

# Feasibility and Acceptability of Community Coronavirus Disease 2019 Testing Strategies (FACTS) in a University Setting

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**Background.** During the coronavirus disease 2019 (COVID-19) pandemic in 2020, the UK government began a mass severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) testing program. This study aimed to determine the feasibility and acceptability of organized regular self-testing for SARS-CoV-2.

**Methods.** This was a mixed-methods observational cohort study in asymptomatic students and staff at University of Oxford, who performed SARS-CoV-2 antigen lateral flow self-testing. Data on uptake and adherence, acceptability, and test interpretation were collected via a smartphone app, an online survey, and qualitative interviews.

**Results.** Across 3 main sites, 551 participants (25% of those invited) performed 2728 tests during a follow-up of 5.6 weeks; 447 participants (81%) completed at least 2 tests, and 340 (62%) completed at least 4. The survey, completed by 214 participants (39%), found that 98% of people were confident to self-test and believed self-testing to be beneficial. Acceptability of self-testing was high, with 91% of ratings being acceptable or very acceptable. A total of 2711 (99.4%) test results were negative, 9 were positive, and 8 were inconclusive. Results from 18 qualitative interviews with students and staff revealed that participants valued regular testing, but there were concerns about test accuracy that impacted uptake and adherence.

**Conclusions.** This is the first study to assess feasibility and acceptability of regular SARS-CoV-2 self-testing. It provides evidence to inform recruitment for, adherence to, and acceptability of regular SARS-CoV-2 self-testing programs for asymptomatic individuals using lateral flow tests. We found that self-testing is acceptable and people were able to interpret results accurately.

**Keywords.** asymptomatic; COVID-19; lateral flow test; self-testing; university.

## KEY POINTS

To determine feasibility and acceptability of rapid SARS-CoV-2 self-testing in a university setting, 551 participants completed 2728 lateral flow COVID-19 swab tests during a mean follow-up

of 5.6 weeks. Ninety-three percent rated testing as acceptable or very acceptable.

During coronavirus disease 2019 (COVID-19) pandemic testing for severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) in the United Kingdom (UK), laboratory-based reverse-transcription polymerase chain reaction (RT-PCR) tests focused only on those with specific symptoms. However, some infected individuals remain asymptomatic, and in symptomatic cases, viral shedding is likely to occur before symptoms develop [1]. This led to calls for population-level asymptomatic SARS-CoV-2 screening [2, 3], which required a reliable, affordable testing strategy that ideally could be self-administered.

In late 2020, lateral flow tests (LFTs) were introduced for rapid detection of the SARS-CoV-2 antigen [4]. LFTs do not require laboratories, can be performed locally, and produce results within 30 minutes. In October 2020, the UK government launched a mass testing initiative using LFTs nationwide

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[5] However, one-off LFT diagnostic performance [6] does not meet the World Health Organization accepted minimum of 97% specificity and 80% sensitivity, and data on diagnostic performance from asymptomatic self-testing are sparse [7]. To improve diagnostic performance of the overall testing strategy, regular retesting was proposed [8]. Potential use of LFTs in population screening became an international research priority. Scientific advice [9] indicated that a  $\geq 90\%$  uptake and self-isolation was necessary for a successful screening strategy [10].

Student populations (typically a high proportion of young adults) are more likely to experience asymptomatic SARS-CoV-2 infection than older people [11] and the potential for transmission in university populations is significant, particularly at term start when students return from disparate locations. Modeling data suggest that very frequent repeated student asymptomatic swabbing and self-testing (every 2–3 days) would be required to prevent SARS-CoV-2 outbreaks [8, 12]. It was unclear, however, if this strategy would be feasible and acceptable to university students and staff as there are no published studies assessing this strategy using LFTs on a university campus.

This study's aims were to determine the feasibility and acceptability of implementing organized, regular, mass self-testing for COVID-19 in asymptomatic University of Oxford students and staff using a smartphone app and qualitative interviews. This work provides important data on wider community COVID-19 testing potential.

## METHODS

### Design, Setting, and Participants

Feasibility and Acceptability of Community Coronavirus Disease 2019 Testing Strategies (FACTS) is a mixed-methods cohort study conducted at the University of Oxford, approved by the University of Oxford Research Ethics Committee (CUREC ethics reference R72896/RE001 October 2020).

Eligible participants ( $\geq 16$  years of age) were those working or studying across 3 university sites. Eligibility criteria included showing no COVID-19 symptoms (new continuous cough, high temperature, and/or loss of/change to sense of smell/taste) and being capable of LFT self-administration following training.

### Recruitment and Follow-up

Two colleges began recruitment on 29 October 2020 and 1 department began recruitment on 17 November 2020 (sites A, B, and C). In late November, recruitment was extended across the university, but stopped in early December when a university-wide COVID-19 screening program was implemented, leaving only sites A, B, and C continuing with FACTS. Invitations to participate and study information were sent by email, first only to students and later to staff.

To participate, individuals download a free app (for iOS or Android operating systems, "CVm-Health+ Education," developed by Sensyne Health PLC, Oxford, UK), to their smartphones; had the option to consent, indicated willingness to be contacted for interview, and provided an email address, sex/gender, date of birth, and ethnicity.

Trainers supervised participants' first test during face-to-face or online training. Electronic training materials and instructions were also available. Participants got an LFT kit, which they used to self-swab and test. After 30 minutes, they interpreted results as negative, positive, or inconclusive (failed test) and uploaded a photograph of the result to the app. Inconclusive tests were repeated using the remaining sample and a new test cartridge. Acceptability of conducting the test was rated on a 1–5 scale ("very acceptable" to "very unacceptable"). The full procedure is shown in [Supplementary Appendix 1](#).

If COVID-19–related symptoms developed or if an LFT result was positive, participants were instructed to self-isolate and book an RT-PCR test. Participants were also asked to upload their health status daily to track development of any COVID-19–related symptoms.

Repeat weekly testing was performed at a central location on sites A, B, and C until late November. Thereafter, participants were supplied with kits to continue testing at home throughout Christmas until 18 January 2021 (study end date). Follow-up did not take place at other recruiting sites. Because of these differences in follow-up potential, all sites other than A, B, and C are grouped together as "other sites."

If a participant received a COVID-19–positive RT-PCR test result, they were asked to stop self-testing. Participants could withdraw from the study without providing a reason.

### Lateral Flow Test

The Innova Rapid SARS-CoV-2 Antigen Test Kit (Innova Medical Group), developed for testing symptomatic individuals, was the LFT used. A positive test result is given within 20 minutes, a negative within 30 minutes [13].

### Data Collection and Analysis

The CVm-Health+ Education app collected all quantitative data. Analyses were restricted to consented participants who uploaded  $\geq 1$  LFT result photograph. Recruitment, follow-up (time between first and last submitted test), and demographics were summarized as numbers and percentages, or mean and standard deviation (SD). Patterns of test results for participants who reported a positive LFT or RT-PCR result were shown graphically. LFT reporting accuracy was assessed by comparing the participant-reported result with the uploaded LFT photograph. App-reported symptom prevalence was summarized and results were broken down for the 3 main sites. Analyses were conducted using the statistical software package R.

## Mixed-Methods Evaluation

A mixed-methods evaluation involving surveys and interviews was nested within the study.

The survey assessed participants' views on testing benefits; barriers to regular testing; trust in test results; and intentions to continue testing, act on a positive result, and self-isolate if indicated ([Supplementary Appendix 2](#)). Survey items were designed for responses on a 7-point Likert scale, ranging from "strongly disagree" to "strongly agree." Additional information collected included type of training received, university role, and whether symptoms were experienced during study participation. A free-text box was included for comments on any aspect of the testing experience. The survey was designed using the Jisc Online survey platform. All participants received an email with a survey web link on 1 December 2020. Quantitative survey data were analyzed using descriptive statistics.

Participants ( $n = 18$ ) were invited for interview using purposive sampling. Following consent, telephone/online interviews were conducted and audio was recorded. Interviews continued until data indicated saturation [14]. Interviews explored views and experiences of test use, regular testing barriers and facilitators, trust in test results, perceived testing benefits, and intentions to act on positive result ([Supplementary Appendix 3, Topic Guide](#)). We conducted rapid data collection and analysis concurrently [15]. Using the survey's free-text comments, we created a framework used for interview analysis. This method was deemed a pragmatic and efficient approach to collect and analyze data rapidly during a public health emergency [15].

## RESULTS

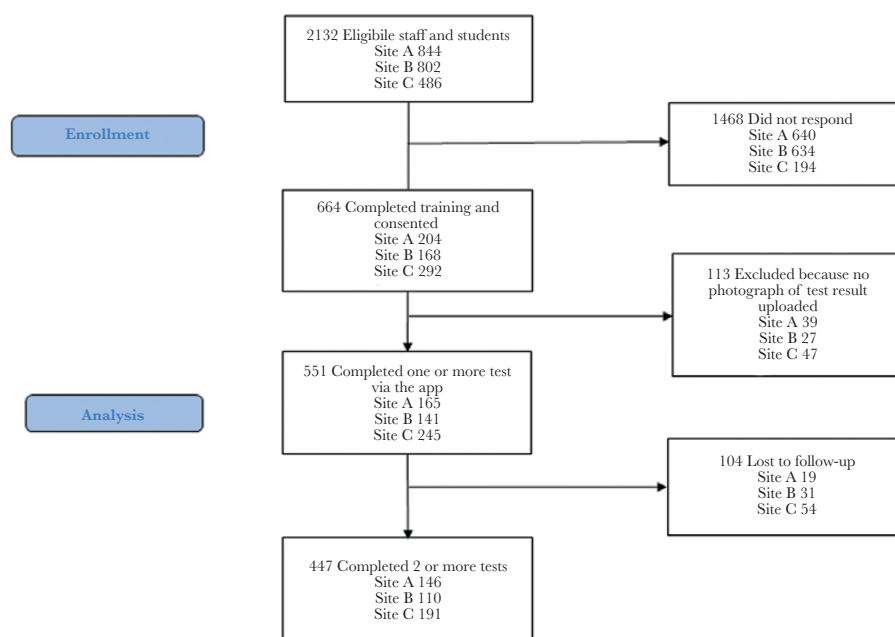
### Recruitment and Testing

At the 3 primary recruitment sites (A, B, and C), 2195 students and staff were eligible, 664 (31%) attended training, and 551 (25%) participated ([Figure 1](#)). An additional 183 participants were recruited across other sites, so the total sample size was 734. One hundred thirteen participants who attended training were ineligible as no LFT result photograph was uploaded. Eighty percent ( $n = 588$ ) of participants were students, with a mean age of 26 (SD, 8) years; 20% ( $n = 146$ ) were staff, with a mean age of 42 (SD, 11) years. Overall, 55% were women and 83% were white. All demographics are presented in [Table 1](#), stratified by recruitment site.

In the 3 primary sites, participants completed 2728 tests, with 447 (81%) completing  $\geq 2$  tests and 340 (62%) completing  $\geq 4$  tests. One hundred fifty-five (28%) stopped testing after just 2 tests. The number of tests completed was slightly higher in staff than students (6.0 vs 4.7, respectively). At the 3 primary sites, mean follow-up time was 5.6 (SD, 3.2) weeks and participants completed a mean of 5.0 tests each. The rate of testing (number of tests from recruitment to study end) was higher in staff (0.81 in staff vs 0.60 in students) ([Table 1](#)). Across all sites, 3187 LFT results were reported, with a mean of 4.3 (SD, 2.9) tests per participant. [Figure 2](#) shows the timing of recruitment and testing over the study period.

### Test Results

Of LFT results reported, 3170 (99.5%) were negative (2711 in the 3 primary sites), 9 (in 8 participants) were positive, and 8



**Figure 1.** Participant flowchart for the 3 primary recruitment sites.

**Table 1. Participant Demographics by Recruitment Site**

Characteristic	Overall	Three Main Sites				Other Sites
		Combined Main Sites	Site A	Site B	Site C	
Total No. of students and staff	...	2132	844	802	486	...
Enrolled	...	664 (31%)	204 (24%)	168 (21%)	292 (60%)	...
Participants with at least 1 test upload	734	551 (26%)	165 (20%)	141 (18%)	245 (50%)	183
Staff	146	115	31	23	61	31
Students	588	436	134	118	184	152
No. of tests	3187	2728	1047	690	991	459
Male sex	327 (45%)	244 (44%)	64 (39%)	56 (40%)	124 (51%)	83 (45%)
Age, y, mean (SD)	28.8 (10.7)	29.3 (10.7)	27.4 (12.0)	25.4 (10.4)	32.7 (8.6)	27.5 (10.7)
Staff	42.2 (11.0)	42.1 (10.8)	41.8 (11.7)	43.3 (10.7)	41.8 (10.5)	42.7 (11.6)
Students	25.5 (7.7)	25.9 (7.6)	24.1 (9.3)	21.9 (5.7)	29.7 (5.1)	24.4 (7.3)
White race	608 (83%)	451 (82%)	150 (91%)	131 (93%)	170 (69%)	157 (86%)
No. of tests per participant, mean (SD) [range]	4.3 (2.9) [1–13]	5.0 (3.0) [1–13]	6.3 (3.0) [1–13]	4.9 (3.2) [1–11]	4.1 (2.5) [1–10]	2.5 (1.6) [1–9]
Staff	5.4 (2.9) [1–10]	6.0 (2.7) [1–10]	7.1 (2.5) [1–10]	6.9 (3.0) [1–10]	5.1 (2.4) [1–9]	3.4 (2.4) [1–9]
Students	4.1 (2.9) [1–13]	4.7 (3.0) [1–13]	6.2 (3.0) [1–13]	4.5 (3.1) [1–10]	3.7 (2.4) [1–10]	2.3 (1.4) [1–8]
No. with:						
1 test	137	104	19	31	54	33
2 tests	159	51	5	18	28	108
3 tests	67	56	11	11	34	11
≥4 tests	371	340	130	81	129	31
Rate of testing (No. of tests/weeks in study)	0.96	0.91	0.91	0.90	0.93	1.10
Staff	0.94	0.93	0.92	0.97	0.92	0.99
Students	0.96	0.91	0.90	0.88	0.93	1.12
Rate of testing (No. of tests/weeks from enrollment to 18 Jan 2021)	0.56	0.64	0.72	0.58	0.63	0.33
Staff	0.73	0.81	0.85	0.82	0.79	0.42
Students	0.52	0.60	0.69	0.54	0.57	0.31
Withdrawals	1	1	...	1	...	...
Final test before 12 Dec 2020	250	109	28	46	35	141

Data are presented as No. (%) unless otherwise indicated.

Abbreviation: SD, standard deviation.

(all different participants) were inconclusive (Table 2). Based on submitted photographs, most LFT results were correctly reported as negative, 5 positive tests were confirmed as positive, but 3 positive tests could not be accurately verified due to unclear photographs. No positive LFT result was incorrectly reported as negative.

Eight positive RT-PCR results (all in different participants) were reported, and 7 of these participants had reported a negative LFT result within the previous week (Supplementary Figure 1). Five who reported a positive LFT result uploaded an RT-PCR test result within 1 week (before or after): 3 of these were positive and 2 were negative (Supplementary Figure 2). All except 1 of those with a positive PCR result, and all except 2 of those with a positive LFT result, stated that they intended to self-isolate.

### Symptoms

App-based symptom tracking was recorded on 2824 occasions by 300 participants (Table 3). Of these, symptoms were reported

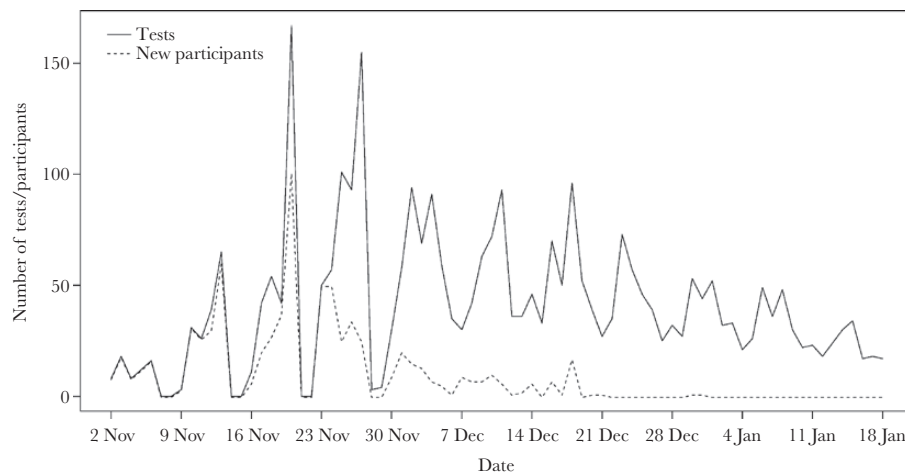
on 29 occasions (1%) in 17 participants. Cough (9 occasions in 7 participants) and tiredness (8 occasions in 7 participants) were the most frequently reported symptoms. All reported temperatures were <38°C.

### Acceptability Reported Through App

All 3187 cases reported acceptability via the app. The majority were acceptable or very acceptable ( $n = 2907$  [91%]), 232 (7.3%) were neutral, and 48 (1.5%) were unacceptable or very unacceptable (Table 3).

### Survey Results

Participants (213) completed the survey (response rate 29%) between 1 December 2020 and 7 January 2021. They completed between 1 and 13 tests (mean, 5.8). Sixty-one respondents were undergraduates (28%), 81 were postgraduate (38%), and 72 were staff (34%). Two hundred nine (98%) reported no COVID-19 symptoms during participation. Overall, respondents reported that self-testing was feasible and acceptable.



**Figure 2.** Number of daily lateral flow test results reported (black line) and recruitment rate of participants (dashed line) throughout the study period (80 days).

Self-testing was reported as beneficial for them (97%), their friends and family (99.5%), people they live with (98%), and their wider community (98.5%). Ninety-eight percent felt confident in self-testing abilities and 100% reported confidence in result interpretation. Fitting self-testing into usual activities (95.7%) and remembering to test (96%) were also reported as easy. There was confidence in test safety (99.5%) and 90% believed that tests provided reliable and accurate results. Ninety-eight percent reported an intention to self isolate after a positive LFT test, whereas 100% said they would self-isolate after a positive PCR. [Supplementary Table 1](#) provides a summary of all survey results.

#### Qualitative—Key Findings (Based on Interviews and Free-Text Comments From the Survey)

Of those contacted for interview, 431 (59%) consented, 52 were approached, and 18 were interviewed (response rate 35%). Three were undergraduate, 3 were postgraduate, and 12 were staff. Interviews took place between 11 December 2020 and 18 January 2021. Each interviewee completed between 3 and 10 tests during the study period (mean, 7.7).

**Table 2. Test Results**

Result	Overall	Site A	Site B	Site C	Other
Total No. of LFTs					
Negative	3170	1041	682	988	459
Positive	9	3	4	2	...
Inconclusive	8	3	4	1	...
Incorrectly interpreted negative result as positive	3	...	3	...	...
Total number of RT-PCR tests					
Positive	8	4	2	2	...
Negative	40	16	2	12	10

Data are presented as No.

Abbreviations: LFT, lateral flow test; RT-PCR, reverse-transcription polymerase chain reaction.

Regular testing was valued for providing reassurance that participants were not infected, and reduced fear of accidentally infecting family, friends, or others. Additionally, knowing if they were infected so they could take appropriate action was important. While several found testing uncomfortable or even “extremely unpleasant,” this did not seem to impact on continued self-testing as participants focused on perceived benefits.

While most viewed the test as providing reassurance about infection status, participants were unsure how accurate the tests are and would have liked more information on the test accuracy, especially in relation to “false negatives.”

**Table 3. Summary of Symptom and Acceptability Data Collected Through the App**

Symptom	Overall	Site A	Site B	Site C	Other
Daily symptom tracking					
Total No. completed	2824	1413	1120	85	206
No. with no symptoms	2795	1393	1111	85	206
No. that completed symptoms at least once	300	115	88	42	55
Symptoms reported, No. of times reported (No. of participants)					
Cough	9 (7)	7 (5)	2 (2)	...	...
Loss of taste or smell	1 (1)	...	1 (1)	...	...
Fever	2 (1 <sup>a</sup> )	2 (1)	...	...	...
Shortness of breath	4 (4)	1 (1)	3 (3)	...	...
Tiredness	8 (7)	5 (4)	3 (3)	...	...
Unable to do usual activities	7 (5)	1 (1)	6 (4)	...	...
Acceptability of all LFTs conducted					
Very acceptable	1716	482	431	547	256
Acceptable	1191	477	214	331	169
Neutral	232	78	34	91	29
Unacceptable	21	6	4	9	2
Very unacceptable	27	4	7	13	3

Abbreviation: LFT, lateral flow test.

<sup>a</sup>Participant self-reported a symptom of fever and a temperature of 37.8°C.



Participants valued the training and information provided, but interviews and survey comments revealed that some felt unsure whether they were swabbing their throat correctly. This in turn made them worry about accuracy of results. Consequently, participants wanted more information on ensuring that they test correctly. Participants who were able to self-test at home, in comparison to those who had to attend a central testing site, reported it easier to take part in regular testing. Full findings from qualitative interviews have been reported separately [16].

## DISCUSSION

### Principal Findings

FACTS provides the first research evidence on recruitment and training, adherence to, and acceptability of regular COVID-19 self-testing for asymptomatic individuals using LFTs. Quantitative and qualitative data show that self-testing was acceptable and results could be correctly interpreted. The survey showed perception of broad benefits to testing for participants and others, and that test accuracy was trusted, but qualitative data revealed that beliefs about test accuracy varied. Interviews highlighted that participants wanted to know their infection status to avoid unintentionally infecting others.

The 25% participation across the 3 primary sites is well below the government's scientific advisory group's minimum [9]. However, not all invited could take part, for example, those not in residence during study recruitment due to COVID-19 restrictions. Eighty-one percent of participants from the 3 primary sites completed  $\geq 2$  tests and 62% completed  $\geq 4$  test, demonstrating that of those who did participate, the majority were willing to undergo further self-testing. Staff had a higher follow-up rate, suggesting that staff were more likely to be compliant to testing and remained in the study for a higher proportion of their potential follow-up time than students. Participants adhered to approximately weekly testing (0.96 tests/week overall and 0.91 tests/week in the 3 main sites).

### Strengths and Weaknesses of the Study

This is the first study to assess feasibility and acceptability of regular SARS-CoV-2 self-testing including test result interpretation. FACTS benefited from a mixed-methods evaluation of perceived acceptability and feasibility of regular rapid diagnostic self-testing, highlighting key barriers and facilitators. Triangulation of survey and qualitative data [17] allowed identification of further insights, especially in relation to perceived accuracy and importance of training.

Participation across the 3 main sites ranged from 18% to 50% of eligible students and staff, but each site had very different recruitment strategies and different proportions of undergraduate and postgraduate students. Staff, largely working from home, were recruited much later.

During follow-up, there were only 9 positive LFTs and of these, only 5 participants uploaded RT-PCR test results. It was not possible to determine whether the 4 others with a positive LFT had an RT-PCR test but did not upload the result. Symptom reporting was poor, but reminders, which may have improved reporting, were not included in this intervention [18–20] and it was not explored whether there were any associations between test results and recent symptom data.

There was potential for selection bias among those who participated in the survey. This could have led to those who believed that self-testing was valuable and feasible being more likely to participate and complete the survey.

### Comparison With Existing Literature

The survey and interviews highlighted that participants saw testing as equally beneficial for themselves, their family and friends, and the wider community. Participants wanted to know their infection status so they could self-isolate if needed and, overall, found self-testing reassuring. This appeared to be linked to viewing test results as reliable and accurate. However, qualitative data highlighted limited understanding of LFT accuracy, especially around false negatives. While previous studies found similar reasons for wanting to have access to SARS-CoV-2 testing, these involved PCR [21] or one-off LFTs [22] rather than repeat self-testing. One study in a university setting previously highlighted the importance of convenience [21]. Our survey and interview data indicate that adherence to repeat self-testing was higher when participants were provided with packs to take home.

Other studies explored the feasibility of university campus testing. One involving students and staff who completed self-swabbing for 2 weeks concluded that this was feasible and acceptable, although laboratory analysis, rather than self-administered LFTs, was used to obtain results [23]. Another UK study explored the feasibility and acceptability of self-testing with disposable fingerprick blood sample devices [24]. Our work differs by providing data on acceptability of self-swabbing, completing the test, and interpreting results.

### Meaning of the Study

This study indicates that self-testing of asymptomatic staff and students in a university setting is both feasible to implement with low intervention training and acceptable to participants. It has provided real-world evidence on likely uptake, follow-up, and adherence to inform rapid self-testing in universities and similar settings, such as schools or workplaces. We found that 81% of participants completed at least 2, and 62% completed 4 or more, tests over the 5.6-week study period. This is far less than the retesting every 2–3 days suggested to be necessary to keep virus reproduction rates sufficiently low [8]. This work indicated that different techniques, such as the inclusion of reminders or incentives, may need to be investigated to encourage

some to continue with testing. People's motivations for doing self-testing are complex, and more work is needed to understand how to encourage more optimal frequency of testing.

It has been reported that of those testing positive in UK universities, the majority are compliant with self-isolation guidance. However, in those without a confirmed test, even with symptoms, self-isolation was lower [25]. Therefore, identifying people willing to self-test when asymptomatic, and who proceed to self-isolate, may be challenging and needs to be considered when rolling out testing schemes [26, 27]. When FACTS began, national COVID-19 prevalence was relatively low. This may have reduced the sense of urgency or concern about contracting or passing on the virus. The study team received informal feedback that some students did not participate because, if they tested positive, their entire household group would have to isolate. Qualitative interviews corroborated this [16]. This is an unintended effect of the national self-isolation guidance, and may influence willingness to participate in future mass testing schemes, particularly among groups who fear a loss of income resulting from self-isolation [28, 29]. Furthermore, incentives may have encouraged adherence; for example, recruitment or follow-up may have increased if those who tested negative were given access to university libraries or face-to-face teaching.

The Innova Antigen Test has been criticized for missing too many infections when not administered by trained health care professionals [30]. Our results suggest that people require accurate information about test performance, especially in relation to false-negative results, as this is a major driver of uptake, adherence, and behavior following a self-test result. It is a possibility that some of the negative LFTs in our study were false negatives. Most of those who had a positive RT-PCR result had performed a negative LFT a few days previously and may later have gone on to develop symptoms. We did not look at accuracy of LFTs, though this has been carried out in another asymptomatic UK university population [31], where LFTs were found to detect 100% of negative cases but detected lower proportions of positive cases. Authors speculated that many previously reported poor LFT results were due to poor sampling technique rather than diagnostic accuracy. Furthermore, they also suggested that most false negatives were just outside the limit of detection for the Innova LFTs, which may be representative of those at the very early or very late stages of infection. They concluded that it is important to perform regular, routine testing to identify infection before transmission.

## CONCLUSIONS

FACTS indicates that regular self-testing of asymptomatic students and staff in a university setting is both feasible to implement with low intervention training and acceptable to participants. Repeat testing has the potential to interrupt transmission in student populations and could be used along with

other measures to control the spread of SARS-CoV-2 when students return to residential campuses [32]. However, testing alone will not prevent transmission and quarantining for those who test positive would need to be followed for it to control transmission [33]. It is therefore important to rigorously assess the strategy, as well as the test, with high-quality studies to ensure it is effective and cost-effective for preventing infections.

## Supplementary Data

Supplementary materials are available at *Open Forum Infectious Diseases* online. Consisting of data provided by the authors to benefit the reader, the posted materials are not copyedited and are the sole responsibility of the authors, so questions or comments should be addressed to the corresponding author.

## Notes

**Author contributions.** F. D. R. H., J. J. L., M. L., B. D. N., R. P., S. T.-C., and M. W. devised the study. F. D. R. H. acquired the funding. F. D. R. H., M. L., J. A. H., B. D. N., I. T., G. D., P. T., C. V., and M. B. managed the planning and running of the study. T. R. F., L. M., and R. P. analyzed the data. J. A. H., M. L., T. R. F., L. M., S. T.-C., and M. W. co-wrote the first draft of the manuscript, and all authors provided critical feedback and helped shape the research, analysis, and final manuscript.

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## CONFIDENCE IN DOVATO ACROSS TREATMENT SETTINGS<sup>4-9</sup>

Treatment-naïve resistance rates, with up to **3 years** of evidence<sup>5-7</sup>

**0%**  
(n=0/1,885)\*<sup>4</sup>  
REAL-WORLD EVIDENCE

**0.1%**  
(n=1/953)\*<sup>4,11,12,13</sup>  
RANDOMISED CONTROLLED TRIALS

Treatment-experienced resistance rates, with up to **5 years** of evidence<sup>1-3</sup>

**0.03%**  
(n=0/35,888)\*<sup>4</sup>  
REAL-WORLD EVIDENCE

**0%**  
(n=0/615)<sup>11,12,13</sup>  
RANDOMISED CONTROLLED TRIALS

## >300,000 PEOPLE LIVING WITH HIV HAVE BEEN TREATED WITH DOVATO GLOBALLY<sup>10</sup>

DOVATO is supported by a wealth of evidence, with the outcomes of **>40,000** people living with HIV captured within clinical trials and real-world evidence, including those with:<sup>4-9,11,12</sup>



**NO PRIOR TREATMENT EXPERIENCE<sup>13</sup>**



**NO BASELINE RESISTANCE TESTING<sup>13</sup>**

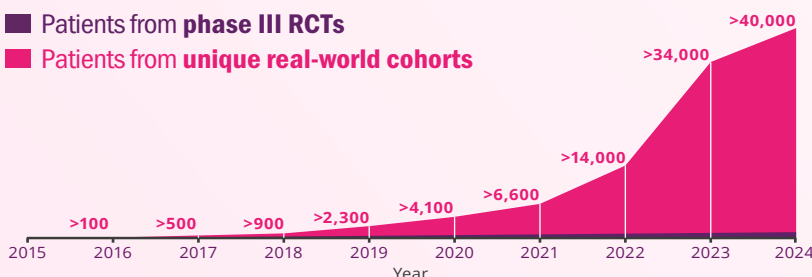


**HIGH BASELINE VIRAL LOAD**  
(>100,000 copies/mL and even >1M copies/mL)<sup>6,13</sup>



**LOW CD4+ COUNT**  
(≤200 cells/mm<sup>3</sup>)<sup>13</sup>

■ Patients from phase III RCTs  
■ Patients from unique real-world cohorts



## IS IT TIME TO RECONSIDER THE VALUE OF THE 2<sup>ND</sup> NRTI?

LEARN MORE ➔

DOVATO is indicated for the treatment of Human Immunodeficiency Virus type 1 (HIV-1) infection in adults and adolescents above 12 years of age weighing at least 40 kg, with no known or suspected resistance to the integrase inhibitor class, or lamivudine.<sup>13</sup>

Adverse events should be reported. Reporting forms and information can be found at <https://yellowcard.mhra.gov.uk/> or search for MHRA Yellowcard in the Google Play or Apple App store. Adverse events should also be reported to GSK on 0800 221441

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## ABBREVIATIONS

**3TC**, lamivudine; **CD4**, cluster of differentiation 4; **DTG**, dolutegravir; **FDA**, United States Food and Drug Administration; **FTC**, emtricitabine; **HIV**, human immunodeficiency virus; **ITT-E**, intention-to-treat exposed; **NRTI**, nucleoside/nucleotide reverse transcriptase inhibitor; **RCT**, randomised controlled trial; **RNA**, ribonucleic acid; **TAF**, tenofovir alafenamide fumarate; **TDF**, tenofovir disoproxil fumarate; **XTC**, emtricitabine.

## FOOTNOTES

\*Data extracted from a systematic literature review of DTG+3TC real-world evidence. Overlap between cohorts cannot be fully excluded.

\*\*The reported rate reflects the sum-total of resistance cases calculated from GEMINI I and II (n=1/716, through 144 weeks), STAT (n=0/131, through 52 weeks), and D2ARLING (n=0/106, through 24 weeks).<sup>5-7</sup>

†GEMINI I and II are two identical 148-week, phase III, randomised, double-blind, multicentre, parallel-group, non-inferiority, controlled clinical trials testing the efficacy of DTG/3TC in treatment-naïve patients. Participants with screening HIV-1 RNA ≤500,000 copies/mL were randomised 1:1 to once-daily DTG/3TC (n=716, pooled) or DTG + TDF/FTC (n=717, pooled). The primary endpoint of each GEMINI study was the proportion of participants with plasma HIV-1 RNA <50 copies/mL at Week 48 (ITT-E population, snapshot algorithm).<sup>13</sup>

‡STAT is a phase IIIb, open-label, 48-week, single-arm pilot study evaluating the feasibility, efficacy, and safety of DTG/3TC in 131 newly diagnosed HIV-1 infected adults as a first line regimen. The primary endpoint was the proportion of participants with plasma HIV-1 RNA <50 copies/mL at Week 24.<sup>6</sup>

§D2ARLING is a randomised, open-label, phase IV study designed to assess the efficacy and safety of DTG/3TC in treatment-naïve people with HIV with no available baseline HIV-1 resistance testing. Participants were randomised in a 1:1 ratio to receive DTG/3TC (n=106) or DTG + TDF/XTC (n=108). The primary endpoint was the proportion of participants with plasma HIV-1 RNA <50 copies/mL at Week 48.<sup>7</sup> Results at week 24 of the study.

|| The reported rate reflects the sum-total of resistance cases calculated from TANGO (n=0/369, through 196 weeks) and SALSA (n=0/246, through 48 weeks).<sup>8,9</sup>

¶TANGO is a randomised, open-label, trial testing the efficacy of DOVATO in virologically suppressed patients. Participants were randomised in a 1:1 ratio to receive DOVATO (n=369) or continue with TAF-containing regimens (n=372) for up to 200 weeks. At Week 148, 298 of those on TAF-based regimens switched to DOVATO. The primary efficacy endpoint was the proportion of subjects with plasma HIV-1 RNA ≥50 copies/mL (virologic non-response) as per the FDA Snapshot category at Week 48 (adjusted for randomisation stratification factor).<sup>8,13</sup>

#SALSA is a phase III, randomised, open-label, non-inferiority clinical trial evaluating the efficacy and safety of switching to DTG/3TC compared with continuing current antiretroviral regimens in virologically suppressed adults with HIV. Eligible participants were randomised 1:1 to switch to once-daily DTG/3TC (n=246) or continue current antiretroviral regimens (n=247). The primary endpoint was the proportion of subjects with plasma HIV-1 RNA ≥50 copies/mL at Week 48 (ITT-E population, snapshot algorithm).<sup>9</sup>