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Online self-sampling kits for human immunodeficiency virus and other sexually transmitted infections: Feasibility, positivity rates, and factors associated with infections in France

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Abstract

Background: Men who have sex with men are increasingly diagnosed with sexually transmitted infections (STI) in France. To address this situation, quarterly screening for HIV combined with hepatitis B (HBV) and hepatitis C (HCV), as well as annual screening for *C.trachomatis* (CT) and *N.gonorrhoeae* (NG) are recommended. The MemoDepistages program offered an at-home screening solution for these infections. This study describes the feasibility of this screening process, the rate of positive test results, and the factors associated with positivity.

Methods: Participants were recruited online. Laboratories verified the quantity and quality of the samples. Logistic regression was used to determine the associated factors for infection.

Results: Overall, 1556 out of 1908 (81.6%) blood samples were tested for at least HIV. A total of eight participants (0.5%) were newly diagnosed with HIV and four with HCV (0.3%). No new infection was confirmed for HBV. Overall positivity was 9.3% for CT and 9.6% for NG. The highest positivity was reported in rectal swabs for CT (7.3%) and in pharyngeal swabs for NG (7.2%). Factors associated with extragenital CT/NG were age under 30 years (for pharyngeal and rectal infections) and having at least 10 partners in the past 6 months ($p<0.001$) (for pharyngeal infections only).

Conclusions: The self-sampling kit for multiple STIs can perform comprehensive tests and identify new infections in young people, especially in extragenital sites.

Keywords

Screening, homosexuality, chlamydia (chlamydia trachomatis), gonorrhea (neisseria gonorrheae), HIV (Human immunodeficiency virus)

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Introduction

Men who have sex with men (MSM) have been disproportionately affected by the human immunodefiency virus (HIV) epidemic since its emergence in the 1980s. In France, this population accounted for 38% of undiagnosed HIV cases in 2014, while its incidence was estimated at 1.15%.[1] At the same time, MSM represent 81% of syphilis cases and 71% of gonococcal infections diagnosed in France.[2] To address this situation and adapt the screening process to sexually transmitted infections (STIs) in this at-risk population, the French National Authority for Health now recommends quarterly HIV screening for MSM if they have had several partners during the last year.[3] Combined screening for HIV, hepatitis B (HBV), hepatitis C (HCV), *Chlamydia trachomatis* (CT), and *Neisseria gonorrhoeae* (NG) and at least annual screening for syphilis are also advised.[4] Surveillance data showed that until 2016, the main screening site for CT and NG was the genital area.[2] The guidelines were updated in 2018, extending the reimbursement from one to three sites for CT and NG screening, because sexual health clinic data revealed a low rate of urine positivity but a high rate of infection in rectal and pharyngeal sites.[5]

In 2017, only 15% of French MSM had conducted at least three tests for HIV during the past 12 months.[6] To meet the guidelines for quarterly screening, solutions to facilitate different screening processes are currently being investigated in France. Even though HIV testing can be done through a wide range of testing solutions (reimbursed laboratory tests, free testing in sexual health clinics, rapid HIV tests, and over-the-counter blood-based HIV self-tests), testing options for other STIs are more limited. In France, rapid testing performed by non-governmental organizations has existed for HCV since 2016. For STIs other than HCV and HIV, testing is only possible at laboratories on prescription or in sexual health clinics. No self-testing or independent solutions are available.

As self-collected blood, urine, pharyngeal, and rectal samples are acceptable and feasible, this led to the development of the postal self-sampling kit (SSK).[7-9] Postal SSKs have been proven to increase not only screening for STIs, particularly in men, but also the rate of positive tests compared to clinician-collected samples.[10,11] Postal SSK services have been developed for the general population, as in the UK national self-sampling service and the SH:24 program,[12,13] or for specific populations like MSM[14] with the objective to address barriers to testing such as the need to make an appointment or even shame to ask for STI testing. The existing offer varies from an HIV-only test[12-14] to a multi-test kit with screening for several STIs, including HIV, syphilis, CT, NG, HBV, and HCV.[15-18] For MSM, the HIV positive test rate was nearly 1% in the UK national self-sampling service[13,16] and 2% in an MSM program organized by an MSM sexual health clinic.[14] It was higher in older MSM,[14] non-white MSM, and those engaging in condomless sex with more than six partners during the past year.[13] When CT and NG tests are offered, positivity is infrequently reported for MSM. The GetCheckedOnline program reported the highest positivity for CT in the rectum (5.1%) and for NG in the rectum and pharynx (2.8% and 2.4%, respectively).[18]

The profile of MSM using postal self-sampling services and testing positive for hepatitis, syphilis, CT, or NG is not well described. In France, previous restrictions relating to the reimbursement of STI screening led to insufficient epidemiological knowledge of these infections in terms of MSM characteristics and infection sites. A description of the results of such comprehensive testing solutions is still needed for different STIs.

Based on these experiences, the MemoDepistages study was developed in France to offer an at-home solution to screen for HIV and other STIs. At enrollment, a home-based kit for HIV, HBV, HCV, syphilis, CT, and NG screening was sent to MSM. We found that highly educated people aged under 30 years and with a recent HIV screening experience were more willing to complete the test after subscribing.[19] The potential to identify new infections using SSK thus needs to be investigated.

The objective of this study is to: (i) describe the feasibility of this screening process, (ii) provide the rate of positivity for each STI in the MemoDepistages population, and (iii) analyze the factors associated with positive tests for CT or NG in pharyngeal, urine, and rectal samples.

Materials and methods

Study population

The program was advertised on gay social media and a dating app (Hornet).[19] Participants were recruited between April 11 and June 10, 2018 after registering for the program and ordering an SSK. Consent was requested online. The study included men aged 18 years and over, living in one of the four French regions with the highest HIV prevalence (Auvergne-Rhone-Alpes, Ile-de-France, Occitanie Est, and Provence-Alpes-Côte d'Azur), and willing to provide their postal and email address; they had social security, reported more than one male partner in the past year, indicated a seronegative or unknown HIV status, and were not taking medically prescribed pre-exposure prophylaxis (PrEP) drugs. Recruitment and participation rates have been described elsewhere.[19]

Data collection

Sociodemographic and behavior data were collected online at the time of inclusion.

SSKs were shipped from a logistics platform to the participant within 48 h after being ordered.

The SSK contained two capillary collection lancets (BD Microtainer® contact-activated lancet, high blood flow), a microtube for the blood sample (BDMicrotainer® serum-separating blood collection microtube), rectal and pharyngeal swabs (Cobas R PCR Dual Swab Sample Kits or Abbott R multi-Collect Specimen Collection Kit) and a urine swab (Copan UriSwab™).[19] No testing selection was allowed at the time of the subscription, and all sample devices were sent to participants. The target for blood collection was 600 µl to allow for full testing. Illustrated sampling instructions were included in the SSK, along with details for phone assistance and links to online video instructions. All samples were collected by users and posted directly to the laboratory in a prepaid envelope.

Only kits sent back by participants between April 11 and August 31 were considered in this analysis. Kits were labeled "complete" when sent with a blood sample along with the urine, pharyngeal, and rectal swabs.

Biological analysis

In each region, a partner clinical laboratory received and performed the analysis according to their own equipment and capacity (see Supplementary file 1, which describes tests used for each laboratory). Test results were disclosed by a sexual health clinic according to participant preference (postal mail, text message, email, or phone call). For phone calls, three attempts were made with a voicemail message asking the participant to call back the clinic within 4 days. People who did not call back within 2 months for their results or treatment were defined as lost to follow-up.

Blood samples were accepted when received less than 8 days after sampling, not hemolyzed (>0.5 g/L), and yielding more than 100 µL serum.

Except for the syphilis test analyzed with a Bioplex assay in one laboratory, fourth-generation combo HIV tests were always given priority followed by other tests if the amount of biological material was sufficient. The order was chosen based on the prevalence level, the serum volume required for each test, and the risk exposure of MSM.

Qualitative detection of hepatitis surface antigen detection (HBsAg) and qualitative detection of hepatitis C virus antibody (anti-HCVAb) were performed. A new infection of HIV, HBV, and HCV was defined as a positive test confirmed by an antecubital blood sample test on individuals without known infection. This confirmation was provided by the sexual health center partner or other health facilities according to participant preference.

Samples were tested for syphilis markers depending on the recipient laboratory equipment: Bioplex Syphilis Total and Rapid Plasma Reagin (RPR) assay (Biorad, Hercules, Californie), Architect Syphilis TP Reagent Kit (Abbott Diagnostics, Hamburg, Germany), or Liaison XLTreponema screen (DiaSorin, Saluggia, Italy). RPR was not available for all MemoDepistages samples. New infection diagnoses were defined by medical history and/or additional blood tests. These investigations were conducted locally and not consistently documented. We defined positive syphilis tests as positive TP assays and did not report new syphilis infection in this article. Urinary, pharyngeal, and rectal swabs were tested separately using the PCR technique for CT and NG in all laboratories. For CT and NG infections, a newly diagnosed infection was defined as a positive PCR test.

Statistical analyses

A description of the sociodemographic characteristics as well as the sexual and preventive behavior of participants tested for at least one infection was performed. All variables were categorical. When the number of newly diagnosed individuals exceeded 10, a multivariate logistic regression using a backward-stepwise procedure was used to determine the associated factors for infection among the variables with a t<0.10 in univariate analysis. *p*-values of <0.05 were considered significant. To assess the positivity rate per infection site, only participants tested at the three sample sites (urinary, pharyngeal, and rectal) were considered for the CT and NG positivity rate analysis. All samples were tested, and all results were reported to participants, even those not included in this analysis.

All analyses were performed using STATA 14.0.

Results

Study population and population characteristics

Among the 3428 MSM who ordered the SSK, 1948 (56.8%) sent their samples to the laboratories. MSM tested using the MemoDepistages SSK were aged between 18 and 82 years, with a median of 30 years [IQR: 25–40]. The majority (*n*=1476/1948; 75.8%) had a college-level education, lived in a large city of more than 100,000 inhabitants (*n*=1076/1948; 55.2%), and considered their financial situation to be good or average (*n*=1637/1948; 84.0%). Most had their last sexual intercourse with a non-steady partner (*n*=1532/1948; 78.6%) and had more than four partners in the past 6 months (*n*=1227/1948; 62.9%). Just over half of them (52.1%) had been tested for HIV in the last 12 months, and nearly half for other STIs (*n*=1015/1948; 47.3%). Only 4.8% (*n*=93/1948) were experienced with PrEP (Table 1).

Biological analysis

For the blood sample, 1556 out of 1908 tests (81.6%) received by the laboratories were tested for at least HIV (see flowchart in Supplementary file 2). The reasons for the tests not being "valid" were insufficient blood volume (*n*=186/1908; 9.7%), hemolyzed samples (*n*=88/1908; 4.6%), and samples received more than 7 days after sampling (*n*=50/

Table 1. Description of the population, MemoDepistages, 2018 (*n*=1948).

	n	%		n	%
Age			Number of male sex partners in the past 6 months		
Under 30 years	897	46.0	0 or 1	90	4.6
30 years and over	1051	54.0	2 to 4	631	32.4
Place of birth			5 to 9	591	30.3
France	1766	90.7	10 or more	636	32.6
Overseas	182	9.3	Last partner		
Place of residence (inhabitants)			Steady	416	21.4
<2000	96	4.9	Non-steady	1532	78.6
2,000–19,999	312	16.0	Self-identified sexual orientation		
20,000–99,999	464	23.8	Homosexual	1632	83.8
>= 100,000	1076	55.2	Bisexual	209	10.7
Level of education			Other	107	5.5
High school or less	472	24.2	Frequenting gay meeting places (with/without sex)		
College or more	1476	75.8	Often	568	29.2
Professional situation			Sometimes	1022	52.5
Employed	1274	65.4	Never	358	18.4
Self-employed	162	8.3	Tested for HIV		
Unemployed	124	6.4	Several times in the past 12 months	508	26.1
Student	332	17.0	Once in the past 12 months	507	26.0
Other	56	2.9	At least once more than 12 months ago	733	37.6
Perceived financial situation			Never	200	10.3
Good	928	47.6	Tested for STIs other than HIV in the past 12 months		
Average	709	36.4	No	1026	52.7
Bad	311	16.0	Yes	922	47.3
Stable partner			With positive result	187	25.1
No	1439	73.9	PrEP* experienced		
Yes	509	26.1	No	1855	95.2
			Yes	93	4.8

*Preexposure prophylaxis.

1908; 2.6%). Several samples were also rejected for miscellaneous reasons (*n*=28/1908; 1.5%), including a problem with subject identification and an open sampling tube.

In total, 27 out of 1556 tested samples were positive for HIV (1.7%). On the confirmation test, 12 positive tests were negative (all in the same region), and seven samples were from people already diagnosed with HIV. Consequently, eight MSM were newly diagnosed with HIV infection (0.5% of tested samples). Among them, seven MSM lived in the Paris area, three were aged under 30 years, four were between 30 and 39 years, and one was over 40 years. Considering their recent sexual behavior, six had more than four partners in the past 6 months, six used a condom at their last intercourse, and seven had their last sexual intercourse with a non-steady partner. In relation to HIV testing, only one had never been tested, five had been tested over 1 year ago, and two were tested once in the last 12 months. The other tests showed that five out of eight HIV-positive MSM were coinfected with CT or NG in extragenital area.

For HCV, eight out of 1399 samples were tested positive (0.6%). Among them, four were newly confirmed positive (0.3% of tested samples), one was a false positive, and three participants were already aware of their infection.

For HBV, four out of 1244 samples were tested positive (0.3%). Among them, two participants were already aware of their infection, and two were lost to follow-up.

For syphilis, 1062 tests were performed, and 130 samples were tested positive for the treponemal test (12.2%). Nevertheless, 401 syphilis tests were not performed due to a supply shortage of Bioplex assay test in Paris laboratory, representing 21% of all the microtainers received.

All three swabs were received and acceptable in 1930 out of 1948 participants (99.1%) (Supplementary file 2). After biological analysis, all pharyngeal swabs were interpretable, although four urinary samples (0.2%) and 51 rectal swabs (2.6%) could not be analyzed.

Overall positivity was 9.3% (*n*=180/1930) for CT with the highest positivity found with the rectal swab (*n*=140/1930; 7.3%). For 80.0% of positive men, CT positivity concerned extragenital swabs and would not have been detected using urine-only samples. Three MSM were positive at all sites.

Overall positivity was 9.6% (*n*=186/1930) for NG, with the highest positivity found in the pharyngeal region (*n*=138/1930; 7.2%). For 94.6%% of positive men, NG positivity concerned extragenital swabs and would not have been found using a urine-only strategy. A total of 10 MSM were positive at all three sites.

When considering both CT and NG infections, 17.1% (*n*=329/1930) of tested individuals were positive at least at one site. The positivity rate of either NG or CT was 2.2% (*n*=43/1930), 8.7% (*n*=167/1930), and 10.6% (*n*=204/1930) for urine, pharyngeal, and rectal swabs, respectively (see Figure 1 and Supplementary file three which describe the positivity for each population group).

Associated factors

Factors associated with being infected with CT or NG varied depending on the location of infection. For rectal infections, the only associated factor was an age under 30 years (ORa= 2.1; IC95% [1.6–2.9]). For urinary infections, participants defining their sexual orientation as neither homosexual nor bisexual had a higher risk of having a positive result (ORa=3.0; IC95% [1.2–7.3] compared to self-identified "homosexual" men). For pharyngeal infections, most at-risk participants were under 30 years (ORa=2.1; IC95% [1.5–2.9]), had been screened at least once for HIV during the past year (compared to those screened more than 1 year ago or never screened), and had 10 partners or more in the past 6 months (ORa<1 for participants with less than 10 partners) (Table 2).

Discussion

Most of the returned SSKs contained all four of the requested samples, showing that when given a comprehensive and easy-to-obtain solution, MSM were highly compliant with the multisite collection and used it appropriately. Among the 1948 kits received, eight new HIV infections were detected. The study also found a high rate of CT and NG infections in extragenital sites.

In the international literature, the quality of blood sampling and the rate of positive tests depend on the target population and how postal SSKs are implemented.[6] In all the MemoDepistages laboratories, the main reason for rejecting the blood samples was insufficient volume. To address this issue, written and video instructions as well as phone assistance were provided to participants based on previous recommendations.[20] The instructions explained the necessity to wash the hands with warm water, stand during the sampling, and milk the finger for the blood testing. However, they did not recommend moving the arm in large circles, which has proven to be an effective method to enhance the blood flow in other projects. With less than 20% non-compliant blood samples, including 10% due to insufficient blood volume, the MemoDepistages program shows better performances than those observed in Sexual Health London (22.8% non-compliant blood samples)[16] or in a study comparing sampling devices where only 55.7% of microtubes could be tested.[21] However, the UK national self-sampling service, which is mainly used by MSM (74%), managed to test 92.6% of samples after 3 years of existence,[13] with an increase observed over the years. Such performances tend to improve over time, as participants become used to the procedure.

New HIV infections were identified through MemoDepistages, even though the positivity rate in our study is slightly lower than that previously observed in sexual health clinics (0.9% positivity in 2018).[22] New infections for HBV and HCV were very low, with cases being lost to follow-up, which did not occur for HIV. By contrast, the

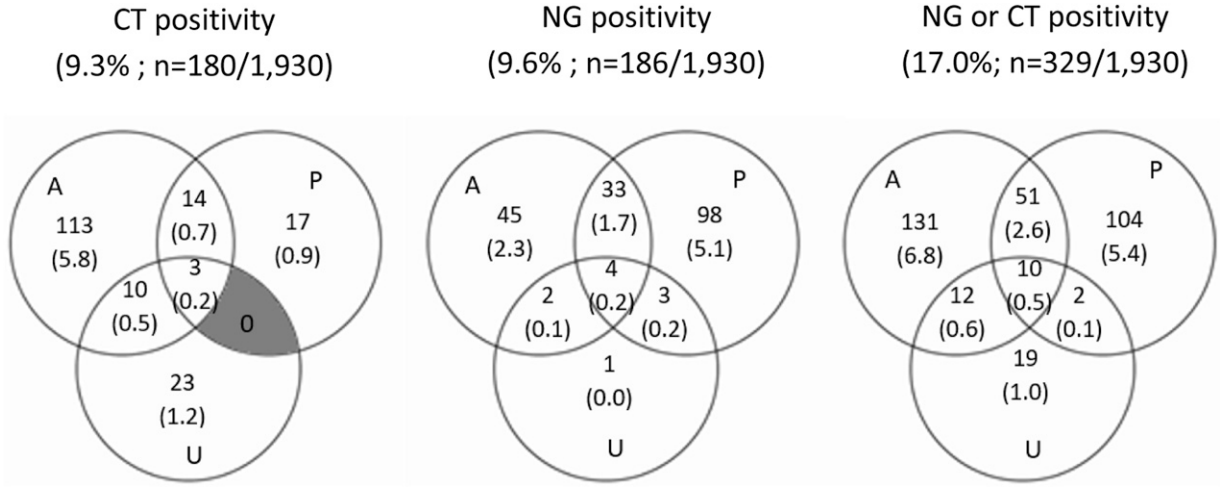

Figure 1. Number of positive tests for Chlamydia trachomatis (CT), Neisseria gonorrhoeae (NG), and CT or NG according to the testing site used during the first round of screening in the MemoDepistages program (2018). A=Anal, P=Pharyngeal, U=Urine.

Table 2. Factors associated with positive tests for Chlamydia trachomatis (CT) and *Neisseria gonorrhoeae* (NG) at each testing site, multivariate analysis MemoDepistages, 2018 (*N*=1930).

	n/N	ORa	p	CI 95%
Positive urinary test				
Self-identified sexual orientation				
Homosexual	170/1679	1		
Bisexual	22/206	1.24	0.67	[0.48 - 3.21]
Other	12/105	3.00	0.02	[1.23 - 7.34]
Positive anal test				
Age				
Under 30 years	128/886	2.14	<0.001	[1.58 - 2.89]
30 years and over	76/1044	1		
Positive pharyngeal test				
Age				
Under 30 years	101/886	2.11	<0.001	[1.52 - 2.94]
30 years and over	66/10441,044	1		
Tested for HIV				
Several times in the past 12 months	61/506	1		
Once in the past 12 months	41/500	0.72	0.12	[0.47 - 1.09]
At least once more than 12 months ago	52/727	0.64	0.03	[0.43 - 0.95]
Never	13/197	0.52	0.05	[0.28 - 0.99]
Number of male sex partners in the past6 months				
0 or 1	3act/90	0.24	0.02	[0.07 - 0.79]
2 to 4	37/621	0.46	<0.001	[0.30 - 0.70]
5 to 9	51/590	0.67	0.04	[0.46 - 0.97]
10 or more	76/629	1		

ORA Adjusted Odd Ratio.
CI 95%: Confidence interval 95%.

positivity rates for CT and NG were very high in this study. Pathogens are mainly found in pharyngeal and rectal sites, as observed in sexual health clinics.[5] In our participants, these sites were infrequently tested in the 12 months preceding the MemoDepistages program.[19] Urine positivity matched the lowest positivity observed in two previous French studies for this population.[5,23] This positivity mostly concerned men who did not identify themselves as homosexual or bisexual. As CT tests are recommended every 3 months for MSM, the CT test offer depends on the heterosexual men having a new partner or being diagnosed with another STI. As a result, self-identified heterosexual men are screened less often than MSM, even in sexual health clinics.[22] Participants who do not identify as MSM may not be offered the opportunity to be screened for these infections in a medical setting. MemoDepistages acted as a "catch-up" system for these men by removing the need to discuss their sexuality in order to access screening.

For extragenital sites, infections were more frequent in men under 30 years. This population also completed the MemoDepistages screening more frequently than older men when they subscribed to it,[19] highlighting the pertinence of this screening process for them.

Pharyngeal positivity showed a peculiarity: positive tests were more frequent in men with 10 partners or more, but also in men who were tested the most frequently for HIV. This result showed that even when the participant identifies himself to be at risk for HIV infection and complies with the recommendations, pharyngeal tests are not systematically offered (in line with the current guidelines), thus leading to missed opportunities to break the cycle of new infections. These data support the 2018 evolution of the guidelines, which recommend the reimbursement of testing at the three anatomical sites. As very few urine-only infections were confirmed, to identify undiagnosed infections, pharyngeal and rectal tests are the most effective means, as previously shown in a sexual health clinic population.[5]

Due to increasing antimicrobial resistance, screening for asymptomatic bacterial infections is currently under debate, particularly for CT.[24] However, MemoDepistages showed that a multi-pathogen screening offer is attractive to MSM and represents an opportunity to test for and find viral infections, especially in CT/NG positive men.

Our study has several limitations. A low rate of positivity is the main issue with this screening system for HIV. The rate of HIV false positives in our study (0.7%) was higher than in other studies,[13,16] and the limited sample volume did

not allow us to perform additional confirmation tests. In this context, the need for further blood draws increased participants' anxiety and led to a delay in the final test result. Implemented in four different French regions and in real-life settings, the biological tests were not identical in each laboratory. Indeed, tests with all false positives being found in a single laboratory.

In the study, the syphilis testing strategy was not highly effective for detecting recent infections. First, a supply shortage in BioplexTP and RPR assays in one laboratory resulted in no syphilis tests being analyzed for 21% of the microtainers. Second, in another laboratory, a positive test for TP or RPR resulted in a medical follow-up to define the status of the infection. Most investigation interviews did not result in the identification of an active infection because of the high prevalence of past infections in the study population. Moreover, the data collection of the confirmation tests for participants with a positive test was incomplete. The use of both TP and non-treponemal tests (VDRL, RPR), which need only a small amount of blood, will be most relevant for such a program. Further, the collection of more information at enrollment could help differentiate recent from old ancient infections and simplify the medical interviews.

Postal SSKs for several infections can perform comprehensive tests and identify new infections, especially in extragenital sites. The analysis of the factors associated with positivity highlights the importance of targeting at-risk young people for non-genital screening in a self-sampling program.

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Author Contributions

DR& NL conceptualized and managed the study; HD, BB CD, HS, TTLT, VI, KH, JD, &ET contributed to the study design; DR, HD, AG, EV, PV, BL, & AP managed the data collection; DR cured, analyzed, and interpreted the data to write the first full draft of the manuscript; NL &SV provided intellectual input for the data interpretation and reviewed the first draft of the manuscript.

Declaration of conflicting interests

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The protocol was approved by local authorities under number ID RCB 2017-A00838-45 and by the ethics committee CPP-OuestII-ANGERS.

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Supplemental Material

Supplemental material for this article is available online.

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