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### ► To cite this version:

V Supervie, L Assoumou, R Breban, F Lert, D Costagliola, et al.. Risk of HIV transmission during combined ART initiation for HIV-infected persons with severe immunosuppression. *CS Entreprise Liaison*, 2017, 81393 (11), pp.75646 - 75659. 10.1093/jac/dkx276 . hal-02023006

**HAL Id: hal-02023006**

**<https://hal.sorbonne-universite.fr/hal-02023006>**

Submitted on 18 Feb 2019

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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<sup>7,8</sup>, L. Slama<sup>4,9</sup> on behalf of the IMEA 040 DATA Study Group<sup>†</sup>.

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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 log<sub>10</sub> 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.<sup>1-4</sup> However, despite cART success, late  
55 presentation for HIV care remains common in most settings,<sup>5, 6</sup> including high-income countries.<sup>6</sup>  
56 More than 30% of patients presenting for care in Europe have advanced HIV disease, defined as  
57 CD4 counts <200 cells/mm<sup>3</sup> or AIDS-defining disease.<sup>6</sup> 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.<sup>7, 8</sup> 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.<sup>9</sup>

62 Recent studies in low and middle-income countries showed that HIV transmission risk  
63 persists during the first 6 months of cART.<sup>2,10</sup> 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 trial<sup>11</sup> 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.<sup>11</sup> 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,<sup>9</sup> 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:<sup>12</sup>  $\beta_1 =$   
102  $2.45^{\log_{10}(V_1/V_0)} \beta_0$ , where  $V_0$  is the average pVL during untreated chronic HIV infection,  $\beta_0$  is the  
103 per-act probability of HIV transmission from a person with pVL  $V_0$ , and  $\beta_1$  is the per-act  
104 transmission probability corresponding to pVL  $V_1$ . We assumed that  $V_0$  was 4.5 log<sub>10</sub>  
105 copies/mL,<sup>12</sup> and  $\beta_0$  was equal to 0.001 for heterosexuals<sup>13</sup> and 0.01 for MSM.<sup>12</sup> 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.<sup>2</sup>

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),<sup>13</sup> 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. condoms<sup>14</sup> or pre-exposure prophylaxis (PrEP),<sup>15,16</sup> 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/mm<sup>3</sup> and median pVL was 5.4 log<sub>10</sub> for  
137 heterosexuals, and respectively 89 cells/mm<sup>3</sup> and 5.2 log<sub>10</sub> 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 log<sub>10</sub> (IQR: 2.1-2.5) for heterosexuals and 2.2 log<sub>10</sub> (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. condoms<sup>14</sup> or PrEP.<sup>15,16</sup>

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  
219 transmission after cART initiation.

220 **Acknowledgements**

221 We would like to thank all patients who participated in this study.

222 IMEA 040 DATA Study group: CHU de Martinique (André Cabié, Sylvie Abel, Patrick Hochedez,  
223 Sandrine Pierre-François, Benoît Rozé); CHU Pitié-Salpêtrière (Médecine Interne: Anne Simon,  
224 Catherine Lupin; Maladies Infectieuses: Christine Katlama, Marc Antoine Valentin; Immunologie:  
225 Brigitte Autran, Assia Samri; Virologie: Sidonie Lambert, Anne Geneviève Marcelin); CHU Bichat  
226 (Roland Landman, V. Joly, Zélie Julia, Stanislas Harent, Emmanuelle Papot, Bao-Chau Phung;  
227 Laboratoire Pharmaco-Toxicologie: Gilles Peytavin, Patrick Lê Minh); CHU Lariboisière (Agathe  
228 Rami, Myriam Diemer, Maguy Parrinello); CHU Louis Mourier (I. Cahitte, Feng Zeng, E. Mortier);  
229 CHU Tenon (Gilles Pialoux, Thomas L'Yavanc, Guillaume Le Loup, Philippe Bonnard, Marie  
230 Gisèle Lebrette, Julie Chas, Valérie Berrebi, Nadège Velazquez, Anne Adda); CHU Necker  
231 (Claudine Duvivier, Fatima Touam, Olivier Lortholary, Michka Shoai-Tehrani, Claire Rouzaud);  
232 Hôpital Dupuytren Service des Maladies Infectieuses et Tropicales (Eric Denes, Sophie  
233 Ducroux-Roubertou, Hélène Durox, Claire Genet, Jean-Philippe Rogez, Sylvie Rogez, Jose  
234 Pascual); CHU Hôpital Européen Georges Pompidou (Laurence Weiss, Juliette Pavie, Erika  
235 Bourzam); CH Perpignan (Hugues Aumaître, Milagros Ferreyra, Matthieu Saada, Martine Malet);  
236 CHU Avicenne, Service des Maladies Infectieuses et Tropicales (Christia Palacios, Patricia  
237 Honore, Irene Zamord); CHU Raymond Poincaré (Huguette Berthe, Stéphanie Landowski,  
238 Pierre de Truchis); CHD Vendée (Philippe Perre); CHU Saint Antoine (Pierre-Marie Girard,  
239 Nadia Valin, Pauline Campa, Bénédicte Lefebvre, Jean-Luc Meynard, Michèle Pauchard, Laure  
240 Surgers).

241  
242 **Funding section**

243 The IMEA 040 DATA trial was funded by a research grant from Bristol-Myers Squibb to the  
244 IMEA foundation.

245

246 **Transparency declarations**

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

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

	<b>Heterosexuals</b> n=47 (56%)			<b>MSM</b> 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 <sup>3</sup> ), median (IQR)	71 (21-137)			89 (37-161)		
pVL (log <sub>10</sub> copies/mL), median (IQR)	5.4 (5.0-5.7)			5.2 (4.9-5.6)		
<b>Self-reported sexual behavior over the past 4 weeks for patients who completed questionnaires</b>	<b>W0</b> n=30	<b>W24</b> n=32	<b>W48</b> n=33	<b>W0</b> n=22	<b>W24</b> n=28	<b>W48</b> 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%)

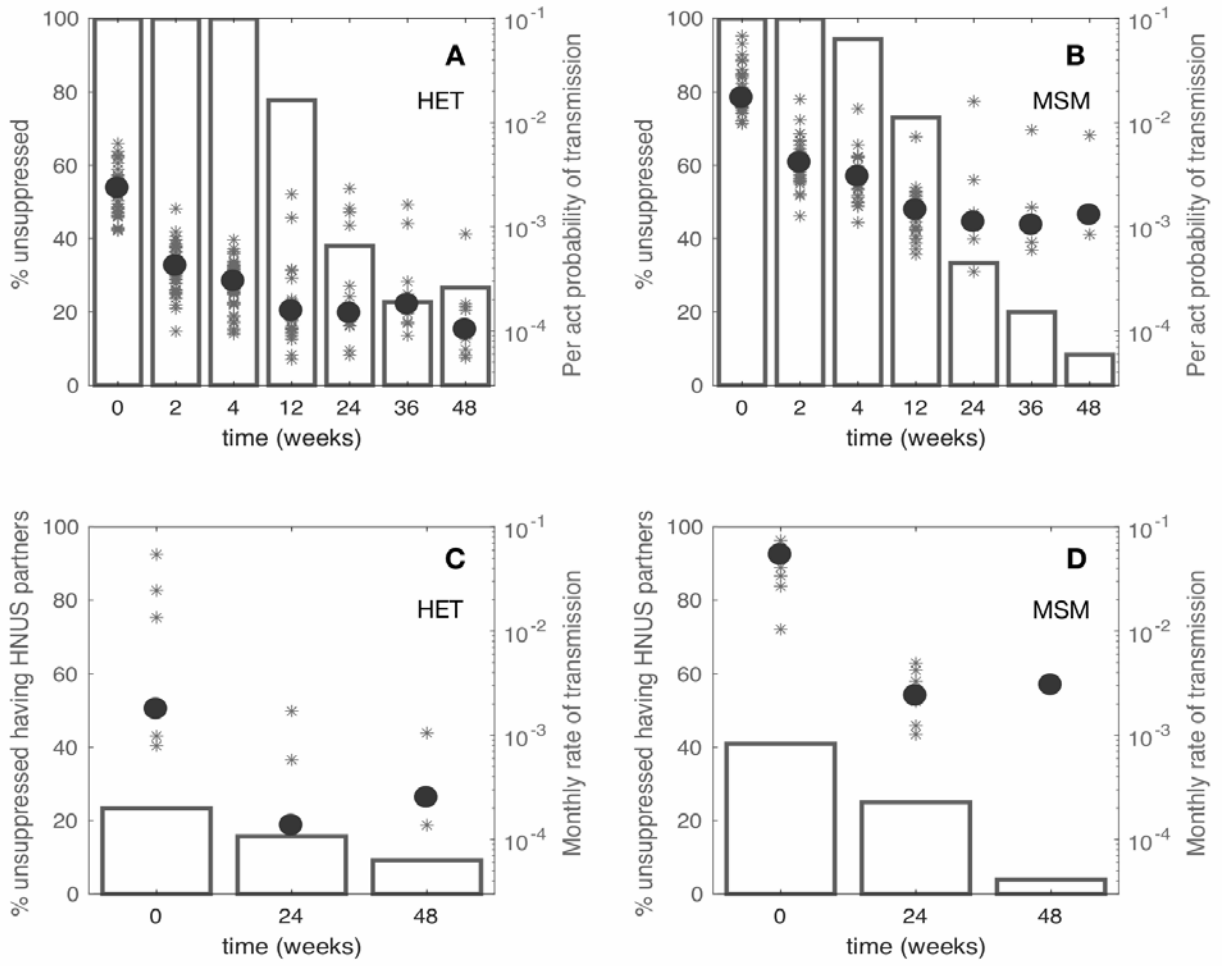
311 pVL: plasma viral load; cART: combination antiretroviral therapies; W0: at cART initiation; W24:  
 312 24 weeks after cART initiation; W48: 48 weeks after cART initiation; HNUS: HIV-negative or  
 313 unknown serostatus.  
 314



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



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QUESTIONNAIRE V.A.S S00

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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:

<sub>1</sub> Yes

<sub>2</sub> No

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

Your partner is: a man <sub>1</sub> a woman <sub>2</sub>

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

In the last 12 months,

Did you have sexual intercourse with your partner? <sub>1</sub>Yes <sub>2</sub>No

How often did you use condom? never <sub>1</sub> rarely <sub>2</sub> often <sub>3</sub> always <sub>4</sub>

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?

<sub>1</sub> Yes

<sub>2</sub> No

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

Your partner is: a man <sub>1</sub> a woman <sub>2</sub>

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

In the last 12 months,

Did you have sexual intercourse with your partner? <sub>1</sub>Yes <sub>2</sub>No

How often did you use condom? never <sub>1</sub> rarely <sub>2</sub> often <sub>3</sub> always <sub>4</sub>

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

<sub>1</sub> Yes

<sub>2</sub> No

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

How often did you use condom: never <sub>1</sub> rarely <sub>2</sub> often <sub>3</sub> always <sub>4</sub>

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

<sub>1</sub> Yes <sub>2</sub> No

Erectile dysfunction

<sub>1</sub> Yes <sub>2</sub> No

Lack of sexual desire, decline or loss of libido

<sub>1</sub> Yes <sub>2</sub> No

5. During your lifetime:

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

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

Overall, how many male sexual partners did you have?

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

6. Do you identify yourself as:

- Heterosexual

<sub>1</sub>

Homosexual

<sub>2</sub>

- Bisexual

<sub>3</sub>

You don't wish to identify yourself

<sub>4</sub>

- You don't wish to answer that question <sub>5</sub>

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 <sub>1</sub>

No <sub>2</sub>

no spouse/main partner <sub>3</sub>

Your children

Yes <sub>1</sub>

No <sub>2</sub>

no child <sub>3</sub>

Your relatives and close-ones

Yes <sub>1</sub>

No <sub>2</sub>

not applicable <sub>3</sub>

Your friends

Yes <sub>1</sub>

No <sub>2</sub>

not applicable <sub>3</sub>

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



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QUESTIONNAIRE VAS S 24

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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

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

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

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

In the last 6 months,

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

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?

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

In the last 6 months,

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

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

<sub>1</sub> Yes

<sub>2</sub> No

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

Did you tell them you were HIV-positive?

<sub>1</sub> no, you did not tell to any of them

<sub>2</sub> yes, but not to all of them

<sub>3</sub> yes, you tell to all of them

How often did you use a condom: never <sub>1</sub> rarely <sub>2</sub> often <sub>3</sub> always <sub>4</sub>

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

<sub>1</sub> Yes <sub>2</sub> No

Did you seek care for a sexually transmitted infection

<sub>1</sub> Yes <sub>2</sub> No

Did you take a treatment for a sexually transmitted infection

<sub>1</sub> Yes <sub>2</sub> No

6. **In the last 6 months:**

You have sought to have mostly HIV-positive sexual partners

<sub>1</sub> Yes <sub>2</sub> No

You felt you were isolated

<sub>1</sub> Yes <sub>2</sub> No

You felt you were supported by your close-ones

<sub>1</sub> Yes <sub>2</sub> No

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

Pain during sexual intercourse

<sub>1</sub> Yes <sub>2</sub> No

Erectile dysfunction

<sub>1</sub> Yes <sub>2</sub> No

Lack of sexual desire, decline or loss of libido

<sub>1</sub> Yes <sub>2</sub> 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 <sub>1</sub>

No <sub>2</sub>

no spouse/main partner <sub>3</sub>

Your children

Yes <sub>1</sub>

No <sub>2</sub>

no child <sub>3</sub>

Your relatives and close-ones

Yes <sub>1</sub>

No <sub>2</sub>

not applicable <sub>3</sub>

Your friends

Yes <sub>1</sub>

No <sub>2</sub>

not applicable <sub>3</sub>





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