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Short running title: HIV transmission risk during combined ART initiation for immunosuppressed HIV-infected persons

Abstract

Background: Individuals presenting for care with severe immunosuppression typically have high plasma HIV viral load (pVL) and may transmit HIV before and after initiation of combination antiretroviral therapies (cART).

Patients and Methods: Using risk equations and data collected in the IMEA 040 DATA trial on sexual behavior and pVL level of 84 HIV-infected patients (23 women), we estimated monthly rates of HIV transmission for each virologically unsuppressed participant (pVL>50 copies/mL) who reported sex with HIV-negative or unknown serostatus (HNUS) partners at cART initiation, 24 weeks (W24) and W48 after; rates were considered negligible for other participants.

Results: At cART initiation, median pVL was 5.4 log10 copies/mL. The percentage of virologically unsuppressed patients decreased, from 100% at cART initiation to 27% (95%CI:16-43%) for heterosexuals and 8% (95%CI:2-22%) for MSM at W48 (ps<0.001). The percentage of patients reporting sex with HNUS partners increased between cART initiation and W48, from 23% (95%CI:10-42%) to 42% (95%CI:25-61%) for heterosexuals (p=0.042) and from 41% (95%CI:21-64%) to 73% (95%CI:52-88%) for MSM (p=0.004). Median monthly HIV transmission rates were 0.0540 (IQR:0.0339-0.0742) for MSM and 0.0018 (IQR:0.0014-0.0191) for heterosexuals at cART initiation, and were reduced by 95% (95%CI:87-100%) for heterosexuals and 98% (95%CI:95-100%) for MSM as early as W24.

Conclusions: Risk of onward transmission for severely immunosuppressed individuals is high before and within the first weeks of cART, and persists, at a substantially reduced level, beyond 24 weeks of cART for some individuals. Earlier cART and protecting HIV-negative partners until full viral suppression is achieved could reduce HIV transmission.

Introduction

Early initiation of effective combination antiretroviral therapies (cART) dramatically improves the prognosis of HIV-infected patients and, by suppressing plasma HIV viral load (pVL), markedly reduces sexual transmission of HIV.[1-4] However, despite cART success, late presentation for HIV care remains common in most settings,[5, 6] including high-income countries.[6] More than 30% of patients presenting for care in Europe have advanced HIV disease, defined as CD4 counts <200 cells/mm^3 or AIDS-defining disease.[6] Advanced stage of infection is typically accompanied with high level of pVL, which requires longer time to achieve viral suppression upon cART initiation.[7, 8] Thus, persons presenting for care with severe immunosuppression may be at high risk to transmit HIV before and after cART initiation, as high pVL implies high risk of sexual HIV transmission.[9]

Recent studies in low and middle-income countries showed that HIV transmission risk persists during the first 6 months of cART.[2,10] However, little is known about the risk of HIV transmission before, and after, cART initiation for individuals presenting for care with severe immunosuppression, notably in high-income countries. Quantifying these risks is critical for HIV-infected patients and their partners, as well as for clinicians and health care policymakers to implement interventions aiming at reducing the risk of onward HIV transmission and accelerating care entry. Here, we used virological and behavioral data collected within the framework of the IMEA 040 DATA trial[11] to quantify, for individuals presenting for care with severe immunosuppression, the risk of HIV transmission before and within the first 48 weeks of cART initiation.

Methods

Study population

The IMEA 040 DATA trial has been described previously.[11] Between April 2011 and January 2013, 120 patients were enrolled into an open-label, non-comparative, randomized, multicenter trial to evaluate the efficacy and tolerability of atazanavir/ritonavir or darunavir/ritonavir as first-line therapy, each in combination with two nucleos(t)ide reverse transcriptase inhibitors. Levels of pVL and CD4 cell counts were assessed at treatment initiation, defined as week (W) 0, and weeks 2, 4, 12, 24, 36 and 48. In addition to assessing the efficacy of cART regimens, an ancillary study was conducted to collect information on sexual behaviors at W0, W24 and W48, using self-reported questionnaires (see Supplementary data) based on 4-week recall. Questions covered sexual activity and condomless sex with main, regular and casual partners as well as partner's HIV status (positive/negative/unknown).

Ethics

The trial respected good clinical practices and the ethical principles of the Declaration of Helsinki. The Ile de France XI ethics review committee approved the study (number 10062) and all the patients gave their written informed consent before participation. The study was registered with ClinicalTrials.gov (NCT01928407).

Analysis

To assess HIV transmission risk before and after cART initiation we evaluated two measures for each patient (i.e. trial participant) who participated to the ancillary study: the per-act risk of HIV transmission and the monthly rate of HIV transmission. Note that we could not ascertain whether HIV seroconversions occurred among partners of trial participants since only trial participants (and not their partners) were followed up during this study. The per-act risk of HIV transmission was estimated for each patient using the dose-response relation between pVL and risk of HIV

transmission,[9] whether or not the patient reported any sexual activity. The per-act probability of HIV transmission was shown to increase by a factor of 2.45 (95% confidence interval (CI): 1.85-3.26) for each log (base 10) increment in pVL, as expressed by the equation:[12] $\beta_1 = 2.45^{\log_{10}(V_1/V_0)} \beta_0$, where V_0 is the average pVL during untreated chronic HIV infection, β_0 is the per-act probability of HIV transmission from a person with pVL V_0, and β_1 is the per-act transmission probability corresponding to pVL V_1. We assumed that V_0 was 4.5 $\log_{10}$ copies/mL,[12] and β_0 was equal to 0.001 for heterosexuals[13] and 0.01 for MSM.[12] Regarding the parameter determining the increase in transmission probability with each one-log increment in pVL, each individual was assigned a value sampled from a normal distribution with mean 2.45 and standard deviation 0.35, corresponding to the 95% CI. The risk of HIV transmission was neglected for undetectable pVL, defined as plasma HIV-RNA concentrations below 50 copies/mL.[2]

We combined virological and behavioral data to quantify, for each patient the monthly rate of HIV transmission using the formula: $C=C_M+C_R+C_C$ where C_M, C_R and C_C were the monthly rates of HIV transmission to HIV-negative main, regular and casual partners, respectively. Monthly rates for each kind of partnership were calculated using the binomial formula: $1 - (1 - \beta_1)^{n-k}(1 - (1-e)\beta_1)^k$ where e was the per-act condom efficacy, n was the number of sex acts over the last 4 weeks, and k was the number of sex acts protected by condom over the last 4 weeks. We assumed that the per-act condom efficacy was 75% (95 CI: 63-83),[13] and thus we assigned a per-act condom efficacy value to each individual, that was sampled from a normal distribution with mean 0.75 and standard deviation 0.05, corresponding to the 95% CI. Partners of unknown status were assumed to be HIV-negative.

We performed sensitivity analyses where we assumed that the per-act risk of HIV transmission during each sexual intercourse was reduced by 95% for all patients. This analysis corresponds to an optimistic scenario where all couples would consistently and correctly use prevention, i.e. condoms[14] or pre-exposure prophylaxis (PrEP),[15,16] to reduce the risk of HIV

transmission. Then we compared estimates obtained under this scenario with those in the baseline analysis to estimate the percentage reduction in the monthly rates of HIV transmission within the optimistic scenario.

Analyses were conducted using Matlab R2015b and IBM SPSS Statistics version 24. Since, viral decay dynamics were similar for the two first-line therapies (atazanavir/ritonavir versus darunavir/ritonavir), we did not stratify the analysis according to the therapy. Generalized estimating equations models were used to analyze changes in parameters over time.

Results

Eighty-four patients participated to the survey and completed at least one of the three questionnaires. Among participants, 56% were heterosexual (24 male, 23 female) and 44% MSM (Table 1). Median time from HIV diagnosis to cART initiation was 4 weeks. At cART initiation (W0), median CD4 cell count was 71 cells/mm^3 and median pVL was 5.4 log_{10} for heterosexuals, and respectively 89 cells/mm^3 and 5.2 log_{10} for MSM.

Using data on pVL at W0, we estimated that the median per-act risk of HIV transmission at cART initiation was more than seven times higher for MSM than for heterosexuals (0.0172 (IQR: 0.0141-0.0282) versus 0.0023 (IQR: 0.0015-0.0029), p<0.001, Figure 1, A and B). The percentage of patients with unsuppressed viral load (pVL>50 copies/mL) decreased from 100% at cART initiation to 78% (95% CI 64-89%) at W12, 38% (95% CI 25-54%) at W24 and 27% (95% CI 16-43%) at W48 for heterosexuals (p<0.001) and respectively 73% (95% CI 56-86%), 33% (95% CI 18-50%) and 8% (95% CI 2-22%) for MSM (p<0.001). Among those who remained virologically unsuppressed, pVL considerably declined within the first 12 weeks of cART -- median pVL was 2.3 log_{10} (IQR: 2.1-2.5) for heterosexuals and 2.2 log_{10} (IQR: 1.9-2.5) for MSM at W12 -- and then remained relatively stable (data not shown). This translated into a reduction of the per-act risk of HIV transmission for virologically unsuppressed individuals, with estimated median values, at W12, of 0.0001 (IQR: 0.0001-0.0002) for heterosexuals (p<0.001 versus W0, Figure 1A) and 0.0010 (IQR: 0.0000-0.0017) for MSM (p<0.001 versus W0, Figure 1B), and mean reductions, when compared to W0, of 90% (86-94%) for heterosexuals and 92% (91-94%) for MSM.

Patients' characteristics of sexual behavior before and after cART initiation are summarized in Table 1. Over the course of treatment, the percentage of patients reporting sex with HIV-negative or unknown serostatus (HNUS) partners increased, from 23% (95% CI 10-42%) at cART initiation to 42% (95% CI 25-61%) at W48 for heterosexuals (p=0.042) and, respectively, from 41% (95% CI 21-64%) to 73% (95% CI 52-88%) for MSM (p=0.004). Among

patients reporting sex with HNUS partners, the percentage of those who reported condomless sex decreased from 43% (95% CI 10-82%) at cART initiation to 14% (95% CI 2-43%) at W48 for heterosexuals (p=0.124) and, respectively, from 56% (95% CI 21-86%) to 32% (95% CI 13-57%) for MSM (p=0.224).

By combining virological and behavioral data, we found that during the month before treatment, 23% (95% CI 10-42%) of heterosexuals (Figure 1C) and 41% (95% CI 21-64%) of MSM (Figure 1D) were virologically unsuppressed and had sex with HNUS partners. Among these patients, estimated median monthly rate of HIV transmission was almost 30 times higher for MSM than heterosexuals, (0.0540 (IQR: 0.0339-0.0742) versus 0.0018 (IQR: 0.0014-0.0191), p=0.008, Figure 1, C and D). Over the course of cART, the percentage of HIV-infected patients who remained virologically unsuppressed and had sex with HNUS partners decreased to reach 16% (95% CI 5-33%) (p=0.291) at W24 and 9% (95% CI 2-24%) (p=0.109) at W48 for heterosexuals and respectively 25% (95% CI 11-45%) (p=0.234) and 4% (95% CI 0-20%) (p=0.010) for MSM. Estimated median monthly rates of HIV transmission for these patients decreased to 0.0001 (IQR: 0.0001-0.0006) for heterosexuals (p=0.053) and 0.0024 (IQR: 0.0017-0.0038) for MSM (p<0.001) at W24 and then remained stable, corresponding to mean reductions, relative to W0, of 95% (87-100%) for heterosexuals and 98% (95-100%) for MSM.

Under an optimistic scenario, i.e. assuming that the per-act risk of HIV transmission during each sexual intercourse reduced by 95% for all patients, the estimated median monthly rate of HIV transmission, among patients who were virologically unsuppressed and had sex with HNUS partners, was 0.0003 (IQR: 0.0002-0.0010) for heterosexuals and 0.0049 (IQR: 0.0037-0.0072) for MSM at cART initiation (p=0.016). This rate decreased to 0.00003 (IQR: 0.00003-0.00013) for heterosexuals (p=0.205) and 0.0004 (IQR: 0.0002-0.0005) for MSM (p<0.001) at W24 and then remained stable. Thus, under the optimistic scenario, the monthly rate of HIV transmission at cART initiation was reduced by 93% (85-100%) for heterosexuals and 98% (95-100%) for MSM at W24, compared to the baseline analysis**.**

Discussion

With an estimated median value of 5%, we found that the monthly rate of HIV transmission before cART initiation was particularly high for MSM – thirty times higher than for heterosexuals – reflecting higher self-reported sexual activity for MSM than heterosexuals but, above all, higher per-act risk of HIV transmission for MSM than heterosexuals. Indeed, taken alone, the higher sexual activity for MSM than heterosexuals contributes to increase the median value of the monthly rate of HIV transmission by a factor 3 while the higher per-act risk of HIV transmission for MSM than heterosexuals contributes to increase this median value by a factor 10 (results not shown). Although sexual activity increased after cART initiation, and more than a third of individuals remained virologically unsuppressed (pVL>50 copies/mL) after 24 weeks of cART, the risk of HIV transmission significantly decreased, as early as 12 weeks of cART, and by ~95% after 24 weeks of cART, even for those who remained virologically unsuppressed. In addition, we found that the monthly rate of HIV transmission before and after cART initiation could be significantly decreased (from 93% to 98%) if all patients or their partners would use consistently and correctly an HIV prevention method, i.e. condoms[14] or PrEP.[15,16]

The main limitation of our study is the sample size. In addition, our estimates of the risk of HIV transmission before cART initiation may have limited application for patients at less advanced stages of HIV infection, when pVL is usually lower, or for undiagnosed HIV infections, when sexual activity may be higher. The main strength of our study is the collection at regular and close time intervals of detailed behavioral and virological data, to inform and reinforce public health policies.

Our findings show a high risk of onward transmission before and within the first weeks of cART initiation for individuals presenting for care with severe immunosuppression, and persistence of a risk of HIV transmission, though at a substantially reduced level, beyond 24 weeks of cART for some individuals. Hence, our study enforces the need to implement effective HIV testing strategies, with a focus on individuals with low HIV testing uptake, and cART

initiation as soon as possible. Furthermore, at cART initiation, communicating about this risk and providing counseling on how to reduce this risk, e.g. by improving condom use or offering PrEP to HIV-negative partners, is essential to reduce the risk of onward transmission until achieving full viral suppression. Partner notification assistance programs, which are not implemented in France, should also be evaluated. This could allow earlier HIV diagnosis for partners of newly diagnosed HIV cases and provide an opportunity to offer PrEP to HIV-negative partners in serodiscordant couples until the HIV-positive partner achieves full viral suppression. In addition, investigating whether faster viral suppression could be achieved for severely immunosuppressed individuals using new drugs, such as integrase inhibitor, is important to reduce the risk of onward transmission after cART initiation.

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Transparency declarations

VS has served on advisory boards for ViiV Healthcare (2016) and reports lecture fees from Gilead (2014, 2015) and MSD (2014), outside the submitted work. DC reports grants from Janssen-Cilag (2014), Merck-Sharp & Dohme-Chibret (2017), ViiV (2015), personal fees from Janssen-Cilag (2016), Merck-Sharp & Dohme-Chibret (2015) for lectures, personal fees from Gilead (2014), ViiV (2015), Janssen-Cilag (2014) for travel/accommodations/meeting expenses, personal fees from Gilead France from 2011 until December 2015 for French HIV board, personal fees from Innavirvax (2015 and 2016) for consultancy, outside the submitted work. GP reports personal fees from Gilead, ViiV Healthcare, Abbvie, BMS, Janssen and MSD outside the submitted work. RL reports grants from IMEA foundation during the conduct of the study. PMG reports personal fees from BMS, Gilead, Janssen, ViiV Healthcare and Abbvie outside the submitted work. LS reports personal fees from BMS, Gilead and ViiV Healthcare outside the submitted work. All other authors: none to declare.

Supplementary Data

The English-translated version of the survey questionnaires completed at W0 and W24 are available as Supplementary data. Note that the same questionnaires were given at W24 and W48.

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Table 1: Baseline and sexual behavior characteristics of the 84 patients

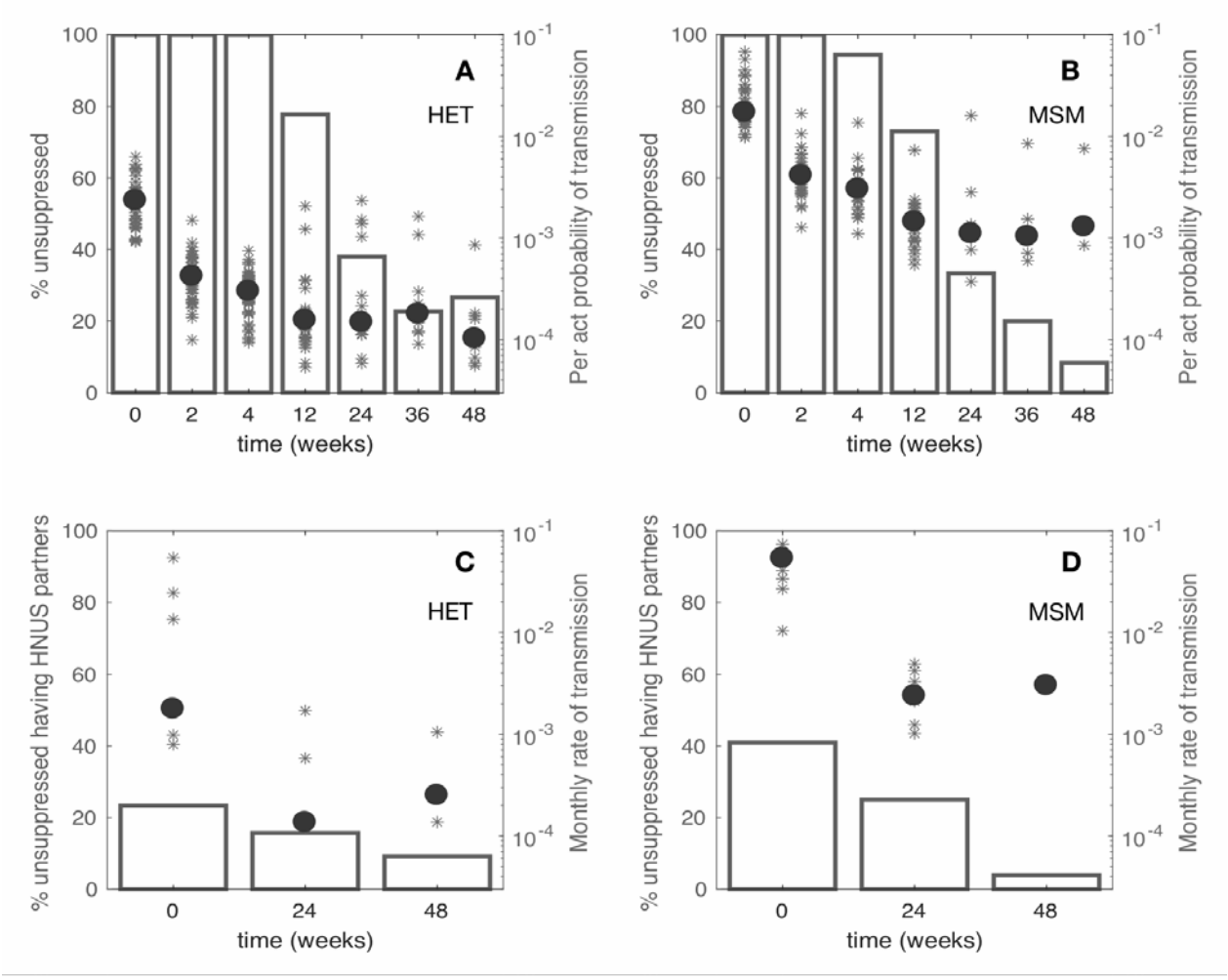
	Heterosexuals n=47 (56%)			**MSM** n=37 (44%)		
Male, n (%)	24 (51%)			37 (100%)		
Age, years, median (IQR)	44 (39-54)			38 (34-48)		
Sub-Saharan African origin, n (%)	17 (36%)			1 (3%)		
European origin, n (%)	23 (49%)			32 (86%)		
Other origins, n (%)	7 (15%)			4 (11%)		
Time from HIV diagnosis to cART initiation (days), median (IQR)	32 (21-71)			28 (16-45)		
CD4 count (cell/mm^3), median (IQR)	71 (21-137)			89 (37-161)		
pVL (log_{10} copies/mL), median (IQR)	5.4 (5.0-5.7)			5.2 (4.9-5.6)		
Self-reported sexual behavior over the past 4 weeks for patients who completed questionnaires	**W0** n=30	**W24** n=32	**W48** n=33	**W0** n=22	**W24** n=28	**W48** n=26
Number of sexually active patients, n (%)	10 (33%)	18 (56%)	18 (55%)	9 (41%)	19 (68%)	20 (77%)
Number of main and regular partners per patient, median (IQR)	1 (0-1)	1 (0-1)	1 (0-1)	1 (0-1)	1 (0.5-1)	1 (0-1)
Number of casual partners per patient, median (IQR)	0 (0-0)	0 (0-0)	0 (0-0)	0.5 (0-1)	0 (0-1)	1 (0-1)
Number of sex acts per patient, median (IQR)	0 (0-3)	2 (0-5)	1 (0-4)	0 (0-6)	4 (0-7)	7 (1-10)
Number of patients with at least one HIV-positive main/regular partner, n (%)	5 (17%)	6 (19%)	7 (21%)	3 (14%)	4 (14%)	6 (23%)
Number of patients reporting sex with HNUS partners, n (%)	7 (23%)	14 (44%)	14 (42%)	9 (41%)	17 (61%)	19 (73%)
Number of patients reporting condomless sex with HNUS, n (%)	3 (10%)	0 (0%)	2 (6%)	5 (23%)	1 (4%)	6 (23%)

pVL: plasma viral load; cART: combination antiretroviral therapies; W0: at cART initiation; W24: 24 weeks after cART initiation; W48: 48 weeks after cART initiation; HNUS: HIV-negative or unknown serostatus.

Figure 1: Risk of HIV transmission before and after treatment initiation.

Percentage of HIV-infected patients with unsuppressed viral load (bars), defined as plasma HIV-RNA concentrations >50 copies/mL, and estimated per-act risk of HIV transmission for each unsuppressed patient (stars, on a log scale) at W0 (i.e. at cART initiation), W2 (i.e., two weeks after cART initiation), W4, W12, W24, W36 and W48 for heterosexual (A) and MSM (B) patients. Percentage of HIV patients with unsuppressed viral load and reporting sex with HIV-negative or unknown serostatus (HNUS) partners (bars), and estimated monthly rate of HIV transmission for each unsuppressed patient reporting sex with HNUS (stars, on a log scale) at W0, W24 and W48 for heterosexual (C) and MSM (D) patients. Filled circles correspond to median estimated values of per-act risk of HIV transmission in (A) and (B) and to median estimated values of monthly rate of HIV transmission in (C) and (D). HET: heterosexuals.

Figure 1


A
HET
B
MSM
C
HET
D
MSM
% unsuppressed
Per act probability of transmission
% unsuppressed having HNUS partners
Monthly rate of transmission
time (weeks)
0
2
4
12
24
36
48

SECTION TO BE COMPLETED BY THE ATTENDING PHYSICIAN

Please: ⓪ Complete Patient ID

⓪ Answer the 2 questions

⓪ Give the questionnaire to the patient

Centre ID	Patient ID	E-patient Code
⌊__⌊__⌊__⌋	⌊__⌊__⌊__⌋	⌊__⌊__⌊__⌋

Did the patient consent to complete the questionnaire ⓪ no ❶ yes

Did the patient need assistance to complete the questionnaire ⓪ no ❶ yes

Date	Name of the physician	Signature
⌊__⌊__⌋ ⌊__⌊__⌋ ⌊__⌊__⌊__⌊__⌋	. . . . .	

Please complete this questionnaire about your affective and sexual life. This questionnaire is confidential. Your physician and other care-givers will not have access to your answers. Once completed, put the questionnaire into the envelope

1. Currently, do you live with a spouse or a partner, whether married or not:

❶ Yes ❷ No

If yes, how long have you been in a relationship? /__/__/__/__/

Your partner is: a man ❶ a woman ❷

Your partner is: HIV-positive ❶ HIV-negative ❷ you don't know ❸

In the last 12 months,

Did you have sexual intercourse with your partner? ❶Yes ❷No

How often did you use condom? never ❶ rarely ❷ often ❸ always ❹

In the last 4 weeks,

How many sexual intercourses did you have with your spouse/stable partner? /__/__/__/

Among these intercourses, how many were protected by condom use? /__/__/__/

2. Currently, do you have a regular partner who is not living with you?

❶ Yes ❷ No

If yes, how long have you been in a relationship: /__/__/__/__/

Your partner is: a man ❶ a woman ❷

Your partner is: HIV-positive ❶ HIV-negative ❷ you don't know ❸

In the last 12 months,

Did you have sexual intercourse with your partner? ❶Yes ❷No

How often did you use condom? never ❶ rarely ❷ often ❸ always ❹

In the last 4 weeks,

How many sexual intercourses did you have with your spouse/stable partner? /__/__/__/

Among these intercourses, how many were protected by condom use? /__/__/__/

3. <u>In the last 12 months, did you have casual sexual partners?</u>

❶ Yes ❷ No

If any, how many casual sexual partners /__/__/__/

How often did you use condom: never ❶ rarely ❷ often ❸ always ❹

<u>Over the last 4 weeks,</u>

How many sexual intercourses did you have with casual partners? /__/__/__/

Among these intercourses, how many were protected by condom? /__/__/__/

4. <u>In the last 12 months</u> did you experience <u>sexual problems?</u> Such as:

Pain during sexual intercourse	❶ Yes	❷ No
Erectile dysfunction	❶ Yes	❷ No
Lack of sexual desire, decline or loss of libido	❶ Yes	❷ No

5. During your lifetime:

To date, how many female sexual partners did you have?

0 ❶ 1 or 2 ❷ 3 to 10 ❸ 11 to 20 ❹ over 20 ❺ don't wish to answer ❻

Overall, how many male sexual partners did you have?

0 ❶ 1 or 2 ❷ 3 to 10 ❸ 11 to 20 ❹ over 20 ❺ don't wish to answer ❻

6. Do you identify yourself as:

- Heterosexual ❶ Homosexual ❷
- Bisexual ❸ You don't wish to identify yourself ❹
- You don't wish to answer that question ❺

7. **Considering your sexual intercourses, how much do you assess between 0 and 10 your risk of transmitting HIV to your sexual partner (circle the number).**

0= no risk at all and 10 = very high risk]

0	1	2	3	4	5	6	7	8	9	10

8. Currently, is your HIV infection known by:

Your spouse/main partner	Yes ❶	No ❷	no spouse/main partner ❸
Your children	Yes ❶	No ❷	no child ❸
Your relatives and close-ones	Yes ❶	No ❷	not applicable ❸
Your friends	Yes ❶	No ❷	not applicable ❸

Thank you, the questionnaire will remain confidential, put it in the envelope.

SECTION TO BE COMPLETED BY THE ATTENDING PHYSICIAN

Please:
- ⓪ Complete Patient ID
- ⓪ Answer the 2 questions
- ⓪ Give the questionnaire to the patient

Centre ID	Patient ID	E-patient Code
⌊_⊥_⊥_⊥_⌋	⌊_⊥_⊥_⊥_⌋	⌊_⊥_⊥_⊥_⌋

Did the patient consent to complete the questionnaire ⓪ no ❶ yes

Did the patient need assistance to complete the questionnaire ⓪ no ❶ yes

Date	Name of the physician	Signature
⌊_⊥_⌋ ⌊_⊥_⌋ ⌊_⊥_⊥_⊥_⊥_⌋	. . . . .	

Please complete this questionnaire about your affective and sexual life. This questionnaire is confidential. Your physician and other care-givers will not have access to your answers. Once completed, put the questionnaire into the envelope

1. During the 6 last months, considering your affective and sexual life:

Did you have sex ❶1 Yes ❶2 No
Did you have one or several new sexual partners ❶1 Yes ❶2 No
Did you separate from your spouse? ❶1 Yes ❶2 No
Did you separate from a regular partner? ❶1 Yes ❶2 No
Did you start a new couple/steady relationship? ❶1 Yes ❶2 No

2. **Currently, <u>do you live with a spouse or a partner, whether married or not:</u>**

❶1 Yes ❶2 No
Your partner is: a man ❶1 a woman ❶2
Your partner is: HIV-positive ❶1 HIV-negative ❶2 you don't know ❶3

<u>In the last 6 months</u>,
Did you have sexual intercourse with your partner? ❶1Yes ❶2No
How often did you use condom? never ❶1 rarely ❶2 often ❶3 always ❶4

<u>In the last 4 weeks,</u>
How many sexual intercourses did you have with your spouse/stable partner? /__/__/__/
Among these intercourses, how many were protected by condom use? /__/__/__/

3. **<u>Currently, do you have a regular partner who is not living with you?</u>**

❶1 Yes ❶2 No
Your partner is: a man ❶1 a woman ❶2
Your partner is: HIV-positive ❶1 HIV-negative ❶2 you don't know ❶3

<u>In the last 6 months</u>,
Did you have sexual intercourse with your partner? ❶1Yes ❶2No
How often did you use condom? never ❶1 rarely ❶2 often ❶3 always ❶4

<u>In the last 4 weeks,</u>
How many sexual intercourses did you have with your spouse/stable partner? /__/__/__/
Among these intercourses, how many were protected by condom use? /__/__/__/

4. <u>In the last 12 months, did you have casual sexual partners?</u>

❶1 Yes ❶2 No

If any, how many casual sexual partners /__/__/__/

Did you tell them you were HIV-positive?

❶1 no, you did not tell to any of them
❶2 yes, but not to all of them
❶3 yes, you tell to all of them

How often did you use a condom: never ❶1 rarely ❶2 often ❶3 always ❶4

<u>Over the last 4 weeks,</u>
How many sexual intercourses did you have with casual partners? /__/__/__/
Among these intercourses, how many were protected by condom? /__/__/__/

5. In the last 6 months:

Did you try to have a child	❶1 Yes ❶2 No
Did you seek care for a sexually transmitted infection	❶1 Yes ❶2 No
Did you tape a treatment for a sexually transmitted infection	❶1 Yes ❶2 No

6. In the last 6 months:

You have sought to have mostly HIV-positive sexual partners	❶1 Yes ❶2 No
You felt you were isolated	❶1 Yes ❶2 No
You felt you were supported by your close-ones	❶1 Yes ❶2 No

7. <u>In the last 12 months</u> did you experience <u>sexual problems?</u> Such as:

Pain during sexual intercourse	❶1 Yes ❶2 No
Erectile dysfunction	❶1 Yes ❶2 No
Lack of sexual desire, decline or loss of libido	❶1 Yes ❶2 No

8. **Considering your sexual intercourses, how much do you assess between 0 and 10 your risk of transmitting HIV to your sexual partner (circle the number).**

0= no risk at all and 10 = very high risk]

0	1	2	3	4	5	6	7	8	9	10

9. Currently, is your HIV infection known by:

Your spouse/main partner	Yes ❶1	No ❶2	no spouse/main partner	❶3
Your children	Yes ❶1	No ❶2	no child	❶3
Your relatives and close-ones	Yes ❶1	No ❶2	not applicable	❶3
Your friends	Yes ❶1	No ❶2	not applicable	❶3

Thank you, the questionnaire will remain confidential, put it in the envelope.