Acceptability and feasibility of HIV testing in general medicine by ELISA or rapid test from finger-stick whole blood

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Summary

Objectives > Guidelines recommend routine universal HIV testing in adults to reduce the pool of infected patients unaware of their status, without specific recommendations concerning the method. We compared acceptability and feasibility of HIV testing by ELISA tests or rapid tests from finger-stick whole blood.

Methods > Prospective randomized multi-center study comparing acceptability and feasibility of routine universal HIV testing by ELISA tests, with a charge, subsequently reimbursed by Social Security for affiliated patients, or rapid tests from finger-stick whole blood, without any charge from the patients or the general practitioner for the study. A single investigator performed all interventions. After consent, all adults (18-70 years old) consulting their general practitioner in Paris, France, unaware of their status, were enrolled. Testing was performed immediately for the patients in the rapid test arm; a prescription was given for testing in a lab for the patients in the ELISA arm. The primary endpoint was acceptability of each method. The secondary endpoint was feasibility of each method, assessed one month after the consultation.

Results > Two hundred and seventy patients were enrolled: 133 patients in the ELISA arm, 137 in the rapid test arm. Acceptability of the rapid test (92%) was higher than that of the ELISA (63.9%), \( P < 0.0001 \). Feasibility of the rapid test (100%) was higher than that of the ELISA (50.5%), \( P < 0.0001 \). A center effect was shown concerning feasibility of ELISA but not concerning feasibility of rapid tests.

\( ^{*} \) The study was registered in ClinicalTrials.gov (Identifier: NCT02574208).
Introduction

Human immunodeficiency virus (HIV) transmission remains a public health issue partly due to a pool of infected individuals unaware of their status. In the USA, 20% of infected individuals might be unaware of their status, and would be responsible for 49% of transmissions [1]. In France, 28,800 individuals might be unaware of their status; 6200 infections occur annually since 2007 [2]. In Europe, over 50% are late presenters (individuals presenting for HIV care with a CD4 cell count of less than 350 cells/μL or an AIDS-defining event) [3,4], and are sources of transmissions for many years before awareness of their status [5-7]. Routine universal HIV testing coupled with treatment is the best way to decrease HIV transmission [5]. In 2006, the US Center for Disease Control issued recommendations supporting routine universal HIV testing for all persons aged 13 to 64 years [8]. In 2006, the French “Conseil National du SIDA” proposed systematic HIV testing to all sexually active adults [9]. In 2009, the French “Haute Autorité de Santé” recommended systematic offering of HIV testing to all adults aged 15 to 70 years, at least once in their life by health professionals including general practitioners [10]. In 2013, the French national guidelines recommended that practitioners offer systematic testing to all...

Résumé

Acceptabilité et faisabilité du dépistage de l’infection par le VIH en médecine générale par un test ELISA ou par un test rapide à partir de sang capillaire : étude prospective multicentrique randomisée

Objectifs > Les autorités de santé recommandent une proposition systématique de dépistage de l’infection par le VIH en routine chez les adultes, pour diminuer le nombre de personnes infectées ignorant leur statut. Elles n’émettent pas de recommandations spécifiques concernant la méthode à utiliser. Nous avons comparé l’acceptabilité et la faisabilité du dépistage de l’infection par le VIH par test ELISA ou par test rapide à partir d’un prélèvement de sang capillaire.

Méthodes > Étude multicentrique randomisée prospective comparant l’acceptabilité et la faisabilité du dépistage universel en routine de l’infection par le VIH par un test ELISA (nécessitant une dépense, même si elle est remboursée ultérieurement pour les patients ayant une prise en charge) ou par un test rapide (ne nécessitant pas de dépense de la part des patients ni du médecin traitant pour l’étude) à partir d’un prélèvement de sang capillaire. L’étude a été réalisée par un seul investigateur à Paris, France. Après avoir donné leur consentement, tous les adultes âgés de 18 à 70 ans qui consultaient leur médecin traitant et qui ne connaissaient pas leur statut VIH participaient à l’étude. Dans le bras « test rapide », le dépistage était réalisé immédiatement; dans le bras « test ELISA », les patients recevaient une ordonnance pour un dépistage au laboratoire d’analyses. Le critère principal de jugement était l’acceptabilité de chaque méthode. Le critère secondaire était la faisabilité de chaque méthode, mesurée un mois après la consultation.

Résultats > Deux cent soixante-dix adultes ont été inclus, 133 dans le bras « test ELISA », 137 dans le bras « test rapide ». L’acceptabilité du test rapide (92 %) était plus importante que celle du test ELISA (63,9 %), p < 0,0001. La faisabilité du test rapide (100 %) était plus importante que celle du test ELISA (50,5 %), p < 0,0001. Un effet centre était retrouvé concernant la faisabilité des tests ELISA, non retrouvé concernant la faisabilité des tests rapides.

Conclusions > L’acceptabilité et la faisabilité du dépistage universel en routine de l’infection par le VIH par un test rapide sont supérieures à l’acceptabilité et la faisabilité du dépistage par un test ELISA. Une utilisation plus large des tests rapides, idéalement gratuits, par les médecins traitants, pourrait diminuer le nombre de personnes infectées ignorant leur statut.
What was already known

- The high acceptability of rapid testing and (high acceptability of) HIV testing in primary setting have been found in previous studies.
- The feasibility equal to acceptability in the rapid test arm has already been found.
- The low feasibility of regular tests has been found in previous studies.

What does this manuscript add?

- Our randomized study is the first showing the preference of users for rapid tests and a higher rate of people knowing the result of the test with rapid test.
- Subgroup analyses of acceptability were in favor of rapid tests.
- “The center effect concerning feasibility of regular tests, lower in the office located in Eastern Paris than in the office located in the center of Paris, explained by a difference in health insurance cover of patients, (lack of cover often leading to not performing regular tests, which needed to be paid first, before a reimbursement). This center effect, related to health insurance cover of patients, has not been described previously.

Methods

This prospective, randomized multi-center study compared acceptability and feasibility of routine universal HIV testing by ELISA from serum (the “regular” arm) or by rapid test from FSB (InstiTM) (the “rapid test” arm). The study was conducted in adult outpatients recruited consecutively the days when the chief investigator of the study was present, from two general medicine offices. There were two general practitioners (GPs) in each office located in different areas in Paris to obtain a mixed-population. One office was located in Eastern Paris where people, often of North or sub-Saharan African origin, have lower incomes and less health insurance coverage; the second office was located in the center of Paris, where the population is more often of Caucasian origin, with higher incomes and better health insurance coverage. The chief investigator of the study, locum for several months of the four GPs during their weekly rest days, was present alternately in one of the two offices at different days in the week to avoid biases due to consultations at fixed days for some patients. All patients between 18 and 70 years of age consulting between the first October and the 31st December 2015 were asked to enroll after written consent. They answered an anonymous questionnaire providing information on sex, birth date, name of general practitioner (to assess any difference between the two offices), marital status, parental status, ethnic origin (Caucasian, North African, or other origins), health insurance cover, education level (achieving a high school diploma), previous HIV testing, HIV risk (unprotected sexual intercourse, intravenous drug injection or blood transfusion) and sexual preference. The patients known to be HIV-positive or who declared having been tested HIV-negative in the previous three months or who could not give informed consent were excluded from the study. The patients who declared having been tested HIV-negative in the previous three months were excluded from the study; even if this time was arbitrarily chosen, we followed the French national guidelines, which recommended in 2013 that practitioners offer systematic testing to all adults without recent testing [11]. Counseling about testing methods (rapid test, free of charge for the study, “regular” ELISA test, with a charge of around 20 € [22.5 USD] in France, fully reimbursed by health insurance), possibility of false negative results in cases of recent exposure, and necessity to confirm a positive result of a rapid test with a “regular” ELISA test were given. The patients were informed that they would be randomized (using RANDM® software) to the rapid test arm or to the regular arm. After the randomization process, HIV testing was proposed by the chief investigator. The primary endpoint was acceptability of each method, defined by the ratio of patients who accepted being tested/patients to whom the test was proposed. HIV testing was performed immediately in the rapid test arm and a prescription was given for HIV testing by ELISA in the regular arm. For the rapid HIV tests, FSB was preferred to oral fluid because of its
higher sensitivity. The INSTM HIV-1 and HIV-2 Rapid Antibody Test FSB (Biolytical TM Laboratories Inc., Richmond, B.C., Canada) was selected, provided by the distributor: Laboratoires Nephrotek, Rungis, France, because it takes two minutes and has a sensitivity of 99% [96.3–99.7] and specificity of 99.3% [14]. The secondary endpoint was feasibility of each method, defined by the ratio of patients who performed the test/patients who accepted being tested, assessed one month later. The chief investigator collected the results of the rapid test immediately. The results of the regular test were sent by mail or by secure e-mails from the laboratories. The patients in the regular arm without an available result one month later were considered as having not performed the test. The goals of the study were to assess acceptability and feasibility of HIV testing by each method, without taking into account the cost and the time needed to perform HIV testing.

The study was approved by the local ethics committees in September 2015 (Institutional Review Board 00003835. Agreement from US Department of Health and Human Services. Study 2015/38SC), and registered in ClinicalTrials.gov (Identifier: NCT02574208).

**Statistical analysis**

Previous studies having showed acceptability of the ELISA test of about 75% [15–17], enrollment of 130 patients in each arm was required to show a superiority of the rapid test, defined by a difference reaching at least 15% with alpha of 0.05 and a power of 90%.

We performed descriptive analyses, the percentages for qualitative data being compared with Chi² tests and Fisher exact test and continuous data with unpaired T-test. We performed planned subgroup analyses from enrolled patients (according to age, sex, ethnic origin, marital status, parental status, having or not health insurance, education level, sexual preference, previous HIV testing, HIV risk group), results being expressed as forest plots. We performed planned single and multiple logistic regressions for univariate and multivariate analyses of criteria influencing acceptability and feasibility of tests. Briefly, tests for homogeneity were performed to determine lack of interaction between pre-specified subgroups and HIV testing method. If the result of the test was not significant, the comparison between the two HIV testing methods, adjusted for the studied subgroup, could be performed, using a Mantel-Haenszel test (with a P-value < 0.05 in favor of higher acceptability of rapid tests from FSB).

**Results**

Two hundred and seventy of the 339 patients were enrolled (figure 1). Baseline characteristics of the enrolled population are shown in table I. One hundred and thirty three (49.3%) patients were randomized to the regular test arm, 137 (50.7%) to the rapid test arm. All the studied parameters were well-balanced between the two arms, except belonging to HIV risk groups, more common in the rapid test arm (P = 0.04), by chance due to the sample size. Global acceptability of HIV testing was 78.1%, higher in the rapid test arm (92.0%) than in the regular test arm (63.9%), P < 0.0001. Global acceptability did not differ between the two offices (78.2 and 78.1%), P > 0.99. Subgroup analyses of acceptability of the two methods are shown (figure 2). In univariate analysis, global acceptability was linked to the method (favoring the rapid tests) (P < 0.0001), and, irrespective
of method, to male sex \( (P = 0.03) \), younger age \( (P = 0.006) \), belonging to HIV risk groups \( (P = 0.001) \), having been previously tested \( (P = 0.03) \), not having health insurance \( (P = 0.04) \), and not having children \( (P = 0.01) \). In multivariate analysis, global acceptability was linked to the method (favoring the rapid tests) \( (P < 0.0001) \), and, irrespective of method, to male sex \( (P = 0.02) \), younger age \( (P < 0.0001) \), and not having health insurance \( (P = 0.01) \).

### Table I

Baseline characteristics of the enrolled population

<table>
<thead>
<tr>
<th></th>
<th>Finger-stick whole blood (FSB)</th>
<th>Standard test</th>
<th>Total</th>
<th>( P )-value</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Number, ( n ) (%)</strong></td>
<td>137 (50.7)</td>
<td>133 (49.3)</td>
<td>270 (100)</td>
<td></td>
</tr>
<tr>
<td><strong>Age (mean ± SD)</strong></td>
<td>45 ± 14.1</td>
<td>43.3 ± 13.5</td>
<td>44.2 ± 13.8</td>
<td>0.29</td>
</tr>
<tr>
<td><strong>Sex</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>M</td>
<td>72 (52.6)</td>
<td>67 (50.4)</td>
<td>139 (51.5)</td>
<td>0.81</td>
</tr>
<tr>
<td>F</td>
<td>65 (47.4)</td>
<td>66 (49.6)</td>
<td>131 (48.5)</td>
<td></td>
</tr>
<tr>
<td><strong>Marital status</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Married</td>
<td>52 (38.0)</td>
<td>52 (39.1)</td>
<td>104 (38.5)</td>
<td>0.9</td>
</tr>
<tr>
<td>Not married</td>
<td>85 (62.0)</td>
<td>81 (60.9)</td>
<td>166 (61.5)</td>
<td></td>
</tr>
<tr>
<td><strong>Parental status</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Having children</td>
<td>66 (48.2)</td>
<td>75 (56.4)</td>
<td>141 (52.2)</td>
<td>0.18</td>
</tr>
<tr>
<td>Not having children</td>
<td>71 (51.8)</td>
<td>58 (43.6)</td>
<td>129 (47.8)</td>
<td></td>
</tr>
<tr>
<td><strong>Area of birth</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Caucasian</td>
<td>82 (59.9)</td>
<td>82 (61.7)</td>
<td>164 (60.7)</td>
<td></td>
</tr>
<tr>
<td>North Africa</td>
<td>27 (19.7)</td>
<td>24 (18)</td>
<td>51 (18.9)</td>
<td>0.44</td>
</tr>
<tr>
<td>Others(^1)</td>
<td>28 (20.4)</td>
<td>27 (20.3)</td>
<td>55 (20.4)</td>
<td></td>
</tr>
<tr>
<td><strong>Previous testing</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>0</td>
<td>31 (22.6)</td>
<td>36 (27.1)</td>
<td>67 (24.8)</td>
<td></td>
</tr>
<tr>
<td>1</td>
<td>34 (24.8)</td>
<td>23 (17.3)</td>
<td>57 (21.1)</td>
<td>0.48</td>
</tr>
<tr>
<td>2-3</td>
<td>25 (18.2)</td>
<td>43 (32.3)</td>
<td>68 (25.1)</td>
<td></td>
</tr>
<tr>
<td>&gt;3</td>
<td>47 (34.3)</td>
<td>31 (23.3)</td>
<td>78 (28.8)</td>
<td></td>
</tr>
<tr>
<td><strong>Sexuality</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Heterosexuals</td>
<td>127 (92.7)</td>
<td>126 (94.7)</td>
<td>253 (93.7)</td>
<td>0.62</td>
</tr>
<tr>
<td>MSM</td>
<td>10 (7.3)</td>
<td>7 (5.3)</td>
<td>17 (6.3)</td>
<td></td>
</tr>
<tr>
<td><strong>HIV risk groups</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Yes(^2)</td>
<td>22 (16.1)</td>
<td>10 (7.5)</td>
<td>32 (11.9)</td>
<td>0.04</td>
</tr>
<tr>
<td>No</td>
<td>115 (83.9)</td>
<td>123 (92.5)</td>
<td>238 (88.1)</td>
<td></td>
</tr>
<tr>
<td><strong>School diploma</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>High</td>
<td>37 (27.0)</td>
<td>44 (33.1)</td>
<td>81 (30)</td>
<td>0.29</td>
</tr>
<tr>
<td>Low</td>
<td>100 (73.0)</td>
<td>89 (66.9)</td>
<td>189 (70)</td>
<td></td>
</tr>
<tr>
<td><strong>Health insurance</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Yes</td>
<td>109 (79.6)</td>
<td>104 (78.2)</td>
<td>213 (78.9)</td>
<td>0.88</td>
</tr>
<tr>
<td>No</td>
<td>28 (20.4)</td>
<td>29 (21.8)</td>
<td>57 (21.1)</td>
<td></td>
</tr>
</tbody>
</table>

All the data (except age) were expressed as number, \( n \), and percentages (%).

\(^1\) Other areas of birth: 40 patients were born in sub-Saharan Africa, 11 were born in Asia, and four in other continents.

\(^2\) HIV risk groups: unprotected sexual intercourse (15 cases), intravenous drug injection (7 cases) or blood transfusion (1 case) in the FSB group; unprotected sexual intercourse (8 cases), or intravenous drug injection (2 cases) in the standard test group. The percentages for qualitative data were compared using Chi\(^2\) tests and Fisher exact test. Continuous data were compared using unpaired T-tests.
All rapid tests from FSB were performed without any failure of blood sampling or undetermined results (feasibility 100%). One result was positive, confirmed by a regular test. In the regular test arm, the result was obtained in 50.5% of patients, lower than in the rapid test arm, $P < 0.0001$. No test was positive in this arm. Subgroup analyses of feasibility of the two methods are shown (figure 3). In univariate analysis, global feasibility was linked to the method (favoring the rapid tests) ($P < 0.0001$), and, irrespective of the method, to younger age ($P = 0.0003$), belonging to HIV risk groups ($P = 0.003$), having been previously tested ($P = 0.01$), not being married ($P = 0.025$), not having children ($P = 0.007$) and sexual preference (favoring MSM) ($P = 0.01$); global feasibility was not linked to male sex ($P = 0.17$) or health insurance cover ($P = 0.75$). In multivariate analysis, global feasibility was linked to the method (favoring the rapid tests) ($P < 0.0001$), and, irrespective of the method, to younger age ($P = 0.0003$), and sexual preference (favoring MSM) ($P = 0.009$) but not to the office location.
We found a center effect relating to feasibility of tests, lower in the office located in Eastern Paris (58.7%) than in the office located in the center of Paris (73.4%), \( P = 0.04 \). The center effect concerning feasibility of tests was related exclusively to regular tests, as we did not find any center effect concerning feasibility of rapid tests.

**Discussion**

Increasing the number of people aware of their status is a key issue of the epidemic. The most important results are the impressive high acceptability of rapid testing and very high acceptability of HIV testing in primary setting, our randomized study being the first showing the preference of users for rapid tests and a higher rate of people knowing the result of the test with rapid test. Subgroup analyses of acceptability were in favor of rapid tests, with the exception of MSM and patients belonging to HIV risk groups, perhaps due to lack of statistical power. All rapid tests were performed, resulting in feasibility of 100%. We did not find any center effect concerning feasibility of rapid tests, probably as rapid tests were free of charge for the study. In the regular test arm, the result was recovered in only half of patients who had accepted the prescription of the test. This difference concerning feasibility of the two strategies was due to a center effect concerning feasibility of regular tests which could be explained by difference in health insurance cover of patients (25.2% of patients in the office located in Eastern Paris, versus 7.8% of patients in the office located in the center of Paris without health insurance). The feasibility of regular tests, lower in the office located in Eastern Paris than in the office located in the center of Paris, was thus explained by a difference in health insurance cover of patients, lack of cover often leading to not performing regular tests, which needed to be paid first, before a reimbursement.

Previous non-randomized multi-center studies in France focused on use of rapid tests from FSB in Emergency Departments [17,18]. Acceptability and feasibility were lower, 69.6% and 90.9% respectively in those who accepted testing (3.9% of the eligible patients) in the first study, 63.1% and 96.4% respectively of the patients who accepted testing (16.3% of the eligible patients) in the second study, than the percentages that we observed. However, the settings: stressful emergency departments versus confidence in their GP differ. It could be thought that the relationship of the patients with their GPs, often for decades, might have led to embarrassment of the patients in answering a questionnaire about belonging to HIV risk groups and sexual preference, and to refusal of HIV testing. Our results do not support this hypothesis. Another mono-center non-randomized study was performed in France focused on use of rapid tests from FSB in Emergency Department [15], with acceptability and feasibility (88%) close to those found in our study.

A non-randomized multi-center study in France focused on use of rapid tests from FSB in general medicine [19], with very high acceptability and feasibility (99.7%); but the patients asked their GP to be tested. Focusing on use of regular tests in general medicine [16], we found previously acceptability similar to the results of the current study (61%). HIV testing was routinely offered to adult patients who had never been tested by a sample of trained French GPs over one week [20]. HIV testing was proposed to 50% of the patients and prescribed to 38%. Four out of ten of the tests prescribed were performed in laboratories. In a cross sectional survey of the barriers for implementing rapid tests among French GPs, the main reasons reported by uninterested GPs were: greater confidence in regular tests, difficulties including rapid tests during the routine consultation, difficulties to screen for other sexually transmitted infections simultaneously, and difficulties to deliver a positive result [21].

Several non-randomized studies of acceptability of targeted HIV screening, using rapid tests from FSB by GPs have been published in other developed countries: in Switzerland, targeting clients of sex workers [22,23] and in Belgium, targeting sub-Saharan African migrants [24,25]. However, the current knowledge of guidelines to physicians in Europe is somewhat worrying: among almost 200 GPs in UK, 44% of the respondents were unaware of the British HIV Association guidelines [26]. Thus, routine testing of people in general practice is still rare, less than 4% of more than 41 000 individuals in UK [27]. Acceptability of routine universal HIV testing with GPs using rapid tests from FSB was 45% in a pilot study in London [28]. In a report of rapid tests from FSB on the street on clients of sex workers in Switzerland [22], acceptability was 27.7%, but the "rapid" test used took about 30 minutes for availability of the results. The same team, two years later, reported acceptability reaching 45-50%, perhaps due to the training of practitioners [23]. In a study using the regular test or rapid tests from FSB by GPs in Belgium on a targeted population with a substantial African community [24], acceptability of the regular test (94%) was higher than in our study and acceptability of rapid test from FSB (94%) comparable to our results. In this study, a regular test was offered first, and, if accepted, a rapid test from FSB was then offered. The lack of randomization between the tests, each patient being offered both, explains that acceptability of regular test was equal to those of rapid test from FSB. Conway et al. [29] surveyed gay and bisexual men in Sydney to assess barriers to testing and characteristics associated with not having previously tested. At least one barrier to testing was reported by more than 95% of participants, the most commonly reported barrier was annoyance at having to return for results and stress in waiting for results. Never testing was independently associated with being non-gay-identified, and not knowing where to test. Some barriers at the level of the patient (fear and worries; accessibility of health services) and at health care provider level (low-risk
identified several years ago [30]. These results spoke strongly to the scarcity of financial and well trained human resources) were perceived as reluctance to address HIV and to offer the test. 

Our study has strength: due to the design of the study (adult outpatients recruited consecutively in days when the chief investigator of the study was present, alternately in one of the two general medicine offices at different days in the week in order to avoid biases due to possible consultations at fixed days for some patients), the reference population is representative of the overall population consulting the four GPs. One of the limits concerns the patients who declared having been tested HIV-negative in the previous three months, who were excluded from the study. We followed the French national guidelines, which recommended in 2013 that practitioners offer systematic testing to all adults without recent testing [11]. Nevertheless, we cannot exclude that some patients declared having been tested HIV-negative in the previous three months, as: 

• they did not want to be tested or, on the contrary; 
• they belonged to more informed groups and would have higher acceptability rates of HIV testing, whatever the used method.

And we did not collect the reasons of refusal, as it was not planned in the design of the study. Moreover, all the studied parameters were well-balanced between the two arms, except belonging to HIV risk groups, more common in the rapid test arm, by chance due to the sample size. This imbalance between the two arms could have contributed, although probably to a small proportion, to the observed higher acceptability in the rapid test arm than in the regular test arm. The other limits concern feasibility. The significant difference between the two methods could be due partly to cost: rapid tests were without any charge from the patients or the GP for the study whereas "regular" ELISA tests were with a charge, subsequently reimbursed by Social Security for affiliated patients. In real-life, the limitations of the routine universal HIV testing by using rapid test are the cost, supported by the GP, rather than the time needed to perform HIV testing (the test selected taking two minutes) and for counseling procedures (taking between five and ten minutes). Moreover, the results of the regular test were sent by mail or by secure e-mails from the laboratories (passive strategy). A higher rate could have perhaps resulted from an active strategy, if the patients in the regular arm without an available result one month later had been called by the GP. And we cannot exclude that some patients had performed "regular" ELISA tests later than one month after prescription and were therefore considered as not having performed the test. Furthermore, it would have been interesting to know the proportion of patients in the standard arm who received a prescription for other blood measurements, and what proportion of them effectively performed the HIV test. It may be assumed that patients with prescription for other lab measurements were more likely to perform the HIV testing than the other. Unfortunately, these data were not collected. Another limit was that the study did not involve GPs themselves, but the locum of the four GPs during their weekly rest days. Even he was present (alternately in one of the two offices at different days in the week) for several months, we cannot exclude that GPs might have more difficulties than the locum to address HIV testing and sexuality with well-known patients. Finally, our results have to be confirmed in other urban or rural areas from developed countries. Our multi-center prospective randomized study demonstrated that acceptability and feasibility of routine universal HIV testing of all adults consulting their GP in an urban area from a developed country were higher, using the rapid test from FSB than the ELISA test. The center effect concerning feasibility of regular tests, with a charge, contrasting with lack of center effect concerning feasibility of rapid tests from FSB, free of charge in our study, spoke for using free of charge rapid test from FSB. The reimbursement of rapid tests in France could have a major public health impact by increasing testing rates and reducing the pool of infected individuals unaware of their status. Complementary strategies, as self-tests, recently introduced in France, could contribute to increase too the number of people aware of their status, that is the key issue of the epidemic.

Authors’ contributions: HD, AL, DC, VD, PC, GS, JE, SM, JFB, PS have read and approved the final manuscript. HD performed all the interventions; AL, DC, VD, PC, JE, SM contributed to design the study and to write the manuscript; GS contributed to design the study, performed all the statistics and contributed to write the manuscript; JFB and PS supervised the design of the study and wrote the manuscript.

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