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1 **Risk of HIV transmission during combined ART initiation**
2 **for HIV-infected persons with severe immunosuppression**
3

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5 P.M. Girard^{7,8}, L. Slama^{4,9} on behalf of the IMEA 040 DATA Study Group[†].

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25
26 **Short running title:** HIV transmission risk during combined ART initiation
27 for immunosuppressed HIV-infected persons

28 **Abstract**

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

32 **Patients and Methods:** Using risk equations and data collected in the IMEA 040 DATA trial on
33 sexual behavior and pVL level of 84 HIV-infected patients (23 women), we estimated monthly
34 rates of HIV transmission for each virologically unsuppressed participant (pVL>50 copies/mL)
35 who reported sex with HIV-negative or unknown serostatus (HNUS) partners at cART initiation,
36 24 weeks (W24) and W48 after; rates were considered negligible for other participants.

37 **Results:** At cART initiation, median pVL was 5.4 log₁₀ copies/mL. The percentage of
38 virologically unsuppressed patients decreased, from 100% at cART initiation to 27% (95%CI:16-
39 43%) for heterosexuals and 8% (95%CI:2-22%) for MSM at W48 (ps<0.001). The percentage of
40 patients reporting sex with HNUS partners increased between cART initiation and W48, from
41 23% (95%CI:10-42%) to 42% (95%CI:25-61%) for heterosexuals (p=0.042) and from 41%
42 (95%CI:21-64%) to 73% (95%CI:52-88%) for MSM (p=0.004). Median monthly HIV transmission
43 rates were 0.0540 (IQR:0.0339-0.0742) for MSM and 0.0018 (IQR:0.0014-0.0191) for
44 heterosexuals at cART initiation, and were reduced by 95% (95%CI:87-100%) for heterosexuals
45 and 98% (95%CI:95-100%) for MSM as early as W24.

46 **Conclusions:** Risk of onward transmission for severely immunosuppressed individuals is high
47 before and within the first weeks of cART, and persists, at a substantially reduced level, beyond
48 24 weeks of cART for some individuals. Earlier cART and protecting HIV-negative partners until
49 full viral suppression is achieved could reduce HIV transmission.

50

51 **Introduction**

52 Early initiation of effective combination antiretroviral therapies (cART) dramatically
53 improves the prognosis of HIV-infected patients and, by suppressing plasma HIV viral load
54 (pVL), markedly reduces sexual transmission of HIV.¹⁻⁴ However, despite cART success, late
55 presentation for HIV care remains common in most settings,^{5, 6} including high-income countries.⁶
56 More than 30% of patients presenting for care in Europe have advanced HIV disease, defined as
57 CD4 counts <200 cells/mm³ or AIDS-defining disease.⁶ Advanced stage of infection is typically
58 accompanied with high level of pVL, which requires longer time to achieve viral suppression
59 upon cART initiation.^{7, 8} Thus, persons presenting for care with severe immunosuppression may
60 be at high risk to transmit HIV before and after cART initiation, as high pVL implies high risk of
61 sexual HIV transmission.⁹

62 Recent studies in low and middle-income countries showed that HIV transmission risk
63 persists during the first 6 months of cART.^{2,10} However, little is known about the risk of HIV
64 transmission before, and after, cART initiation for individuals presenting for care with severe
65 immunosuppression, notably in high-income countries. Quantifying these risks is critical for HIV-
66 infected patients and their partners, as well as for clinicians and health care policymakers to
67 implement interventions aiming at reducing the risk of onward HIV transmission and accelerating
68 care entry. Here, we used virological and behavioral data collected within the framework of the
69 IMEA 040 DATA trial¹¹ to quantify, for individuals presenting for care with severe
70 immunosuppression, the risk of HIV transmission before and within the first 48 weeks of cART
71 initiation.

72 **Methods**

73
74 **Study population**

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

85
86 **Ethics**

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

91
92 **Analysis**

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

99 transmission,⁹ whether or not the patient reported any sexual activity. The per-act probability of
100 HIV transmission was shown to increase by a factor of 2.45 (95% confidence interval (CI): 1.85-
101 3.26) for each log (base 10) increment in pVL, as expressed by the equation:¹² $\beta_1 =$
102 $2.45^{\log_{10}(V_1/V_0)} \beta_0$, where V_0 is the average pVL during untreated chronic HIV infection, β_0 is the
103 per-act probability of HIV transmission from a person with pVL V_0 , and β_1 is the per-act
104 transmission probability corresponding to pVL V_1 . We assumed that V_0 was 4.5 log₁₀
105 copies/mL,¹² and β_0 was equal to 0.001 for heterosexuals¹³ and 0.01 for MSM.¹² Regarding the
106 parameter determining the increase in transmission probability with each one-log increment in
107 pVL, each individual was assigned a value sampled from a normal distribution with mean 2.45
108 and standard deviation 0.35, corresponding to the 95% CI. The risk of HIV transmission was
109 neglected for undetectable pVL, defined as plasma HIV-RNA concentrations below 50
110 copies/mL.²

111 We combined virological and behavioral data to quantify, for each patient the monthly
112 rate of HIV transmission using the formula: $C=C_M+C_R+C_C$ where C_M , C_R and C_C were the
113 monthly rates of HIV transmission to HIV-negative main, regular and casual partners,
114 respectively. Monthly rates for each kind of partnership were calculated using the binomial
115 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
116 of sex acts over the last 4 weeks, and k was the number of sex acts protected by condom over
117 the last 4 weeks. We assumed that the per-act condom efficacy was 75% (95 CI: 63-83),¹³ and
118 thus we assigned a per-act condom efficacy value to each individual, that was sampled from a
119 normal distribution with mean 0.75 and standard deviation 0.05, corresponding to the 95% CI.
120 Partners of unknown status were assumed to be HIV-negative.

121 We performed sensitivity analyses where we assumed that the per-act risk of HIV
122 transmission during each sexual intercourse was reduced by 95% for all patients. This analysis
123 corresponds to an optimistic scenario where all couples would consistently and correctly use
124 prevention, i.e. condoms¹⁴ or pre-exposure prophylaxis (PrEP),^{15,16} to reduce the risk of HIV

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

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

132 **Results**

133 Eighty-four patients participated to the survey and completed at least one of the three
134 questionnaires. Among participants, 56% were heterosexual (24 male, 23 female) and 44%
135 MSM (Table 1). Median time from HIV diagnosis to cART initiation was 4 weeks. At cART
136 initiation (W0), median CD4 cell count was 71 cells/mm³ and median pVL was 5.4 log₁₀ for
137 heterosexuals, and respectively 89 cells/mm³ and 5.2 log₁₀ for MSM.

138 Using data on pVL at W0, we estimated that the median per-act risk of HIV transmission
139 at cART initiation was more than seven times higher for MSM than for heterosexuals (0.0172
140 (IQR: 0.0141-0.0282) versus 0.0023 (IQR: 0.0015-0.0029), p<0.001, Figure 1, A and B). The
141 percentage of patients with unsuppressed viral load (pVL>50 copies/mL) decreased from 100%
142 at cART initiation to 78% (95% CI 64-89%) at W12, 38% (95% CI 25-54%) at W24 and 27%
143 (95% CI 16-43%) at W48 for heterosexuals (p<0.001) and respectively 73% (95% CI 56-86%),
144 33% (95% CI 18-50%) and 8% (95% CI 2-22%) for MSM (p<0.001). Among those who remained
145 virologically unsuppressed, pVL considerably declined within the first 12 weeks of cART --
146 median pVL was 2.3 log₁₀ (IQR: 2.1-2.5) for heterosexuals and 2.2 log₁₀ (IQR: 1.9-2.5) for MSM
147 at W12 -- and then remained relatively stable (data not shown). This translated into a reduction
148 of the per-act risk of HIV transmission for virologically unsuppressed individuals, with estimated
149 median values, at W12, of 0.0001 (IQR: 0.0001-0.0002) for heterosexuals (p<0.001 versus W0,
150 Figure 1A) and 0.0010 (IQR: 0.0000-0.0017) for MSM (p<0.001 versus W0, Figure 1B), and
151 mean reductions, when compared to W0, of 90% (86-94%) for heterosexuals and 92% (91-94%)
152 for MSM.

153 Patients' characteristics of sexual behavior before and after cART initiation are
154 summarized in Table 1. Over the course of treatment, the percentage of patients reporting sex
155 with HIV-negative or unknown serostatus (HNUS) partners increased, from 23% (95% CI 10-
156 42%) at cART initiation to 42% (95% CI 25-61%) at W48 for heterosexuals (p=0.042) and,
157 respectively, from 41% (95% CI 21-64%) to 73% (95% CI 52-88%) for MSM (p=0.004). Among

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

162 By combining virological and behavioral data, we found that during the month before
163 treatment, 23% (95% CI 10-42%) of heterosexuals (Figure 1C) and 41% (95% CI 21-64%) of
164 MSM (Figure 1D) were virologically unsuppressed and had sex with HNUS partners. Among
165 these patients, estimated median monthly rate of HIV transmission was almost 30 times higher
166 for MSM than heterosexuals, (0.0540 (IQR: 0.0339-0.0742) versus 0.0018 (IQR: 0.0014-0.0191),
167 $p=0.008$, Figure 1, C and D). Over the course of cART, the percentage of HIV-infected patients
168 who remained virologically unsuppressed and had sex with HNUS partners decreased to reach
169 16% (95% CI 5-33%) ($p=0.291$) at W24 and 9% (95% CI 2-24%) ($p=0.109$) at W48 for
170 heterosexuals and respectively 25% (95% CI 11-45%) ($p=0.234$) and 4% (95% CI 0-20%)
171 ($p=0.010$) for MSM. Estimated median monthly rates of HIV transmission for these patients
172 decreased to 0.0001 (IQR: 0.0001-0.0006) for heterosexuals ($p=0.053$) and 0.0024 (IQR:
173 0.0017-0.0038) for MSM ($p<0.001$) at W24 and then remained stable, corresponding to mean
174 reductions, relative to W0, of 95% (87-100%) for heterosexuals and 98% (95-100%) for MSM.

175 Under an optimistic scenario, i.e. assuming that the per-act risk of HIV transmission
176 during each sexual intercourse reduced by 95% for all patients, the estimated median monthly
177 rate of HIV transmission, among patients who were virologically unsuppressed and had sex with
178 HNUS partners, was 0.0003 (IQR: 0.0002-0.0010) for heterosexuals and 0.0049 (IQR: 0.0037-
179 0.0072) for MSM at cART initiation ($p=0.016$). This rate decreased to 0.00003 (IQR: 0.00003-
180 0.00013) for heterosexuals ($p=0.205$) and 0.0004 (IQR: 0.0002-0.0005) for MSM ($p<0.001$) at
181 W24 and then remained stable. Thus, under the optimistic scenario, the monthly rate of HIV
182 transmission at cART initiation was reduced by 93% (85-100%) for heterosexuals and 98% (95-
183 100%) for MSM at W24, compared to the baseline analysis.

184 **Discussion**

185 With an estimated median value of 5%, we found that the monthly rate of HIV
186 transmission before cART initiation was particularly high for MSM – thirty times higher than for
187 heterosexuals – reflecting higher self-reported sexual activity for MSM than heterosexuals but,
188 above all, higher per-act risk of HIV transmission for MSM than heterosexuals. Indeed, taken
189 alone, the higher sexual activity for MSM than heterosexuals contributes to increase the median
190 value of the monthly rate of HIV transmission by a factor 3 while the higher per-act risk of HIV
191 transmission for MSM than heterosexuals contributes to increase this median value by a factor
192 10 (results not shown). Although sexual activity increased after cART initiation, and more than a
193 third of individuals remained virologically unsuppressed (pVL>50 copies/mL) after 24 weeks of
194 cART, the risk of HIV transmission significantly decreased, as early as 12 weeks of cART, and
195 by ~95% after 24 weeks of cART, even for those who remained virologically unsuppressed. In
196 addition, we found that the monthly rate of HIV transmission before and after cART initiation
197 could be significantly decreased (from 93% to 98%) if all patients or their partners would use
198 consistently and correctly an HIV prevention method, i.e. condoms¹⁴ or PrEP.^{15,16}

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

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

210 initiation as soon as possible. Furthermore, at cART initiation, communicating about this risk and
211 providing counseling on how to reduce this risk, e.g. by improving condom use or offering PrEP
212 to HIV-negative partners, is essential to reduce the risk of onward transmission until achieving
213 full viral suppression. Partner notification assistance programs, which are not implemented in
214 France, should also be evaluated. This could allow earlier HIV diagnosis for partners of newly
215 diagnosed HIV cases and provide an opportunity to offer PrEP to HIV-negative partners in
216 serodiscordant couples until the HIV-positive partner achieves full viral suppression. In addition,
217 investigating whether faster viral suppression could be achieved for severely immunosuppressed
218 individuals using new drugs, such as integrase inhibitor, is important to reduce the risk of onward
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241
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259

260 **Supplementary Data**

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

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307 *retrovirus and Opportunistic Infections, Boston, Massachusetts, 2016.* Abstract 886.
- 308

309 **Table 1:** Baseline and sexual behavior characteristics of the 84 patients
 310

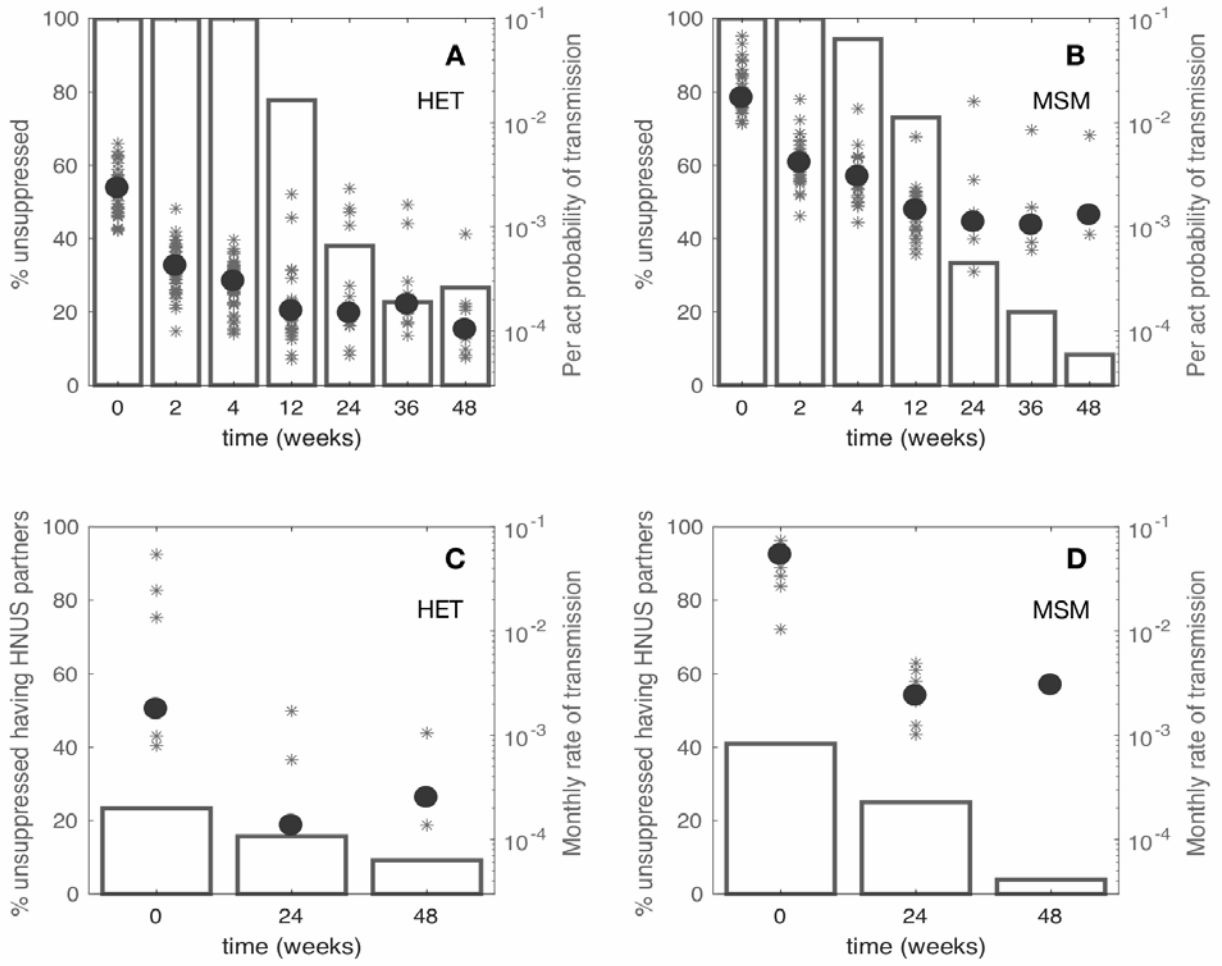
	Heterosexuals n=47 (56%)			MSM n=37 (44%)		
Male, n (%)	24 (51%)			37 (100%)		
Age, years, median (IQR)	44 (39-54)			38 (34-48)		
Sub-Saharan African origin, n (%)	17 (36%)			1 (3%)		
European origin, n (%)	23 (49%)			32 (86%)		
Other origins, n (%)	7 (15%)			4 (11%)		
Time from HIV diagnosis to cART 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%)

311 pVL: plasma viral load; cART: combination antiretroviral therapies; W0: at cART initiation; W24:
 312 24 weeks after cART initiation; W48: 48 weeks after cART initiation; HNUS: HIV-negative or
 313 unknown serostatus.
 314

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

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

326 **Figure 1**



327



**ESSAI IMEA 040 DATA
QUESTIONNAIRE V.A.S S00**

QVAS
Version 1.0 du 28/02/11

SECTION TO BE COMPLETED BY THE ATTENDING PHYSICIAN

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

Centre ID _ _ _	Patient ID _ _ _	E-patient Code _ _ _
Did the patient consent to complete the questionnaire	<input type="radio"/> no	<input type="radio"/> yes
Did the patient need assistance to complete the questionnaire	<input type="radio"/> no	<input type="radio"/> yes
Date _ _ _ _ _	Name of the physician	Signature



ESSAI IMEA 040 DATA
QUESTIONNAIRE V.A.S S00

QVAS
Version 1.0 du 28/02/11

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:

₁ Yes

₂ No

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

Your partner is: a man ₁ a woman ₂

Your partner is: HIV-positive ₁ HIV-negative ₂ you don't know ₃

In the last 12 months,

Did you have sexual intercourse with your partner? ₁Yes ₂No

How often did you use condom? never ₁ rarely ₂ often ₃ always ₄

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?

₁ Yes

₂ No

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

Your partner is: a man ₁ a woman ₂

Your partner is: HIV-positive ₁ HIV-negative ₂ you don't know ₃

In the last 12 months,

Did you have sexual intercourse with your partner? ₁Yes ₂No

How often did you use condom? never ₁ rarely ₂ often ₃ always ₄

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? /_/_/_/_/_/



ESSAI IMEA 040 DATA
QUESTIONNAIRE V.A.S S00

QVAS
Version 1.0 du 28/02/11

3. In the last 12 months, did you have casual sexual partners?

₁ Yes

₂ No

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

How often did you use condom: never ₁ rarely ₂ often ₃ always ₄

Over the last 4 weeks,

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

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

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

Pain during sexual intercourse

₁ Yes ₂ No

Erectile dysfunction

₁ Yes ₂ No

Lack of sexual desire, decline or loss of libido

₁ Yes ₂ No

5. During your lifetime:

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

0 ₁ 1 or 2 ₂ 3 to 10 ₃ 11 to 20 ₄ over 20 ₅ don't wish to answer ₆

Overall, how many male sexual partners did you have?

0 ₁ 1 or 2 ₂ 3 to 10 ₃ 11 to 20 ₄ over 20 ₅ don't wish to answer ₆

6. Do you identify yourself as:

- Heterosexual

₁

Homosexual

₂

- Bisexual

₃

You don't wish to identify yourself

₄

- You don't wish to answer that question ₅

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 ₁

No ₂

no spouse/main partner ₃

Your children

Yes ₁

No ₂

no child ₃

Your relatives and close-ones

Yes ₁

No ₂

not applicable ₃

Your friends

Yes ₁

No ₂

not applicable ₃

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



ESSAI IMEA 040 DATA
QUESTIONNAIRE VAS S 24

QVAS
Version 1.0 du 28/02/11

SECTION TO BE COMPLETED BY THE ATTENDING PHYSICIAN

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

Centre ID _ _ _ _ _	Patient ID _ _ _ _ _	E-patient Code _ _ _ _ _
Did the patient consent to complete the questionnaire	<input type="radio"/> no	<input type="radio"/> yes
Did the patient need assistance to complete the questionnaire	<input type="radio"/> no	<input type="radio"/> yes
Date _ _ _ _ _	Name of the physician	Signature



ESSAI IMEA 040 DATA
QUESTIONNAIRE VAS S 24

QVAS
Version 1.0 du 28/02/11

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 ₁ Yes ₂ No
Did you have one or several new sexual partners ₁ Yes ₂ No
Did you separate from your spouse? ₁ Yes ₂ No
Did you separate from a regular partner?
No ₁ Yes ₂
Did you start a new couple/steady relationship? ₁ Yes ₂ No

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

- ₁ Yes ₂ No
Your partner is: a man ₁ a woman ₂
Your partner is: HIV-positive ₁ HIV-negative ₂ you don't know ₃

In the last 6 months,

- Did you have sexual intercourse with your partner? ₁Yes ₂No
How often did you use condom? never ₁ rarely ₂ often ₃ always ₄

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

- ₁ Yes ₂ No
Your partner is: a man ₁ a woman ₂
Your partner is: HIV-positive ₁ HIV-negative ₂ you don't know ₃

In the last 6 months,

- Did you have sexual intercourse with your partner? ₁Yes ₂No
How often did you use condom? never ₁ rarely ₂ often ₃ always ₄

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? /__/_/_/_/



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QVAS
Version 1.0 du 28/02/11

4. In the last 12 months, did you have casual sexual partners?

₁ Yes

₂ No

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

Did you tell them you were HIV-positive?

₁ no, you did not tell to any of them

₂ yes, but not to all of them

₃ yes, you tell to all of them

How often did you use a condom: never ₁ rarely ₂ often ₃ always ₄

Over the last 4 weeks,

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

₁ Yes ₂ No

Did you seek care for a sexually transmitted infection

₁ Yes ₂ No

Did you take a treatment for a sexually transmitted infection

₁ Yes ₂ No

6. In the last 6 months:

You have sought to have mostly HIV-positive sexual partners

₁ Yes ₂ No

You felt you were isolated

₁ Yes ₂ No

You felt you were supported by your close-ones

₁ Yes ₂ No

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

Pain during sexual intercourse

₁ Yes ₂ No

Erectile dysfunction

₁ Yes ₂ No

Lack of sexual desire, decline or loss of libido

₁ Yes ₂ 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 ₁

No ₂

no spouse/main partner ₃

Your children

Yes ₁

No ₂

no child ₃

Your relatives and close-ones

Yes ₁

No ₂

not applicable ₃

Your friends

Yes ₁

No ₂

not applicable ₃



ESSAI IMEA 040 DATA
QUESTIONNAIRE VAS S 24

QVAS
Version 1.0 du 28/02/11

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