Journal of Primary Care & Community Health
Volume 12: 1–8

DOI: 10.1177/21501327211047782
journals.sagepub.com/home/jpc
SAGE

Self-Testing as an Invaluable Tool in Fighting the COVID-19 Pandemic

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Abstract

Objectives: The United Kingdom and a number of European Union countries are offering and distributing rapid antigen detection tests (RADTs) for self-test use to detect SARS-CoV-2. For instance, Greece, in the midst of its third wave of COVID-19, announced the provision of RADTs for self-testing through retail pharmacies. With the aim to determine the acceptability and feasibility of COVID-19 self-testing, we ran a cross-sectional survey on residents of Greece and Cyprus, aged over 18 years. **Methods:** An online survey using the JISC platform was distributed to 1000 individuals who completed the survey anonymously. Data was collated and analyzed for complete responses by chi-squared and logistic regression analyses. **Results:** A total of 248 complete responses were obtained, with balanced gender distribution and particular demographics representative of the 2 countries. The majority of participants (79%; n = 196) reported willingness to self-test and the remaining individuals reported no (10.5%; n = 26) or don't know (10.5%; n = 26). Being a university graduate significantly predicted the likelihood of being willing to self-test (odds ratio [OR] = 3.455, $P < .001$). Pearson Chi-square test found significant differences between university graduates versus non-graduates on the type of COVID-19 test preferred ($\chi^2 = 8.95$, df = 3, $P < .03$); graduates were more likely to prefer saliva testing and less likely to prefer the finger prick test than non-graduates. **Conclusions:** Our survey data evidences the acceptability of home-based self-testing, with a preference for saliva as choice of biological material for sampling. A number of factors, such as accessible reporting, contact tracing infrastructures, central registration, and validation for the implementation of different RADTs need to be taken collectively into consideration before self-testing can be universally and reliably scaled up.

Keywords

public health policy, communicable diseases, COVID-19, epidemiology, public health, self-testing

Dates received: 6 August 2021; revised: 2 September 2021; accepted: 2 September 2021.

A 3-Question Summary Box

- COVID-19 case identification has mostly been driven by molecular diagnostic tests.
- Molecular diagnostic tests have limitations and some countries have employed rapid antigen detection tests (RADTs) as a tool to rapidly and effectively identify positive cases in populations.
- Our survey conducted in Greece and Cyprus on 248 participants over 18 years of age, identified a strong preference for saliva home-based self-testing.
- A screening approach by repeated use of RADTs, including by self-testing, presents clear benefits in keeping COVID-19 incidence at lower levels.
- Appropriate monitoring and evaluation of RADT implementation by self-testing with a focus on end-users should be actively undertaken.

Introduction

From the onset of the COVID-19 pandemic, case identification through testing has been a critical pillar of the global response, with a focus on molecular testing by reverse transcriptase-PCR (PCR) for diagnosis. PCR remains the gold standard in all countries,[1] with the majority of countries

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also employing it for diagnostic and surveillance purposes. Despite the fact that PCR can provide the viral load measurement through the cycle threshold value, results are still routinely reported as positive or negative, treating all infected individuals the same way.[2] Also, although PCR is invaluable in COVID-19 diagnostics and could be useful in tracking epidemiological dynamics during an outbreak,[3] it has limitations including cost, the laboratory infrastructure typically required to conduct the test and the turnaround of results in a timely fashion.

Rapid antigen detection tests (RADTs), in the form of lateral flow assays, have been recognized as having great potential to address the limitations of PCR, particularly for low and middle income countries.[4] They have been developed both as laboratory-based tests that require specialist equipment and as point-of-care tests with easy conduct and result readout. The World Health Organization[5] has published guidance on the use of RADTs, and it recommends them for administration by health professionals, while the European Centre for Disease Control and Prevention (ECDC) recently released 2 technical reports highlighting considerations on the use of self-tests with RADTs both for asymptomatic individuals and in occupational settings.[6,7] Self-testing is defined as the process by which a person collects their own specimen from their nose/throat (nose swab, throat swab, saliva, or combination of above), and proceeds to conduct the test and interpret the results themselves. Larremore et al[8] based on their modeling, have advocated for re-thinking current public health strategies in testing by shifting toward scale-up of RADTs, with a focus on ensuring repeated use and frequency across settings and populations in an effort to allow countries to open up their societies and economies.

From a public health perspective, RADTs are extremely useful in identifying active infections.[9,10] They also enhance the individuals' accessibility to testing and thanks to the speed of obtaining the result permit the early detection of positive cases, further controlling disease transmission. Furthermore, the availability of RADTs has not just improved convenience for many people who would have had difficulties getting to a testing site, it has also made testing more accessible for those who are vulnerable, shielding, self-isolating, or awaiting elective hospital surgery.[11] On the other hand, RADTs rely on the individual's willingness and ability to correctly perform the self-test and report a positive result, leading to both underreporting and an increase in the number of both false positives and false negatives, depending on the epidemiological landscape.[6] Thus, mis-employing them might make it challenging to monitor disease trends over time. Also, self-testing samples are not available for sequencing and monitoring variants of concern.[6]

The reluctance of some countries to try additional screening and diagnostic approaches other than PCR, has shifted their focus to big vaccination programs. In a Herculean scientific effort, specific single or double-dose vaccines for COVID-19 (Pfizer, Astra Zeneca, Moderna, Johnson & Johnson) have received emergency use authorization by regulator authorities and are currently being deployed worldwide. The safety and high levels of efficacy in preventing symptomatic disease demonstrated in randomized clinical trials are being documented from "effectiveness" real-life implementation studies in the US, UK, and Israel.[12-14] More recent data also has highlighted the role of vaccines, including those by Pfizer-BionTech and Moderna, in preventing asymptomatic infection in those being vaccinated,[12] although waning sterilizing immunity is being reported during Delta variant circulation.[15] Despite the great promise in reducing hospitalizations and mortality, there are limited quantities of vaccine globally, which are hampering our efforts in the race to vaccinate the world.[16] Vaccine hesitancy is also challenging governments in their efforts to get people to accept vaccination at a time of heightened anxiety and pandemic fatigue.[17-20]

In Europe, self-testing has been employed as a complementing tool in case identification and the identification of individuals who have developed some form of immunity to SARS-CoV-2, enabling people to safely return to work as well as gaining intelligence on the evolution of the epidemic, including on when a threshold for herd immunity has been reached.[21-24] Governments in both the UK and Greece have adopted the use of surge testing with RADTs in an attempt to slowly open up businesses, schools, and retail and more recently to control local outbreaks of SARS-CoV-2 variants, such as the delta-variant (B1.617.2) in UK hotspots.[25] The use of free RADTs for the detection of SARS-CoV-2 using nasopharyngeal swabs was offered to all business in the UK in March 2021, followed by twice-a-week testing for all asymptomatic people in early April 2021.[24] Similarly, Greece has introduced the use of 2 free nasal RADTs for weekly use by asymptomatic individuals in schools, businesses, and community settings.[26] Though, the use of lateral flow antigen tests was authorized by the U.S. Food and Drug Administration (FDA)[27] in March 2020, a prescription was initially required for its use by the general public. Two rapid at-home antigen tests are now sold over the counter on drugstore shelves, without the need for prescription for asymptomatic people in the U.S., enabling the country to mitigate the chain of transmission and reduce prevalence of SARS-CoV-2.[28]

As more countries are moving toward different modes of COVID-19 testing in expanding their testing policies, we were interested in investigating the acceptability and feasibility of self-testing. For this purpose, we conducted a cross-sectional survey of residents in Greece and Cyprus aged >18 years, with a focus on the island of Lesvos, Greece in the period 16 January to 16 March 2021 using the JISC online platform, so as to determine participant preferences on COVID-19 testing and identify any relationship between particular demographics and their views on self-testing.

Methods

Study Design and Participants

The online survey was created in the JISC platform, which is designed for educational and research institutions (https://www.onlinesurveys.ac.uk/about/). The survey was distributed to 1000 individuals via email lists and social media using the public URL https://uow-survey.onlinesurveys.ac.uk/covid-19-testing-and-long-term-symptoms and it was open in the period 16 January to 16 March 2021. All responses were anonymous and validation of the survey questions and ethical approval was provided by the University of Wolverhampton FSE ethics committee (LSEC/202021/PG/52).

Individuals over the age of 18 were recruited via Les Mills gym network, Greece and Paraskevi Goggolidou's academic and professional network in Greece and Cyprus. Stratified sampling was employed to ensure appropriate gender and age distribution of the online survey. Ten or more responses were required per age group (18-24, 35-44, 45-54, 55-64, 65+) for it to be included in the study analysis. Emphasis on participant recruitment was placed on individuals permanently residing in Lesvos, Greece, because of its geographical location and representative setting. Lesvos is the third biggest island in Greece, it has got a manageable population size and it is representative of the Greek demographics. It also holds a big refugee integration center and had a steep incline in the number of COVID-19 positive cases in late 2020/early 2021.

The survey was open to participants for the duration of the study but it could not be re-accessed by the same email address account holder, once fully completed. The online survey consisted of the participant information sheet and consent, followed by a range of questions comprising: individual demographics and the responder's ability to employ non-pharmaceutical interventions, such as physical distancing during the COVID-19 pandemic; history of prior COVID-19 testing and disease manifestation; preference on COVID-19 sampling, testing methodology and settings. A survey map is provided in Supplemental Figure 1. In all cases, where data was missing the responses of this particular individual's answers to all the questions were excluded, so that only fully completed responses were taken into account.

Data Analysis

As the outcome measurement used collected categorical data, frequencies were used to present descriptive data. Chi-square tests were performed to compare sociodemographic and attitudinal data between the willing to self-test and not willing/don't know groups and for demographic predictors of test preferences. A logistic regression analyses were performed to evaluate factors may predict willingness to self-test. A P value of $<.05$ was considered statistically significant.

Results

Of the 1000 individuals that the survey was distributed to 860 participants accessed the online survey and a 62% response rate was obtained. Excluding incomplete responses, a total of 248 complete responses were received. Around 60% of the responders were based on the island of Lesvos, Greece, 20% in the rest of Greece and 20% in Cyprus. The accepted responses were of balanced gender distribution (55% women, 45% men) and particular demographics characteristic of the region (97.6% white, 98% Greek as mother tongue, 72% higher education degree, 83.1% Christian, 62% employed; Table 1). About 14% of the respondents had suspected or confirmed COVID-19 prior to participating in the survey and 63% had already had a COVID-19 diagnostic test conducted by a professional. About 62% reported that they had not been able to maintain social distancing, 59% were working in confined spaces, and 26% were a close contact of a Covid-19 case (data not shown).

The majority of the participants (79%; n=196) reported willingness to self-test and the remaining individuals reported no (10.5%; n=26) or don't know (10.5%; n=26). For data analysis purposes, the no and don't know groups were combined (21%; n=52) into one group (no/don't know group). Pearson Chi-square was performed to measure whether there were any significant demographic differences between the willing and no/don't know groups. Analysis revealed that those who are willing to self-test are more likely to be university graduates than those who were in the no/don't know groups ($\chi^2=15.398$, df=1, $P<.001$). No other demographic differences were found between the willing and no/don't know groups (Table 2, results for the significant variables only).

Logistical regression models were performed on significant chi-square variables to measure predictors of willingness to self-test. Being a university graduate significantly predicted the likelihood of being willing to self-test (odds ratio [OR]=3.455, $P<.001$). Location of the test site did not predict willingness to self-test. When asked on preference for sampling method, the majority of the participants indicated that they preferred a saliva test (73%; n=180), followed by finger prick test (13%; n=32); nose swab (11%; n=27); or throat swab (7%; n=9). Pearson Chi-square test found significant differences between university graduates versus non-graduates on the type of COVID-19 test preferred ($\chi^2=8.95$, df=3, $P<.03$); graduates were more likely to prefer saliva testing and less likely to prefer the finger prick test than non-graduates (Table 3). Further, chi-square found that non-Greeks were significantly more likely to prefer the saliva test and less likely to prefer the nose swab than Greeks ($\chi^2=9.12$, df=3, $P<.028$); no other significant differences related to the participants' other characteristics (eg, age, gender, language, employment) were detected. Further, no significant differences were revealed between individuals' sampling method preferences

Table 1. A Summary of Participants' Demographics.

Socio-demographic variable	Sample (N = 248)
Gender	Female = 55%
	Male = 45%
Age	18-24 = 7%
	25-34 = 16%
	35-44 = 36.7%
	45-54 = 26%
	55-64 = 12%
	65+ = 5%
Highest qualification	University graduates = 72%
	Non-university graduates = 28%
	Breakdown
	PhD = 10%
	Postgraduate degree = 33%
	Undergraduate degree = 29%
	Other higher education below degree level = 12%
	Certificate of graduation from upper secondary education (Lykeio) = 10%
	Certificate of graduation from lower secondary education (Gymnasio) = 0.4%
	Certificate of graduation from primary education = 0.4%
	Another type of qualification INFO: includes other vocational or professional or foreign qualifications = 5%
	I'd rather not say = 0.4%
Employment	Employed/self-employed = 69%
	Other = 30%
	Breakdown
	Employed = 62%
	Self-employed = 8%
	Unemployed = 9%
	Have own business = 13%
	Receiving state support = 1%
	I'd rather not say = 1%
	Pensioner = 7%
Country born	Greece = 90%
	Non-Greece = 10%
	Breakdown
	Greece = 90%
	Cyprus = 6%
	UK = 0.4%
	France = 0.4%
	Germany = 1%
	Sweden = 0.4%
	Another country = 2%
Native language	Greek = 98%
	Non-Greek = 2%
	Breakdown
	Greek = 98%
	English = 2%
	Italian = 0.4%
Ethnicity	White = 97%
	Non-White = 2%
	Breakdown
	White = 97%
	Black/African/Caribbean/Mixed = 1%
	Other ethnic group = 1%
	I don't know = 0.4%
Religion	Christian = 83%
	Non-Christian = 17%
	Breakdown
	Christian = 83%
	Agnostic = 3%
	Atheist = 11%
	Rather not say = 3%

The majority of the participants were female, aged between 35 and 44 years, university graduates, employed, born in Greece, spoke Greek, were white and of Christian faith. Percentages may not add to 100% due to figure rounding up.

Table 2. A Summary of the Significant Differences Between the Groups That Were Willing to Perform a COVID-19 Self-Test at Home and Those Who Responded No/Don't Know.

Significant variable	% Count willing to self-test	% Count no/don't know about self-test	Test results
Education	Graduates = 78%	Graduates = 50%	$\chi^2 = 15.398$, df = 1, $P < .001$
	Non-graduates = 22%	Non-graduates = 50%	
Preference for occurrence of self-test	Daily = 2%	Daily = 2%	$\chi^2 = 33.800$, df = 4, $P < .001$
	Every 3-4 days = 10%	Every 3-4 days = 2%	
	Once a week = 47%	Once a week = 15%	
	Once a month = 18%	Once a month = 19%	
	Never = 22%	Never = 62%	
Preference for test site	Home = 57%	Home = 33%	$\chi^2 = 36.331$, df = 6, $P < .001$
	EODY/YDY = 5%	EODY/YDY = 19%	
	Hospital = 5%	Hospital = 10%	
	Private clinic = 8%	Private clinic = 19%	
	Don't mind = 24%	Don't mind = 14%	
	None of these = 1%	None of these = 0%	
	Don't know = 0%	Don't know = 6%	

Table 3. Pearson Chi-Square Test Found Significant Differences Between University Graduates Versus Non-Graduates and Greeks Versus Non-Greeks on the Type of COVID-19 Test Preferred.

Significant variable	Type of test preference	Test results
Graduates vs non-graduates	Saliva: 76.4% vs 62.9%	$\chi^2 = 8.95$, df = 3, $P < .03$
	Finger prick test: 9% vs 22.9%	
	Nose swab: 10.7% vs 11.4%	
	Throat swab: 3.9% vs 2.9%	
Greeks vs non-Greeks	Saliva: 71.7% vs 80%	$\chi^2 = 9.12$, df = 3, $P < .028$
	Finger prick test: 13.5% vs 8%	
	Nose swab:12.1% vs 0%	
	Throat swab: 2.7% vs 12%	

and their willingness to self-test or not/don't know ($\chi^2 = 3.652$, df = 3, $P > .05$).

Notably, the majority of participants would prefer to take the test once a week (40%; n = 100), <1 in 5 of the people surveyed chose to have the test done once a month (19%; 46), while around 1 in 3 answered that they never wished to get tested (31%; n = 76). Pearson Chi-square test found significant differences between the 2 groups; those willing to self-test preferred once a week, whereas those who reported no/don't know preferred never (Table 2). Lastly, over half of participants would prefer taking the test at home (52%; n = 129) or had no preference on testing site (22%; n = 54). Pearson Chi-square test found significant differences between the 2 groups ($\chi^2 = 36.331$, df = 6, $P < .001$); the willing group preferred to be tested at home whereas the no/don't know group preferred home, private clinic, or EODY/YDY settings (Table 2).

Discussion

Our data shows an overall preference for COVID-19 self-testing in the least invasive manner, with a preference for saliva as the biological material of choice. In the current self-testing practices, nasal swabs are usually acquired.[29] Saliva needs to be considered as an additional biological sample for COVID-19 testing, as even though its sensitivity is lower than swab PCR,[30] it is a clinically acceptable material[31] and its user-friendliness allows for easy, repeated testing, which increases the likelihood of detection of positive cases. In addition, the non-invasive nature of saliva acquisition permits sample collection in children, disabled, vulnerable, or anxious individuals and where resources are sparse and although it has limitations, it may increase acceptance for repeated testing.[29]

The concept of self-testing was very novel at the time we were designing our survey. Although our study was cross-sectional in nature, the survey population was limited and an over-representation of university graduates was observed in the survey population, our findings give us an insight into the preference of individuals to self-test. The survey was conducted on an adult population representing the country demographics, with the only barrier to participation being access to a technological device. This was addressed with the help of local volunteers that assisted 7 participants with

no online access to fill in the questionnaires. Some participants also initially submitted incomplete responses; where this was evident, our local volunteers assisted them with re-submitting a complete response. It should also be noted that although we tried to include survey participants that may benefit from self-testing access and who understand barriers to access such as cost, it was challenging to obtain participation on preferences of vulnerable populations (eg, refugees and migrants)[32] and as such, these findings are only reflective of the mainly Greek population. In the future, this limitation could be addressed by diversifying the points from which participants accessed the survey, as this could have enhanced the diversity of the sample population. Further limitations of the study include the fact that it was completed before self-testing for asymptomatic screening was launched in Greece; it is possible that after repeated exposure and conduct of twice-a-week nasal testing, the participants' preferences on frequency and method of testing might have changed. Our study did not access the preferences of individuals under 18 years of age, thus no conclusion can be made on their views on self-testing.

The use of self-testing RADTs could represent a vital part of helping a government to cautiously lift restrictions to open its economy and society.[6,7,30] It can also be critical during a rapid surge in cases, as more recently evidenced in India, where the government guidance indicates a reactive antigen home test to be a definitive positive.[33] As of 31 March 2021, the US Food and Drug Administration (FDA) had authorized 4 tests for over-the-counter use without a prescription for asymptomatic serial testing for SARS-CoV-2.[34] In Greece, self-testing RADTs are being distributed to all registered citizens through pharmacies since early April[35] and a similar approach for twice-weekly self-testing was undertaken in the UK.[24] The use of an online system for reporting reactive COVID-19 results on a lateral flow assay is essential and has successfully been applied by the NHS using the Trace and Contact app in the UK.[36] Individuals with a reactive result for COVID-19 in Greece report it via an online platform.[37] In addition to testing, contact tracing must complement case identification, as it enables to break chains of transmission by rapidly identifying clusters or outbreaks in specific settings,[38] and even if positive cases do not formally report or mis-report their result, they may inform their contacts, which may have a positive impact on transmission control.

Hence although self-testing can enhance a country's response against COVID-19 even as vaccination coverage increases, a number of factors need to be considered before self-testing can be universally and reliably scaled up. In Europe, manufacturers must demonstrate compliance with the applicable legal requirements of EU Directive 98/79/EC for in vitro diagnostic medical devices, so as to be able to market a RADT.[39] Concerns have already been expressed about the high rate of false negatives in RADTs with sensitivities of 72% and 58% observed in cohorts of symptomatic and asymptomatic participants, respectively. Furthermore, a recently published Cochrane review reported variations in sensitivities between brands ranging from 34% to 88%[40] and another study investigated RADTs with promising performance characteristics, identifying Innova RADT as one such test with excellent specificity.[11] As the market for over the counter detection kits rapidly expands through government-backed self-testing programs, the ability to centrally register and evaluate efficacy of different antigen tests becomes paramount.

For mass self-testing approaches to be successful in breaking the chains of transmission, countries will need to focus on end users, provide the tests widely and freely and build trust in the process. Our findings show that 52% of participants prefer to be tested at home compared to other alternative settings and 31% are reluctant to get tested because of the financial cost. Easily accessible and freely available self-testing would be a strategy to address these barriers. In order to be able to obtain meaningful results, users will need to be provided with clear instructions on how to conduct self-testing and a few key members of the community will need to be trained in and act as ambassadors for self-testing. Furthermore, a proactive approach in reporting a result will need to be employed, either with the adoption of specially-designed apps or by a dedicated, easy to access website. In Greece, since free self-testing was launched, 42 million RADTs were distributed to 4.6 million citizens and around 85 000 positive cases were confirmed by PCR.[41] Different countries have diverse practices on the validation of self-testing results and our recommendation is that a reactive result will need to be validated by PCR, in a way that does not disadvantage or cause harm to the individual or society; self-sampling and home collection of sample for validation might be a solution. It should also be noted that while the number of false positives will vary based on background prevalence,[8,9] the success of the approach will depend on the participation of the population which can be encouraged by education campaigns and community ambassadors, the effective and timely reporting and validation and the provision of state support to positive cases during the period of quarantine and isolation.

Conclusions

Although vaccine-induced immunity is the vehicle to control and end the pandemic, COVID-19 self-testing as part of a comprehensive testing approach should be prioritized in parallel as vaccination campaigns proceed across countries. Appropriate monitoring and evaluation of RADT implementation by self-testing should be actively undertaken, where testing metrics are shared rapidly and publicly, as has been done with vaccination roll-out in

countries. Importantly, self-testing with RADTs should be understood as a screening strategy, instead of a diagnostic test, while saliva needs to be considered as an additional sampling material, especially in cases of young, vulnerable, and hard to reach populations. A screening approach by repeated use of RADTs, including by self-testing, presents clear benefits over what is deemed lower analytical sensitivity of the assay compared to more costly molecular diagnostic testing. Pandemics require innovation and being bold in policy development. Expanding testing to include self-testing can be critical in keeping COVID-19 incidence at lower levels, especially as we move into the next phase of the COVID-19 global response in an era of increasing, albeit limited, vaccination coverage.

Declaration of Conflicting Interests

The author(s) declared no potential conflicts of interest with respect to the research, authorship, and/or publication of this article.

Funding

The author(s) received no financial support for the research, authorship, and/or publication of this article.

Ethics and Patient and Public Involvement

All the responses collected for our survey were anonymous. Ethical approval for the study was provided by the University of Wolverhampton Faculty of Science and Engineering ethics committee (approval number: LSEC/202021/PG/52).

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Supplemental Material

Supplemental material for this article is available online.

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