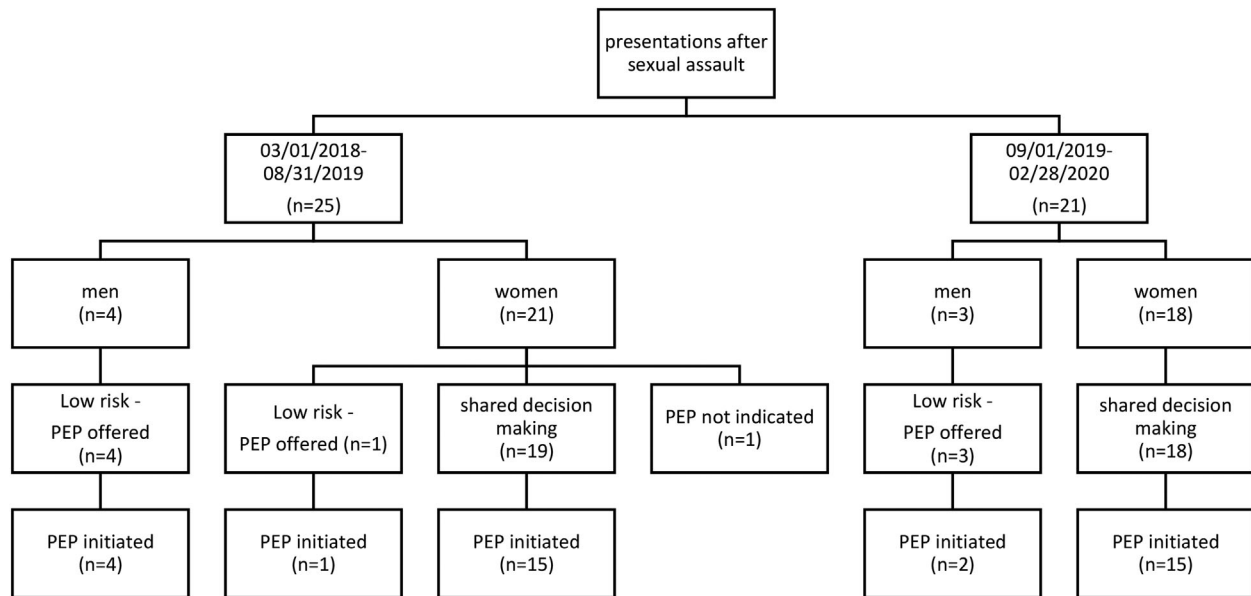


Figure 1. Presentations for counseling following sexual assault. PEP: post-exposure prophylaxis.

Presentations following other non-occupational exposures

Presentations after non-professional needlestick injuries, mostly in the context of administering drugs intravenously, occurred with comparable frequency in both time intervals [5.8 ($n=9$) vs. 3.9% ($n=6$), $p=0.4375$]. During each period, one first responder presented after contact with blood of a patient with HIV. One presentation during the first observation period was after a bite wound. In the first observation period, seven clients were recommended to start PEP due to a high HIV transmission risk, and all clients agreed to start PEP accordingly. In the second observation period, only one client was strongly recommended to start PEP due to increased HIV transmission risk, and another four clients were offered the choice – all five agreed.

Initiation of PEP and follow-up in the infectious disease outpatient clinic

PEP was recommended with equal frequency in both time periods [75.3 ($n=116$) vs. 78.1% ($n=121$), $p=0.5611$]. There also was no statistically significant difference in the number of PEP regimes started [71.4 ($n=110$) vs. 71.6% ($n=111$), $p=0.9690$]. When PEP was indicated, only a small number of clients declined [9.5 ($n=11$) vs. 9.9% ($n=12$), $p=0.9174$].

The number of clients who presented for follow-up to the infectious disease outpatient clinic did not differ statistically significantly between both study periods: of 110 clients who were prescribed PEP in the first group, 75 (68.2%) presented for follow-up. In 72 of these cases (96%), the infectious disease specialist

confirmed the proper indication for PEP and issued a follow-up prescription. In the second group, 78 of those 111 clients (70.2%, $p=0.7480$) who were prescribed PEP in the ED presented for follow-up, and of these in 73 cases (93.6%, $p=0.5062$) the indication of PEP was confirmed. Of the 44 persons where PEP was not started in the ED in the first observation period, 3 (6.8%) presented to for follow-up, and in one case (33.3%) the infectious disease specialist prescribed a PEP regime over-ruling the initial assessment. In the second study interval, 2 of the 44 persons (4.5%, $p=0.6422$) who were not prescribed PEP in the ED presented to the outpatient clinic. However, neither of them received a PEP prescription, thus confirming the initial assessment.

In the first observation period, results of an HIV test after three months were recorded for 60 clients, in the second interval for 52 clients. All these tests remained negative.

Discussion

In our analysis, we found no statistically significant differences in frequency of ED presentations for PEP counseling following the coverage of PrEP by the German statutory health insurance. This was true for presentations following occupational as well as non-occupational exposure, including those following sexual encounters for which PrEP was approved (particularly sex between men).

The high number of PEP regimes continued by the infectious disease outpatient clinic (94% of presentations) suggests that following proper training and using standard operating procedures as well as specialist

consultations by phone, non-specialist ED physicians can correctly prescribe PEP. This is consistent with evaluations of other EDs estimating the number of correct indications at 88%-99%.¹²⁻¹⁴

We detected no new HIV infections within three months after PEP initiation. The two men whose HIV tests upon ED presentation came back positive had evidence of previous risk behavior in their patient history. This and multiple presentations for PEP counseling by a total of eleven clients, all MSM, indicate that there is a continued need for education regarding safer sex strategies in this group, particularly since long-term studies show a risk of 2.2-4.4% for persons using PEP, most significantly MSM, to contract HIV later in life.^{15,16} Furthermore, despite intensive awareness campaigns as well as the availability of low-threshold services at least in all major German cities, by the end of 2020 there were still an estimated number of 6,200 MSM in Germany who did not know of their HIV diagnosis, constituting about 11% of MSM living with HIV¹. Therefore, presentations to the ED for PEP counseling might be a good opportunity to identify possible candidates for PrEP¹⁷⁻²¹ and to educate and motivate them about PrEP as an efficacious prevention strategy.^{22,23}

Currently there is only limited research on the impact of PrEP use or availability on presentations for non-occupational PEP. While two Australian studies found PrEP-uptake by health insurances to cause a decrease in PEP presentations,^{24,25} a study from Scotland saw no influence.²⁶ An explanation why we found no differences in the number of PEP presentations to our ED could be that at least some of the targeted individuals with regular high-risk contacts – who in previous research have been shown to have high knowledge of PrEP^{27,28} – had already begun to use PrEP before it was added to the health insurance fund, meaning the decrease in the need for PEP counseling in this group happened before our study period started. In other cases, MSM engaging in unsafe sexual acts might not use PrEP either due to lack of access to a prescribing physician, ignorance, or individual choice. Especially those engaging only very infrequently in high-risk sex have been shown to be apprehensive about daily PrEP use. For this group, PEP will remain a viable strategy for the prevention of new HIV infections.

The second study interval (Sept 1st, 2019–Feb 28th, 2021) was over-shadowed by the COVID-19 pandemic and two lock-downs (03/20–05/20 and 12/20–03/21) of public life in Germany. During this time, a reduction of social contacts – including sexual encounters – were encouraged. Nonetheless, the number of PEP

prescriptions following sexual encounters in our ED remained unchanged. One explanation might be previous PrEP users, who reportedly discontinued PrEP during lockdown due to expected decrease in sexual contacts^{29,30} presenting for PEP counseling following an unplanned unprotected sexual encounter. However, presentations following heterosexual intercourse remained unchanged as well, therefore it stands to reason that people had sex to the same extent they did before the pandemic. However, to fully establish the influence of these factors and to understand to what extent they evened out, more research into sex and PrEP use during the COVID-19 pandemic is needed.

PEP will remain an important prevention strategy for victims of sexual assault. While men-on-men sexual assault has always been an indication for PEP, in December 2021, the German-Austrian guidelines were adapted to offer PEP after non-consensual unprotected sexual assault against women, reasoning that while the risk of HIV transmission is low (less than 1:10.000 in Germany and Austria),¹¹ initiating PEP can alleviate the victim's anguish when the assailant is unknown and their HIV status cannot be obtained.

Occupational risk contacts can only be reduced by prevention strategies like education on proper behavior (e.g. no re-capping of needles), the use of safe instruments (needles and scalpels with safety devices) and use of protective gear. For these, PrEP will have no relevant impact and PEP will remain the only viable prevention strategy once possible HIV transmission has already occurred.

A limitation of our study is the retrospective study design. Furthermore, the overall incidence of presentations may have been skewed, since persons seeking PEP during regular working hours could present to either HIV specialist practices or the infectious disease out-patient clinic on-campus, and only outside of their working hours presented to the ED. However, the ratio of occupational and non-occupational contacts as well as the rate of MSM presenting after sexual contacts are consistent with other German EDs with 24-h availability of PEP.^{12,31-33} Furthermore, since distribution remained unchanged over both study periods, we assume the data to be representative for our ED.

Our study shows that PEP remains an important strategy for HIV prevention. EDs with their round-the-clock presence offer an important point of contact outside regular opening hours of HIV outpatient clinics and specialist practice. Therefore, they should offer a basic expertise regarding indications of PEP as well as establish regularly updated standard operating procedures (SOP) and be able to obtain expert advice. Efforts should be made to identify and link patients at

increased risk for HIV infection who would benefit from PrEP to appropriate practices and outpatient clinics. Prospective multicenter studies could help to further explore this strategy.

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The authors report there are no competing interests to declare.

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