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

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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,  
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23 manuscript and subsequent drafts after revisions. CK reviewed all versions of the manuscript; VB, AE,

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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  $\leq 26$  years old in February 2016<sup>1</sup> and for all boys aged 11-  
34 19 in December 2019<sup>2</sup>. 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<sup>3,4</sup>.

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 1<sup>st</sup>, 2016 and December 31<sup>st</sup>, 2020  
40 with  $\geq 1$  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  $\leq 26$  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  $\leq 26$  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 users<sup>5</sup>.

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  $\leq 26$ . 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  $\leq 26$   
70 years. These results are in agreement with those of other studies which report infrequent HPV  
71 vaccination prescription by physicians<sup>4,6</sup>. Following prescription, the HPV vaccine completion rate  
72 was 54.6% (83/152) including 64.4 % (29/45) in participants aged  $\leq 26$  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 vaccination<sup>7</sup>, 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 men<sup>8</sup>, 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 UK<sup>9</sup> – would help to improve targeted vaccination campaigns in this at-risk  
86 population<sup>6,7,10</sup>.

	<b>Non-immune (HAV/HBV) or non-vaccinated (HPV) at PrEP initiation</b>	<b>Vaccine prescription rate in case of no prior immunity (HAV, HBV) or vaccination (HPV)</b>	<b>Vaccine completion rate after prescription at PrEP initiation</b>	<b>Overall immune protection (HAV, HBV) * and HPV vaccine coverage</b>
<b>Hepatitis A</b>	250/591 (42.3%)	233/250 (93.2%)	200/233 (85.8%)	541/591 (91.5%)
<b>Hepatitis B</b>	157/591 (26.6%)	137/157 (87.2%)	125/137 (91.2%)	559/591 (94.6%)
<b>HPV</b>				
<b>All ages</b>	584/591 (98.8%)	152/584 (26.0%)	83/152 (54.6%)	90/591 (15.2%)
<b>≤ 26 y.o.</b>	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]
<b>&gt; 26 y.o.</b>	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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