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The 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)

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KEYWORDS

STI, online testing, GBMSM, Transgender, chlamydia, gonorrhoea

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. Aims: 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 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. 810% of positive cases were linked to the health system, and 96.9% of those were treated. We estimate that 5 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-test 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.

STATEMENTS AND DECLARATIONS

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Montoro-Fernández and Y. Díaz did the statistical analysis. V. Gonzalez, G. Fernandez-Rivas, and A. Ramirez Marinero were responsible for the laboratory analysis. C. Pericas, D. Palma, H. Adell, M. Villar, H. Gonzalez Quiles, and J. Sotomayor Cortés collaborated with the recruitment of participants in the community entities. S. Gomez assisted with the field work. All signatories have read, reviewed and approved the final version prior to its submission for publication.

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INTRODUCTION

In 2020, the incidence of STIs in the European Region, according to the 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) (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).

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 offer and self-sample collection platform demonstrated high acceptability and feasibility in providing HIV and HCV kits to GBMSM and TG woman 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 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-randomized study involving GBMSM and TG individuals 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, NGO websites and others) or advertisements in GBMSM or TG leisure spaces ; 2) Accompanied recruitment in community centres in Catalonia (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 (ASPB) 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 (**Supplementary Figure 1**):

1) Access, information, and informed consent form. 2) Request a free NG and CT self-sampling kit 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. 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 (HUGTiP). 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, NJ) was used according to the manufacturer's instructions. Remaining samples were tested using the Allplex™ STI Essential Assay (Seegene Inc, South Korea), which includes *C. trachomatis*, *Mycoplasma genitalium*, *Mycoplasma hominis*, *N. gonorrhoeae*, *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 categorized 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 two to four 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 two 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 HIV (7) 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 self-sampling kit, 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% confidence interval of CT and NG were estimated. The number of tests required to find a positive result was calculated using Ene (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.

Ethics statement

All identifying data collected on the website was encrypted. The study was approved by the Ethics Committee of the Hospital Germans Trias i Pujol (PI 21-172), and all participants signed the informed consent form.

RESULTS

Response rates to the intervention are shown in **Supplementary 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 **Supplementary Table 1**. 183 (37.1%) had had 10 or more penetrative sexual partners in the previous 12 months. Not using a condom in their last penetrative intercourse was 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 15.2-25.7). 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 ($p=0.043$) (Table1). We estimated the prevalence of CT to be 12.7% (95% CI 9.4-16.0), and NG to be 9.8% (95% CI 6.9-12.8). We estimate that approximately 5 kits (≈ 4.9) should be performed to detect a positive case of CT or NG.

Eleven infections (10 CT and 1 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 (8 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 (**Supplementary Figure 3**).

Satisfaction

Eighty-four responses to the anonymous satisfaction survey were received, representing 21.8% of the returned kits (**Supplementary table 2**). The average score for evaluating the experience was 4.74/5. 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?", if they had a choice the preferred methods of results delivery were via the web (72.6%) and SMS (22.6%). Additionally, 97.6% of respondents expressed their intention to repeat the process, and the vast majority (98.8%) indicated that they would recommend the chlamydia and gonorrhoea self-test offered by TESTATE STI.

Willingness

Among participants who responded to the survey (**Supplementary 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 Asian (11) 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 to others can be explained by the characteristics of the target population (GBMSM and transgender people), 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 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 weight 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 5 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 to the online self-sampling study for HIV in Spain (TESTATE HIV)(7), and showed higher linkage than the hepatitis C virus 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 Health Care 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 utilization and satisfaction, they don't 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.

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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.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
More than 1 million inhabitants	295 (59.8%)	236 (61.1%)	183 (59.6%)	53 (67.1%)	
Between 500,000-999,999 inhabitants	2 (0.4%)	2 (0.5%)	2 (0.7%)	0 (0.0%)	
Between 100,000-499,999 inhabitants	90 (18.3%)	66 (17.1%)	54 (17.6%)	12 (15.2%)	
Between 49.000-99.999 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%)	
Less than 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%)	
Post-graduate 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%)	
Number of times charged for sex work in the last 12 months:					0.690
1 - 2	6 (7.8%)	5 (6.9%)	3 (6.5%)	2 (7.7%)	
3 - 10	15 (19.5%)	13 (18.1%)	10 (21.7%)	3 (11.5%)	
11 - 50	23 (29.9%)	21 (29.2%)	13 (28.3%)	8 (30.8%)	
More than 50	28 (36.4%)	28 (38.9%)	18 (39.1%)	10 (38.5%)	
DK/DA	5 (6.5%)	5 (6.9%)	2 (4.4%)	3 (11.5%)	