Effect of extending PrEP initiation to primary care settings: a nationwide cohort study in France

Sophie Bamouni, Sophie Billioti de Gage, David Desplas, Julie Valbousquet, Julie Lamant, Jean-Philippe Joseph, François Dabis, Agnès Viot, Mojgan Hessamfar, Salim Fakir, Rosemary Dray-Spira, Michel Carles

Summary

Background Pre-exposure prophylaxis (PrEP) medicines are key to reducing HIV infection. Improving access, increasing initiation, and expanding the populations covered is therefore important. In June, 2021, in France, PrEP initiation was extended to primary care. The aim of this study was to describe the deployment and characteristics of PrEP initiation in primary care.

Methods We did a nationwide cohort study using data obtained from the French National Health Data System (Système National des Données de Santé). We included all people aged 15 years or older, who initiated PrEP in primary care between June 1, 2021, and Dec 31, 2022. We estimated the number of PrEP initiations per month over the period, and the characteristics of people initiating PrEP and prescribers, and PrEP use.

Findings 13 500 individuals initiated PrEP in primary care during the study period. The mean number of PrEP initiations increased from 654 (SD 64) per month between July and December, 2021, to 783 (SD 86) per month between July and December, 2022. Individuals initiating PrEP were predominantly male (12 996 [96·3%] of 13 500 individuals) with a mean age of 36 years (SD 11·8), who lived in large urban areas (9581 [71·0%]). 1012 (7·5%) of 13 500 individuals were socioeconomically disadvantaged. Of the 5125 PrEP initiation prescribers, 4542 (88·6%) were general practitioners (GPs), and 4713 (44·7%) of 10 525 were the patient's family practitioner. In the 6 months after PrEP initiation, 6216 (70·8%) of 8783 PrEP initiators had at least one monthly renewal (mean 3·3 renewals [SD 1·7]). 11 961 (82·4%) of 14 507 renewals were made by the same practitioner who had initiated PrEP, and this proportion was higher when the prescriber who had initiated PrEP was the family practitioner (6225 [92·5%] of 7135 renewals).

Interpretation Although the number of PrEP initiations in primary care steadily increased over the study period, the profile of users was unchanged when compared with before extension. The high proportion of PrEP initiations not prescribed by family practitioners highlights potential barriers to sharing sexual health concerns with the family practitioner. Extending PrEP to women, individuals who are socioeconomically disadvantaged, and all those who might benefit from it will require increased awareness among target audiences and practitioners.

Funding French National Agency for Medicines and Health Products Safety.

Lancet Public Health 2025

Published Online
April 8, 2025
https://doi.org/10.1016/S2468-2667(25)00062-3

See Online/Comment
https://doi.org/10.1016/S2468-2667(25)00067-2

Department of Infectious Diseases, Nice University Hospital Center, Universite Cote d'Azur, Nice, France (S Bamouni PhD, Prof M Carles MD); **EPI-PHARE, Epidemiology of Health Products (French National Agency for Medicines and Health Products Safety [ANSM] and French National Health Insurance [CNAM]), Saint-Denis, France** (S Bamouni, S Billioti de Gage PhD, D Desplas MSc, R Dray-Spira PhD); **Regional Coordination for the Fight against HIV (COREVIH) PACA-EST, Nice, France** (J Valbousquet MSc, A Viot MSc, S Fakir MSc, Prof M Carles); **Regional Coordination for the Fight against HIV (COREVIH) Nouvelle-Aquitaine, Bordeaux, France** (J Lamant MSc, Prof F Dabis MD, M Hessamfar MD); **Department of General Medicine** (Prof J-P Joseph MD) **and ISPED, INSERM U1219** (M Hessamfar), **University of Bordeaux, Bordeaux, France; Bordeaux University Hospital Center, Bordeaux, France** (M Hessamfar); **Mediterranean Center of Molecular Medicine, INSERM U1065, Côte d'Azur University, Nice, France** (Prof M Carles)

Correspondence to:
Prof M Carles, Department of Infectious Diseases, Nice University Hospital Center, Nice 06200, France
carles.m@chu-nice.fr

Introduction

Pre-exposure prophylaxis (PrEP) constitutes one of the major advances in combating the HIV pandemic.[1–5] In France in 2022, among people newly diagnosed with HIV, 41% were men who have sex with men, of whom 27% were born in France and 14% abroad; 31% were women, mostly born abroad (80%) and infected through sexual transmission (97%). Transgender individuals accounted for 2% of new diagnoses and were infected via sexual transmission. The French overseas territories represented the regions with the highest incidence of HIV infection, reaching up to 1149 cases per 1 000 000 inhabitants in 2022. In mainland France, the highest incidence was observed in the Île-de-France region, with 190 cases per 1 000 000 inhabitants.

Oral PrEP can be administered either daily or on demand. In France, PrEP is a fixed-dose combination of two reverse-transcriptase inhibitors, tenofovir disoproxil fumarate and emtricitabine, and must remain associated with other preventive measures: condom use, regular HIV and sexually transmitted infections (STIs) screening, and use of single-use equipment when injecting drugs.

Since January, 2016, PrEP is fully covered by the French public health insurance for people considered at high risk of HIV acquisition, whether because of a history of multiple STIs, multiple sexual partners, or as part of a specific key population. PrEP can be dispensed in pharmacies with a medical prescription and is reimbursed for all residents who use it and are affiliated with social security. Undocumented migrants can also access PrEP through governmental medical aid (Aide Médicale de l'Etat). PrEP is also dispensed free of charge in sexual health centres, regardless of citizenship or social rights. The Scientific Interest Group EPI-PHARE team in charge of monitoring the roll-out of PrEP in France[6] since its launch reported that 42 159 people had

Research in context

Evidence before this study

We searched PubMed for articles published between June 1, and Oct 31, 2022, about HIV pre-exposure prophylaxis (PrEP) prescription, using the following search terms: "HIV pre-exposure prophylaxis", "PrEP", "HIV pre-exposure prophylaxis prescription", "HIV pre-exposure prophylaxis use", "HIV pre-exposure prophylaxis users profiles", "HIV preexposure prophylaxis in primary care", "HIV pre-exposure prophylaxis and general practitioners", "HIV pre-exposure prophylaxis and primary care physicians", "barriers to HIV pre-exposure prophylaxis use", and "barriers to HIV pre-exposure prophylaxis prescription". No language restrictions were applied. We also searched for recommendations on the prescription and use of PrEP in France on the French Health Authority website. In France, until mid-2021, HIV PrEP initiation with tenofovir disoproxil fumarate and emtricitabine was limited to hospitals and sexual health centres. Previous studies about PrEP use in France showed that users were mainly men, socioeconomically advantaged, and living in large urban areas. Since June, 2021, PrEP initiation has been extended to any practitioner, including primary care practitioners, to improve access to PrEP and diversify the profile of users. We found no previous studies on nationwide PrEP initiations and use in primary care since the extension of first prescription. Knowing how PrEP is implemented and used in primary care could help develop the necessary strategies to improve access to PrEP and increase prescriptions to reach all those who could benefit from it.

Added value of this study

This study provides nationwide data on PrEP prescription and use in primary care in France since the prescription of initiations was extended to general practitioners (GPs) in 2021. Using the National Health Data System (Système National des Données de Santé), we showed that the profile of users remains similar to that observed before extension of PrEP initiations in primary care (ie, mainly men, mean age 36·0 years, mostly living in large urban areas, less socioeconomically disadvantaged). Additionally, this study showed that prescribers were mostly GPs, less than half of whom were the patient's family practitioner. In the 6 months after PrEP initiation, 70·8% of PrEP initiators had at least one renewal, most of which were made by the practitioner who had initiated the prescription.

Implications of all the available evidence

This study showed an increase in PrEP initiation in primary care during the study period linked to the initiation of PrEP by GPs. The user profile has not changed, suggesting that beyond regulatory developments, improving access to PrEP requires complementary actions such as training GPs in addressing sexual health, training health-care staff in primary care in less densely populated areas, and using teleconsultation. The high proportion of PrEP initiations not prescribed by the patient's family practitioner highlights potential barriers of sharing sexual health concerns with family practitioners and the need for more awareness among target audiences and practitioners. A better tracking of biological tests required at PrEP initiation is also needed to confirm compliance with national guidelines.

initiated PrEP between 2016 and 2021, with the following key findings:[7] (1) an insufficient diversity of the population, as PrEP users were mainly men (97·5%), living in large metropolitan areas (73·8%), and with a high socioeconomic status (93%); (2) a decline in PrEP use during the COVID-19 pandemic, as reported for other medicines in France.[8] These findings have been reported previously,[9–12] and barriers such as living in rural areas far from health-care facilities, or lack of awareness of the available PrEP prescribers have been highlighted.[13]

Until mid-2021, PrEP initiation was limited in France to specialised physicians working in hospitals and sexual health centres. As of June 1, 2021, prescription of PrEP initiation was extended to all prescribing physicians, including primary care practitioners to increase PrEP coverage.[14] Additionally, PrEP reimbursement has been authorised for all people in need, according to the practitioner's evaluation. To assist practitioners with PrEP prescription, an online education platform for initial PrEP prescription and monitoring in private practice has been made freely accessible to all physicians who wish to prescribe PrEP. The aim of this study was to evaluate the effect of extending PrEP initiation to primary care practitioners in the first 19 months since implementation, in terms of initiation uptake and the profile of users and prescribers.

For more on **Système National des Données de Santé** see https://www.snds.gouv.fr/SNDS/Accueil

See Online for appendix

Methods

Data sources

We analysed data from the French National Health Data System (Système National des Données de Santé [SNDS]), which covers 99% of French residents. The SNDS is a comprehensive national database containing anonymised individual data on reimbursed health-care usage (appendix p 2). The database combines data from the French National Health Insurance information system (Système National d'Information Inter-régimes de l'Assurance Maladie) linked to the National Hospital Database (Programme de Medicalisation des Systèmes d'Information) and data from the Center for Epidemiology of Deaths Medical Causes. SNDS data do not contain information on the results of biological examinations, medical indications for prescriptions, or on the sexual behaviour of individuals. Ethical approval and informed

consent are not required for studies based on the SNDS databases, since these data are anonymous and the methodology is exclusively observational. Under the permanent regulatory access granted to EPI-PHARE, this observational study was registered internally with SDNS (number T2022-10-428).

Study population

Using an algorithm developed by the EPI-PHARE team,[7,15] we defined PrEP users as individuals aged 15 years and older, receiving a dispensation of tenofovir disoproxil fumarate and emtricitabine alone (ie, not combined with a same day dispensation of another HIV antiretroviral drug), who did not have HIV at the time of dispensation. HIV infection at the time of tenofovir disoproxil fumarate and emtricitabine dispensation was defined by any of the following criteria: (1) full coverage of health-care expenditures due to a long-term disease-affiliation for HIV infection diagnosis, (2) any hospital stay in the previous 5 years during which a primary diagnosis of HIV infection was recorded, (3) any hospital stay in the previous year during which a secondary diagnosis of HIV infection was recorded, (4) any insurance coverage for a laboratory test specific of HIV infection monitoring, within 12 months before and 1 month after the date of dispensation of tenofovir disoproxil fumarate and emtricitabine alone, with the exception of HIV viral load testing, for which at least three reimbursements were required, or (5) at least three outpatient or inpatient dispensations on different dates of an HIV antiretroviral drug (with the exception of tenofovir disoproxil fumarate and emtricitabine) within 12 months before and 1 month after the date of dispensation of tenofovir disoproxil fumarate and emtricitabine alone. Full exclusion criteria are in the appendix (p 3).

We included all individuals receiving a first PrEP dispensation in primary care settings between June 1, 2021, and Dec 31, 2022, with no PrEP dispensation before June 1, 2021. We considered all private practitioners and all health centres not linked to hospitals or sexual health centres as primary care settings. Health centres were identified using their unique identifier linked to the national nominative health-care facilities database.

For each individual, we registered all PrEP dispensation dates during the study period. Individuals covered by the affiliation to complementary solidarity-based health coverage, which is given to residents with limited resources, were considered as socioeconomically disadvantaged. The methods used to gather data on PrEP initiation, context, and referrals to primary care are in the appendix (p 4).

We collected data on biological testing for HIV infection, STIs (chlamydia, syphilis, and gonorrhoea), renal and liver functions, and the dispensation of nephrotoxic drugs (appendix (pp 5–7) at the time of PrEP initiation. The coprescription of nephrotoxic drugs was identified by at least two reimbursements for the same nephrotoxic drug within 6 months before PrEP initiation. Finally, we collected some sexual and general health-care usage data such as STI (chlamydia, syphilis, and gonorrhoea) treatments (appendix (p 8), reported contraceptive method, gynaecologist, proctologist, and dermatologist consultations, and hepatitis A, B, and human papillomavirus (HPV) immunisation during the 6 months following PrEP initiation (appendix (p 9).

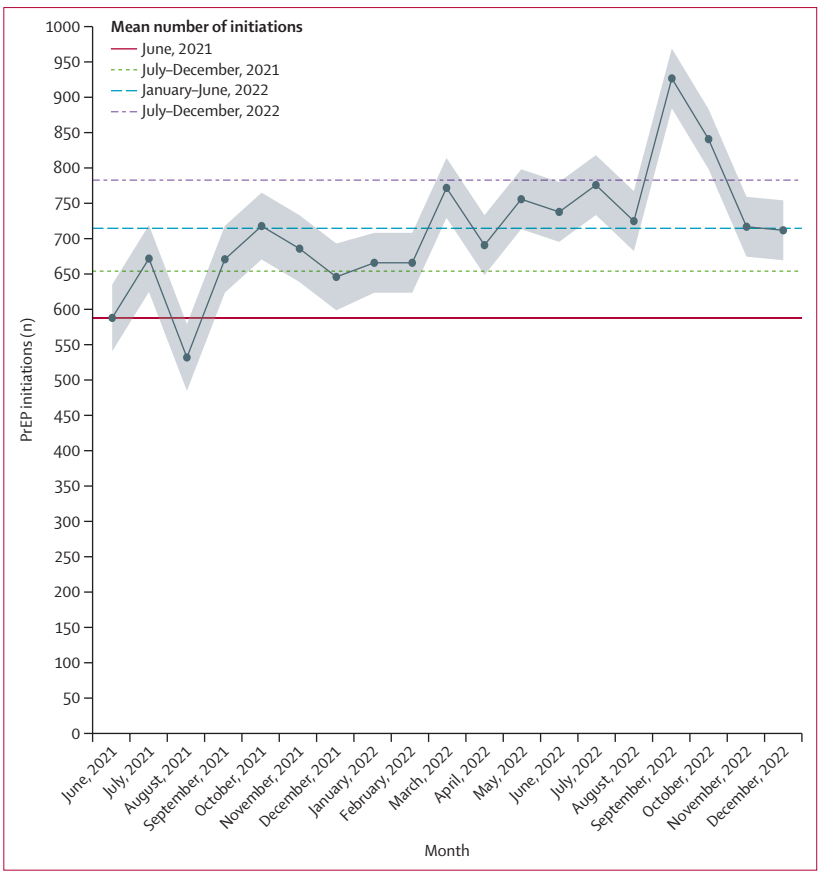

Figure 1: **Monthly number of PrEP initiations in primary care (June 1, 2021 –Dec 31, 2022)**
Data were obtained from Système National des Données de Santé (France). Grey shaded area shows 95% confidence intervals. PrEP=pre-exposure prophylaxis.

Statistical analysis

We reported the overall and monthly number of PrEP initiators (ie, new users) in primary care over the study period. Continuous data were expressed as mean with SD or median with IQR. The plan for analysing results based on age category, access to general practitioner (GPs), qualitative variables related to social protection, prescribing areas, and prescriber characteristics is outlined in the appendix (pp 10–12). The same applies to screening tests, biological check-ups, use of specialist consultations, and the frequency of renewals according to reimbursement terms (appendix pp 10–11). We

	Individuals initiating PrEP (n=13 500)
Sex	
Men	12 996 (96·3%)
Women	504 (3·7%)
Age, years	
Mean (SD)	36·0 (11·8)
Median (IQR)	33 (27–44)
Age categories, years	
≤25	2796 (20·7%)
>25–35	4822 (35·7%)
>35–45	2839 (21·0%)
>45–55	2012 (14·9%)
>55–65	854 (6·3%)
>65	177 (1·3%)
Complementary solidarity-based health coverage	
No	12 488 (92·5%)
Yes	1012 (7·5%)
Government medical aid	
No	13 488 (99·9%)
Yes	12 (0·1%)
Size of the urban area of residence (number of inhabitants)	
<2000	1090 (8·1%)
2000 to 9999	749 (5·5%)
10 000 to 49 999	757 (5·6%)
50 000 to 199 999	1108 (8·2%)
≥200 000	9581 (71·0%)
Missing data	215 (1·6%)
APL (number of GP consultations accessible per inhabitant per year)	
Mean (SD)	4·3 (1·2)
Median (IQR)	4·3 (3·5–5·1)
Localised potential accessibility categories	
≤2	347 (2·6%)
3–4	4587 (34·0%)
≥5	8319 (61·6%)
Missing data	247 (1·8 %)

Data were obtained from Système National des Données de Santé (France). Data are n (%) unless otherwise specified. Localised potential accessibility describes the level of accessibility to GPs in primary care, expressed as a ratio between the number of GP consultations and the number of accessible visits in general practice per standardised inhabitant per year. PrEP=pre-exposure prophylaxis. APL=localised potential accessibility. GP=general practitioner.

Table 1: **Sociodemographic characteristics of PrEP users at the time of PrEP initiation (June 1, 2021–Dec 31, 2022)**

compared the sociodemographic characteristics of PrEP users at the time of PrEP initiation for the study period (June 1, 2021 to Dec 31, 2022) with a time period before the extension of PrEP initiation in primary care (Jan 1, 2020 to June 1, 2021), for which data have already been published (appendix p 12).[7]

Role of the funding source

The funder had a role in study design, data collection, data analysis, data interpretation, and writing of the report.

Results

Between June 1, 2021, and Dec 31, 2022, 13 500 individuals initiated PrEP in primary care (appendix p 13). The monthly number of PrEP initiations varied over the period, with an overall increase of 20% between the second half of 2021 (mean 654 initiations per month [SD 64]) and the second half of 2022 (mean 783 initiations per month [86]; figure 1; appendix p 14). A temporary peak in initiations was observed in September and October, 2022, with respective increases of 18·4% and 7·4% compared with the mean number of initiations in the second half of 2022 (783 initiations per month [SD 85·9]), and up to 30·5% and 18·4% when compared with the mean number of initiations over the study period (710 per month [86]).

Individuals initiating PrEP were mainly men (12 996 [96·3%] of 13 500 individuals), with a mean age of 36·0 years (SD 11·8; table 1). 1012 (7·5%) of 13 500 individuals were socioeconomically disadvantaged. 12 (<1%) of 13 500 individuals benefited from government medical aid. 13 324 (98·7%) of 13 500 individuals who initiated PrEP lived in mainland France. 9581 (71·0%) of 13 500 individuals lived in large urban areas with more than 200 000 inhabitants. 5548 (41·1%) of 13 500 individuals who initiated PrEP in primary care lived in the Ile-de-France region, with 3247 (24·1%) residing in Paris. The global distribution of PrEP initiators is shown in figure 2. Individuals who initiated PrEP lived in areas with a mean of 4·3 GP consultations per inhabitant per year (SD 1·2; table 1). However, 4934 (36·6%) of 13 500 individuals lived in areas where access to GPs for primary care was below the national mean of 4·1 GP consultations per inhabitant per year.

The prescriber's identifier was available for 10 976 (81·3%) of 13 500 PrEP initiations. The remaining 2524 PrEP initiations (2524 [18·7%] of 13 500 PrEP initiations) for which prescriber identification was not available were mainly reported at health-care centres that were not hospitals or sexual heath-care centres.

5125 physicians were identified as working in private practice, most of whom (4542 [88·6%] of 5125) were GPs. Of the physicians who were not GPs, dermatologists (67 [1·3%] of 5125 physicians), gynaecologist-obstetricians (62 [1·2%]), and psychiatrists (54 [1·1%]) initiated the most PrEP prescriptions (table 2). 4903 (95·7%) of 5125 physicians prescribed between one and five PrEP initiations with nearly three-quarters (3822 [74·6%] of 5125) prescribing a single PrEP initiation over the study period (appendix p 15). The mean number of initiations per prescriber was estimated at 2·1 (SD 7·4).

Among the 5125 physicians who initiated PrEP, more than half were men (3154 [61·5%]), with a mean age of 50·6 years (SD 13·2; table 2). They mainly worked in large urban areas (3316 [64·7%] of 5125), with almost a third based in the Ile-de-France region (4398 [29·8%] of 5125; figure 2).

4528 (88·4%) of 5125 prescribers were so-called contracted medical practitioners (ie, individuals affiliated

with French social security [Sécurité Sociale]), the majority of whom had a fully private practice (appendix p 16). They prescribed a mean of 2·1 initiations per prescriber. Physicians who work part-time in hospital (259 [5·1%] of 5125 prescribers) had the highest mean number of PrEP initiations per prescriber (5·9 [SD 23·8]). When PrEP initiation prescribers and family practitioners' identification numbers were both documented (10 525 [78·0%] of 13 500 individuals who initiated PrEP), PrEP was initiated by a prescriber other than the family practitioner in 5812 (55·3%) of 10 525 cases. Among the 5812 people who initiated PrEP through a physician who was not their family practitioner, 1359 (23·4%) had a family practitioner who had already prescribed PrEP to other people over the study period.

Among the 13 500 individuals who initiated PrEP, 9986 (73·9%) were reimbursed for an HIV test done between 30 days and 60 days before the first PrEP dispensation (appendix p 17). 8881 (65·8%) of 13 500 individuals were reimbursed for syphilis screening tests and 8186 (60·6%) were reimbursed for chlamydia and gonorrhoea screening tests. 9160 (67·9%) of 13 500 individuals were reimbursed for renal function tests and 7485 (55·4%) individuals were reimbursed for liver function tests. 3902 (28·9%) of 13 500 individuals were reimbursed for hepatitis A screening, 7600 (56·3%) for hepatitis B screening, and 8670 (64·2%) for hepatitis C screening tests. Of the 504 women who initiated PrEP, 89 (17·7%) were reimbursed for a blood or urinary β-human chorionic gonadotropin dosing. Among the 13 500 individuals who initiated PrEP, 2371 (17·6%) were co-medicated with at least one nephrotoxic drug.

Between June 1, 2021 and June 30, 2022, 8783 PrEP initiations were registered (after the exclusion of 19 people with HIV in the 6 months after initiation). 6216 (70·8%) of 8783 initiations were renewed at least once in the following 6 months. The mean number of renewals, among those with at least one renewal (n=6216) was 3·3 (SD 1·7). At 6 months, 1897 (21·6%) of 8783 individuals had renewed PrEP at least five times. Since individuals receive a 1-month supply of PrEP with each prescription, these five renewals in addition to the initial dispensation can be interpreted as continuous PrEP use. The remaining 6896 (78·4%) who had less than six deliveries of PrEP over 6 months were considered as on-demand PrEP users (table 3).

20 313 renewals were registered within the 6 months after PrEP initiation. 17 882 (88·0%) of 20 313 renewals were prescribed by a GP (appendix p 18). The prescribers' identification numbers were provided for both initiation and renewal for 14 507 (71·0%) of 20 313 cases. 11 961 (82·4%) of 14 507 renewals were prescribed by the same practitioner as for initiation and the mean number of renewals per prescriber was 2·9 (SD 1·7). For individuals who initiated PrEP in health-care centres, 1479 (56·2%) of 2632 renewals were prescribed in the same health centres.

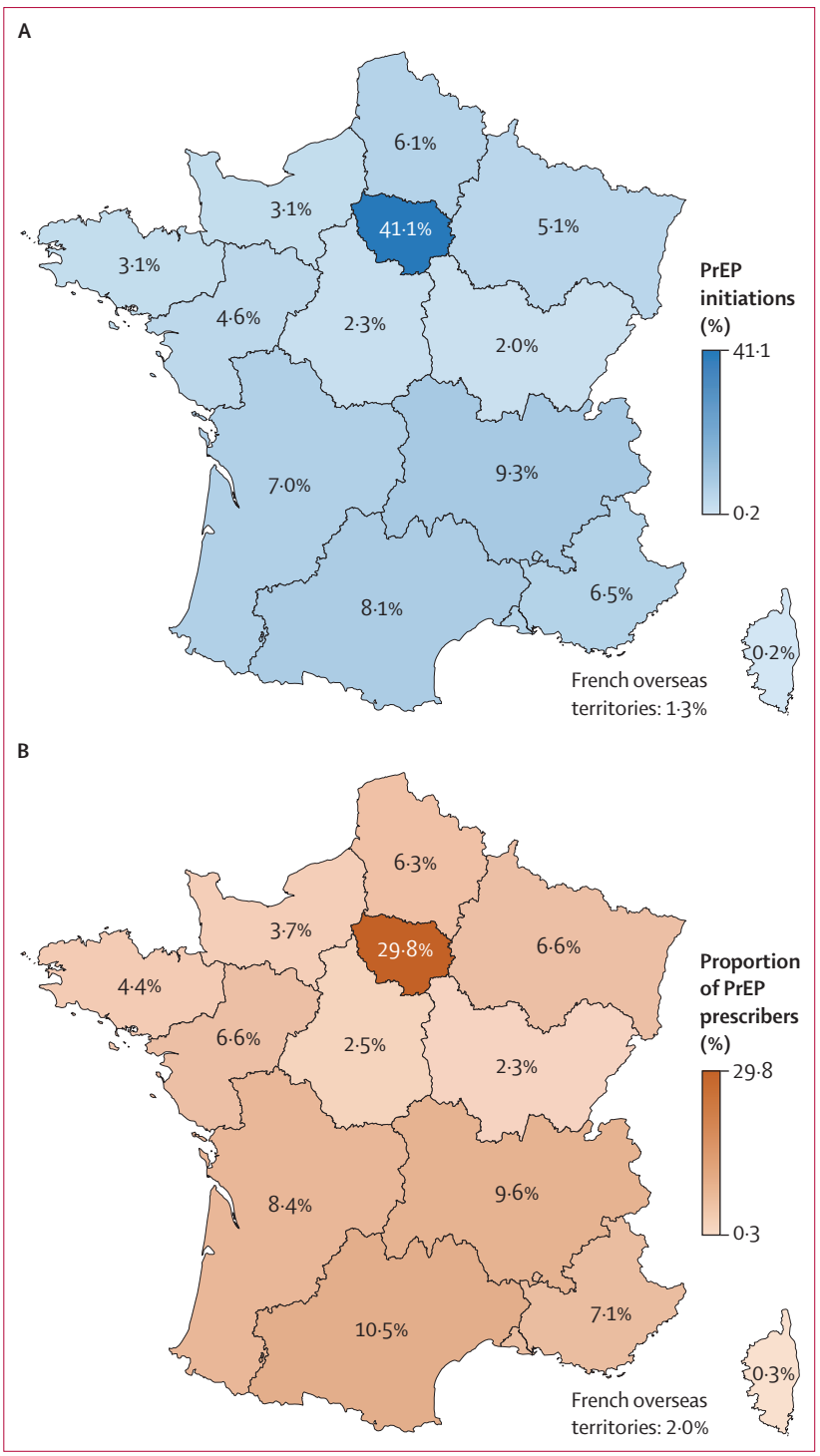

***Figure 2*: Regional distribution of PrEP initiations (n=13 500) and prescribers (n=5125) in France (June 1, 2021–Dec 31, 2022)**

Data were obtained from Système National des Données de Santé (France). The distribution of PrEP initiations according to user's region of residence at initiation (A) and the distribution of PrEP initiation prescribers according to region of their main practice (B) over the study period. PrEP=pre-exposure prophylaxis.

	Prescribers (n=5125)
Medical specialty	
GPs	4542 (88·6%)
Non-GPs	583 (11·4%)
Internists	23 (0·4%)
Infectious diseases specialists	10 (0·2%)
Dermatologists	67 (1·3%)
Gynaecologist-obstetricians	62 (1·2%)
Psychiatrists	54 (1·1%)
Other	367 (7·2%)
Sex	
Men	3154 (61·5%)
Women	1938 (38·4%)
Data missing	3 (0·1%)
Age, years	
Mean (SD)	50·6 (13·2)
Median (IQR)	51 (38–62)
Age categories, years	
≤35	890 (17·4%)
>35–45	1180 (23·0%)
>45–55	931 (18·3%)
>55–65	1398 (27·3%)
>65–75	625 (12·2%)
>75–91	90 (1·8%)
Missing information	4 (0·1%)
Size of urban area of main office (number of inhabitants)	
<2000	343 (6·7%)
2000 to 9999	505 (9·9%)
10 000 to 49 999	415 (8·1%)
50 000 to 199 999	519 (10·1%)
≥200 000	3316 (64·7%)
Data missing	27 (0·5%)

Data are n (%), unless otherwise specified. PrEP=pre-exposure prophylaxis. GP=general practitioner.

Table 2: **Medical specialties and sociodemographic characteristics of PrEP initiation prescribers working in private practice (June 1, 2021–Dec 31, 2022)**

	Renewals in the 6 months after PrEP initiation (n= 8783)*
Number of PrEP renewals	
Mean (SD)	3·3 (1·7)
Median IQR)	2·0 (2–5)
Number of renewals	
0	2567 (29·2%)
1–2	2453 (27·9%)
3–4	1866 (21·2%)
≥5	1897 (21·6%)

Data were obtained from Système National des Données de Santé (France). PrEP=pre-exposure prophylaxis. *Individuals who initiated PrEP between June 1, 2021, and June 30, 2022; 19 people with HIV were excluded.

Table 3: **Number of PrEP renewals in the 6 months after PrEP initiation (June 1, 2021–Dec 31, 2022)**

Among the 2931 PrEP initiators whose first prescription was made by the family practitioner, 2179 (74·3%) received a total of 7135 renewals in the 6 months following initiation (mean number of renewals of 3·3 [SD 1·7]), and 6225 (92·5%) of 7135 prescriptions were renewed by the family practitioner. Among the 13 500 individuals who initiated PrEP, 9185 individuals renewed at least once over the study period. In the interval between 60 days before first renewal and 30 days after the first renewal dispensation, 6595 (71·8%) of 9185 individuals were reimbursed for HIV screening tests and 6255 (68·1%) of 9185 individuals were reimbursed for renal function tests.

Between 60 days before and 6 months after PrEP initiation, 1573 (11·7%) of 13 500 individuals received a reimbursement for dermatologist consultations. Other reimbursed preventive measures, including consultations with sexologists and proctologists, condom reimbursements, vaccination against hepatitis A, B, and HPV, and treatments for gonorrhea, chlamydia, and syphilis, are reported in the appendix (p 20).

Between Jan 1, 2020, and June 1, 2021, similar to the sociodemographic characteristics of PrEP users during the study period, PrEP users were mainly men (16 216 [97·5%] of 16 636), with a mean age of 35·5 years (SD 11·8). 1256 (7·5%) of 16 636 were socioeconomically disadvantaged, and 11 993 (72·1%) of 16 636 individuals lived in a large urban area of more than 200 000 inhabitants

Discussion

Using comprehensive data from the SNDS, we found that 13 500 individuals initiated PrEP in primary care between June 1, 2021 and June 30, 2022 in France. The number of initiations increased steadily each month during the study period. Users were almost exclusively men; fewer than 10% were socioeconomically disadvantaged, and most lived in large urban areas. GPs accounted for the majority of initiations (88%). However, less than half of the GPs were the user's family practitioner. Regarding biological tests at the time of initiation, reimbursements for HIV tests were recorded for 9986 (74·4%) of 13 500 individuals who initiated PrEP. Among 8783 PrEP initiators, 6216 (70·6%) renewed PrEP at least once in the 6 months after initiation.

During the same period, PrEP initiation by in-hospital or public prescribers has continued to increase,[16] showing that the increase observed in primary care is probably not a transfer of PrEP initiation from hospitals to primary care, but rather a real appropriation of PrEP prescription by primary care practitioners. This has contributed to a 39·5% increase in PrEP initiations overall in France in the second half of 2022 compared with the first half of 2021 (ie, before the extension of prescription to primary care physicians), which is almost equivalent to the levels observed before the COVID-19 pandemic.[16] We observed a peak of initiations in September and October, 2022, with increases of 30·5% and 18·4%, respectively,

compared with the mean number of initiations during the study period (710 per month). This peak in the number of initiations could be explained by the impact of the mpox (formerly known as monkeypox) vaccination campaign, which took place between July and August, 2022, during the epidemic and helped raise awareness of PrEP. However, this peak was not sustained.

A previous study was done on the use of PrEP in France between 2016 and June, 2021 (ie, before the extension of first prescription to primary care) using the SNDS.[7] When we compared the sociodemographic characteristics of PrEP users between our study period and an equivalent 18-month period from these previous data, we identified no major differences. As observed during the study period, over an 18-month period before June 1, 2021 (start of extension to primary care), most users were men (97·5% before extension not primary care *vs* 96·3% after extension to primary care), with a mean age of 35·5 years (*vs* 36 years after extension), living in a large urban area (72·1% before extension *vs* 71·0% after extension), with a minority being socioeconomically disadvantaged (7·5% before *vs* 7·5% after extension). With the extension of PrEP initiation to all physicians, health-care authorities expected to reach not only a larger, but also a more diverse population. However, we observed that the PrEP user profile remained similar to that before June, 2021, with a minority of women and people with socioeconomic disadvantages or living in rural areas. The low representation of women among PrEP users contrasts with HIV epidemiological data and the target populations who need PrEP in France. 31% of incident HIV infections in 2022 in France were in women and 97% of infections were sexually acquired.[17] Therefore, a greater increase in the percentage of women among PrEP users would be expected if the population profile of PrEP initiation is diversifying in line with the epidemiology of HIV in France. This is consistent with other countries, such as the USA, where a study reported a lower PrEP-to-need ratio (ie, the number of PrEP users divided by new HIV diagnoses) among women than men.[10] In Belgium, until 2021, PrEP users were exclusively men (99%).[11,12] Another contrast between the need for PrEP and its actual use is observed at geographical level. The French overseas territories are areas with the greatest need for PrEP as they had the highest rates of incident HIV infections in 2022,[17] but this is where the level of PrEP initiations is lowest (1%) and remained as low as before June 2021.[7] For mainland France, excluding the Île-de France region, where the HIV notification rate and PrEP initiation levels are the highest, substantial heterogeneity exists.[17]

In primary care, most physicians are GPs and are usually the family practitioners. In our study, although the PrEP initiation prescribers were mostly GPs, more than half of individuals who initiated PrEP saw a GP other than their family practitioner for initiation. This highlights the reservations users might experience in discussing sexual health issues with their family practitioner. A study that evaluated the barriers to PrEP prescription among GPs in one region of France reported that the scarcity of information about the patient's sexual behaviour was one of the main barriers to prescribing PrEP for 53% of the GPs surveyed.[18] The same study also surveyed PrEP users and more than half declared that they do not like to discuss their sexuality with their GPs. The knowledge about PrEP of family doctors, also studied in other countries, might represent a barrier to prescription.[18,19] Remote consultations for PrEP could help, in particular, to enable certain individuals to enter and remain in medical care follow-up (ie, helping to facilitate PrEP prescription for some); this point has been discussed previously.[20,21] In the French PrEP prescription guidelines, biological tests such as HIV and renal function must be done before prescription, and testing for STIs, hepatic function, and pregnancy is recommended.[22,23] The completed tests were not always traceable in the SNDS. As a result, we cannot conclude that PrEP users for whom these tests were not recorded in the SNDS did not benefit from them. This issue was reported in a previous study that evaluated HIV testing in the month after PrEP initiation, with 36% of PrEP users without reimbursement for an HIV test tracked in the SNDS data.[15] Regarding renal function monitoring, it was not possible to assess the risks associated with nephrotoxic drugs prescribed in the study. Evidence from the WHO Programme for International Drug Monitoring suggests that the risk of drug interactions between PrEP and non-steroidal anti-inflammatory drugs, antibiotics, steroids, and medications that are frequently prescribed in primary care is low. Nevertheless, prescribers should be aware of these potential interactions and monitor renal function appropriately.

For more on the **WHO Programme for International Drug Monitoring** see https://who-umc.org/about-the-who-programme-for-international-drug-monitoring

In the 6 months after PrEP initiation, 70·6% of initiators had at least one renewal, with a mean of 3·3 renewals. Regarding PrEP renewals, prescriptions in primary care remained similar to those before June, 2021.[7] The PrEP schedule (ie, on demand *vs* continuation *vs* mixed PrEP) was not clear in this study, but the 21·6% of PrEP users who renewed PrEP at least five times can be considered as continuous PrEP users. This rate is lower than that reported for continuous PrEP users (30%) when PrEP was mainly prescribed in hospital and sexual health-care centres.[7] Since appointments in primary care are easier to obtain, it is easy to refer to GPs to obtain an on-demand PrEP prescription quickly, which could explain the high proportion of on-demand PrEP in our study. A previous study[24] in France showed that 49·5% of PrEP users opted for on-demand PrEP dosing, which could explain the low number of renewals observed in the 6 months after PrEP initiation. Additionally, we found that a high proportion (82·4%) of PrEP follow-ups were performed by the initiating prescriber, whether or not this was the users' family practitioner. 56·2% of renewals for individuals who initiated PrEP in health centres were prescribed in the same health centre. Since most of the facilities in France

had few PrEP prescribers, we can assume that the same prescriber made these renewals. The proportion of PrEP prescriptions made by the same prescriber in private health centres is therefore lower than that observed for private practice outside health centres.

The use of the SNDS, which is a comprehensive database covering more than 99% of residents in France, enabled us to describe the number of initiations, their evolution over the 18-month period and their spatial distribution, and the characteristics of users and prescribers in the whole country. Additionally, we used an algorithm based on SNDS data to define PrEP users, the validity of which was established in a previous study.[5] To our knowledge, our study is the first to provide data on PrEP initiation and use in primary care on a national scale since the extension of the initial prescription of PrEP to all physicians, including primary care prescribers. Several studies have assessed PrEP in primary care, but focused on the willingness to prescribe[25] or barriers to prescribing[18] and did not provide data on actual prescribing in primary care. Other studies have identified factors associated with PrEP persistence, including in primary care settings.[26]

However, our study has some limitations. Since the SNDS data provide only data on health expenditures per patient, there is therefore no data available on the actual PrEP consumption by the beneficiaries. Notably, the validity of the PrEP use definition was consolidated in a previous study.[7] Similarly, PrEP tablets can be provided for free in sexual health facilities, and these deliveries are not recorded in SNDS data. Therefore, people who had previously received PrEP delivery in a sexual health care centre, and then switched to pharmacy delivery following a primary care prescription would be recorded in SNDS data as having a first dispensation of tenofovir disoproxil fumarate and emtricitabine. Therefore these people might have been erroneously considered as PrEP initiators in our study. However, these situations are infrequent and probably only affect a small number of centres and occasional dispensation rather than all PrEP dispensations.

Considering our algorithm for defining HIV infection, which has already been used in other published studies[5,7] and which combines multiple identification parameters, the inclusion of people living with HIV among PrEP users seems unlikely. The SNDS database does not contain information on sexual behaviour, or information allowing the identification of transgender people or sex workers, hindering the analysis of these important groups. No data were available to identify populations at risk of HIV, such as data on recent migrant status, which would have enabled us to better characterise the study population. However, we used the variable affiliation to government medical aid, which enabled the identification of undocumented immigrants. Our study did not include long-acting injectable PrEP, which could be of particular interest to some people who are less likely to adhere to a daily oral regimen, because cabotegravir was not yet authorised in France during the study period. In the SNDS, people who benefit from government medical aid have a temporary identification number that changes when they become legal residents, making it difficult to follow up these individuals over time in the database. This might have contributed to underestimation of the number of renewals within 6 months of PrEP initiation. However, government medical aid beneficiaries represented less than 1% of our study population, limiting this underestimation.

This study described the national roll-out of PrEP initiation in France, since its extension to all prescribers in June, 2021, using comprehensive data from SNDS. The number of initiations steadily increased over the study period. However, the profile of users remained similar to that observed before the extension to primary care. Although GPs were most often the prescribers, the high rate of PrEP initiation not carried out by the user's family practitioner highlights potential barriers to sharing sexual health concerns with family practitioners. Extending PrEP to women and socioeconomically disadvantaged people will require increased awareness among target users and practitioners.

Our study, in addition to the 2023 French epidemiological survey,[17] offers crucial insights for improving PrEP accessibility. In particular, regional and territorial analysis could help advance the following: (1) a so-called social marketing approach—ie, targeted communication adapted to specific profiles to offer PrEP to populations identified as exposed and underusers of PrEP (eg, individuals who do not access PrEP due to social inequalities in health, including geographical, gender, or racial inequalities, and men who have sex with men who are distant from the lesbian, gay, bisexual, and transgender community and do not consider themselves to be at risk and eligible for PrEP); (2) the implementation of diverse prevention strategies, including PrEP, as early as possible in the life course of newly arrived migrant populations; (3) programming a targeted analysis of overseas territories; (4) identifying factors related to low persistence; (5) the continuation of awareness programmes to encourage vigilance among family practitioners for identifying PrEP indications within their patient population.

Contributors

SB was involved in methodology, data extraction, formal analysis, writing the original manuscript draft, and reviewing and editing the manuscript. SBdG conceptualised the study and was involved in methodology, supervision, data analysis, verification and interpretation, and writing, reviewing, and editing the manuscript. DD conceptualised the study and was involved in data curation, extraction, and verification.

JV and JL conceptualised the study and were involved in funding acquisition, data extraction, and reviewing and editing the manuscript. J-PJ and FD conceptualised the study and were involved in data interpretation and reviewing and editing the manuscript.

AV conceptualised the study and was involved in funding acquisition and reviewing and editing the manuscript. MH conceptualised the study and was involved in data interpretation and reviewing and editing the manuscript. SF was involved in funding acquisition and reviewing and editing the manuscript. R-DS conceptualised the study and was involved in methodology, supervision, data verification, data interpretation,

project administration, and writing and reviewing the manuscript. MC conceptualised the study and was involved in methodology, funding acquisition, supervision, data interpretation, project administration, and writing, reviewing, and editing the manuscript. SB, SBdG, R-DS, DD, and MC had full access to and verified the data. All authors were responsible for the decision to submit the manuscript.

Declaration of interests

We declare no competing interests.

Data sharing

The data that support the findings of this study are available on reasonable request from the corresponding author (carles.m@chu-nice.fr) and EPI-PHARE research team. The data are not publicly available due to privacy or ethical restrictions on studies using SNDS data.

Acknowledgments

The French National Agency for Medicines and Health Products Safety (ANSM) funded the study (reference 2021S023). We thank all the healthcare professionals and PrEP prescribers who agreed to answer our questions to gain a better understanding of the PrEP use pathway. We thank David Chirio who helped us to review the language used in the manuscript.

References

1 McCormack S, Dunn DT, Desai M, et al. Pre-exposure prophylaxis to prevent the acquisition of HIV-1 infection (PROUD): effectiveness results from the pilot phase of a pragmatic open-label randomised trial. *Lancet* 2016; **387:** 53–60.

2 Grant RM, Lama JR, Anderson PL, et al. Preexposure chemoprophylaxis for HIV prevention in men who have sex with men. *N Engl J Med* 2010; **363:** 2587–99.

3 Molina JM, Charreau I, Spire B, et al. Efficacy, safety, and effect on sexual behaviour of on-demand pre-exposure prophylaxis for HIV in men who have sex with men: an observational cohort study. *Lancet HIV* 2017; **4:** e402–10.

4 Molina JM, Capitant C, Spire B, et al. On-demand preexposure prophylaxis in men at high risk for HIV-1 infection. *N Engl J Med* 2015; **373:** 2237–46.

5 Jourdain H, de Gage SB, Desplas D, Dray-Spira R. Real-world effectiveness of pre-exposure prophylaxis in men at high risk of HIV infection in France: a nested case-control study. *Lancet Public Health* 2022; **7:** e529–36.

6 Billioti de Gage S, Desplas D, Dray-Spira R. Suivi de l'utilisation de Truvada ou génériques pour une prophylaxie pré-exposition (PrEP) au VIH. https://www.epi-phare.fr/rapports-detudes-et-publications/suivi-utilisation-prep-vih-2022/ (accessed March 24, 2025).

7 Billioti de Gage S, Desplas D, Dray-Spira R. Roll-out of HIV pre-exposure prophylaxis use in France: a nationwide observational study from 2016 to 2021. *Lancet Reg Health Eur* 2022; **22:** 100486.

8 Weill A, Drouin J, Desplas D, Cuenot F, Dray-Spira R, Zureik M. Usage des médicaments de ville en France durant l'épidémie de la Covid-19 – point de situation jusqu'au 25 avril 2021. https://www.epi-phare.fr/app/uploads/2021/05/epi-phare_rapport_6_medicaments_covid_20210527.pdf (accessed March 24, 2025).

9 Wang H, Molina JM, Dray-Spira R, et al. Spatio-temporal changes in pre-exposure prophylaxis uptake among MSM in mainland France between 2016 and 2021: a Bayesian small area approach with MSM population estimation. *J Int AIDS Soc* 2023; **26:** e26089.

10 Siegler AJ, Mouhanna F, Giler RM, et al. The prevalence of PrEP use and the PrEP-to-need ratio in the fourth quarter of 2017, United States. *Ann Epidemiol* 2018; **28:** 841–49.

11 Sciensano. Epidemiologie van AIDS En HIV-Infectie in België, Rapport 2021. https://www.sciensano.be/sites/default/files/rapport_hiv_2022_nl.pdf (accessed Nov 14, 2023).

12 Rotsaert A, Reyniers T, Jacobs BKM, et al. PrEP user profiles, dynamics of PrEP use and follow-up: a cohort analysis at a Belgian HIV centre (2017-2020). *J Int AIDS Soc* 2022; **25:** e25953.

13 Antonini M, Silva IED, Elias HC, Gerin L, Oliveira AC, Reis RK. Barriers to pre-exposure prophylaxis (PrEP) use for HIV: an integrative review. *Rev Bras Enferm* 2023; **76:** e20210963.

14 Haute Autorité de Santé. Réponses rapides dans le cadre de la COVID-19–Prophylaxie (PrEP) du VIH par ténofovir disoproxil/emtricitabine dans le cadre de l'urgence sanitaire. https://vihclic.fr/wp-content/uploads/2021/06/reco_435__reponse_rapide_prep_au_vih_150421_cd_vudoc_am_pg_vd_mel_v0.pdf (accessed July 11, 2022).

15 Tassi MF, Laurent E, Gras G, et al. PrEP monitoring and HIV incidence after PrEP initiation in France: 2016–18 nationwide cohort study. *J Antimicrob Chemother* 2021; **76:** 3002–08.

16 Billioti de Gage S, Desplas D, Dray-Spira R. Suivi de l'utilisation de Truvada ou génériques pour une prophylaxie pré-exposition (PrEP) au VIH à partir des données du Système National des Données de Santé (SNDS). Actualisation des données jusqu'au 30 Juin 2023. https://www.epi-phare.fr/rapports-detudes-et-publications/prep-vih-2023/ (accessed March 24, 2025).

17 Santé Publique France. Bulletin de santé publique VIH-IST. Novembre 2023. https://www.santepubliquefrance.fr/maladies-et-traumatismes/infections-sexuellement-transmissibles/vih-sida/documents/bulletin-national/bulletin-de-sante-publique-vih-ist.-novembre-2023 (accessed Dec 1, 2023).

18 Quicray S. Etude des freins à la prescription initiale de la prophylaxie pré-exposition (PrEP) au VIH par les médecins généralistes de Bretagne: une etude quantitative. https://ged.univ-rennes1.fr/nuxeo/site/esupversions/9f2a24e0-dc17-4c0b-8487-44366febed2c?inline (accessed Nov 14, 2023).

19 Lane W, Heal C, Banks J. HIV pre-exposure prophylaxis: knowledge and attitudes among general practitioners. *Aust J Gen Pract* 2019; **48:** 722–27.

20 Faussat C, Bonnin A, Hilt D, et al. Étude qualitative de l'acceptabilité de la téléconsultation pour le traitement préventif du VIH. *Sante Publique* 2022; **34:** 537–47.

21 Faussat C, Bonnin A, Hilt D, et al. Advantages and limits of remote consultations for HIV pre-exposure prophylaxis health pathway: ePrEP qualitative study. *J Epidemiol Popul Health* 2024; **72:** 202201.

22 RecoMédicales. Recommandations: prophylaxie pré-exposition (PrEP). 2022. https://recomedicales.fr/recommandations/prophylaxie-preexposition-prep/ (accessed Nov 15, 2023).

23 Agence Nationale de Sécurité du Médicament et des produits de santé (ANSM). Informations importantes concernant le bon usage de l'emtricitabine/ténofovir disoproxil* dans l'indication prophylaxie pré-exposition (PrEP) – AU-VIH. Document destiné au médecin prescripteur. https://ansm.sante.fr/uploads/2021/07/05/emtricitabine-et-tenofovir-disoproxil-brochure-d-information-pds-version4-2021-juin.pdf (accessed Nov 15, 2023).

24 Molina JM, Ghosn J, Assoumou L, et al, and the ANRS PREVENIR Study Group. Daily and on-demand HIV pre-exposure prophylaxis with emtricitabine and tenofovir disoproxil (ANRS PREVENIR): a prospective observational cohort study. *Lancet HIV* 2022; **9:** e554–62.

25 Edelman EJ, Moore BA, Calabrese SK, et al. Primary care physicians' willingness to prescribe HIV pre-exposure prophylaxis for people who inject drugs. *AIDS Behav* 2017; **21:** 1025–33.

26 Le Roux C, Tassi MF, Faussat C, et al. Factors associated with PrEP persistence and loss of follow-up: a 5-year historic cohort. *Arch Sex Behav* 2024; **53:** 2445–52.

27 Bezin J, Duong M, Lassalle R, et al. The national healthcare system claims databases in France, SNIIRAM and EGB: powerful tools for pharmacoepidemiology. *Pharmacoepidemiol Drug Saf* 2017; **26:** 954–62.