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## LETTER

### **An on-line hepatitis C virus self-sampling strategy for gay, bisexual and other men who have sex with men and trans women: TESTATE C PLUS 2020-2021**

Héctor Martínez-Riveros<sup>1, 2, 3</sup>, Elisa Martró<sup>3, 4, 5</sup>, Marcos Montoro-Fernandez<sup>1</sup>, Yesika Diaz<sup>1, 5</sup>, Esteve Muntada<sup>1</sup>, Pol Romano-deGea<sup>1, 2</sup>, Sergio Moreno-Fornés<sup>1, 5</sup>, Rubén Mora<sup>6</sup>, Luis Villegas<sup>6</sup>, Juan Mena<sup>6</sup>, Quim Roqueta<sup>7</sup>, Juanse Hernández<sup>8</sup>, Miguel Vázquez<sup>8</sup>, Cristina Rius<sup>9</sup>, Francisca Román<sup>9</sup>, Anna Not<sup>3, 4, 5, 11</sup>, Laura Muntané<sup>3, 4</sup>, Joan Colom<sup>10</sup>, Jordi Casabona<sup>1, 3, 5, 11</sup>, Cristina Agustí<sup>1, 3, 4</sup>

1 Centre for Epidemiological Studies on Sexually Transmitted Infections and AIDS of Catalonia, Ministry of Health of the Government of Catalonia, Badalona, Spain

2 Doctorate Program in Methodology of Biomedical Research and Public Health, Department of Pediatrics, Obstetrics and Gynecology and Preventive Medicine, Universitat Autònoma de Barcelona (UAB), Badalona, Spain

3 Germans Trias i Pujol Research Institute, Campus Can Ruti, Badalona, Spain

4 Microbiology Department, Laboratori Clínic Metropolitana Nord, Hospital Universitari Germans Trias i Pujol, Institut d'Investigació Germans Trias i Pujol, Badalona (Barcelona), Spain.

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

6 Stop, Barcelona, Spain

7 Gais Positius, Barcelona, Spain

8 Grupo de Trabajo sobre Tratamientos del VIH (gTt-VIH), Barcelona, Spain.

9 Epidemiology Service. Public Health Agency of Barcelona (ASPB). Barcelona, Spain.

10 Programa de prevenció, control i atenció al virus d'immunodeficiència humana, les infeccions de transmissió sexual i les hepatitis víriques, Public Health Agency of Catalonia, Barcelona, Spain.

11 Departament of Genetics and Microbiology, Autonomous University of Barcelona, Badalona, Spain.

## Correspondence

Hector Martínez-Riveros, Centre for Epidemiological Studies on Sexually Transmitted Infections and AIDS of Catalonia, Ministry of Health of the Government of Catalonia, Badalona, Spain. Email: [hmr.badalona@gmail.com](mailto:hmr.badalona@gmail.com)

The World Health Organization (WHO) global hepatitis strategy aims to reduce new infections by 90% and deaths by 65% by 2030.<sup>1</sup> In 2019 it was estimated that of the 58 million people infected worldwide only 21% were diagnosed and 62% of these treated with direct-acting antivirals.<sup>1</sup>

Evidence of hepatitis C virus (HCV) transmission and emerging acute HCV infection among gay, bisexual and other men who have sex with men (GBMSM), especially in human immunodeficiency virus (HIV)-infected individuals has risen over the past two decades.<sup>2</sup> In 2018, European Centre for Disease Prevention and Control reported the.<sup>3</sup> Chemsex, recreational drug use for sex is an important risk factor for primary infection and the risk of transmission is increased with snorting (injecting drugs).<sup>4</sup> The SWEETIE study (HIV and sexually transmitted infection prevalence study in GBMSM and trans women sex workers) identified trans women (TW) as a vulnerable population with an HCV seroprevalence of 1.2%.<sup>5</sup>

Research and engagement are urgently needed to integrate evidence-based interventions with HIV/sexually transmitted infections (STI) prevention in programmes that support screening and linkage to care.<sup>6</sup> An example is the Disfrutasin-C a partnership with three non-governmental organizations (NGOs) in Barcelona to inform about hepatitis C prevention.

The WHO recommends the collection of dried blood spots (DBS) by finger prick due to ease of use and high sensitivity and specificity for HCV ribonucleic acid (RNA) detection, but use is limited as many tests lack regulatory approval.<sup>7</sup> The WHO has also recently published the first self-testing and self-sampling guidelines for HCV to expand access to screening.<sup>7</sup> Digital technologies to deliver information and sexual health interventions (sexual e-health) are increasingly used. A recent study in Amsterdam demonstrated that DBS self-sampling was feasible without compromising the sensitivity of HCV RNA detection and concluded that such intervention is a practical solution to improve access to testing for at-risk GBMSM.<sup>8,9</sup> To our knowledge, no online self-sampling intervention for screening for HCV viremic infection by viral RNA detection has been performed in Spain. Might there be a need for innovative approaches to improve

wider access to HCV testing and to extend coverage to populations previously unreached by existing strategies in Spain?

This study aimed to design and implement a pilot intervention (TESTATE C PLUS) to assess the feasibility and acceptability of offering online DBS self-sampling kits for HCV viremic infection screening among GBMSM and TW in Spain. This prospective, non-randomised study included GBMSM and TW  $\geq 18$  years old living in Spain who agreed to sign the informed consent form between October 2020 and November 2021. The study was approved by the Ethics Committee of the Germans Trias i Pujol Hospital (PI-20-093).

Access to self-sampling was based on the HCV- Men who have sex with men Observational Study of Acute Infection with hepatitis C (MOSAIC) risk practices identification questionnaire.<sup>10</sup> Participants were recruited in collaboration with the *Agència de Salut Pública de Barcelona* (ASPB) and three NGOs (*STOP*, *Gais Positius* and *Gtt-HIV*), which are widely recognised by the target community. The recruitment strategy is described elsewhere.<sup>11</sup>

The TESTATE website (<https://testate.org/>) was expanded to include the offer of free HCV self-sampling kits. Users logged in and completed a socio-demographic and behavioural survey, which included the HCV-MOSAIC questionnaire. Users at HCV risk were sent a DBS collection kit by post. Participants collected the sample by finger prick at home and sent the sample to the laboratory by post with a pre-paid envelope. The results were delivered online. All participants who returned a sample were emailed an anonymised acceptance survey (Supplementary Material).

The DBS samples underwent quality check, blood elution, automated nucleic acid extraction, and reverse transcription (RT) and real-time PCR to detect HCV RNA in the m2000 system using the Abbott RealTime HCV assay (Abbott Molecular). Valid results were classified as positive or negative. The lower limit of detection for this assay in DBS samples is 462 IU/mL, compared to 12 IU/mL for the same assay in venous plasma. This assay has been approved for in vitro diagnostics (European in-vitro diagnostic devices directive, CE-IVD) using DBS samples.<sup>12</sup>

Participants who tested positive were asked to see a doctor to confirm the diagnosis and access treatment. Participants with a confirmed positive result received a second call two months after the first call to find out if they had started treatment. A final call was made 6 months after the first call to find out if the HCV treatment had been effective. We estimated HCV prevalence by calculating the proportion of confirmed HCV-positive

persons out of the total number of persons tested with a valid DBS sample. The 95% confidence interval was calculated.

Self-sampling kits were requested by 657 participants (characteristics shown in Table 1). The majority were male (98.93%) and 84.63% of participants identified themselves as gay. The median age was 36.85 years, 149 (22.68%) were immigrants. The majority (37.44%) living in cities with populations over 1 million.

Of the participants who responded to the HCV questions (N=393), half (45.04%) had never been tested for HCV and of those tested, 68.43% had been tested within the previous 6 months to 5 years or more and 29.82% within the previous 6 months. In the last 6 months, 73.79% had had receptive condomless anal sex, 31.30% had shared sex toys and 17.56% had engaged in fisting. Regarding drug use in the last year, 31.0% had practised chemsex, 6.36% had injected drugs and 28.50% had shared "rollers" (intranasal drug delivery devices) and 17.81% were on PrEP (Supplementary Table 1).

Three hundred fifty-three returned a sample to the reference laboratory (53.73% return rate), but 42 (11.89%) of these were considered invalid and not tested. There were 306 negative and 5 positive samples. Supplementary Figure 1 shows a summary diagram of participants in the intervention.

The characteristics of the five positive participants are shown in Table 1. Among them, 4 were successfully contacted; two had their result confirmed and were referred for treatment, but the other two, with a low-level signal, were not (2/311 were considered false positive; 0.6% of participants tested). One positive participant could not be contacted but the presence of HCV RNA in the DBS sample was confirmed by amplifying and sequencing the NS5B gene region<sup>12</sup>, which produced specific results. Considering confirmed positive cases, the estimated prevalence was 0.96% (3/311, 95% CI 0.00 to 2.05).

Fifty-four of the participants who returned the sample (15.29%) responded to the acceptability survey. The median age of participants was 39 years. For participant satisfaction from one to five the mean score was 4.63 (standard deviation 0.95). 90.74% said they would repeat the experience and 92.59% would recommend it to a friend. The advantages most identified were convenience (88.89%), free testing (87.04%) and privacy (85.19%). The disadvantages most identified were risk of sample loss in shipping (55.56%) and long waiting time for results (31.48%) (Supplementary Material and Supplementary Table 2).

The TESTATE C PLUS study demonstrates that the provision of self-sampling kits for the detection of HCV viral infection in DBS and online consultation of results is feasible in Spain, as it is in other European states.<sup>8,9</sup> The intervention has enabled access to HCV testing for people at risk of HCV infection. Additionally, many of the participants had never been tested for HCV (45.04%).

Complementary testing modalities to existing testing strategies for HIV, hepatitis and STIs are important options to diversify and optimise access to testing and should be regulated and available as part of national policy and practice. E-health testing, such as TESTATE C PLUS, can circumvent the inconvenience and stigma associated with face-to-face services and could expand access to populations that do not use standard/mainstream services.<sup>13</sup>

The study had high rates of confirmation and referral to care for participants with positive results. In community screening centres in Catalonia in 2019, GBMSM and TW had a 0.31% HCV RNA detection rate, which is below that of TESTATE C PLUS.<sup>5</sup>

The study has several limitations. Firstly, due to a flaw in the algorithm, some participants were unable to answer the questions on HCV-MOSAIC risk and that may have influenced the low detection of infection. Although the HCV-MOSAIC tool has not been validated for HIV-negative individuals, we believe it may be useful for selecting those at higher risk of HCV infection who therefore should be offered screening. Furthermore, the response rate was relatively low, which could introduce bias in the interpretation of the findings; we have no information on why people ordered kits but did not return samples. We found 0.56% of false positive results similarly to previous studies when directly assessing low-prevalence populations with an HCV RNA assay.<sup>14,15</sup> These results may be due to artefacts in the assay giving low-level noise<sup>15</sup>.

The study has several strengths. In a COVID-19 pandemic situation, or in other cases of population quarantine, it makes even more sense to increase access and testing, to reduce the burden of primary care and STIs consultations, and to reduce people's mobility. TESTATE could also bring testing closer to rural areas with less accessible medical resources.

In conclusion, TESTATE C PLUS is potentially a practical solution to improve access to HCV testing in GBMSM and TW at risk and most study participants deemed it acceptable and user-friendly. Implementing this strategy alongside existing ones might aid in HCV micro-elimination among the intended population. This study demonstrates the benefits and the need to work together with community entities. Our intervention has

proven to be feasible and could be consolidated as a service and easily adapted to include self-sampling kits suitable for other infections such as chlamydia, gonorrhoea and HIV, enteric infections such as shigellosis or new infections such as mpox. Further research is required to achieve integration into the public health system.

### **Conflict of interest**

E.M. received lecture fees and research grants from Abbott GmbH & Co. KG, Gilead, Cepheid and Abbvie, and advisory fees from Gilead, out of the present work. The other authors declare no competing interests.

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**Table 1. Main characteristics of participants from TESTATE C PLUS October 2020-November 2021**

	DBS kit sent N=657	DBS sample received N=311	HCV RNA negative N=306	HCV RNA positive N=5
<b>Median age (IQR)</b>	36 [29 - 44]	36 [28 - 44]	36 [28 - 44]	36 [35 - 44]
<b>Gender</b>				
Cis man	650 (98.90%)	307 (98.70%)	302 (98.70%)	5 (100.00%)
Trans person	7 (1.10%)	4 (1.30%)	4 (1.30%)	0 (0.00%)
<b>Sexual orientation</b>				
Gay	556 (84.60%)	269 (86.50%)	264 (86.30%)	5 (100.00%)
Heterosexual	8 (1.20%)	2 (0.60%)	2 (0.70%)	0 (0.00%)
Bisexual	90 (13.70%)	38 (12.20%)	38 (12.40%)	0 (0.00%)
Other	3 (0.50%)	2 (0.60%)	2 (0.70%)	0 (0.00%)
<b>Country of birth</b>				
Spain	508 (77.30%)	66 (21.20%)	65 (21.20%)	1 (20.00%)
Other	149 (22.70%)	245 (78.80%)	241 (78.80%)	4 (80.00%)
<b>Region</b>				
Andalucía	71 (10.80%)	36 (11.60%)	36 (11.80%)	0 (0.00%)
Aragón	10 (1.50%)	6 (1.90%)	6 (2.00%)	0 (0.00%)
Canarias	17 (2.60%)	9 (2.90%)	9 (2.90%)	0 (0.00%)
Cantabria	4 (0.60%)	2 (0.60%)	2 (0.70%)	0 (0.00%)
Castilla-La Mancha	9 (1.40%)	5 (1.60%)	5 (1.60%)	0 (0.00%)
Castilla y León	12 (1.80%)	7 (2.30%)	7 (2.30%)	0 (0.00%)
Cataluña	267 (40.60%)	128 (41.20%)	124 (40.50%)	4 (80.00%)
Ciudad Autónoma de Melilla	1 (0.20%)	1 (0.30%)	1 (0.30%)	0 (0.00%)
Comunidad de Madrid	136 (20.70%)	59 (19.00%)	59 (19.30%)	0 (0.00%)
Comunidad Foral de Navarra	6 (0.90%)	3 (1.00%)	3 (1.00%)	0 (0.00%)
Comunitat Valenciana	51 (7.76%)	17 (5.47%)	17 (5.56%)	0 (0.00%)
Extremadura	2 (0.30%)	2 (0.64%)	2 (0.65%)	0 (0.00%)

Galicia	23 (3.50%)	11 (3.54%)	10 (3.27%)	1 (20.00%)
Illes Balears	10 (1.52%)	3 (0.96%)	3 (0.98%)	0 (0.00%)
La Rioja	1 (0.15%)	1 (0.32%)	1 (0.33%)	0 (0.00%)
País Vasco	23 (3.50%)	14 (4.50%)	14 (4.58%)	0 (0.00%)
Principado de Asturias	6 (0.91%)	4 (1.29%)	4 (1.31%)	0 (0.00%)
Región de Murcia	8 (1.22%)	3 (0.96%)	3 (0.98%)	0 (0.00%)
<b>Town or city inhabitants</b>				
More than 1 million inhabitants	246 (37.40%)	107 (34.40%)	103 (33.70%)	4 (80.00%)
Between 500,000-999,999 inhabitants	45 (6.85%)	15 (4.82%)	15 (4.90%)	0 (0.00%)
Between 100,000-499,999 inhabitants	126 (19.20%)	61 (19.60%)	61 (19.90%)	0 (0.00%)
Between 49,000-99,999 inhabitants	66 (10.00%)	33 (10.60%)	32 (10.50%)	1 (20.00%)
Between 10,000-49,000 inhabitants	85 (12.90%)	46 (14.80%)	46 (15.00%)	0 (0.00%)
Less than 10,000 inhabitants	43 (6.54%)	24 (7.72%)	24 (7.84%)	0 (0.00%)
DK/DA	46 (7.00%)	25 (8.04%)	25 (8.17%)	0 (0.00%)
<b>Level of studies</b>				
Complete primary school	18 (2.74%)	7 (2.25%)	7 (2.29%)	0 (0.00%)
Complete secondary school	81 (12.30%)	47 (15.10%)	47 (15.40%)	0 (0.00%)
Complete vocational studies	189 (28.80%)	94 (30.20%)	93 (30.40%)	1 (20.00%)
Complete university	201 (30.60%)	90 (28.90%)	87 (28.40%)	3 (60.00%)
Post-graduate studies (master, PhD, <i>etc</i> )	161 (24.50%)	67 (21.50%)	66 (21.60%)	1 (20.00%)
DK/DA	7 (1.07%)	6 (1.93%)	6 (1.96%)	0 (0.00%)
<b>HIV positive</b>				
Yes	40 (6.09%)	13 (4.18%)	12 (3.92%)	1 (20.00%)
No	417 (63.50%)	200 (64.30%)	198 (64.70%)	2 (40.00%)
DK/DA	200 (30.40%)	98 (31.50%)	96 (31.40%)	2 (40.00%)
<b>HIV status of your partner at last anal intercourse</b>				
HIV negative	176 (26.80%)	93 (29.90%)	92 (30.10%)	1 (20.00%)
HIV positive with undetectable viral load	49 (7.46%)	22 (7.07%)	22 (7.19%)	0 (0.00%)
HIV positive with detectable viral load	3 (0.46%)	2 (0.64%)	2 (0.65%)	0 (0.00%)

HIV positive and I don't know if his viral load was detectable or undetectable	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
I don't know your HIV status	318 (48.40%)	149 (47.90%)	146 (47.70%)	3 (60.00%)
DK/DA	111 (16.94%)	45 (14.46%)	44 (14.19%)	1 (20.00%)
<b>Last STI</b>				
In the last month	24 (3.65%)	8 (2.57%)	8 (2.61%)	0 (0.00%)
In the last 6 months	74 (11.30%)	26 (8.36%)	24 (7.84%)	2 (40.00%)
In the last 12 months	79 (12.00%)	31 (9.97%)	30 (9.80%)	1 (20.00%)
Within the last 5 years	158 (24.00%)	80 (25.70%)	79 (25.80%)	1 (20.00%)
More than 5 years ago	25 (3.81%)	15 (4.82%)	15 (4.90%)	0 (0.00%)
DK/DA	297 (45.21%)	151 (48.52%)	150 (49.00%)	1 (20.00%)
<b>Number of men or trans women receptive or insertive anal intercourse last 12 months</b>				
I have not had anal intercourse in the last 12 months	17 (2.59%)	8 (2.57%)	8 (2.61%)	0 (0.00%)
With 1	39 (5.94%)	19 (6.11%)	19 (6.21%)	0 (0.00%)
2-4	118 (18.00%)	61 (19.60%)	60 (19.60%)	1 (20.00%)
5-9	97 (14.80%)	49 (15.80%)	47 (15.40%)	2 (40.00%)
10-20	74 (11.30%)	34 (10.90%)	34 (11.10%)	0 (0.00%)
More than 20 pairs	107 (16.30%)	45 (14.50%)	43 (14.10%)	2 (40.00%)
DK/DA	205 (31.23%)	95 (30.51%)	95 (31.03%)	0 (0.00%)
<b>Condom use in last anal sexual intercourse</b>				
Yes	203 (30.90%)	105 (33.80%)	103 (33.70%)	2 (40.00%)
No	437 (66.50%)	199 (64.00%)	196 (64.10%)	3 (60.00%)
DK/DA	17 (2.59%)	7 (2.25%)	7 (2.29%)	0 (0.00%)

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IQR, interquartile range; DK/DA, don't know/don't answer; HIV, human immunodeficiency virus; STI, sexually transmitted infection.