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► To cite this version:

Vincent Bérot, Anton Eremin, Antoine Fauchois, Jeanne Dechamp, Luminita Schneider, et al.. Hepatitis A, hepatitis B and HPV vaccine needs and coverage in MSM initiating HIV PrEP in a sexual health clinic in Paris. *Sexually Transmitted Infections*, 2023, pp.sextrans-2023-055802. 10.1136/sextrans-2023-055802 . hal-04099039

HAL Id: hal-04099039

<https://hal.sorbonne-universite.fr/hal-04099039v1>

Submitted on 16 May 2023

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1 **Hepatitis A, hepatitis B and HPV vaccine needs and coverage in MSM initiating HIV PrEP in a**
2 **sexual health clinic in Paris**

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18 **TRANSPARENCY DECLARATION**

19 No competing interest.

20 **CONTRIBUTORS**

21 VB, RP, JD, CK contributed to the study design and developing analysis plan. AF, JD, RA, CK, VB,
22 AE contributed to the analysis and interpretation of data. VB, AE wrote the first draft of the
23 manuscript and subsequent drafts after revisions. CK reviewed all versions of the manuscript; VB, AE,

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25 participants, reviewed the final version of the manuscript and contributed to the interpretation of the
26 data.

27

28 Pre-exposure prophylaxis (PrEP) with tenofovir disoproxil/emtricitabine (TDF/FTC) is a powerful tool
29 to prevent HIV acquisition and provides an opportunity to offer comprehensive prevention services,
30 including assessment for sexually transmitted infections and evaluation of immune status towards
31 vaccine-preventable viral infections such those due hepatitis A virus (HAV), hepatitis B virus (HBV)
32 and human papillomavirus (HPV). In addition to the programme in girls aged 11-19, French guidelines
33 recommended HPV vaccination for MSM ≤ 26 years old in February 2016¹ and for all boys aged 11-
34 19 in December 2019². There are no restrictions on HPV vaccine use beyond these age limits, but the
35 cost is not covered by the French Health Service. In real-life settings, suboptimal vaccination coverage
36 against HPV as well as HBV has been reported among European MSM^{3,4}.

37 Our objective was to evaluate HAV, HBV and HPV vaccine needs and coverage in individuals
38 initiating PrEP in a sexual health clinic in Paris. In this observational retrospective single-centre study,
39 we reviewed all individuals who initiated PrEP between January 1st, 2016 and December 31st, 2020
40 with ≥ 1 year of follow-up after PrEP initiation. At baseline, we assessed the presence of HAV and
41 HBV antibodies and HPV vaccination status. Immune protection against HAV and HBV was defined
42 as the presence of anti-HAV IgG index S/CO > 1.00 and anti-HBs IgG > 10 International Units/L
43 (IU/L), respectively. HPV vaccination status at baseline was assessed through the participants' recall.
44 Subsequently, we assessed vaccine prescription by physicians for non-immune and unvaccinated
45 participants, followed by a review of completion of vaccination. Vaccination schedules were
46 considered complete after 2 doses for HAV with a time interval of 0 and 6 months, 3 doses for HBV
47 with an interval of 0, 1, 6 months, and 3 doses for HPV with an interval of 0, 2, 6 months. Contrary to
48 HAV and HBV vaccines, HPV vaccine was not accessible in the sexual health center and had to be
49 purchased from a private pharmacy. Finally, we assessed overall HAV, HBV immune status
50 combining immune protection acquired in the past or by vaccination after PrEP initiation and HPV

51 vaccine coverage. HPV vaccine completion was analysed by ≤ 26 y.o. or > 26 y.o. age groups. If any
52 information was missing, individuals were contacted by phone or email to determine whether
53 vaccination had been performed and if not, the reason why. All clinical, biological and prescription
54 data are routinely documented in an electronic health record (NADIS), for which all patients gave
55 consent for the collection and use of their anonymized data after approval by the CNIL (French Data
56 Protection Authority; CNIL authorisation number: 2085881). Statistical data are presented with total
57 numbers and proportions and compared by a chi-square test. A P-value <0.05 was considered
58 statistically significant.

59 A total of 591 PrEP users were analysed. All were MSM with a median age of 33 years (IQR 28-41),
60 including 118 participants (20%) aged ≤ 26 y.o.

61 At baseline (Table 1), 57.7% (341/591) of PrEP users were immune against HAV and 73.4%
62 (434/591) against HBV. Vaccines were prescribed for 93.2% (233/250) of HAV non-immune and
63 87.2% (137/157) of HBV non-immune participants. Vaccination was completed in 85.8% (200/233)
64 and in 91.2% (125/137) individuals with an HAV and HBV vaccine prescription, respectively. Our
65 results are consistent with other studies where HAV vaccination rates were high, especially among
66 PrEP users⁵.

67 With regards to HPV, only seven of the 591 (1.2%) individuals had been vaccinated before PrEP
68 initiation, including 4/118 (3.4%) individuals aged ≤ 26 . The prescription rate by physicians remained
69 low throughout the study period at 26% (152/584) for all ages and 39.5% (45/114) for those ≤ 26
70 years. These results are in agreement with those of other studies which report infrequent HPV
71 vaccination prescription by physicians^{4,6}. Following prescription, the HPV vaccine completion rate
72 was 54.6% (83/152) including 64.4 % (29/45) in participants aged ≤ 26 years. Of 69 individuals who
73 did not complete HPV vaccination despite prescription, 5 (7%) participants did not respond to the
74 questionnaire, 64 (93%) reported the following reasons: forgetting to go to a pharmacy for vaccine
75 delivery (n=29), not feeling at risk (n=20), lost prescription (n=6) and vaccine cost (n=9, all > 26 y.o.).
76 Several factors may explain our findings: recentness of the French guidelines, vaccine cost and lack of

77 motivation for HPV vaccination⁷, as one third of the participants described not feeling at risk for this
78 viral oncogenic disease.

79 Finally, combining immunity acquired in the past or by vaccination after PrEP initiation, the overall
80 immune protection rate for these 591 MSM initiating PrEP was 91.5% for HAV, 94.6% for HBV and
81 15.2% for HPV, including 28% in the ≤ 26 years age group and 12% in the > 26 years age group.

82 Given the high burden of HPV-attributable lesions in MSM compared to heterosexual men⁸, a change
83 in prevention approaches is required. Greater vaccine promotion against sexually transmitted viruses,
84 including vaccination in PrEP guidelines, and expanding the age criteria for HPV vaccination in MSM
85 – as recommended in the UK⁹ – would help to improve targeted vaccination campaigns in this at-risk
86 population^{6,7,10}.

	Non-immune (HAV/HBV) or non-vaccinated (HPV) at PrEP initiation	Vaccine prescription rate in case of no prior immunity (HAV, HBV) or vaccination (HPV)	Vaccine completion rate after prescription at PrEP initiation	Overall immune protection (HAV, HBV) * and HPV vaccine coverage
Hepatitis A	250/591 (42.3%)	233/250 (93.2%)	200/233 (85.8%)	541/591 (91.5%)
Hepatitis B	157/591 (26.6%)	137/157 (87.2%)	125/137 (91.2%)	559/591 (94.6%)
HPV				
All ages	584/591 (98.8%)	152/584 (26.0%)	83/152 (54.6%)	90/591 (15.2%)
≤ 26 y.o.	114/118 (96.6%)	45/114 (39.5%) [p<0.001 vs. hepatitis A, p<0.001 vs. hepatitis B]	29/45 (64.4%) [p<0.001 vs. hepatitis A, p<0.001 vs. hepatitis B]	33/118 (28.0%) [p<0.001 vs. hepatitis A, p<0.001 vs. hepatitis B]
> 26 y.o.	470/473 (99.3%)	107/470 (22.8%) [p<0.001 vs. hepatitis A, p<0.001 vs. hepatitis B]	54/107 (50.4%) [p<0.001 vs. hepatitis A, p<0.001 vs. hepatitis B]	57/473 (12.0%) [p<0.001 vs. hepatitis A, p<0.001 vs. hepatitis B]
y.o.: years old; * combining immune protection acquired in the past (assessed by the presence of antibodies) or by vaccination after PrEP initiation				

87 **Table 1. Baseline immune status, vaccine prescription and uptake in PrEP users (n=591)**

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