




TESTATE STI project: an online chlamydia and gonorrhoea self-sampling strategy for gay, bisexual and other men who have sex with men and trans people in Catalonia (Spain)

Héctor Martínez-Riveros ^{1,2,3} Victoria Gonzalez Soler ^{2,4,5} Yesika Díaz,^{2,4} Marcos Montoro-Fernandez,² Gema Fernandez-Rivas,⁵ Carles Pericas,⁶ David Palma,^{4,6} Marta Villar,⁷ Héctor Adell,⁷ Héctor Gonzalez Quiles,⁸ Javier Sotomayor Cortés,⁹ Silvia Gomez,² Aida Ramirez Marinero,⁵ Pol Romano-de Gea,^{2,3} Esteve Muntada,² Jordi Casabona,^{2,3,4,10} Cristina Agusti ^{2,3,4}

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For numbered affiliations see end of article.

Correspondence to

Héctor Martínez-Riveros; hmr.badalona@gmail.com

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ABSTRACT

Objectives TESTATE STI is an online offer of self-sampling kits (SSKs) for the detection of *Chlamydia trachomatis* (CT) and *Neisseria gonorrhoeae* (NG) among gay, bisexual and other men who have sex with men (GBMSM) and transgender people (TG) in Catalonia. The aims of this study are: 1) to develop and evaluate the effectiveness, satisfaction and willingness of a pilot online intervention that includes the offer of SSKs for CT/NG screening with online consultation of subsequent results and (2) to analyse its potential as an effective strategy to encourage diagnosis, linkage to treatment and to describe contact notification by participants with a positive diagnosis.

Methods The distribution of SSKs, which included a urine collection tube, a pharyngeal and a rectal swab, was conducted through two recruitment strategies: autonomously via social media and GBMSM or TG leisure spaces, or accompanied by community-based organisations. Participants completed a socio-demographic, biobehavioural and satisfaction survey.

Results A total of 386 kits were tested in the laboratory. The estimated positivity rate for having at least one STI was 20.7%. TESTATE STI indicates that approximately 90.0% of positive participants were extragenital. 81.0% of positive cases were linked to the health system, and 96.9% of those were treated. We estimate that five kits must be performed to detect a positive CT/NG with the TESTATE STI intervention. Almost all participants (98.8%) would recommend taking the chlamydia and gonorrhoea self-sampling with TESTATE STI.

Conclusion The TESTATE STI project concluded that the deployment of SSKs for the detection of CT/NG is a viable and feasible strategy for GBMSM and TG in Catalonia. TESTATE STI is an effective strategy for encouraging diagnosis, treatment linkage and contact notification. Implementing TESTATE STI would increase access to confidential testing and promote early STI detection.

INTRODUCTION

In 2020, the incidence of sexually transmitted infections (STIs) in the European region, according

WHAT IS ALREADY KNOWN ON THIS TOPIC

⇒ The TESTATE platform validated HIV and HCV self-sampling was validated and accepted in Spain for gay, bisexual and other men who have sex with men (GBMSM) and transgender people (TG). In the same population, in other parts of Europe and the world, there were known studies for *Chlamydia trachomatis* (CT) and *Neisseria gonorrhoeae* (NG) that were already valid. Additionally, different studies confirm that samples taken by patients and doctors are equally accurate in diagnosing CT and NG at extragenital sites.

WHAT THIS STUDY ADDS

⇒ This is the first time that an online platform (www.testate.org) has been used in Catalonia (Spain) to offer STI self-sampling kits in GBMSM and TG.

HOW THIS STUDY MIGHT AFFECT RESEARCH, PRACTICE OR POLICY

⇒ TESTATE ITSSTI is an effective strategy to encourage diagnosis, linkage to treatment and contact notification. The implementation of TESTATE ITSSTI would increase access to confidential testing and promote early detection of STIs.

to WHO, was 23 million.¹ In 2022, in Catalonia, gay, bisexual and other men who have sex with men (GBMSM) were the second-largest group to report a *Chlamydia trachomatis* (CT) infection (22.8%) and the first in *Neisseria gonorrhoeae* (NG) infection (54.3%).² In relation to transgender people (TG), 27 cases of CT and 40 cases of NG were reported.²

Barriers to healthcare access for GBMSM and TG in Catalonia include cultural and language differences, administrative challenges and stigma, leading to unmet healthcare needs, especially in STI services.^{3,4}



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Telemedicine offers different benefits for patients and has been shown to be at least as cost-effective as traditional clinical care for infectious diseases. Self-sampling for STIs/HIV from web-based platforms is a valuable strategy to offer variety within sexual health services.⁵

Studies confirm that there is no difference in diagnostic accuracy between self-samples taken by patients and those taken by clinicians; they are equally accurate in diagnosing CT and NG in extragenital sites.⁶

The TESTATE (*Test Yourself* in Spanish) online platform for offering self-sample collection kits demonstrated high acceptability and feasibility in providing HIV and hepatitis C virus (HCV) kits to GBMSM and TG women in Spain.^{7,8} The objectives of the TESTATE STI study were: (1) to develop and evaluate the effectiveness, satisfaction and willingness of a pilot online intervention in Catalonia offering self-collection kits for CT/NG screening with online consultation of subsequent results and (2) to analyse its potential as an effective strategy to encourage diagnosis, facilitate linkage to treatment and to describe contact notification by participants with a positive diagnosis.

METHODS

Study design and inclusion criteria

The pilot intervention was based on the TESTATE project.^{7,8} The study consisted of offering CT and NG self-sampling kits (SSK) online through a secure website. This was a prospective, non-randomised study involving GBMSM and TG aged ≥ 18 years living in Catalonia.

Recruitment took place over 7 months in two phases: (1) December 2021 to February 2022 and (2) January 2023 to June 2023. Participants were recruited through two strategies: (1) autonomous self-access via the project website, through online banners on social networks (Telegram, X, Instagram, non-governmental organisation (NGO) websites and others) or advertisements in GBMSM or TG leisure spaces and (2) accompanied recruitment in community centres in Catalonia (community-based voluntary counselling and testing (CBVCT)), where participants were invited to participate and provided with a space for self-sampling. This was done in collaboration with the Barcelona Public Health Agency and three NGOs (ColorsSitgesLink, STOP and AntisidaLleida) in Catalonia.

Web-based intervention and participatory process

The website (<https://testate.org/>), which was originally designed only for HIV and HCV self-sampling, was extended to include the offer of free SSK for the molecular detection of CT and NG. The procedure consisted of five steps (online supplemental figure 1): (1) access, information and informed consent form; (2) request a free NG and CT SSK and complete an online survey on socio-demographic and behavioural data (age, gender, country of birth, size of city of residence, sexual orientation, HIV testing, STIs diagnosed in the past 5 years, condom use, number of sexual partners in the past 12 months, chemsex and PrEP use); (3) the SSKs were delivered by mail (inside white envelopes) or in person at the CBVCTs; (4) samples were sent free of charge by the participants themselves in the self-recruitment mode, or, by the CBVCTs in the accompanied mode. SMS alerts were sent explaining how to consult the results privately on the website and (5) complete an anonymous survey (satisfaction, willingness to repeat or recommend the service, perceived advantages or disadvantages, and preferred way of receiving the results).

Self-sampling kits and laboratory methods

SSK included a tube for urine collection (Sarstedt, Nümbrecht, Germany) and a pharyngeal and a rectal swab for sample collection (Molecular Biology Swabs, Deltalab, Rubí, Spain)—these swabs are pending CE Mark approval for self-sample collection in Spain.

Samples were received at the Microbiology Service of the Laboratorio Clínico Metropolitana Norte at the Hospital Universitari Germans Trias i Pujol. During the first phase, pharyngeal and rectal samples were pooled for CT/NG detection, and the real-time PCR technique (BD Max CT/GC assay, Becton Dickinson, Franklin Lakes, New Jersey, USA) was used according to the manufacturer's instructions. Remaining samples were tested using the Allplex STI Essential Assay (Seegene, South Korea), which includes CT, *Mycoplasma genitalium*, *Mycoplasma hominis*, NG, *Trichomonas vaginalis*, *Ureaplasma parvum* and *Ureaplasma urealyticum*, following the manufacturer's instructions.

Follow-up of positive participants

SMS alerts were sent to participants to inform them that they could view their results privately on the website. Results were categorised as positive, negative or invalid for each site (oral, pharyngeal and rectal) and whether they were NG and/or CT. Positive cases were advised on the website to contact their general practitioner, STI centre or CBVCT. After reviewing the participants' results, the coordinating centre contacted them by telephone 2–4 weeks later. The purpose of this contact was to find out whether they had accessed the health system, received treatment and provided information to their sexual partners in the previous 2 months. If they had not, they were encouraged to do so. The information was self-reported by the participant.

Evaluation of the intervention

The feasibility of the TESTATE STI screening strategy was evaluated among its users based on previous models used in TESTATE HIV⁷ and TESTATE C PLUS.⁸ The adapted framework divides the concept of feasibility into the following subdomains: effectiveness, satisfaction and willingness.

Effectiveness was defined as the participants' ability to make the effort and take the time to order the SSK, obtain the sample, send it to the reference laboratory, consult the results online and follow the linkage procedure to health-care, if necessary. Satisfaction was described as the perception that getting tested for NG and CT through the TESTATE intervention was convenient and that it was a process they would like to experience again. Willingness was defined as the participants' intention to follow the entire procedure.

The number of individuals with a positive result for either STI among all individuals tested (positivity rate) was calculated. The prevalence and 95% CI of CT and NG were estimated. The number of tests required to detect a positive result was calculated using Ene (V.3.0), assuming a precision of 1.0%.

The linkage to care rate was assessed by calculating the proportion of people who were positive for NG or CT, and reported having been linked and/or treated by a specialist.

A descriptive analysis was conducted comparing socio-demographic characteristics, behavioural characteristics and risk of STI acquisition. The STI cascade of care was calculated.

RESULTS

Response rates to the intervention are shown in online supplemental figure 2. A total of 493 people requested an SSK, 333 were recruited autonomously and 160 were accompanied in CBVCT. The return rate for autonomous participants was 67.9% (226/333), and 100% for accompanied participants (160/160). In total, 386 kits were analysed in the laboratory.

A total of 1158 samples (386 urine, 386 pharyngeal and 386 rectal) were analysed in the laboratory. Of these, 0.56% of the urine samples and 1.12% of the rectal self-samples

were invalid, while 100% of the pharyngeal samples were valid.

STI prevalence and participant characteristics

Table 1 presents the main characteristics of all TESTATE STI participants.

Their socio-behavioural characteristics are listed in online supplemental table 1. 183 individual (37.2%) had 10 or more penetrative sexual partners in the previous 12 months. Not using a condom in their last penetrative intercourse was

Table 1 Main population characteristics from TESTATE STI (December 2021–June 2023, Catalonia, Spain; n=493)

	Sent (n=493)	Received (n=386)	Negative (n=307)	Positive (n=79)	P value (overall)
Median age (IQR)	34(28–41)	33(28–41)	34(28–41)	31(26–37)	0.026
Gender					0.478
Cis man	468 (94.9%)	361 (93.5%)	289 (94.1%)	72 (91.1%)	
Trans person	25 (5.1%)	25 (6.5%)	18 (5.9%)	7 (8.9%)	
Trans person					0.419
Trans man	1 (4.0%)	1 (4.0%)	1 (5.6%)	0 (0.0%)	
Trans woman	21 (84.0%)	21 (84.0%)	16 (88.9%)	5 (71.4%)	
Non-binary person	3 (12.0%)	3 (12.0%)	1 (5.6%)	2 (28.6%)	
Sexual orientation					0.113
Gay	392 (79.5%)	298 (77.2%)	234 (76.2%)	64 (81.0%)	
Bisexual	82 (16.6%)	69 (17.8%)	60 (19.5%)	9 (11.4%)	
Straight	16 (3.3%)	16 (4.2%)	10 (3.7%)	6 (7.6%)	
DK/DA	3 (0.6%)	3 (0.8%)	3 (1.0%)	0 (0.0%)	
Country of birth					0.004
Spain	321 (65.1%)	235 (60.9%)	199 (64.8%)	36 (45.6%)	
Other	166 (33.7%)	149 (38.6%)	106 (34.5%)	43 (54.4%)	
DK/DA	6 (1.2%)	2 (0.5%)	2 (0.7%)	0 (0.0%)	
Town or city inhabitants					0.743
>1 million inhabitants	295 (59.8%)	236 (61.1%)	183 (59.6%)	53 (67.1%)	
Between 500 000 and 999 999 inhabitants	2 (0.4%)	2 (0.5%)	2 (0.7%)	0 (0.0%)	
Between 100 000 and 499 999 inhabitants	90 (18.3%)	66 (17.1%)	54 (17.6%)	12 (15.2%)	
Between 49 000 and 99 999 inhabitants	25 (5.1%)	19 (4.9%)	16 (5.2%)	3 (3.8%)	
Between 10 000 and 49 000 inhabitants	67 (13.6%)	53 (13.7%)	45 (14.7%)	8 (10.1%)	
<10 000 inhabitants	14 (2.8%)	10 (2.6%)	7 (2.3%)	3 (3.8%)	
Level of studies					0.372
Never went to school	2 (0.4%)	2 (0.5%)	2 (0.7%)	0 (0.0%)	
Complete primary school	7 (1.4%)	6 (1.6%)	4 (1.3%)	2 (2.5%)	
Complete secondary school	66 (13.4%)	54 (14.0%)	39 (12.7%)	15 (19.0%)	
Complete vocational studies	106 (21.5%)	82 (21.2%)	64 (20.9%)	18 (22.8%)	
Complete Baccalaureate	161 (32.7%)	130 (33.7%)	102 (33.2%)	28 (35.4%)	
Postgraduate studies (master, PhD, etc)	149 (30.2%)	111 (28.8%)	95 (30.9%)	16 (20.2%)	
DK/DA	2 (0.4%)	1 (0.3%)	1 (0.3%)	0 (0.0%)	
HIV positive					0.630
Yes	44 (8.9%)	34 (8.8%)	25 (8.1%)	9 (11.4%)	
No	410 (83.1%)	325 (84.2%)	261 (85.0%)	64 (81.0%)	
DK/DA	39 (7.9%)	27 (7.0%)	21 (6.8%)	6 (7.6%)	
Taking PrEP:					0.043
Yes	105 (23.4%)	81 (23.0%)	58 (20.6%)	23 (32.9%)	
No	343 (76.4%)	271 (77.0%)	224 (79.4%)	47 (67.1%)	
DK/DA	1 (0.2%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	
Sex work:					<0.001
Yes	77 (15.6%)	72 (18.7%)	46 (15.0%)	26 (32.9%)	
No	416 (84.4%)	314 (81.4%)	261 (85.0%)	53 (67.1%)	

DA, don't ask; DK, don't know; STI, sexually transmitted infection.

reported by 59.2% and 17.0% had engaged in chemsex in the previous year. Furthermore, 29.0% of participants reported that they had never been tested for CT or NG before, indicating that they were first-time testers.

Seventy-nine positive results were detected for NG and/or CT. The positivity rate for having at least one STI (NG and/or CT) was 20.7% (95% CI 15.2 to 25.7). Among the participants who tested positive for CT and/or NG, 76 (96.2%) reported having no symptoms. Additionally, 10.1% (8/79) of the positive cases were positive for both CT and NG.

Among the 79 positive participants, the median age was 31 years (IQR 26–37) ($p=0.026$), and 54.4% were migrants ($p=0.004$). In the past 12 months, 32.9% had engaged in sex work ($p<0.001$). In addition, of the HIV-negative participants, they were taking PrEP regularly ($p=0.043$) (table 1). We estimated the prevalence of CT to be 12.7% (95% CI 9.4 to 16.0), and NG to be 9.8% (95% CI 6.9 to 12.8). We estimate that approximately five kits (≈ 4.9) should be performed to detect a positive case of CT or NG.

Eleven infections (10 CT and one NG) were detected in the urine self-samples (11/386, 2.9% of total urine samples). Of the extragenital self-samples that were analysed without pooling ($n=320$), 46 infections (30 CT and 16 NG) were detected in the rectum (46/320, 14.4%), and 31 infections (eight CT and 23 NG) in the pharynx (31/320, 9.7%).

Effectiveness

In the service cascade, we assessed the effectiveness of the process among participants who tested positive. A total of 79 positive results were identified (positivity rate of 20.5%, 79/386). Of these, 64 (81.0%, 64/79) were linked to care, and 62 (96.9%, 62/64) received treatment. Finally, 49 (79.0%, 49/62) contacted one or more of their sexual partners (online supplemental figure 3).

Satisfaction

Eighty-four responses to the anonymous satisfaction survey were received, representing 21.8% of the returned kits (online supplemental table 2). The average score for evaluating the experience was 4.7/5. The most commonly identified advantages were convenience (95.2%) and privacy (84.5%). In response to the question, “What do you think is the best way to receive your result?”, the preferred methods of results delivery, if given a choice, were via the web (72.6%) and SMS (22.6%).

Willingness

Among participants who responded to the survey (online supplemental table 2), 97.6% indicated that they would repeat the process, and 98.8% stated that they would recommend the chlamydia and gonorrhoea self-sampling offered by TESTATE STI.

DISCUSSION

The TESTATE STI study demonstrates that offering SSKs for the detection of CT/NG in the rectum, pharynx and urine, as well as the online consultation of results, is feasible in Catalonia, as it is in other European^{9 10} and Asian¹¹ states. This intervention has enabled access to CT/NG screening for individuals at risk of acquiring STIs. Additionally, we highlight that the study has provided first-time access to testing for 143 participants (29.0%) who had never been tested for STIs before.

Previous studies of postal SSK in GBMSM at the European level have had a lower prevalence of CT in the UK (5.9% vs 12.7%) and France (9.3% vs 12.7%), while in Hong Kong, a

higher prevalence was observed (16.0% vs 12.7%).^{9–11} Regarding NG, the prevalence detected in our study was higher than in the studies mentioned above: the UK (4.5% vs 9.8%), France (9.6% vs 9.8%) and Hong Kong (7.0% vs 9.8%).^{9–11} The higher prevalence of STIs observed in this study compared with others can be explained by the characteristics of the target population (GBMSM and TG), who have higher STI rates in our region.² In addition, most of the STI cases in our sample came from large cities, and several studies have shown that GBMSM in urban areas have higher STI incidence rates in Catalonia.¹² The self-recruitment of the sample in leisure spaces and NGOs may have favoured the participation of individuals with greater exposure to risk. It should be noted that, as this was an opportunistic sample, the results are not representative of the entire GBMSM and TG population in Catalonia.

All three studies tested for CT and NG in the rectum, pharynx and urine. As in the TESTATE STI study, approximately 90% of participants had positive extragenital samples. Among all participants positive for NG/CT, 89.9% (71/79) were positive in an extragenital area. Therefore, urine screening may be given less priority than it is currently given in traditional clinical practice. These shared results support the need to always test at all three sites in both GBMSM and TG.

We estimate that only five STI SSKs need to be performed to diagnose one person with a positive CT or NG result through the TESTATE STI intervention. A cost-benefit analysis of TESTATE ITS is necessary, and further research is required to assess the sustainability of the TESTATE intervention.

The TESTATE STI study demonstrated high rates of linkage to the health system (81.0%) and of infected individuals accessing treatment (96.9%), comparable with the online self-sampling study for HIV in Spain (TESTATE HIV),⁷ and showed higher linkage than the HCV study (TESTATE C PLUS).⁸ The high linkage rate observed in our study can be attributed to several factors, including comprehensive follow-up, the involvement of community-based organisations, accessible online consultations of the public Catalan Healthcare System and the proactive engagement of GBMSMs and TGs in seeking healthcare. However, around 20% of participants were lost to follow-up. It is plausible that these individuals sought medical care and received treatment, and even informed their partners, but we were unable to ascertain this information for a variety of reasons, such as lack of response, possible changes in contact (phone or email) or other factors.

E-health tests like TESTATE can potentially address barriers to healthcare access for vulnerable populations, such as cultural and language differences, administrative challenges and stigma. While our results show high utilisation and satisfaction, they do not provide direct evidence of overcoming these barriers. The design aimed to reduce barriers through anonymous access and community involvement. However, future research should explicitly evaluate this impact, incorporating qualitative data to explore how the platform may have helped participants overcome these obstacles.⁴

Political will is needed to implement this strategy in Spain and to overcome institutional obstacles, such as legal issues and sample transport.

Asymptomatic GBMSM and TG can transmit STIs.^{13 14} Kenyon *et al*¹⁴ express doubts about screening for some STIs in asymptomatic individuals because of possible microbial resistance. From TESTATE STI, we argue that it is important to continue screening key populations given the known risks of STIs. It is essential to identify asymptomatic individuals to break the chain of transmission, initiate early contact tracing, avoid

sequelae and prevent transmission of other STIs,¹³ including HIV.

Our study has several limitations. The sample, while representing users of the TESTATE service, was self-selected, making it opportunistic and not representative of all GBMSM and TG in Catalonia. The TG sample size was small. Additionally, it was unclear whether participants who did not return their samples chose not to or if they were lost in shipment.

The study also has strengths. The website is easily adaptable for self-sampling or self-testing for other populations that are used to new technologies, such as the youth population.

In conclusion, TESTATE STI is an effective strategy for encouraging diagnosis, treatment linkage and contact notification by GBMSM-positive and TG-positive participants. Defining the target population with cost-effectiveness criteria and addressing legal challenges in Spain is necessary. Implementing TESTATE STI would increase access to confidential testing and promote early STI detection. The public health impact of online self-sampling services is tied to detection, diagnosis and treatment rates.

Author affiliations

¹Doctorate Programme in Methodology of Biomedical Research and Public Health, Department of Paediatrics, Obstetrics and Gynaecology and Preventive Medicine, Universitat Autònoma de Barcelona, Barcelona, Catalunya, Spain

²Centre of Epidemiological Studies of HIV/AIDS and STI of Catalonia (CEEISCAT), Health Department, Generalitat de Catalunya, Badalona, Barcelona, Spain

³Germans Trias i Pujol Research Institute (IGTP), Campus Can Ruti, Badalona, Catalunya, Spain

⁴Biomedical Research Center Network for Epidemiology and Public Health (CIBERESP), Instituto de Salud Carlos III, Madrid, Comunidad de Madrid, Spain

⁵Microbiology Department, Clinical Laboratory North Metropolitan Area, Germans Trias i Pujol University Hospital. Department of Genetics and Microbiology, Univ Autònoma de Barcelona, Badalona, Catalunya, Spain

⁶Epidemiology service, Agència de Salut Pública de Barcelona (ASPB), Barcelona, Catalunya, Spain

⁷ONG Stop, Barcelona, Catalunya, Spain

⁸Fundació Antisida de Lleida, Lleida, Spain

⁹Colors Sitges Link, Barcelona, Spain

¹⁰Department of Paediatrics, Obstetrics and Gynaecology and Preventive Medicine, Universitat Autònoma de Barcelona, Badalona, Catalunya, Spain

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X Héctor Martínez-Riveros @hectorgranota

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ORCID iDs

Héctor Martínez-Riveros <http://orcid.org/0000-0003-3372-6134>

Victoria Gonzalez Soler <http://orcid.org/0000-0003-3787-0272>

Cristina Agusti <http://orcid.org/0000-0002-5259-2242>

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