Roll-out of HIV pre-exposure prophylaxis use in France: A nationwide observational study from 2016 to 2021

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Summary

Background Oral HIV pre-exposure prophylaxis (PrEP) has been available and fully reimbursed for people at high risk of sexually acquired HIV infection in France since January 2016. Its dissemination has been widely promoted to reduce HIV incidence in high-risk populations. This study aimed to assess the roll-out of PrEP use in France from its implementation until mid-2021.

Methods Using the French National Health Data System (SNDS) covering 99% of people residing in France, all PrEP users defined as individuals aged 15 years or older who received at least one dispensing of PrEP between 1 January 2016 and 30 June 2021 were identified. PrEP users number and their socio-demographic and PrEP use characteristics were assessed over time.

Findings As of 30 June 2021, a total of 42,159 individuals had initiated PrEP in France. Monthly PrEP initiations increased steadily up to 1027 in February 2020, and then slowed down sharply from the onset of the COVID-19 epidemic until a recovery in the first half of 2021. PrEP users were overwhelmingly men (97.5%, 41,126/42,159), aged 36 years on average, living in a large metropolitan area (73.8%, 31,096/42,159), and among whom a minority (7.0%, 2966/42,159) were socio-economically disadvantaged. Throughout the study period, 80-90% of users renewed PrEP from one semester to another, suggesting a good level of maintenance among those engaged in treatment. Nevertheless, for 20.1% (7148/35,549) of new PrEP users no prescription renewal was recorded in the first six months after initiation, suggesting a substantial proportion of early treatment discontinuation. Private practitioners accounted for a minority (21.3%, 77,885/366,399) of PrEP renewal prescriptions.

Interpretation PrEP roll-out has been markedly impacted by the COVID-19 pandemic in France. Although PrEP deployment has been substantial among men who have sex with men, further action is needed to expand access to PrEP to all other population groups who could benefit from it and to promote adherence to treatment.

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Introduction

Human immunodeficiency virus (HIV) pre-exposure prophylaxis (PrEP) using the fixed-dose combination of oral tenofovir disoproxil fumarate and emtricitabine (TDF-FTC), has been shown to be a highly effective individual protection strategy for HIV-negative people in randomized control trials and real-life studies, provided adherence is high. This oral combination of two HIV reverse transcriptase inhibitors has been authorized for HIV PrEP in Europe since March 2017. In France, daily oral use of PrEP with TDF-FTC has had a pre-marketing approval since January 2016 and has been fully reimbursed since then for people at high risk of sexually acquired HIV infection (i.e. men or transgender people who have sex with men, persons who inject drugs, sex workers, people in vulnerable situations at risk of condomless sex in the context of high HIV prevalence or exposure) as a complement to a comprehensive prevention strategy. PrEP management includes quarterly HIV and STI screening and promotion of PrEP adherence and condom use.
PrEP initiation was reserved to physicians, including general practitioners (GPs), in hospital or in sexual health centers. Since June 2021, clinicians experienced in the management of HIV practicing in multiple pharmacoepidemiological studies. 4,14–18

This study was approved by the French Data Protection Supervisory Authority (Commission Nationale de l’Informatique et des Libertés). No informed consent is required for studies based on the SNDS databases, as these data are anonymous.
Identification of PrEP users during the study period
All individuals aged 15 years and older who received a first dispensing of TDF-FTC (ATC code J05AR03) for HIV PrEP between 1 January 2016 and 30 June 2021 (i.e. study period) were considered as ever PrEP users. PrEP dispensing was considered as an indicator of PrEP use independently of available data on sexual behaviour. Each date of PrEP dispensing during the study period was registered. PrEP was considered as the indication of TDF-FTC prescription if TDF-FTC was dispensed alone (i.e. not combined with same-day dispensation of any other HIV antiretroviral drugs) to an HIV-uninfected individual. Previous HIV infection was identified by the presence of at least one of the following criteria at the date of dispensing TDF-FTC alone: (i) 100% healthcare coverage for a long-term illness with a diagnosis of HIV infection, (ii) at least one hospital stay in the last five years during which a primary diagnosis of HIV infection was recorded, (iii) at least one hospital stay in the previous year during which a secondary diagnosis of HIV infection was recorded, (iv) at least one reimbursement for a laboratory test specific of HIV infection monitoring, with the exception of HIV viral load testing for which at least three reimbursements were required, or (v) at least three outpatient or inpatient dispensations on different dates of an HIV antiretroviral drug (except TDF-FTC) within 12 months before and one month after the date of dispensation of TDF-FTC alone. The parameters used to exclude patients with HIV infection (i.e. ICD-10 codes related to HIV, ATC codes related to HIV antiretroviral drugs, laboratory tests specific to HIV monitoring) are detailed in Supplementary Material Table S1.

Among individuals identified as PrEP users, the first date of dispensing of TDF-FTC alone recorded during the study period was considered as the date of initiation. Subsequent PrEP dispensations were considered as treatment renewals.

Outcomes studied
The following criteria were used to assess the number of PrEP users over the study period and their characteristics in terms of PrEP use characteristics and socio-demographic profile.

The number of PrEP users over time was assessed by (i) the number of individuals initiating PrEP each month during the study period (or new users by month) and (ii) the total number of PrEP users by semester (or current PrEP users), including for each semester both new users who initiated PrEP during the semester (or new users in a given semester) and individuals with at least one PrEP renewal dispensation during the semester (or users in renewal in a given semester). For each semester, PrEP continuation rate was calculated by dividing the number of users in renewal during the semester by the overall number of users on PrEP during the preceding semester. Individuals who had initiated PrEP previously but without any PrEP renewal dispensation during a given semester were considered as discontinued users during that semester. During the subsequent semesters, discontinued users were either again considered as discontinued users in case they still did not have any PrEP renewal dispensation, or as users in renewal if they resumed PrEP.

Among individuals who initiated PrEP between 1 January 2016 and 31 December 2020, the number of PrEP renewals within the first six months following initiation was assessed by year of initiation. In France, a dispensation of PrEP usually corresponds to one box of 30 oral tablets, which covers one month of daily dosing. Thus, five renewals within six months of initiation theoretically cover (in addition to the initial prescription) the entire six-month period and may correspond to continuous use during this period. A lower number of renewals may reflect on demand-use or discontinuation of treatment. Characteristics of prescribers of PrEP renewals included their type of practice (hospital or private) and, for private practitioners only, their specialty (GP or specialist).

Socio-demographic characteristics of PrEP users included age, sex, CMU-C coverage, region of residence, and size of the urban area of residence at the time of PrEP initiation.

Statistical analyses
For quantitative or ordinal variables (i.e. age, sex, CMU-C coverage, region of residence, size of the urban area of residence, number of renewals within six months of PrEP initiation, type of prescriber for PrEP renewals) the number and frequency of each modality were reported. When these variables were not binary the following categories were considered: (i) 1 to 24, 25 to 34, 35 to 44, 45 to 54, 55 to 64, >65 years for age, (ii) Ile-de-France (i.e. Paris region), other region with high HIV incidence rate (i.e. Auvergne-Rhône-Alpes, Centre-Val de Loire, Grand Est, Nouvelle-Aquitaine, Occitanie, Provence-Alpes-Côte d’Azur, French overseas departments, for which ≥50 new HIV contaminations per million inhabitants had been recorded in 2018) and other regions (i.e. Bourgogne-Franche-Comté, Bretagne, Corse, Hauts-de-France, Normandie, Pays de la Loire) for region of residence and, (iii) <10 000, 10 000 to 49 000, 50 000 to 199 000 and ≥200 000 inhabitants for the size of the urban area of residence. Missing values, if any, were considered in a specific category. For quantitative variables, the mean and standard deviation, and the median and interquartile range were reported.

Statistical analyses were performed using SAS Enterprise Guide software, version 7.15.

Role of funding sources
No funding or sponsorship was received for this study.
Results

Number of PrEP users over time

A total of 42 159 individuals initiated PrEP between 1 January 2016 and 30 June 2021. The monthly number of PrEP initiations steadily increased between the first half (H1) of 2016 (190 initiations per month on average) and the second half (H2) of 2019 (919 initiations per month on average). The increase continued in January and February 2020 (948 and 1027 initiations, respectively, i.e. 988 per month on average), until the beginning of the first wave of the COVID-19 pandemic in France in March 2020. During the first lockdown (17 March to 10 May 2020), the monthly number of PrEP initiations fell to 618 in March 2020 (i.e. a 37% decrease compared to the average of January and February 2020), 247 in April (-75%) and 474 in May (-52%). PrEP initiations resumed in June 2020 (914 initiations) and then stabilized at a level close to that observed before the start of the pandemic (966 initiations per month on average in H2 2020). In H1 2021, the number of PrEP initiations started to rise again, first moderately during the period from February to May, which was marked by the third wave of the COVID-19 pandemic (average of 1054 monthly initiations) and then more markedly in June (1466 initiations). (Figure 1 and Supplementary Material Table S2).

Each semester between H1 2016 and H2 2019, the current number of PrEP users steadily increased up to a total of 18 500, including 5513 new users (average increase between two semesters: +26%) and 12 987 users in renewal (+52%) during H2 2019 (Figure 2 and Supplementary Material Table S3). Subsequently, with the onset of the COVID-19 pandemic the number of new users decreased in H2 2020 (4228, i.e. -23% compared to H2 2019) before returning to pre-pandemic levels in H2 2020 (5798 vs. 5513 in H2 2019) and resuming an upward trend in H1 2021 (6610, i.e. +14% compared to H2 2020). The number of users in renewal continued to increase, but to a lesser extent than in the pre-pandemic period (15 486 in H1 2020, 17 561 in H2 2020 and 20 202 in H1 2021, i.e. +19%, +13% and +15%, respectively). Overall, 26 812 individuals used PrEP in H1 2021, representing 64% of the total 42 159 individuals who had initiated PrEP since H1 2016.

Characteristics of PrEP users at the time of PrEP initiation

The socio-demographic characteristics of PrEP users at the time of treatment initiation are presented in Table 1. Throughout the study period, PrEP users were mainly men (97.5%), aged 36 years on average. A minority (7-0%) were covered by the CMU-C. The majority (73.8%) lived in a large urban area of more than 200,000 inhabitants, in the Paris region or in another region with high HIV incidence rate (44.4% and 40.1% respectively). Individuals residing in French overseas departments (regions with the highest HIV incidence rates in France) accounted for only 1.3% of PrEP users. Details of the number of PrEP users by region and by year of initiation are presented in Supplementary Material Table S4.

While the proportion of men remained fairly stable over time, the average age at PrEP initiation decreased, from 38 to 35 years between 2016 and H1 2021. The proportion of people aged 25 years or younger steadily increased from 9.1% in 2016 to 20.7% in H1 2021. CMU-C beneficiaries accounted for 8% of new PrEP users in H1 2021, a proportion slightly higher than in the previous years. The proportion of people living in large urban areas, especially Paris region, gradually decreased over time (from 80.8% in 2016 to 71.0% in H1 2021) in favour of other French regions.

Characteristics of PrEP use

Each semester from H2 2016, users in renewal accounted for the large majority of people who had used PrEP in the preceding semester, resulting in a PrEP continuation rate from one semester to another consistently reaching 80 to 90% (mean: 84.9%) throughout the study period (Figure 2 and Supplementary Material Table S3). Among users in renewal, more than 90% each semester had received a PrEP dispensation during the preceding semester. Though, each semester a substantial proportion of individuals previously on PrEP did not receive any PrEP renewal during the semester and were thus considered as discontinued users during this semester. This proportion, which reached 12% each semester in average overall, tended to decrease over time, ranging from 21% in H2 2016 to 7% in H2 2020 (Figure 2 and Supplementary Material Table S3).

Among the 35 549 people who initiated PrEP between 1 January 2016 and 31 December 2020, the average number of PrEP renewals within the six months following initiation was 2.9. Overall, during the first six months of treatment 30.0% received at least five renewals (corresponding, including initial dispensation, to a continuous use), 23.9% received three to four renewals, 26.0% received one to two renewals and 20.1% did not receive any renewal (Table 2). The number of PrEP renewals within the six months following initiation remained stable for initiations between H1 2016 and H1 2019 (mean 3.0 renewals), but was lower when initiation took place in H2 2019 or in 2020 (mean 2.7 renewals). Among individuals who initiated PrEP in H2 2019 or in 2020, 28% had only one or two renewals and 23% had no renewal within the first six months of treatment, while these proportions reached 24% and 18%, respectively, among those who initiated PrEP between 2016 and H1 2019.

Between H1 2016 and H1 2021, a total of 413 425 PrEP renewals were recorded among the 42 159 PrEP...
Figure 1. Number of PrEP initiations in France between 1 January 2016 and 30 June 2021, by month. The dotted lines indicate the average number of initiations per semester. Abbreviations: H1: first half of the concerned year; H2: second half of the concerned year.

Figure 2. Number of PrEP users and PrEP continuation rate in France between 1 January 2016 and 30 June 2021, by semester. The PrEP continuation rate for each semester was calculated by dividing the number of users in renewal during the semester by the overall number of users on PrEP during the preceding semester. Note: Discontinued users of PrEP in a given semester who resumed it in a later semester were considered users in renewal in that later semester. Abbreviations: H1: first half of the concerned year; H2: second half of the concerned year.
| TOTAL | 2016 N = 3065 | 2017 N = 4791 | 2018 N = 7375 | 2019 N = 10 292 | 2020 N = 10 026 | 2021 H1 N = 6610 |
|-------|---------------|---------------|---------------|----------------|----------------|-----------------|
| N = 42 159 |               |               |               |                |                |                 |

**Men, n (%):**

| Age categories (years), n (%) | 2016 | 2017 | 2018 | 2019 | 2020 | 2021 H1 |
|-------------------------------|------|------|------|------|------|---------|
| 25                            | 41 126 (97.5) | 2965 (96.7) | 4697 (98.0) | 7205 (97.7) | 10 043 (97.6) | 9740 (97.1) |
| 26-35                         | 6881 (16.3) | 280 (9.1) | 562 (11.7) | 1094 (14.8) | 1664 (16.2) | 1913 (19.1) |
| 36-45                         | 15 523 (36.4) | 1090 (35.6) | 1726 (36.0) | 2655 (36.0) | 3740 (36.3) | 3813 (38.0) |
| 46-55                         | 10 648 (25.3) | 992 (32.4) | 1505 (31.4) | 1965 (26.6) | 2505 (24.3) | 2284 (22.8) |
| 56-65                         | 6673 (15.8) | 780 (16.3) | 1243 (16.9) | 1705 (16.6) | 1454 (14.5) | 938 (14.2) |
| >65                           | 2003 (4.8) | 21 (0.7) | 33 (0.7) | 74 (1.0) | 127 (1.2) | 101 (1.0) |

**Age (years):**

- Mean (SD): 36 (11) | 38 (10) | 37 (10) | 37 (11) | 36 (11) | 35 (11)
- Median (IQR): 34 (28-44) | 37 (30-45) | 35 (29-44) | 35 (28-45) | 33 (27-43) | 33 (27-43)

**CMU-C, n (%):**

| Region of residence, n (%) | 2016 | 2017 | 2018 | 2019 | 2020 | 2021 H1 |
|----------------------------|------|------|------|------|------|---------|
| Ile-de-France (Paris region) | 18 721 (44.4) | 1597 (52.1) | 2207 (46.1) | 3556 (48.2) | 4437 (43.1) | 4247 (42.4) |
| Other regions with high HIV incidence$^a$ | 16 919 (40.1) | 1121 (36.6) | 1888 (39.4) | 2724 (36.9) | 4223 (41.0) | 4192 (41.8) |
| Other regions$^b$ | 6410 (15.2) | 329 (10.7) | 674 (14.1) | 1071 (14.5) | 1609 (15.6) | 1572 (15.7) |
| Missing information | 2966 (7.0) | 209 (6.8) | 319 (6.7) | 477 (6.5) | 705 (6.8) | 725 (7.2) |

**Size of the urban area of residence, number of inhabitants (%):**

| Size of the urban area of residence, number of inhabitants (%) | 2016 | 2017 | 2018 | 2019 | 2020 | 2021 H1 |
|---------------------------------------------------------------|------|------|------|------|------|---------|
| <10 000           | 4881 (11.6) | 261 (8.5) | 475 (9.9) | 784 (10.6) | 1290 (12.5) | 1229 (12.3) |
| 10 000 to 49 999  | 2098 (5.0) | 100 (3.3) | 269 (5.6) | 308 (4.2) | 542 (5.3) | 510 (5.1) |
| 50 000 to 199 999 | 3353 (8.0) | 166 (5.4) | 347 (7.2) | 567 (7.7) | 883 (8.6) | 810 (8.1) |
| ≥200 000          | 31 996 (73.8) | 2477 (80.8) | 3618 (75.5) | 5585 (75.7) | 7423 (72.1) | 7302 (72.8) |
| Missing information | 731 (1.7) | 61 (2.0) | 82 (1.7) | 131 (1.8) | 154 (1.5) | 175 (1.7) |

Table 1: Socio-demographic characteristics of PrEP users at the time of PrEP initiation, overall and by year.

Abbreviations: CMU-C, complementary universal health coverage; SD, standard deviation; IQR, interquartile range; 2021 H1, first half of 2021.

$^a$ Auvergne-Rhône-Alpes, Centre-Val de Loire, Grand Est, Nouvelle-Aquitaine, Occitanie, Provence-Alpes-Côte d’Azur, French overseas departments, for which ≥50 new HIV contaminations per million inhabitants had been recorded in 2018.

$^b$ Bourgogne-Franche-Comté, Bretagne, Corse, Hauts-de-France, Normandie, Pays de la Loire.
### Table 2: Number of PrEP renewals within the 6 months following initiation, overall and by semester of PrEP initiation.

| Semester of PrEP Initiation | 2016 H1 | 2016 H2 | 2017 H1 | 2017 H2 | 2018 H1 | 2018 H2 | 2019 H1 | 2019 H2 | 2020 H1 | 2020 H2 | 2021 H1 | 2021 H2 |
|----------------------------|--------|--------|--------|--------|--------|--------|--------|--------|--------|--------|--------|--------|
| RENEWALS (n)               |        |        |        |        |        |        |        |        |        |        |        |        |
| Mean (SD)                  | 2.9 (2.1) | 3.0 (2.2) | 3.1 (2.3) | 3.0 (2.2) | 3.0 (2.2) | 3.0 (2.2) | 3.0 (2.2) | 3.0 (2.2) | 3.0 (2.2) | 3.0 (2.2) | 3.0 (2.2) | 3.0 (2.2) |
| 25%ile                     | 0      | 0      | 1.0      | 1.1      | 1.1      | 1.1      | 1.2      | 1.2      | 1.2      | 1.2      | 1.2      | 1.2      |
| 75%ile                     | 5.0    | 5.1    | 5.4      | 5.5      | 5.6      | 5.7      | 5.8      | 5.8      | 5.9      | 5.9      | 6.0      | 6.0      |
| 25% of PrEP initiators (%)  | 2.9%    | 2.9%    | 3.1%     | 3.0%     | 3.0%     | 3.0%     | 3.0%     | 3.0%     | 3.0%     | 3.0%     | 3.0%     | 3.0%     |

#### Discussion

Based on data of the French National Health Data System (SNDNS), we showed that a total of 42 159 people aged 15 years and over initiated treatment with TDF-FTC for PrEP in France between 1 January 2016 and 30 June 2021. PrEP initiations increased steadily between the first half of 2016 and February 2020, until the onset of the first wave of the COVID-19 pandemic in March 2020. By then, PrEP initiations fell by up to 75%, probably as a result of a decreased accessibility to healthcare services, especially those offering PrEP, but also a lower level of exposure to sexual risk of HIV acquisition during lockdown.10,20–23 PrEP initiations progressively resumed following the end of the first lockdown (from June 2020), but stagnated at the level observed before the start of the pandemic during the rest of year 2020. A trend toward a recovery in increase in PrEP initiations emerged from February 2021 and more particularly in June 2021, marked by the end of the third wave of the COVID-19 pandemic. This suggests that PrEP initiations during the second half of 2020 and the first half of 2021 were much less affected than during the first wave of the pandemic despite the continuation of some pandemic-related restrictions throughout these periods.

We found that in the first half of 2021, only about two thirds (64%) of individuals who had ever initiated PrEP since its implementation in 2016 were still using it. Our results suggest that after initiating PrEP, the vast majority of users (80–90%) renew their treatment from one semester to another, suggesting a good level of maintenance among those engaged in treatment. This level of PrEP maintenance improved over time since 2016. However, for 20% of new PrEP users no prescription renewal was recorded in the first six months after initiation, suggesting a substantial proportion of early treatment discontinuation. This phenomenon has even been more marked since the beginning of the COVID-19 pandemic. This could be explained by a reduction in the quantity of PrEP consumed due to the social distancing measures in place during the COVID-19 pandemic, particularly in case of intermittent (on-demand) PrEP use which is frequent in France (i.e. around 50% of PrEP users).31–34 Both daily and on-demand PrEP have been shown to be highly effective in preventing HIV acquisition provided that adherence is good.35 Promoting both modes of PrEP use and choosing appropriately according to individuals preferences and risk profile could improve adherence to treatment and allow access to this effective HIV prevention tool to a greater
number of users. According to the ERAS COVID-19 survey, almost 60% of PrEP users had stopped PrEP and about 6% had switched from continuous to on-demand use during the first wave of COVID-19 pandemic in France. PrEP discontinuation or switch from continuous to on-demand use during the pandemic has also been reported in other countries.

These results confirm the major impact of the COVID-19 pandemic on PrEP use in France, as already reported for other health products and in other countries. In addition, they draw attention to the substantial frequency of early PrEP discontinuation. The negative impact of PrEP discontinuation on its real-life preventive effectiveness was demonstrated in a recent study conducted by our team.

As of June 2021, in France PrEP users have been almost exclusively socio-economically advantaged men, aged 36 on average and living in Paris region or other large metropolis. They are likely to be mainly MSM. In metropolitan France, the regional distribution of PrEP initiations globally reflects that of new HIV diagnoses, with almost half of initiations (45%) in Paris region. Although the proportion of PrEP users under 25 years of age, residing outside Paris region or large urban areas, and/or socio-economically disadvantaged level increased continuously over time, the use of PrEP has remained limited in certain population subgroups who could particularly benefit from it. In particular, women accounted for only 2.5% of PrEP users, highlighting the fact that PrEP is probably rarely offered in situations where women are at high risk of HIV acquisition (e.g., injecting drug use, sex workers, vulnerability to condomless sex in a context of high HIV prevalence or exposure). Furthermore, PrEP initiations in French overseas departments have remained scarce (1% of initiations), even though these departments account for the highest burden of new HIV diagnoses in France. Until June 2021, PrEP renewals were generally carried out by non-private practitioners, although PrEP prescribing by private practitioners has increased over time. The extension of PrEP initial prescription to all prescribers since June 2021 in France is expected to further increase this trend.

This large real-life study provides a comprehensive overview of the roll-out of PrEP use since its approval in France, as well as its characteristics. To date, available data on PrEP use in real-life were restricted to specific subgroups in France. Several representative studies on PrEP use and users characteristics were conducted in other countries but did not cover the period of the COVID-19 pandemic which had a significant impact on access to prevention services, including PrEP. Large scale, real-life studies assessing PrEP number of users and patterns of use, such the one presented here, are essential to guide health authorities in promoting the use of PrEP.
Conclusion
This comprehensive real-life study provides evidence of a major impact of the COVID-19 pandemic on PrEP roll-out in France which deserves to be further monitored in the longer term. It also highlights the needs for further measures to expand access to PrEP to all potential beneficiaries, including women, socio-economically disadvantaged people and those living in remote areas, as well as to improve adherence to treatment. Future studies are needed to assess the impact of the recent extension of PrEP initiation to all prescribers in France.

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Data sharing statement
David Desplas and Sophie Billioti de Gage have full access to all of the data in the study and take responsibility for the integrity of the data and the accuracy of the data analysis. The datasets generated during and/or analyzed during the current study are available from the corresponding author on reasonable request.

Declaration of interests
No conflicting relationship exists for any author.

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Supplementary materials
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