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Country of birth is associated with antiretroviral therapy choice in treatment-naïve persons with HIV in France

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Objectives: We aimed to describe factors associated with the choice of first antiretroviral therapy (ART) in persons with HIV (PWH) in France, included the country of birth, as well as the time to undetectable viral load and treatment discontinuation.

Design: Observational study conducted from the national Dat'AIDS prospectively collected database.

Methods: We included all adults who started their first ART between 01 January 2014 and 31 December 2020, with a pretherapeutic plasma viral load (pVL) at least 400 copies/ml. Univariable and multivariable logistic regressions were used to analyze PWH characteristics driving to an integrase strand transfer inhibitors (INSTI)-based first prescribed regimen. We also analyzed time to first line discontinuation, and to a first undetectable pVL, using Kaplan–Meier model.

Results: We analyzed data from 9094 PWH: 45% MSM, 27% women and 27% heterosexual men; 48% born abroad; 4.7 and 2.8% with concomitant hepatitis B and tuberculosis, respectively. INSTIs were prescribed as first-line therapy in 50% of PWH, which increased over time. Native French PWH were more likely to receive an INSTI-based regimen than PWH born abroad [adjusted prevalence ratio 1.47, 95% confidence interval (CI) 1.33–1.60], as were high pVL at diagnosis, hepatitis B or concomitant tuberculosis. Time before discontinuation of the first ART and reaching a first undetectable pVL was not different according to the place of birth.

Conclusion: Despite unrestricted access to INSTIs in France, independently from HIV disease parameters, PWH born abroad received INSTIs less frequently as a first regimen than those born in France. Qualitative data are needed to better understand physicians' prescribing practices.

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Introduction

To decrease the morbidity and mortality associated with HIV and to prevent the risk of transmission [1,2], all persons with HIV (PWH) are recommended to receive antiretroviral treatment (ART). Initial ART usually consists in a three-drug therapy based on two nucleoside reverse transcriptase inhibitors (NRTIs) and a third agent. The availability of integrase strand transfer inhibitors (INSTIs) was a key turning point for the management of HIV. Second-generation INSTIs [dolutegravir (DTG), and bictegravir (BIC)] are well tolerated drugs with high viral potency and genetic barrier, very few drug–drug interactions, and almost no contraindications [3,4], making – in theory at least – INSTI a preferential choice in antiretroviral combinations for ART-naïve PWH in most settings [5–7].

In Europe, boosted protease inhibitors (bPIs) and nonnucleoside reverse transcriptase inhibitors (NNRTIs) are still recommended in initial ART. Limited risk of additional resistance-associated mutations in case of persistent virological replication when using last generation protease-inhibitors [8] make bPI-based combinations appealing when sub-optimal adherence is expected. Adherence in ART-naïve PWH is multifactorial and difficult to predict, and some populations in France – such as PWH from Sub-Saharan Africa – may be systematically assumed to be less adherent, impeding access to better tolerated INSTI combinations. Some authors have highlighted inequalities in treatment based on race, driven by implicit bias among physicians [9–12]. Recent results from a French monocentric study showed that PWH born abroad may not receive similar first-line regimens as PWH born in France [13]. It should be mentioned that in France, health insurance is free of charge, including for undocumented individuals. Therefore, incomes of PWH do not affect the choice of treatment.

Thus, our main objective was to assess, in a large prospective cohort, patients' characteristics, including country of birth, associated with the choice of first ART in recent years. Second objectives were to analyze the time to undetectable viral load and treatment discontinuation.

Methods

Information was collected from 26 centers participating in the Dat'AIDS cohort (Clinicaltrials.gov reference: NCT02898987) after approval by the Nantes Institutional

Review Board and the French National Committee on Informatics and Human Rights (CNIL number: 1357652). The Dat'AIDS cohort was started in 2000, including at that time all PWH with their previous medical history, and all new PWH in care since then have become part of the cohort after they were fully informed and provided written consent [14]. The authors did not have access to any patient-identifying information. For this analysis, we selected adults (≥ 18 years old) who were prescribed a first triple therapy since 01 January 2014 (which corresponds to the availability of DTG in France), with a plasma viral load (pVL) of more than 400 copies/ml before ART prescription. Dual therapies as first antiretroviral treatment, including DTG/lamivudine, were not recommended in international guidelines during the study period, and are, therefore, not included in this analysis. Individuals for whom the place of birth was not available ($< 2\%$ of the total studied population) were also excluded from the analyses. People who inject drugs ($< 2\%$ of the total studied population) were included in their respective gender group (including MSM for those who had both risk factors).

For the selected individuals, we collected sex, place of birth (grouped by 'France' or 'abroad'), age at HIV diagnosis, HIV infection mode and year of HIV diagnosis, year of first ART, type of third agent (classified as INSTI, bPI, NNRTI or 'other'), pVL and CD4⁺ T-cell count at the time of diagnosis, CDC stage before initiation, chronic hepatitis B status and ongoing tuberculosis concomitant to ART initiation. To be considered valid, pretreatment CD4⁺ T-cell counts and pVL values had to be available within 1 month of starting ART. Duration of the first ART was also collected, censored on the first occurrence of any of the following; death, loss-to-follow-up, date of PWH switching care to another center and, therefore, not participating in the cohort, or on 01 January 2021 (censoring date). Undetectable viral load was defined as below 50 copies/ml, and treatment discontinuation was considered whatever the reason (including simplification).

Statistical analysis

For our primary objective, univariate and multivariate logistic regressions were built to analyze relations between PWH characteristics and the prescription of an INSTI-based first regimen. The multivariable model first included all characteristics related with the outcome in univariate model (with $P < 0.10$) and then following a backward elimination process, variables were removed from the model starting with those with the largest P values. Because women may require different ART strategies in relation with planned or ongoing

pregnancies, and were predominantly born abroad, we repeated the models using data from men only. For the duration of first regimen and time to undetectable viral load, we used Kaplan–Meier method. For the purpose of this analysis, we constructed a ‘gender’ category intrincating sex and HIV infection mode: women, MSM and men declaring to have sex with women only (MSW). All statistics were done using R (R Foundation for Statistical Computing, Vienna, Austria; 2020).

Results

After excluding 179 individuals for whom the place of birth was not available, we analyzed data from 9094 PWH; 48% of whom were born abroad (29% from sub-Saharan Africa, 5% from North Africa or Middle East, 4% from Central or South America and 10% various other places). The patients’ characteristics, according to country of birth and to INSTI prescription, are shown in Table 1. Although MSM were mostly born in France, 77% of the women were born abroad. CD4⁺ T cells were lower at HIV diagnosis in individuals born abroad. Tuberculosis and hepatitis B were more frequent in individuals born abroad. an INSTI-based regimen was less frequently initiated on PWH born abroad (44 versus

56%). Time from HIV diagnosis to first ART prescription was slightly longer for individuals born abroad, but below 3 months in 75% of the cases.

Among the 4535 PWH who started with an INSTI, 1723 received DTG, 1227 received boosted elvitegravir, 1153 received BIC and 432 received raltegravir. In 69% of them, the treatment was given as a single tablet regimen.

Characteristics related with the choice of an INSTI-based regimen (4535 PWH) are shown in Table 2. In the multivariable model, after adjustment, the year of ART initiation was clearly related with the choice of an INSTI-based regimen, with a stepwise increase of odds ratios with each passing year. INSTIs were more frequently proposed to PWH with high pVL or concomitant tuberculosis. Being born in France was also independently associated with an INSTI-based combination as a first-line therapy (adjusted prevalence ratio 1.73, 95% CI 1.59–1.87), and this result was similar when the analysis was restricted to men (adjusted prevalence ratio 1.47, 95% CI 1.33–1.60).

Plasma viral load below 50 copies/ml was obtained within a median of 3 months in individuals receiving an INSTI-based regimen, independently of all studied

Table 1. Persons with HIV characteristics, depending on the place of birth, and on the choice of an integrase strand transfer inhibitors as first regimen.

	Born in France (N = 4730)	Born abroad (N = 4364)	First ART with INSTI (N = 4535)	First ART without INSTI (N = 4559)
Gender and sexual orientation [N (%)]				
Women	576 (23.4)	1888 (76.6)	979 (39.7)	1485 (60.3)
MSM	3086 (74.1)	978 (25.9)	1784 (43.9)	2280 (56.1)
MSW	1051 (43.0)	1386 (57.0)	1224 (50.2)	1213 (49.8)
Born in France				
Yes	–	–	2623 (55.5)	2107 (44.5)
No	–	–	1912 (43.8)	2452 (56.2)
Age at HIV diagnosis (years, median [IQR])	37 [27–48]	34 [28–43]	38 [28–47]	37 [27–45]
Time from HIV diagnosis to ART initiation (months)	0.79 [0.39–1.70]	1.05 [0.49–2.91]	0.82 [0.39–1.80]	1.01 [0.46–2–55]
Year of ART initiation [N (%)]				
2014	766 (16.2)	600 (13.7)	295 (21.6)	1071 (78.4)
2015	815 (17.2)	600 (13.7)	557 (39.4)	858 (60.6)
2016	782 (16.5)	709 (16.2)	655 (43.9)	836 (56.1)
2017	745 (15.8)	684 (15.7)	806 (56.4)	623 (43.6)
2018	637 (13.5)	627 (14.4)	714 (56.5)	550 (43.5)
2019	574 (12.1)	720 (16.5)	884 (68.3)	410 (31.7)
2020	411 (8.7)	424 (9.7)	624 (74.7)	211 (25.3)
VL before initiation (log ₁₀ copies/ml) (median [IQR])	4.87 [4.3–5.5]	4.82 [4.2–5.4]	4.95 [4.35–5.52]	4.78 [4.15–5.4]
CD4 ⁺ T cells at HIV diagnosis (median [IQR])	404 [234–580]	290 [147–441]	350 [192–525]	343 [180–520]
CD4 ⁺ T cells at ART initiation [N (%)]				
<200	1 008 (21)	1451 (33)	1181 (48)	1278 (52)
200–350	940 (20.5)	1122 (27.2)	1040 (50)	1022 (50)
350–500	1061 (23.6)	859 (20.5)	969 (50.7)	941 (49.3)
>500	1558 (35)	766 (19.3)	1183 (50.9)	1141 (49.1)
Missing	163 (3.4)	166 (3.8)	162 (47.8)	177 (52.2)
CDC stage C (%)	604 (12.8)	734 (16.8)	679 (50.7)	659 (49.3)
Chronic hepatitis B (%)	71 (1.5)	360 (8.2)	184 (42.7)	247 (57.3)
Concomitant ^a tuberculosis (%)	31 (0.5)	220 (4.2)	171 (68.1)	80 (31.9)
ART classes (%)				
INSTI based	2623 (55.5)	1912 (43.8)	–	–
bPI based	1259 (26.6)	1688 (38.7)	–	–
NNRTI based	620 (13.1)	553 (12.7)	–	–
Other	228 (4.8)	211 (4.8)	–	–
Length of follow-up (months, median [IQR])	37 (18–58)	33 (16–54)	29 [13–48]	44 [23–64]

ART, antiretroviral therapy; INSTI, integrase strand transfer inhibitors; IQR, interquartile range; MSW, men declaring to have sex with women only; NNRTI, nonnucleoside reverse transcriptase inhibitors.

^aDiagnosis in the 6 months before and after ART initiation.

Table 2. Characteristics related with the choice of an integrase strand transfer inhibitor-based first antiretroviral therapy, prevalence ratios using logistic models.

		All patients				Men only				
		Univariate		Multivariate ^a		Univariate		Multivariate ^a		
		PR	95% CI	aPR	95% CI	PR	95% CI	aPR	95% CI	
Age at HIV diagnosis	≤ 27	Ref		Ref		Ref		–	–	
Classes by quartiles	28-35	0.96	0.90–1.01	0.97	0.86–1.09	0.99	0.92–1.05	–	–	
	36-46	1.00	0.94–1.06	1.09	0.97–1.22	0.98	0.92–1.04	–	–	
	>46	1.11	1.05–1.18	1.19	1.06–1.35	1.04	0.98–1.11	–	–	
	Women	Ref	–	–	–	–	–	–	–	
Gender and sexual orientation	MSM	1.41	1.33–1.49	–	–	Ref	–	–	–	
	MSW	1.25	1.17–1.33	–	–	0.77	0.70–0.85	–	–	
	Born in France (yes)	1.64	1.50–1.78	1.73	1.59–1.87	1.34	1.21–1.49	1.47	1.33–1.61	
Year of ART initiation	2014	Ref		Ref		Ref		Ref		
	2015	2.12	1.80–2.49	2.18	1.88–2.54	1.79	1.58–2.05	1.96	1.69–2.28	
	2016	2.66	2.27–3.12	2.57	2.22–2.98	1.99	1.76–2.27	2.27	1.96–2.64	
	2017	3.82	3.25–4.48	3.62	3.12–4.20	2.54	2.25–2.87	3.08	2.67–3.57	
	2018	4.00	3.40–4.71	3.70	3.19–4.31	2.59	2.29–2.93	3.15	2.72–3.66	
	2019	5.60	4.72–6.62	5.16	4.43–6.02	3.16	2.81–3.55	4.15	3.57–4.82	
	2020	6.37	5.32–7.62	5.86	4.98–6.90	3.30	2.93–3.72	4.37	3.75–5.10	
VL at initiation (log ₁₀ copies/ml)	≤4.3	Ref		Ref		Ref		Ref		
	Classes by quartiles	4.31–4.85	1.16	1.03–1.32	1.19	1.07–1.34	1.06	0.99–1.14	1.13	0.99–1.28
	4.86–5.5	1.43	1.26–1.62	1.51	1.34–1.69	1.12	1.06–1.20	1.21	1.07–1.37	
	>5.6	1.21	1.05–1.38	1.32	1.17–1.50	1.13	1.06–1.21	1.07	0.94–1.22	
Chronic hepatitis B (yes)	0.72	0.59–0.88	0.80	0.65–0.98	0.67	0.52–0.84	0.75	0.59–0.94		
Concomitant tuberculosis (yes)	3.11	2.26–4.28	2.49	2.02–3.06	1.97	1.39–2.79	2.13	1.65–2.75		
CD4 ⁺ T cells at initiation	<200	Ref		–	–	Ref	–	–	–	
	200–350	1.02	0.95–1.08	–	–	1.05	0.98–1.12	–	–	
	350–500	1.04	0.97–1.10	–	–	1.05	0.98–1.12	–	–	
	>500	1.04	0.98–1.10	–	–	1.02	0.95–1.09	–	–	
CDC stage C	1.08	0.95–1.22	–	–	0.98	0.85–1.13	–	–		

ART, antiretroviral therapy; CI, confidence interval; aPR, adjusted prevalence ratios; VL, viral load.

^aVariables ‘Born in France’ and ‘Gender’ brought collinearity in the models, we chose to keep the place of birth.

characteristics. Subsequently, first ART line was modified in 68% of the PWH born in France, and in 67% of those born abroad ($P=0.15$), after a median time of, respectively 19 (IQR 18–20) and 17 (IQR 16–18) months ($P=0.07$). Major reasons for treatment modification were the reduction of the number of pills (29% of the modifications in individuals born in France and 30% in those born abroad), or the switch for a two-drug regimen (18 and 11%, respectively). Median first ART duration depending on baseline characteristics is described in Fig. 1 and Table 3. In univariate analysis, the timing of treatment modification was related with the choice of the first regimen (sooner in case of bPI), the person’s gender, the presence of a concomitant tuberculosis at initiation, the initial viral load but not by the country of birth (Table 3).

Discussion

In this large population of PWH in care in France since the availability of second-generation INSTIs, these drugs clearly became the major choice for first-line ART. However, we observed differences in the initial prescriptions between the PWH born in France and those born abroad.

Many characteristics differentiated the two populations at the time of entry in care, with notable differences between populations regarding characteristics that may drive the regimen choice. INSTIs has been avoided in women with planned pregnancies because of a small increased risk of neural tube defects [15]. On the other hand, INSTIs are usually preferred in case of concomitant tuberculosis so as to avoid drug–drug interactions. High initial viral load and low CD4⁺ T-cell count may promote the use of the most potent drugs, thus favoring INSTIs. All these situations were more frequent in PWH born abroad. But multivariable analyses showed that, in addition to these well known reasons of choice, being born in France was clearly related (aOR 1.85; 95% CI 1.68–2.04) with the choice of an INSTI as first line. We also performed a sensitivity analysis restricting it to men, to eliminate the potential confounding effect of gender and pregnancy, and this analysis strengthened the result. These findings come as a confirmation to what was found in a previous smaller study by Palich *et al.* [13].

Among the reasons that could explain this difference, some physicians may anticipate that because of difficult social conditions treatment adherence may be poor, or that some persons will travel back and forth between countries and may have difficulties to find the drugs in their country of origin, or have to hide the drugs when

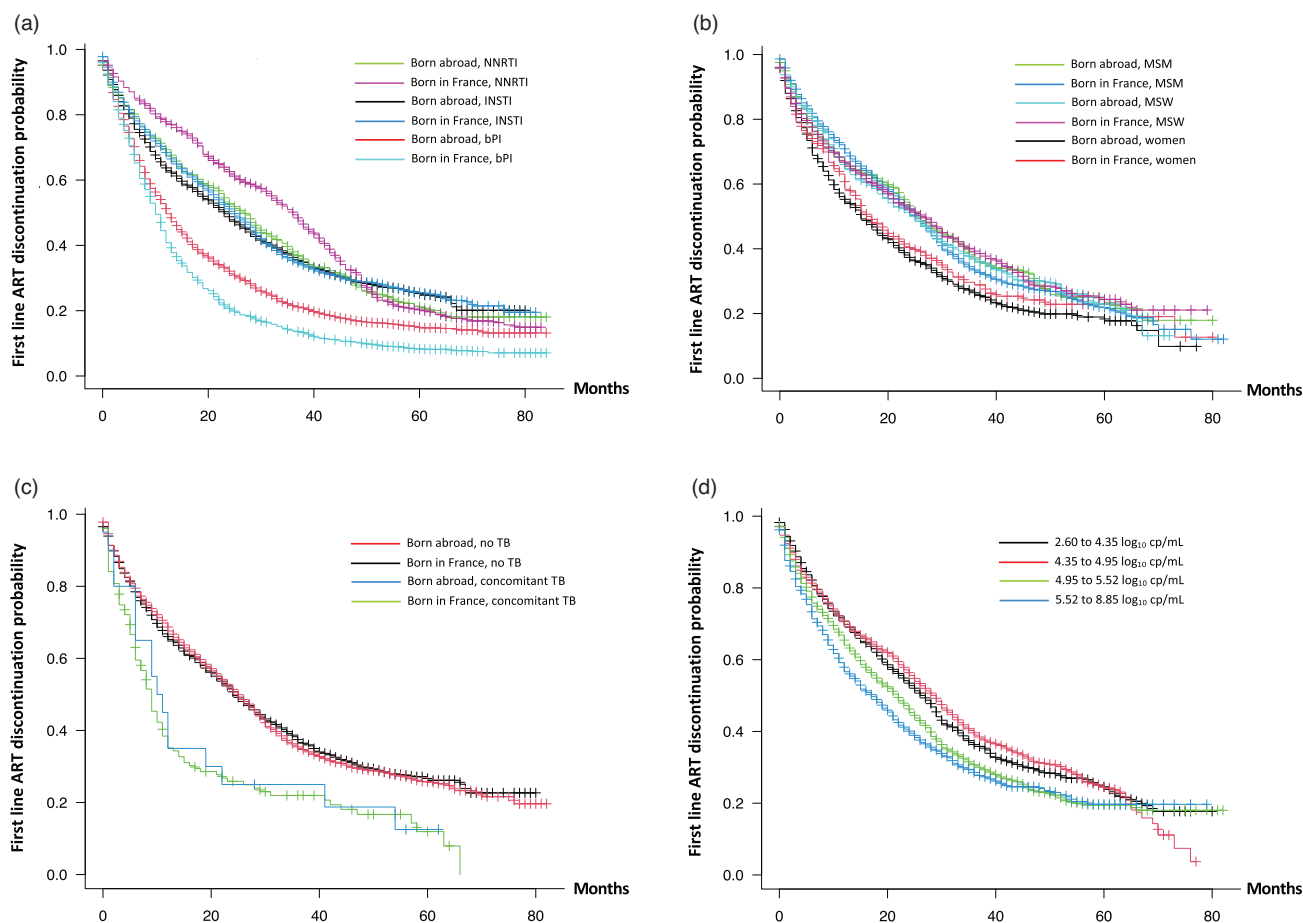


Fig. 1. First regimen persistence, following treatment choice and place of birth (panel a), gender and place of birth (panel b), concomitant tuberculosis and place of birth (panel c), or initial plasma viral load (panel d).

Table 3. Median duration of first antiretroviral therapy (months), depending on patients' and antiretroviral therapy characteristics, and compared by use of log-rank tests.

		Median	95% CI	Log-rank, <i>P</i>
Choice of antiretroviral drugs and place of birth	INSTI, born in France	25	23–26	0.03
	INSTI, born abroad	22	20–24	
	bPI, born in France	10	10–11	
	bPI, born abroad	12	12–13	
	NNRTI, born in France	36	33–38	
	NNRTI, born abroad	27	23–29	
Gender and place of birth	Women born abroad	15	13–18	<0.0001
	Women born in France	16	14–22	
	MSM born abroad	26	23–30	
	MSM born in France	25	24–27	
	MSW born abroad	25	21–28	
	MSW born in France	27	21–30	
Concomitant tuberculosis	Positive, born abroad	8	6–10	<0.0001
	Positive, born in France	10	6–12	
	Negative, born abroad	18	16–19	
	Negative, born in France	19	18–20	
Initial plasma viral load	<4.35 log copies/ml	27	24–29	<0.0001
	4.35–4.95	29	26–30	
	4.96–5.52	22	19–24	
	>5.52	17	15–19	

bPI, boosted protease inhibitor; CI, confidence interval; INSTI, integrase strand transfer inhibitors; MSM, men declaring to have sex with women only; NNRTI, nonnucleoside reverse transcriptase inhibitors.

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back in family. In our opinion, these fears are outdated since the availability of second-generation INSTIs, which have high genetic barrier and fewer side effects than bPIs, which help to increase adherence to treatment. Moreover, bPI associated with INTIs are not available as a single tablet regimen in France, which also work against this choice, as well as the worldwide availability of DTG, recommended as a first-line ART since 2019 in low-income countries.

In Western Europe today, migrants (i.e. people who are living outside their country of birth or longest residence, as defined by the Office of the High Commissioner for Human Rights) constitute a growing proportion of people in care for HIV, as illustrated by our study population in which 48% of PWH starting ART since 2014 were born abroad. This proportion is expected to increase sharply in Western European hospitals in the future, because of population movements and lower new HIV diagnoses among native-born individuals in high-income countries in the era of preexposure prophylaxis [16–18]. Various studies have highlighted inequalities in treatment based on race, driven by implicit bias among physicians [9–12]. Several studies conducted in the United States reported false beliefs about racial differences that could lead to different therapeutic attitudes based on skin color [19–21]. These implicit biases could be maintained by lack of awareness during medical studies [22–24], race being a particularly divisive subject in society at present. We assume that unconscious discrimination can partly explain the differences observed in our study.

The absence of observed difference in time to undetectable viral load, whatever the PWH characteristics, is due both to the high potency of the drugs and to high individuals' adherence to these easy to tolerate regimens. It should be considered as an indication that PWH are equally able to take the drugs on a regular basis, whatever their country of origin. The impact of the place of birth on physicians' attitude once the infection is under control needs to be assessed.

The main strength of our study is the large prospectively followed population. Nevertheless, there are limitations. We were not able to take into account the individuals' social situation, which is not collected in the cohort. However, the social situation should not be related to ART availability nor to the choice of the drugs in a country with unrestricted access. We were only interested in tuberculosis and hepatitis B as comorbidities, because they are known to have consequences on the choice of the ART. It is possible that other comorbidities not taken into account in our study could also have an impact on the choice. Weight gain associated with INSTI use has been reported to be more frequent in women of African heritage, especially if they were already overweight [25,26]. Consequence of these weight gains are still

unclear, and physicians may have acted with caution, especially in the last years of prescription. Finally, being 'born abroad' describes a very heterogenous group. In our population, 70% of PWH born abroad were of African origin and the others coming from various places around the world. Thus, our results may not apply to PWH born in North hemisphere countries, but they were too few to be analyzed separately. Finally, we excluded a very small number of the total studied population (<2%) because of missing country of birth. However, we believe that excluding them would not bias the results.

In conclusion, our results show differences in terms of the choice of initial ART according to birth country, without clear clinical, virological or immunological justification. With this work, we hope to encourage questioning of current practices, promoting more equity in prescriptions according to geographical origin so as to offer all PWH the best therapeutic options.

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Conflicts of interest

There are no conflicts of interest.

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