RESEARCH ARTICLE

Developing an ethical framework for asymptomatic COVID-19 testing programmes in higher education institutions [version 1; peer review: 1 not approved]

Caitriona Cox1, Akbar Ansari1, Meredith McLaughlin1,2, Jan Van der Scheer1, Kathy Liddell3, Jenni Burt1, James McGowan1, Jennifer Bousfield4, Jenny George4, Brandi Leach4, Sarah Parkinson4, Mary Dixon-Woods1

1The Healthcare Improvement Studies (THIS) Institute, University of Cambridge, Cambridge, UK
2Homerton College, University of Cambridge, Cambridge, UK
3Faculty of Law, University of Cambridge, Cambridge, UK
4RAND Europe, Cambridge, UK

First published: 07 May 2021, 6:101
https://doi.org/10.12688/wellcomeopenres.16807.1
Latest published: 07 May 2021, 6:101
https://doi.org/10.12688/wellcomeopenres.16807.1

Abstract

Background: Mass asymptomatic COVID-19 testing programmes are being introduced in a range of settings, including in higher education institutions (HEIs). We aimed to produce an ethical framework to identify the range of ethical considerations relevant to HEI testing programmes and to support organisational decision-making.

Methods: We conducted a mixed-method consultation (survey and semi-structured interviews) with students and staff at a case study university that was running a student testing programme. Survey data were analysed descriptively; data analysis for interviews was based on the Framework method. The findings of the consultation were combined with literature review, legal/ethical analysis and expert views to produce an ethical framework.

Results: A total of 239 people took part in the consultation: 213 completed surveys (189 students, 24 staff) and 26 (16 students, 7 staff) participated in interviews. The survey identified clear support (99% of survey respondents) for the testing programme. Around two-thirds (62%) supported non-mandatory participation. Over half (54%) felt that the programme would need to be at least moderately effective to be acceptable. Over three-quarters (76%) felt the university had some responsibility to run a testing programme. Synthesis of consultation findings and further analysis identified nine areas of ethical consideration for HEIs looking to implement mass asymptomatic testing programmes: design and operation; goals; properties of the test; enabling isolation; choices about participation; benefits, harms and opportunity costs; responsibilities between students and institutions; privacy, confidentiality and data-sharing; and
communication. The ethical framework includes recommendations in each of these areas, with illustrative examples of how they might be put into practice.

**Conclusions:** By identifying ethical considerations relevant to university student testing programmes using analysis and consultation, the framework we developed has potential to facilitate deliberation about ethical aspects of such programmes, as well as informing decision-making about their introduction, design and delivery.

**Keywords**
COVID-19, bioethics, public health, education, testing, mixed-methods

---

**Corresponding author:** Caitriona Cox (clc70@cam.ac.uk)

**Author roles:** Cox C: Conceptualization, Data Curation, Formal Analysis, Investigation, Methodology, Project Administration, Writing – Original Draft Preparation, Writing – Review & Editing; Ansari A: Data Curation, Formal Analysis, Investigation, Methodology, Writing – Review & Editing; McLaughlin M: Data Curation, Formal Analysis, Investigation, Methodology, Writing – Review & Editing; Van der Scheer J: Methodology, Writing – Review & Editing; Liddell K: Writing – Review & Editing; Burt J: Formal Analysis, Visualization, Writing – Review & Editing; McGowan J: Writing – Review & Editing; Bousfield J: Formal Analysis, Writing – Review & Editing; Leach B: Formal Analysis, Writing – Review & Editing; Parkinson S: Formal Analysis, Writing – Review & Editing; Dixon-Woods M: Conceptualization, Funding Acquisition, Methodology, Supervision, Writing – Original Draft Preparation, Writing – Review & Editing

**Grant information:** This study is funded by Mary Dixon-Woods’ NIHR Senior Investigator award (NF-SI-0617-10026), by the Wellcome Trust through a contract award for a project on ethical issues in COVID-19 testing, and by The Healthcare Improvement Studies Institute (THIS Institute), University of Cambridge. THIS Institute is supported by the Health Foundation, an independent charity committed to bringing about better health and healthcare for people in the UK. Caitriona Cox, Academic Clinical Fellow, lead researcher, is funded by the National Institute for Health Research (NIHR). The views expressed in this article are those of the authors and not necessarily those of the NHS, the NIHR, or the Department of Health and Social Care or the Wellcome Trust. The funders had no role in study design, data collection and analysis, decision to publish, or preparation of the manuscript.

**Competing interests:** No competing interests were disclosed.

**Copyright:** © 2021 Cox C et al. This is an open access article distributed under the terms of the Creative Commons Attribution License, which permits unrestricted use, distribution, and reproduction in any medium, provided the original work is properly cited.

**How to cite this article:** Cox C, Ansari A, McLaughlin M et al. Developing an ethical framework for asymptomatic COVID-19 testing programmes in higher education institutions [version 1; peer review: 1 not approved] Wellcome Open Research 2021, 6:101 https://doi.org/10.12688/wellcomeopenres.16807.1

**First published:** 07 May 2021, 6:101 https://doi.org/10.12688/wellcomeopenres.16807.1
**Introduction**

Mass testing of asymptomatic individuals is now a feature of a range of settings as part of efforts to control the transmission of coronavirus disease 2019 (COVID-19). Large-scale testing may have a particular role in reducing the spread of the virus in well-defined and concentrated populations, such as students living in university accommodation. However, concerns, including ethical issues, have been raised about asymptomatic testing programmes\(^6\).\(^7\).\(^8\).\(^9\).\(^10\).\(^11\).\(^12\). Although the importance of establishing a transparent process whereby ethical issues are identified and addressed with involvement from different stakeholders has been repeatedly emphasised\(^6\),\(^8\), this need has not yet been addressed in the context of mass asymptomatic testing in higher education institutions (HEIs).

One challenge is to identify an appropriate theoretical framing for the ethics of asymptomatic testing, given that infectious diseases raise specific ethical issues by virtue of their communicability. For instance, testing might be seen to activate a set of concerns derived from clinical ethics, based on principles (such as autonomy, non-maleficence, beneficence, and justice) relevant to individuals in their interactions with healthcare systems\(^1\). Certainly, testing does have some characteristics of a medical procedure: it may be invasive or uncomfortable (depending on the test used), and generates health information about an individual. However, framing testing for an infectious disease solely as a matter for individuals may be too limited to inform decisions about large-scale programmes during a public health emergency\(^6\),\(^9\).

Mass testing for asymptomatic COVID-19 also has some of the characteristics of population-based screening programmes. Well-established ethical principles, many of them dating back over 50 years to the Wilson-Jungner criteria\(^1\),\(^2\),\(^3\), are used in evaluating these programmes. Some, but not all, of these principles are directly applicable in the context of the COVID-19 pandemic. One distinction, for example, is that testing programmes are directed at infection control in a population, rather than realising a health benefit for the individual being screened.

Another source of ethical sensitisation is the growing literature on public health ethics, including a number of approaches designed to guide the implementation of public health interventions\(^4\),\(^5\). They include Kass’s framework, which proposes that the greater the burdens posed by a programme (e.g., in terms of cost, constraints on autonomy, or targeting vulnerable segments of the population), the stronger the evidence must be to demonstrate that the programme will achieve its goals\(^5\). Kass’s framework also identifies key harms to be considered when implementing a programme, including risks to privacy and confidentiality, to liberty and self-determination, and to justice\(^5\). These general principles helpfully identify a range of ethical considerations, but need to be customised for testing programmes during a pandemic.

Of course, academic ethical reasoning is only one element in generating satisfactory answers to complex questions posed by mass asymptomatic testing programmes. Recent work in applied ethics has emphasised the need for participatory approaches to help in addressing these kinds of challenges\(^13\),\(^14\).\(^15\). For example, Ives et al. have urged attentiveness to how ethical issues are experienced and negotiated in practice, and emphasised the need to develop solutions that consider the concerns of the relevant stakeholders in a meaningful way\(^13\). A number of public health ethical frameworks have also highlighted the importance of explicitly providing opportunities for stakeholder involvement\(^9\).

In this paper, we combine a participatory approach involving a mixed-method consultation with legal and ethical analysis to generate a practical ethical framework for asymptomatic COVID-19 mass testing programmes in higher education institutions\(^15\).

**Methods**

We used a multi-stage iterative process to develop an ethical framework, involving literature review and development of an initial provisional ethical framework; mixed-method consultation with stakeholders at a case-study institution; analysis of the consultation findings; and synthesis of the findings with further author-led legal/ethical analysis and public health expertise to produce the final ethical framework.

**Ethical considerations**

The survey and interview consultation received approval from the University of Cambridge Psychology Research Ethics Committee (Application No: PRE.2020.138). All participants provided their written consent prior to the interview or survey.

**Initial provisional ethical framework**

To identify a set of sensitising concepts for ethical analysis likely to be relevant to asymptomatic testing of students in HEIs, we drew extensively on a previously-developed ethical framework for COVID-19-testing in NHS workers\(^17\) and we undertook a broad informal review of relevant literatures on public health, ethics and screening. The initial provisional framework we identified was used to guide both the development of our study instruments for the consultation and to support (though not constrain) analysis of the findings.

**Mixed-method consultation: data collection**

The consultation used a mixed-method approach (semi-structured interviews and an online survey) to gather views of students and staff at a case-study institution, the University of Cambridge.

The university had introduced a programme involving weekly asymptomatic pooled COVID-19 testing of students living in college accommodation in October 2020. Its programme was based on obtaining nasal swabs, which were tested by polymerase chain reaction (PCR) in university laboratories. Testing was based around ‘households’ (consisting of 8–10 students, often arranged around a shared kitchen or bathroom facilities), with nasal swabs from individual students all being tested in a pool. If a pooled sample tested positive, students within the
household were asked to isolate immediately. Confirmatory individual testing by PCR then took place. If any of the students within the household tested positive on this confirmatory testing, all in the household were required to isolate for 14 days. The testing programme was available to all students living in college-owned accommodation at the time of our consultation, and participation was voluntary for individual students.

For the consultation, we invited students (undergraduate and postgraduate) and staff (both academic and non-academic) from the university. Participants were recruited via email: emails were sent to students via the mailing list used to contact all students with updates about the testing programme, whilst staff were emailed via contacts running the testing programme at individual colleges. Eligible participants were over 18 years old, able to understand and speak English, and were either currently registered University of Cambridge students (any subject or year of study), or a member of staff currently employed by the University of Cambridge or a college. Emails included full details of the project and an explanation of how to take part. Interested people were asked to register on Thiscover, an online research and development platform created and developed by THIS Institute at the University of Cambridge. They were able to choose to participate in an interview or complete an online survey. All participants provided their written consent prior to the interview or survey.

Data were collected over a single period running from 20 November to 11 December 2020. Semi-structured interviews, which lasted 30–60 minutes, took place either online using audio-video software or by telephone. Interviewers (CC, AA and MM) were researchers at THIS institute who had no relationship to the participants. They were guided by a prompt guide (see extended data, supplement 18), which was developed using the provisional ethical framework and then refined through three pilot interviews with students. Brief notes were taken during calls to facilitate discussion between interviewers, but were not used in formal analysis. The interviews were transcribed verbatim.

The survey was administered using Qualtrics (see extended data, supplement 21), and took approximately 15 minutes to complete. It contained a mixture of closed, open and Likert-scale questions, closely aligned with those used in the interview prompt guide. An initial version of the survey was developed and piloted with ten students in order to refine the questions.

All individuals who responded to the email to request an interview, and with whom it was possible to make arrangements, were interviewed. Similarly, all individuals who responded to the request to participate in the survey were included in the study. It was not possible to take further steps to limit bias in respondents. All data were anonymised so that neither individuals nor colleges were identifiable.

Mixed-method consultation: analysis

The quantitative closed-ended survey questions were analysed on Excel using descriptive statistics and Likert-scale questions were visualised using diverging stacked bar charts19. Our analysis approach for the textual data (open-ended survey responses) and qualitative interview data was broadly based on the Framework Method20, which allowed multiple analysts to scrutinise the data, looking for commonalities and divergences in the data by comparing views of participants. After the familiarisation process, three analysts (JG, JBI and BL) independently coded the first three interview transcripts deductively using pre-defined codes based on the provisional ethical framework. A group of researchers then scrutinised the work of the two analysts to agree on a set of codes to apply to all transcripts, including an ‘other’ code to host data that did not fit any of the pre-defined codes. This coding framework was subsequently applied to all transcripts to produce a matrix: quotes from interview transcripts were copied into an Excel spreadsheet (Microsoft 365). A summary was then written for each code, including references to interesting or illustrative quotes. Free-text responses to survey questions were analysed in a similar manner, with the production of a separate matrix and coding summaries for these data.

We integrated the three data types – qualitative (interview), textual (survey open-question responses) and quantitative (survey closed question responses) – at the interpretation stage of analysis21. We discussed patterns arising across our analyses of the three types of data through an iterative process that involved examining all the data for identified themes and considering convergence or divergence between sources. Insights from interviews and the survey were given equal priority in the interpretation. We did not undertake a formal test for theoretical saturation; we instead used the principle of “information power”, which indicated that we have achieved sufficient range and depth of views22.

Production of the final framework

We sought to develop a final framework that would take account of the consultation findings, and also engage in wider ethical thinking. Public health decisions can rarely be made on the basis of complete scientific certainty; they must instead rely on processes of risk assessment and of reasoned and deliberative justification23. In this project, this took the form of multiple rounds of iterative analysis and discussion involving members of the study team over several weeks to interpret the consultation findings and synthesise them with the team’s professional expertise and knowledge of the literature across law, ethics, social science, anthropology, public health and healthcare improvement. We considered the extent to which the findings aligned with, or were divergent to, theories, principles and frameworks in relevant areas, with attention to the potential moral and legal challenges relevant to a COVID-19-testing programme. Recommendations were also checked for compliance with current laws and regulations relating to testing and information governance.

Results

A total of 239 people took part in the consultation; 26 participated in semi-structured interviews (‘interview participants’) and 213 completed surveys (‘survey respondents’) (Table 1).
Findings of the consultation are briefly reported in a joint display table (Table 2), which organises the results using the thematic structure of the study instruments.

The final ethical framework (Table 3) is based on multiple inputs (including the consultation data, literature review, ethical and legal analysis, and professional expertise), but it is not possible to dissect out the relative contributions for each theme. The framework can also be accessed on the THIS Institute website through this link (https://ethical-framework-testing-hei.carrd.co/). For some themes, the framework drew heavily upon the consultation findings, while for others it was influenced more by public health principles and ethical and legal reasoning grounded in the literature. In what follows, we briefly offer the reasoning underpinning each element of the framework, with reference to both relevant consultation data and other inputs that influenced the recommendations.

**Design and operation of the programme**

**Main recommendation: Assess if a testing programme is the right choice and whether you can deliver all aspects of it. Make sure public and legal duties will be met.**

The framework encourages HEIs to start by making a thorough assessment of whether an asymptomatic testing programme is the
### Table 2. Joint display of major findings from interview and survey analyses.

| Theme | Interview findings | Survey open question responses | Survey closed question responses | Overall inferences |
|-------|--------------------|--------------------------------|---------------------------------|--------------------|
| **1. Goals of the programme** | Participants identified several programme goals:  
- Major focus was on need to reduce transmission to protect vulnerable members of the community, and to potentially allow more activities to occur without restrictions.  
- Contribution to scientific research.  
- Psychological reassurance. | Respondents identified several programme goals, mostly similar to those identified interview participants:  
- Major focus was on need to reduce transmission, ensure fewer outbreaks, and enable more normal life (e.g. face-to-face teaching).  
- Contribution to scientific research.  
- Recurrent comments about 'peace of mind'. | Clear support for programme  
99% of survey respondents strongly supported or somewhat supported the programme. | The primary goals of reducing virus transmission, data collection for research, and providing psychological reassurance were mentioned consistently both in interviews and survey responses. Strong support for the programme and its goals, which were seen as legitimate and worthy of pursuit. |
| **2. Choices about testing** | Participants reported strong support for voluntary testing:  
- Participants emphasised the need to respect individual choice, despite a perceived moral obligation to be tested.  

**Diverse views on mandatory testing:**  
- Many saw mandatory testing as not ethically reasonable.  
- Some felt that mandatory testing could be justified as a condition of living in college, sometimes drawing parallels with other mandatory measures such as mask-wearing. | Respondents reported strong support for voluntary testing:  
- Support for individual opt-out justified by invoking respect for personal liberty and individual choice.  

**Diverse views on mandatory testing:**  
- Where present, support for mandatory testing was justified with reference to common good, or was considered a reasonable condition of living in college. | Large degree of support for voluntary testing  
62% agreed (40% agree, 22% strongly agreed) that individual students should be able to opt out.  
65% (40% agreed, 25% strongly agreed) were worried that not everyone would take part, reducing the value of the programme. | Non-mandatory participation in testing for individual students was supported on grounds of respecting individual choice. |
| Theme | Interviews | Survey | Overall inferences |
|-------|------------|--------|-------------------|
|       | Interview findings | Survey open question responses | Survey closed question responses |  |
|       | Incentives were variably perceived by participants: | Incentives were variably perceived by respondents: | Small incentives supported by majority: | Incentives were viewed more favourably than penalties, but evidence was mixed across survey and interview. Some highlighted that education and emphasis on community benefits of testing might be more effective than incentives in encouraging participation. |
|       | - Incentives could demonstrate appreciation and might be well-received by many. | - Some saw no problem with using them. | 75% agreed with the use of small incentives (e.g. coffee vouchers) to encourage participation (42% agreed and 33% strongly agreed). |  |
|       | - They could undermine the programme and ‘cheapen’ its value. | - Possible use only if programme uptake very low. |  |
|       | - Effectiveness of small incentives questioned. | - Some concerns that they could undermine individual choice. |  |
|       | - Effective communication about potential benefits may work better than incentives. | - Effectiveness of small incentives questioned. |  |
|       | - Incentives should be similar in nature and value across different colleges. | |  |
| 3. Balancing and distributing risk, harms, burdens and benefits | Minimal risk perceived: | Need to consider cost/benefit: | Spread of views on effectiveness vs acceptability: |  |
|       | - Perceived individual cost of participation low; small impacts (e.g. detecting small number of asymptomatic cases) sufficient to justify the programme. | - Some proposed need to consider the public health benefits achieved by such a testing programme in comparison with other potential uses of resources. | - 54% reported the programme should be at least moderately effective to be acceptable. |
|       | - Some highlighted need for overall cost-benefit analysis when evaluating the programme. | | - 32% reported that even a small effect would be enough to justify it. |
|       | | | - A minority (14%) reported that the testing programme should be highly effective in reducing transmission to be acceptable. |
| 4. Relationships between stakeholders: reciprocal responsibilities and solidarity | Participants felt that the university has a duty of care: | Respondents felt the university had responsibility to run the testing programme because: | The perception that even small effects on transmission were worthwhile, given the minimal harms for individuals of taking part in testing, was reported more strongly in the interviews than in the survey free text responses. Survey respondents suggested the need to judge whether the programme justified the associated use of resources. The quantitative findings – the majority feeling that the programme would have to be at least moderately effective – reflect this reasoning. |
|       | - Duties as an educator, pastoral support provider, employer of staff, and (heavily emphasised) as a landlord to students living in college were expressed. | i. It had encouraged students to return in person to campus. |  |
|       | - Special vulnerabilities of non-academic staff (e.g. cleaners), and the role that participation can play in protecting them was noted. | ii. It has the financial and technological resources available, and there are limits in government testing capacity. |  |
|       | The limits of university's responsibilities were less clear: | Mixed views on university responsibilities to wider, non-university community. Some identified testing programme as an exceptional service, but not one that the university had a strict responsibility to provide. |  |
|       | - Participants tended to disagree regarding university versus government responsibilities, and responsibilities to the wider community (including city residents and family members of staff and students), | |  |
| Theme | Interviews | Survey | Overall inferences |
|-------|------------|--------|-------------------|
| **5. Isolating** | Participants reported that isolating is challenging:  
- Discussion of multiple emotional and psychological effects, including difficulties with mental health, lack of access to outside space, problems with ability to study.  
Isolating has variable impact:  
- Isolating was disproportionately more difficult for certain student groups, e.g. those in lower income groups.  
Isolating needs support:  
- Students identified a need for access to outside space, online mental health support, social activities, and educational support.  
- Students expressed anxiety about needing to isolate, and uncertain of support available.  
- Staff identified multiple considerations in managing a student household in isolation: household necessities, meals, delivering post, laundry, exercise, social support, mental health services and beyond.  
Respondents reported isolation has variable impact:  
- Some respondents noted that quarantining was disproportionately more challenging for certain groups: those from lower incomes, with pre-existing mental health problems, students studying science subjects, who miss out on time in the laboratory.  
Isolating requires support:  
- Basic necessities (food and household essentials)  
- Online educational resources  
- Mental health services  
- Medical care for those with symptoms  
- Access to private outdoor space. | Concerns about impact of isolation:  
90% of respondents worried about the impact of isolation on students’ mental health: 70.4% were worried about practical issues such as getting food and medical supplies, and 66.7% about the impact on students’ studies. | Across the interviews and surveys, multiple challenges were identified with isolation, including psychological impact. These challenges were seen as disproportionately burdensome for some groups. There was clear identification of university responsibilities to support students. |
| **6. Properties of the test** | Participants saw the test as generally acceptable:  
- Use of polymerase chain reaction (PCR) testing seen as an advantage (compared to the use of lateral flow tests).  
- Small number of participants concerned about potential for incorrect self-swabbing technique/purposeful falsification of results.  
Participants described self-swabbing as tolerable. | Respondents expressed some concern around false negatives:  
- False positives or false negatives were raised as potential disadvantages to the programme; false negatives generally seen as more concerning.  
- Possibility of false reassurance impacting on behaviour raised by a few. | Only minor concerns about the discomfort of the test itself. | More concern around false negatives than false positives:  
- 43% agreed and 18% strongly agreed that they were worried about false negatives.  
- 33% agreed and 6.6% strongly agreed that they were worried about false positives.  
Only 6.6% were worried about the discomfort of the test. | All data streams suggest that false negatives were more of a concern than false positives, although for many the accuracy of the test was not a major source of worry. Self-swabbing was associated with only very minor discomfort and was generally considered tolerable. |
| **7. Privacy, confidentiality, and information-sharing** | All participants felt that data collected for the programme should be used for research:  
- Caveat from some: only with explicit consent of those involved.  
- Some supported even without specific consent. | Respondents reported that programme data should be used for research:  
- Value of using data for research purposes recognised: some describing it as ‘wasteful’ to not do so. | 97% supported the use of anonymised data (87% strongly agreed, 10% agreed). | There was clear support for using anonymised data for scientific purposes. |
| Theme | Interview findings | Survey open question responses | Survey closed question responses | Overall inferences |
|-------|--------------------|--------------------------------|--------------------------------|--------------------|
| **Interviews** | | | | |
| Participants recognised need for some defined sharing of information. | - Wide support for informing certain people (e.g. staff who provide isolation/quarantine support; those who run the programme) if a household tests positive. | N/A: There were no open text questions on this topic | Relevant college staff should be informed about a positive pooled test result: | Views on sharing information on positive test results indicated support only for “need to know” individuals being informed. |
| | - Mixed views on others being informed, but also acknowledgement that news is likely to travel. | | - 86% supported college staff who might have contact with a household being informed if a pooled sample tested positive. | |
| | | | - 70% also agreed college nurse should be informed. | |
| | | | - Only 18% of survey participants supported the idea of all students in the college being informed. | |
| Participants emphasised need to protect identity of individuals: | - Participants generally did not want the names of individual students who tested positive to be shared widely. Some raised issues about stigma (e.g. risk that a positive test could be interpreted as reflecting reckless or irresponsible behaviour). | N/A: There were no open text questions on this topic | Identifying individual positive-testing students: | There was support for households to be informed which members had tested positive and for some other limited sharing linked to need, but otherwise an emphasis on individual privacy. |
| | - Participants generally did not want the names of individual students who tested positive to be shared widely. Some raised issues about stigma (e.g. risk that a positive test could be interpreted as reflecting reckless or irresponsible behaviour). | | - 85% agreed that the students in a household should be informed which individual tested positive. | |
| | | | - 69% agreed college staff who might have had contact with that household should be told. | |
| | | | - 64% supported the college nurse being informed. | |
| | | | - Only 4.2% felt that all students should be told the name of an individual positive-testing student. | |
| **Survey** | | | | |
| 8. Communication | Participants emphasised the need for clear communication about the programme: | Respondents suggested various types of additional information to be communicated: | Clear communication important: The majority of rated as very important; communication about where and when testing is taking place; how students will be told about results and who else will be told; what support is available if students have to isolate; and regular updates about how many people test positive. | Clear communication is a priority; interview data provided detailed information regarding the importance of communicating effectively to address concerns and encourage participation, which was also supported by the survey responses. |
| | - Some wanted more information, for example about rates of infection broken down by college or about the evidence behind certain methods of testing. | A range of suggestions regarding further information respondents would like to receive, e.g. infection rates broken down by college, more detail about test properties, the evidence base and impact. | | |
| | - Some discussion about the potential for information overload, e.g. receiving too many long emails, with difficulty in picking out important information. | | | |
| **Participants expressed uncertainty about how to raise concerns:** | Participants were often not clear about how they would raise concerns about the testing programme. | N/A – no open text questions on this topic | Raising concerns through website: | In interviews, participants did not always seem to know how they would raise concerns if they had them. The survey suggests that a specific website to allow anonymous reporting would be welcomed. |
| | | | - 89% reported that the best way to raise concerns about the programme would be anonymous reporting through a programme website. | |
### Table 3. Ethical framework for asymptomatic mass coronavirus disease 2019 (COVID-19) testing of students in higher education institutions (HEIs).

| Ethical consideration                                      | Recommendations                                                                                                                                                                                                 | Illustrative examples of how a HEI might put these recommendations into practice                                                                                                                                                                                                 |
|------------------------------------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| **Design and operation of the programme**                  | Start by making an assessment of whether a programme is the right choice for the HEI, taking account of the available evidence, current pandemic conditions, and available resources and capabilities. | • One HEI identifies all the components that need to be in place for an asymptomatic testing programme for its students. Having satisfied itself that it can deliver on all of these, it decides to proceed. It establishes a governance structure for the programme, identifying key responsibilities and accountabilities in the programme team and a clear decision-making structure. It decides that major decisions should be made by its COVID-19 ‘gold’ committee, alongside other important decisions for managing the impact of the pandemic. Recognising that running an asymptomatic testing programme is very different from the University's usual operations, it sets up a committee with broad membership which liaises closely with an operational management team. |
|                                                           | Ensure that all other infection control measures are in place both prior to making a decision about introducing a testing programme and subsequent to the decision (whether or not it is to proceed). A testing programme should be seen as one element in a multi-modal strategy. |                                                                                                                                                                                                                                                                             |
|                                                           | Recognise that a testing programme requires a whole-system approach that is designed end-to-end. Testing on its own is not enough; there must also be confidence that the key control measure (isolation of confirmed cases and their close contacts) can be achieved. A HEI should therefore sign up in full to delivering on all of the components necessary for the programme. | • A different HEI, having reviewed the resources required to deliver all elements of a testing programme effectively, determines that it lacks the financial and logistical capabilities to run a sufficiently quality-assured, effective programme. It therefore decides not to proceed. |
|                                                           | Set up a governance structure capable of dealing with all aspects of the programme, including clear decision-making, operational oversight, quality assurance, communication, and facilities for consultation and ethical advice. | • A HEI running a testing programme models a number of scenarios, including situations where testing is conducted routinely during a period of stability, and situations where there is a current outbreak that needs to be managed. It puts plans in place to cope with these, including, for example, scenarios where large-scale staff absences may mean that it is difficult to support isolation, including appropriate meal provision. |
|                                                           | Plan for a range of scenarios and ensure that contingencies are in place.                                                                                                                                                                                                 |                                                                                                                                                                                                                                                                             |
| **Goals of the testing programme**                         | Ensure that the goals of the programme are well-defined and have a clear rationale based on disrupting viral transmission through early control measures. The goals should be clearly explained to the student population and other stakeholders. If there are multiple programme goals, they should be acknowledged explicitly. | • A HEI identifies the goals of its testing programme. It distinguishes between primary goals (reducing viral transmission through identification and isolation of cases and their contacts) and secondary goals (providing reassurance for students and staff). It explains the rationale and goals of the programme to its stakeholders, emphasising potential benefits it hopes to achieve for students (e.g. reduced risk of contracting the virus, more normality of educational experience, and psychological reassurance) and for those in the wider community (reduced general transmission of the virus). It also acknowledges the current scientific and uncertainties associated with demonstrating whether the programme can deliver on these. |
|                                                           | Goals should be realistically attainable, based on current understanding of the epidemiology of COVID-19, the properties of the selected testing regime, and the available resources and measures for managing risk. |                                                                                                                                                                                                                                                                             |
|                                                           | Specify criteria to judge the effectiveness of the programme in reaching its goals.                                                                                                                                                                                                 |                                                                                                                                                                                                                                                                             |
|                                                           | Keep the programme goals under active review, mindful that they may evolve over time. Goal drift (uses of the programme for purposes not specified) should be avoided.                                                                                                                                                                                                                      |                                                                                                                                                                                                                                                                             |
|                                                           |                                                                                                                                                                                                                                                                           | • A HEI keeps the goals of the programme under active review as conditions, technology, policy, guidance, and scientific understanding evolve. The HEI clearly signals any changes to all stakeholders.                                                                                                                                                      |
| Ethical consideration                                                                 | Recommendations                                                                                                                                                                                                                                                                                                                                                   | Illustrative examples of how a HEI might put these recommendations into practice                                                                                                                                                                                                                           |
|--------------------------------------------------------------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Properties of the test(s) selected for the programme                                     | Be alert to the properties of test selected for the programme and the implications of these. Test properties, such as sensitivity and specificity, may vary considerably depending on the test used and the setting (including whether or not swabbing is self-administered). Ensure that the methods of obtaining the sample (e.g. swabbing) satisfy criteria of tolerability and acceptability (e.g. should not induce excessive discomfort, pain, or anxiety). Consider the probabilities of false negative and false positive test results associated with the chosen testing regime, and identify and mitigate the possible associated risks and harms. Acknowledge the implications of false negatives and false positives in communications about the programme. Emphasise prominently and consistently the importance of continuing to observe guidance on masking, social distancing, hygiene and ventilation in the event of negative tests. Clearly communicate what should happen in response to a positive test, including any opportunity for confirmatory testing. Be alert and responsive to changes in evidence surrounding testing technologies, and be aware of current government guidance. Be mindful of relevant legal and regulatory requirements relevant to testing. Amongst other things, HEIs should consider the current authorisation and certification of the devices being used for testing, and any requirements for laboratories being used (whether in-house or under contract) to be certified. |   
•   A HEI makes a full assessment of the available testing options. It considers validity and reliability, convenience and speed of administration and test result, tolerability of the test for students, costs, logistical burden and test certification. 
•   One HEI having reviewed the latest government advice and other sources, selects lateral flow testing (LFT) as its testing approach. However, it recognises the limitations of the currently available form of the technology, including the risk that its poor sensitivity could generate high false negative rates. Accordingly, the HEI emphasises in all communications that, for the present, the main goal of the programme is to detect positive cases in asymptomatic individuals. It stresses that the programme cannot provide evidence of non-infection, and that negative results should not be used to support relaxation of social distancing, face coverings, or hygiene rules. 
•   A different HEI also conducts a full assessment of the available testing options. It decides to use polymerase chain reaction (PCR) testing because of its superior sensitivity, but it also recognises some of the downsides (e.g. longer time to test results). It repurposes some of its own lab capacity to provide the testing facility but takes care to ensure compliance with any regulatory or certification requirements that may apply. 
•   A HEI discovers that an unintended consequence of the programme is that those who test negative may engage in more risk-taking behaviour because they believe themselves to be free of infection. In response, it explicitly communicates that a negative test result means a student “has tested negative, but could still be infected with the virus”. It informs students that the asymptomatic testing programme is “one tool in a multi-component risk reduction strategy” and re-emphasises the importance of complying with other measures designed to minimise transmission. 
•   A HEI notes that in the event of a false positive, the student would be erroneously required to isolate, as would their close and household contacts (who may not be part of the programme). To mitigate this risk, it decides to offer swift confirmatory testing to anyone who tests positive. |
| Enabling isolation                                                                     | Ensure that adequate support is in place for isolation after a positive test, both at individual and household level. Programme effectiveness in breaking chains of transmission depends on individuals (and their households) isolating after a positive test. Students in HEI accommodation are likely to require the support of their institutions to isolate for practical purposes (e.g. food, laundry etc) general health (e.g. fresh air and basic exercise) and for reasons of mental health (e.g. anxiety, loneliness). Be clear in communication about both about the requirement for isolation and the available support. A dialogue should take place to ensure that those isolating feel heard, and the experiences should be used to guide the refinement of support systems. | A HEI identifies, by listening to students, the challenges associated with asking people to isolate for the specified period and takes them seriously. It identifies and organises the support – practical, psychological, social and educational – required to isolate effectively. It considers cohorting strategies to enable students to move safely outside their own bedroom in a controlled way. 
A HEI publishes a clear statement outlining policies regarding students who may be educationally disadvantaged as a result of isolating. For example, students who are unable to carry out experimental work are reassured that reasonable adjustments will be made, so that as far as is possible isolating will not result in academic detriment. 
A HEI communicates clearly with its students about what to do if they receive a positive result, or are a close contact of someone with a positive result, what support is available if they must isolate and how they can access it. Its communication acknowledges concerns and anxiety around having to isolate. |
| Ethical consideration | Recommendations | Illustrative examples of how a HEI might put these recommendations into practice |
|-----------------------|-----------------|---------------------------------------------------------------------------------|
| Choices regarding participation in testing programmes | Make a reasoned decision about individual choice regarding participation. Generally favour the least intrusive approach possible proportionate to achieving the goals of the programme and bearing in mind risks, benefits, current levels of scientific certainty and pandemic conditions. Any decision to seek to increase the degree of compulsion should be considered very carefully and should be accompanied by consultation with stakeholders, with the justification openly communicated. Consider the use of any incentives carefully. If used, they should be small and presented as tokens of appreciation rather than stimulation to take part. In general, avoid penalties (or measures that have the appearance of penalties), because they have the potential to impact on trust, undermine solidarity, cause resentment, or lead to a burden of complaints to be managed. Policies on choices about programme participation should be broadly consistent within a HEI and ideally across the HEI sector, though local differences or adaptations may sometimes be necessary. | • A HEI offers individual students the choice whether to participate in the testing programme or not, supported by clear communication surrounding the potential benefits of the programme (including the shared benefits of health protection and community solidarity). Entire accommodation blocks as a whole are not permitted to opt out. • A HEI, following consultation, concludes that offering small incentives (such as a free coffee for taking part) to encourage participation would be acceptable, because students appreciate their efforts being recognised. It monitors for any unintended consequences, such as the perception that offering either excessively trivial or unduly large rewards could undermine a programme built on community spirit. • A HEI considers whether it would be acceptable to restrict access to face-to-face teaching for students who decline to participate in the programme, following complaints from some students about having to share space with untested colleagues. Following consultation, it concludes that it could be seen as punitive and could damage support for the programme overall. It decides to reiterate the principle that participation in testing is voluntary at an individual level, but makes it clear that it strongly encourages students who attend face-to-face teaching to participate (unless medically exempt) for the safety of others. It commits to keeping the policy under review, particularly if evidence emerges that untested students are associated with higher rates of infection. • An advocacy group lobbies the HEI to make asymptomatic testing programme mandatory for students residing in HEI accommodation because of the cross-infection risks for local townspeople. The HEI explains that it will consider carefully the concerns, alongside other practical and ethical considerations. As uptake in the programme is high even with voluntary participation, it decides that it cannot justify making participation mandatory, since it concludes that the potential additional benefit of changing the policy is not proportionate to the risk at the time. |
| Ethical consideration | Recommendations | Illustrative examples of how a HEI might put these recommendations into practice |
|-----------------------|----------------|---------------------------------------------------------------------------------|
| Benefits, harms, and opportunity costs | Consider the possible benefits, risks and harms of the programme, and put in place appropriate mitigations. Be attentive to issues of equality, diversity and inclusion. Identify any student groups who may be disproportionately affected by having to isolate and seek to mitigate the effects. Consider the trade-offs and opportunity costs of running the programme, the range and nature of uncertainties, and how to balance values and interests that may be difficult to reconcile. Be able to give an account of the reasonableness of the decision-making process and decisions made for the programme. Reasonable people may disagree about how a HEI should weigh up possible benefits, risks and harms, so be prepared to explain how the decisions have been made. | • A HEI considers the possible benefits, risks and harms of the programme and explicitly considers equity, diversity and inclusion in relation to these. It gives specific consideration to people for whom isolating is likely to be disproportionately more challenging: for example, those with lower incomes who need to work part-time to support their studies, those with pre-existing mental health problems, and those whose studies require physical presence in particular settings (e.g. labs) who may be disadvantaged by being unable to attend in person. It puts appropriate measures in place to address these challenges. • A HEI decides that it lacks sufficient resources to test its all students individually, but it can provide a limited testing programme for students residing in its own halls of residence. It has a communications plan for addressing concerns raised by students in other accommodation and is sensitive to issues of inclusion and diversity in this communication. • A HEI considers alternative uses to which the resources needed for the programme might be put. Given current evidence, it decides that the programme is a justified expenditure to reduce transmission of COVID-19 for students, staff and the local area, while enabling a better student experience. The HEI reviews this assessment at key points, for example when affordability becomes a problem or when benefits decrease (e.g. during a period when students are generally advised not to attend campus in person during a national lockdown, or when wide uptake of vaccines has reduced transmission). It explains that it is making decisions using careful assessment of the evidence, current government guidance, consultation, and assessment of its own resources and capabilities, but it acknowledges that not everyone will agree with those decisions. |

| Responsibilities between students and institutions | Be clear about the responsibilities for both institutions and students in achieving programme goals, recognising the special context of higher education, where staff and students are part of a community and where cooperation will be key to achieving shared aims. Consider whether or not there might be a duty of care to students to operate a testing programme under specific conditions and what that might entail in terms of responsibilities for both students and institutions. | • A HEI believes, based on its assessment, that a testing programme could reduce risk for all members of its community and improve the educational experience of students. It conceptualises its testing programme as a benefit to the community. It presents the programme to its stakeholders in this way. In making clear the expectations of students in relation to the programme, it seeks to promote cooperation, trust and solidarity. The HEI identifies any factors that might undermine trust (e.g. treating some groups unfairly, appearing to be irrational, communication failures, and poor logistics) and takes steps to address these issues. • A HEI that has required its students to return to campus makes a full assessment of the likely benefits of the programme in reducing risk. Based on current evidence, it concludes that, while it is not a full solution, it has a duty of care to offer the programme in order to make the living and educational environment as safe as is reasonably possible. This duty derives from its responsibilities for the welfare of students, for optimising their educational experience, and for controlling risks for staff. It has further responsibilities as a landlord for students in its accommodation. It recognises that its choice to run the programme means it has responsibilities and accountabilities for the programme, including its ability to resource it appropriately. |

Wellcome Open Research 2021, 6:101 Last updated: 19 AUG 2021

Page 13 of 28
| Ethical consideration | Recommendations | Illustrative examples of how a HEI might put these recommendations into practice |
|-----------------------|-----------------|--------------------------------------------------------------------------------|
| Privacy, confidentiality and data-sharing | Design and operate sound systems for information governance, recognising that information about test participation and test results should be handled with full respect for principles of data protection and confidentiality. Data should be processed fairly, lawfully, transparently and securely and in accordance with data protection principles specified in General Data Protection Regulation (GDPR). Confidential health information can only be used with the individuals consent, or where it is necessary and proportionate to protect public safety and the health and safety of other people. Consider whether a data protection impact assessment is needed for the programme. Ensure that individuals processing programme data are properly trained. Communicate clearly with students about who will be informed in the event of a positive test result, with clear justification for any sharing of health data. For example it should be clear that public health authorities may be notified of positive test results, to activate contact tracing mechanisms. Be aware that a HEI that conducts contact tracing on-site (e.g. until public health authorities are able to take over) has a duty to inform contacts that they have been exposed (which may result in deductive disclosure as students may guess the identity of the infected individual). Be mindful of relevant legal and ethical requirements of any use of data for research purposes. | • A HEI establishes clear workflows for handling data at every stage, ensuring full compliance with the principles specified in GDPR. Data is pseudonymised or anonymised where possible. The HEI establishes a secure system where test data are stored in a protected space with access limited to dedicated testing programme managers. It trains individuals handling data, ensuring that they are aware that data concerning health is confidential. It provides a privacy notice that provides information on sharing of personal data. • A HEI needs to share some limited information about positive test results so that it can facilitate support for students who need to isolate and identifies the minimum necessary to achieve this. It informs students that the staff needed to provide practical support (e.g. food, laundry) will be informed of the location of a positive test result, but not the name. It also informs students that positive test results will be shared with relevant other staff (for example, those with pastoral responsibilities), with the option to opt out. • The HEI’s policy specifies that student households will be notified in the event of a positive test so that household members can isolate as contacts. It also specifies the name of the individual student who has tested positive will not be shared. The possibility of deductive disclosure is acknowledged. • A HEI makes sure test results from the laboratory it has commissioned for its programme is feeding the results through to its country’s established public health channels. • A HEI seeks the consent of students for their test results to be used for scientific purposes, and obtains the proper approvals to enable use for research purposes. Those who decline consent are reassured that there will be no detriment to them. • A HEI decides to collect and make publicly available fully anonymised information about infection rates and informs students that it will be doing this. |
| Ethical consideration | Recommendations                                                                 | Illustrative examples of how a HEI might put these recommendations into practice |
|-----------------------|---------------------------------------------------------------------------------|----------------------------------------------------------------------------------|
| Communication         | Prioritise high quality communication about the programme.                      | • A HEI has a sound communications plan for the programme. It understands that    |
|                       | Provide clear and understandable information in a range of accessibility-friendly| students need clear information about a range of topics surrounding a testing      |
|                       | formats.                                                                        | programme. It designs concise brochures, posters, website and emails, using       |
|                       | Communication should mindful of the need for programme trustworthiness and      | appropriate language and images that are accessibility-compliant, and it offers    |
|                       | should be respectful and well-judged. It should address issues of diversity,      | clear signposting to more detailed information. It emphasises consistently the      |
|                       | equality and inclusion appropriately, including in choice of images and language. | importance of isolation in response to a positive test and the need to continue to |
|                       | Provide a dedicated channel for participants to provide feedback and to raise    | observe guidance on face-coverings, social distancing, hygiene and ventilation in  |
|                       | concerns about the programme, for example anonymous reporting through a programme| response to negative tests.                                                    |
|                       | website.                                                                        | • A HEI running a programme reassures students that there is only mild physical   |
|                       |                                                                                | discomfort associated with swabbing. It posts a video showing the correct        |
|                       |                                                                                | technique featuring students themselves from diverse backgrounds. The HEI        |
|                       |                                                                                | acknowledges the possibility that some people might experience anxiety about     |
|                       |                                                                                | the test and ensures that this is not trivialised. It provides opportunities for  |
|                       |                                                                                | students to talk to people who have already had the test to answer any questions.|
|                       |                                                                                | • A HEI identifies that communication via email is efficient and acceptable, but  |
|                       |                                                                                | also that there is a need to avoid overload. It sends the minimum number of emails |
|                       |                                                                                | possible. It supplements email communication with other resources, including a    |
|                       |                                                                                | dedicated and regularly updated programme website. Links are provided to brief    |
|                       |                                                                                | videos and other resources.                                                     |
|                       |                                                                                | • A HEI regularly releases statements outlining how it has been collecting        |
|                       |                                                                                | feedback from stakeholders on the programme, outlining what changes, if any, it     |
|                       |                                                                                | has made in response. As part of this, it learns through feedback that contact    |
|                       |                                                                                | tracing before the public health authorities take over is not being done         |
|                       |                                                                                | effectively, and acts to address this problem.                                  |
|                       |                                                                                | • A HEI becomes aware of the possibility of stigma linked to testing positive (for)|
|                       |                                                                                | example owing to a perception that it reflects reckless or selfish behaviour). In |
|                       |                                                                                | an effort to address this, the HEI emphasises in its communication that testing  |
|                       |                                                                                | positive can occur even if an individual has tried their best to follow         |
|                       |                                                                                | guidelines on social distancing.                                               |
right option for them. This recommendation acknowledges current empirical uncertainties about such programmes, including those relating to the relative public health importance of asymptomatic infection\textsuperscript{24,25}, and whether mass asymptomatic testing confers a significant benefit in reducing COVID-19 transmission beyond other measures (such as symptomatic testing and contact tracing)\textsuperscript{26,27}.

Testing is only one element of a multi-modal strategy; on its own it is insufficient to control infection\textsuperscript{27,28}. The framework therefore recommends that HEIs give close attention to the design and operation of the programme end-to-end, recognising that the effectiveness of a testing regimen depends on a whole systems approach that requires, for example, the key control measure (isolation) to be in place. Our consultation data suggest that stakeholders appreciated this point, with some interview participants discussing the role of the testing programme in relation to ongoing adherence to other measures (such as social distancing and face-coverings).

The framework emphasises that it is essential to plan multiple programme components in advance – such as how results will be handled, how positive cases and their households will be supported to isolate, and how close contacts will be traced and tested. This recommendation is consistent with the broad principles of public health systems design, including the need to deliver, coordinate and quality assure each element\textsuperscript{53}. A SAGE (Scientific Advisory Group for Emergencies) consensus statement, for example, stressed the requirement to take a systems view of mass testing programmes, describing them as a “complex end-to-end process”\textsuperscript{30}. More broadly, the literature has advocated a systems-based approach (with understanding of disease dynamics and epidemiology, as well as the logistics of mass distribution) to solve issues surrounding COVID-19-testing\textsuperscript{31}.

The framework also encourages HEIs to plan for challenging scenarios, for example where large numbers of students and staff test positive at the same time. This could pose challenges for the number of PCR tests needed for confirmatory testing, and staff needed to support students in isolation. This recommendation recognises the controversies that arose in Autumn 2020, when the quality and cost of the food provided to isolating students in a number of institutions was criticised\textsuperscript{12}.

Goals of the testing programme

Main recommendation: Identify the programme goals, explain why they were chosen, tell students about them, and keep them under review.

The framework sets out that HEIs should identify clear, well-defined goals based on a sound rationale. Clarity and legitimacy of goals are important features of public health ethics\textsuperscript{6,12}. The SAGE consensus statement on mass testing stressed the requirement for clear and specific aims for any mass testing programme, also noting that those objectives should include achieving equitable outcomes\textsuperscript{36}.

In the context of a mass asymptomatic COVID-19 testing programme, one clear goal is to control spread of infection in the population of interest\textsuperscript{10}. This should reduce transmission of the virus and minimise health consequences. In our consultation, stakeholders broadly accepted the aim of reducing viral transmission and consequently protecting the wider (and potentially more vulnerable) population, identifying this as a key potential benefit of the testing programme. The overwhelming support for the university’s programme and its goals – 99% of survey respondents supported or strongly supported it – suggests that they were seen as legitimate and worthy of pursuit.

As Kass acknowledges, benefits other than the primary public health goal may accrue as a result of interventions\textsuperscript{5}. In our consultation, stakeholders identified a number of benefits in addition to the main goal of the programme. Other benefits identified by stakeholders – which might be regarded as secondary goals – included protecting the well-being of the student population, allowing more normalcy of educational experience, and aiding scientific understanding of the virus and its control. There was particularly strong support for the research element of the testing programme: 97% of survey respondents supported or strongly supported the use of anonymised data from the programme for research purposes. In interviews and survey free-text responses, there was some evidence that promoting the research objective could be helpful in encouraging participation, as it gave students a positive sense that they were contributing to the scientific effort against COVID-19. These findings suggest that it may be important to acknowledge all the potential benefits, or secondary goals, of a mass COVID-19-testing programme, in addition to primary stated goals. For this reason, the framework encourages HEIs to explicitly acknowledge multiple goals where they are present.

The importance of evaluating the effectiveness of a public health intervention in achieving its goals has been emphasised in the literature\textsuperscript{3}, since it is important in assessing whether the intervention is ethically justified\textsuperscript{1}. In the early stages of a public health response to an emerging infectious disease, the precautionary principle is often required to guide public health responses (in particular when harm is very likely or potentially severe)\textsuperscript{13,14}. As more evidence comes to light, the extent to which a programme is able to effectively achieve its stated aims can be assessed. Our consultation data also indicate that the effectiveness of a testing programme in achieving its goals may influence stakeholder opinions about its acceptability: for example, 54% of survey respondents reported that the programme should be at least moderately effective to be acceptable, 32% reported that even a small effect would be enough to justify an asymptomatic testing programme, and only 14% of respondents reported that the testing programme must be highly effective in reducing transmission to be acceptable. Considering this – and the wider public health literature on the importance of assessing the effectiveness of interventions – the framework recommends that there are specified criteria to judge how effective a programme is at reaching its goals, and that the goals are kept under regular review.
Properties of the test(s) selected for the programme

Main recommendation: Assess the available testing options, considering current evidence and guidance. Acknowledge uncertainty and take action to address risks associated with the chosen test.

The framework recommends that HEIs are alert to the properties of the test(s) used in a programme, and the implications of these. This recommendation is partly informed by established criteria relating to screening programmes, which emphasise the relevance of test properties such as sensitivity, specificity, positive predictive value, and negative predictive value. One currently debated aspect of potential COVID-19 mass-testing programmes concerns choice of test methods, since lateral flow testing and PCR testing have different test properties (PCR currently offers much greater reliability and validity). As the available technologies and evidence may continue to evolve (perhaps rapidly), HEIs will need to consider a wide range of factors when considering which testing method to use: validity and reliability, convenience and speed of administration and test result, tolerability of the test for students, costs, logistical burden and test certification. Contemporary government guidance and policy will also be relevant.

Established public health principles stress the need to recognise the burdens or harms associated with an intervention, and take steps to minimise them. In the case of COVID-19, the potential harms associated with false negatives – in particular the risk that those with undetected infection could unknowingly go on to infect others – have been widely acknowledged. In our consultation, stakeholders identified false negatives as the predominant concern in relation to test accuracy. To a somewhat lesser extent, participants also saw false positives as worrying, citing the impact on student well-being, restricted access to education, and deprivation of liberty associated with an unwarranted isolation period. PCR testing was seen to offer an advantage by some interview participants because of its better sensitivity (i.e. ability to detect infection) compared with other testing regimens (such as lateral flow testing).

Given how stakeholders expressed these concerns, and the existing public health literature, the framework recommends that HEIs consider the implications of both false negatives and false positives, communicate with stakeholders about these implications, and take steps to mitigate the associated harms. For example, false positives for COVID-19 can be mitigated through confirmatory testing, which may be particularly important in low prevalence settings.

Acceptability and tolerability are also important features of tests, as identified in the Wilson-Jungner criteria and elsewhere, since an invasive or ineffective test may engender hostility or undermine support for a testing programme. The framework thus recommends that HEIs ensure that the methods of obtaining the sample (e.g. swabbing) satisfy these criteria (e.g. should not induce excessive discomfort, pain, or anxiety). Our consultation found that the experience of nasal swabbing was tolerable, with minimal discomfort reported, though we did find some evidence of concern surrounding the method of self-swabbing (e.g. incorrect technique).

Enabling isolation

Main recommendation: Provide suitable support – practical, psychological, social and educational – for students who test positive.

The framework emphasises the importance of ensuring that adequate support is in place for isolation after a positive test, both at individual and household level. The basis for this is the basic public health principle that detection of positive cases on its own is insufficient to disrupt transmission of infection: it must be combined with effective isolation. In the context of COVID-19, the critical importance of ensuring that adequate support is in place to facilitate self-isolation has been repeatedly emphasised. There is some evidence that adherence to self-isolation is suboptimal, and that practical support and financial reimbursement might improve this.

In the wider public health literature, the ethical issues surrounding isolation and quarantine for communicable diseases have been discussed, for example in considering when restrictive measures might be ethically justified. Reciprocity has been identified as an important element in justifying such autonomy-limiting public health measures. According to this principle, “if individuals [are] to curtail their liberties for the good of others, society has a reciprocal obligation to assist them in the discharge of their obligations.” This obligation might, for example, take the form of providing individuals with adequate food, shelter and psychological support, as well as ensuring that they are not financially penalised or stigmatised as a result of quarantining.

Our consultation found that stakeholders strongly felt that the university should support students who must isolate as a result of its testing programme, for example by providing support for practical, psychological, and educational issues, as well as access to outside space. Stakeholders discussed a number of challenges faced by students who must isolate, particularly emphasising the psychological burden of extended self-isolation: the vast majority (91%) of survey respondents agreed or strongly agreed that they were worried about the impact of isolating on students’ mental health. This is in keeping with the existing literature on the subject, which considers the psychological impact of isolation and how it might be reduced. Overall, our consultation data – in combination with public health principles – suggest that HEIs must give specific attention to the needs of students, and not trivialise the burdens associated with isolation.

In our consultation, we found that lack of clarity over the available support was a source of anxiety for some stakeholders. The importance of providing clear communication about the rationale for restrictive measures, and information about protocols to support those in isolation has been suggested as a measure to reduce the psychological burden of isolating.
We have therefore also recommended that HEIs are particularly clear and explicit in communicating the reasons for requiring isolation in response to a positive test, and support available during this period.

**Choices regarding participation in testing programmes**

**Main recommendation: Generally, favour the least intrusive approach to individual choice about participation.**

The framework recommends that HEIs make a reasoned decision about individual choice regarding participation, with advice to favour the least intrusive approach consistent with achieving the goals of the programme, bearing in mind risks, benefits, current levels of scientific certainty and pandemic conditions.

The tension between a need to respect individual autonomy and a need to promote and protect the health of the population is well-recognised, and is often presented as a key distinction between public health ethics and clinical ethics. Though it is important not to oversimplify this tension – some have, for example, criticised it on the grounds of relying on too narrow a conceptualisation of autonomy – it is relevant for evaluating the reasonableness of restrictive public health measures. A practical example of how to balance restrictive public health interventions with individual liberty can be seen in the Nuffield Council of Bioethics “Intervention Ladder”, in which movement ‘up’ the ladder – towards more restrictive measures which limit choice – requires increasingly greater justification. In this model, measures such as the use of incentives or penalties are ‘rungs’ in the ladder, moving between totally voluntary choice and strict compulsion. This discussion can be applied to important questions around the ethical acceptability of mandatory participation in student COVID-19 testing programmes, and whether options for encouraging testing (such as incentives or penalties) are justified.

In our consultation, there was support for voluntary, not mandatory, participation in student testing: 62% of survey respondents agreed or strongly agreed that testing should be voluntary at the individual student level. In interviews and in survey free-text responses, it was clear that the principle of respecting individual choice – particularly with regard to medical interventions, including COVID-19 swab testing – was of critical value. Although some participants identified circumstances in which mandatory testing might be acceptable (for example, if virus levels were much higher, or the associated mortality/morbidity worse) it was not seen as generally ethically reasonable by a large proportion of participants. The consultation data can thus be seen as supporting the widely-acknowledged principle of the ‘least restrictive means’, which suggests that measures such as mandating participation at individual level should only be considered in extreme circumstances, when it would be proportionate to the level of risk and benefit, and not achievable in a less intrusive way.

There was majority opposition (64% of survey respondents) to use of penalties for non-participation in the programme. In interviews, some thought it would be reasonable to restrict access to face-to-face teaching for non-participants, in order to protect the safety of others. Others found the idea of an educational institution limiting access to teaching in this way fundamentally troubling, particularly given that students pay tuition fees. HEIs might need to consider whether such a measure is acceptable; the results of our consultation suggest that it would be a contentious issue.

In our consultation, the idea of using small incentives to encourage participation was viewed more favourably than use of penalties. However, some suggested that robust communication about the programme’s benefits would be more effective than incentives. This is in keeping with a review which suggested that reinforcing the principle that quarantine is altruistic and can keep others safe may lessen the psychological burdens and improve cooperation. Some stakeholders expressed concern that incentives seen as menial – such as a free coffee – might undermine the value of the testing programme and shift focus away from community benefits. Literature on the potentially corrosive impact that incentives can have on valuable social norms previously un-monetised could be relevant here. Taking these views into account, it might be preferable for HEIs to frame small benefits for participants as tokens of appreciation rather than stimulation to take part.

The framework recommends that policies regarding choice to participate should, if possible, be implemented consistently within a HEI and ideally across the HEI sector. This recommendation is supported by consultation data that suggested that significant discrepancies in the value or nature of incentives offered to different students, for example, could generate hostility and undermine trust.

**Benefits, harms, and opportunity costs**

**Main recommendation: Assess possible benefits, costs, risks and harms and be prepared to explain decisions.**

The framework recommends that HEIs consider the possible benefits, risks and harms of a testing programme, and put in place appropriate mitigations. In so doing, they should be attentive to issues of equality, diversity and inclusion.

These recommendations draw upon the concept of proportionality, based on the principle that “it is essential to show that the probable public health benefits outweigh the infringed general moral considerations”. In order for a public health intervention to be considered legitimate, there must be a reasonable balance between any burdens or costs – both to individuals and to society – and the benefits; the actions taken should not be disproportionate to the actual risk to the population. For example, a programme demanding strict isolation of individuals for a common cold would not seem proportionate, while it might in the face of Ebola or SARS: the threat of the disease may justify more restrictive measures. As a general principle, therefore, the greater the burdens associated with an intervention, the more effective it needs to be at bringing about a benefit for the population health. Similarly, the SAGE
consensus statement on mass testing highlighted that any asymptomatic testing programme should provide benefits beyond existing symptomatic testing programmes. In our consultation, it was clear that stakeholders balanced burdens and benefits when considering the legitimacy of the testing programme, particularly when asked how effective an asymptomatic testing programme would need to be for it to be acceptable. The perceived cost to the individual of participating in the programme was seen as low. Consequently, many felt that even a small impact – for example, picking up a few asymptomatic cases, or protecting even one vulnerable person – would be sufficient to justify the programme.

Harm/benefit analysis of a mass testing programme must, of course, take into account not just harms to individual stakeholders, but also the overall costs (and opportunity costs) of developing and running it. In interviews, some participants – although not all – explicitly referred to the costs of the programme when considering its justification. Some speculated that if the financial burden of the programme was very high and effectiveness was low, it might not be acceptable. The opportunity costs associated with running a mass testing programme are likely to be considerable, and HEIs will need to carefully consider whether it is a good use of resources. As with many healthcare resource allocation decisions, the ethical legitimacy of the cost-benefit decision will be partially dependent on the HEI’s ability to give an account of the reasonableness of its decision-making process.

The framework recommends not just considering the balance of harms and benefits associated with a testing programme, but also their respective distributions across the population. Kass, amongst others, has highlighted the need to ensure fair distribution of benefits and burdens associated with a public health intervention. Our consultation data suggested that isolation could be disproportionately more challenging for certain groups, including those from lower incomes or with pre-existing mental health problems. Identifying and supporting student groups who could be disproportionately affected by isolation is important for a fair distribution of burdens across different groups; as a recent editorial noted, “a fair, equitable and effective public health response requires the integration of supportive services.”

Responsibilities between students and institutions

Main recommendation: Clarify that institutions and students both have responsibilities if shared goals are to be achieved.

The framework recommends that HEIs should be attentive to responsibilities that a HEI and its students might jointly have in achieving programme goals, recognising the special relational context of a higher education institution as well as broader principles of reciprocity and solidarity in pursuit of public health.

The value of taking a relational approach to public health ethics – requiring a “conception of persons as embedded within communities in particular ways” – has often been emphasised, especially in the context of pandemic response, with the recognition that many public health interventions rely on community solidarity for their effectiveness. As Bayliss et al. state, “to be successful in public health, we must acknowledge our mutual vulnerability... we need to recognize that the pursuit of public goods for health, for the benefit of us all requires trust, collective responsibility and accountability.” The possibility of virus transmission in a university setting is likely to raise ethical concerns that are relational and social in character. Individuals and institutions may have to consider, in more or less explicit ways, their responsibilities, duties, and obligations to care for others, including those who are vulnerable in particular. The concept of interdependence can help to guide approaches in well-defined community settings such as higher education. For example, HEIs may need to consider whether or not there might be a duty of care to students to operate a testing programme under specific conditions, and what that might entail in terms of responsibilities for both students and institutions.

Relational issues were prominent in our consultation. Survey responses and interview accounts clearly acknowledged the distribution of responsibility between the university and its students and staff, and between the university and its broader community (including residents of Cambridge and the families of students and staff). For example, 76% of survey respondents agreed or strongly agreed that overall, the university has a responsibility to run a COVID-19 testing programme. Within interview accounts, this responsibility was situated within the university’s duty of care in reference to its various roles as an educator and as an employer of staff (who may be more vulnerable in some cases than students). The duty of care associated with the role as a landlord to students living in university or college-owned accommodation was particularly strongly emphasised.

These findings suggest that the distinctive relational context of higher education, including stakeholder views on their respective and joint responsibilities and duty of care, is likely to be an important ethical consideration in testing programmes.

Privacy, confidentiality and data-sharing

Main recommendation: Ensure information governance systems meet data protection and confidentiality requirements. Be clear who is informed about test results and why.

The framework notes the importance of ensuring information governance systems are sound, recognising that information about test participation and test results should respect principles of data protection and confidentiality. Many of the framework recommendations on this topic are derived from the existing literature. As Hodge notes, “identifiable health data are the lifeblood of public health practice.” However, privacy remains a concern, especially in data collection, sharing and retention. To control infectious disease, it may
be necessary to share some information, for example as part of contract tracing, which may involve sensitive information (e.g. an individual’s name, their condition and the names of other contacts they have had). Contact tracing has potential to invade the privacy of individuals whose names are disclosed by the index case. While individuals have a right to privacy of health information, it is not absolute. In certain circumstances, including certain public health emergencies, protection of population health and prevention of serious harm to others may take priority. As with many other elements of a public health intervention, a proportional response is required: private health information (such as the name of a positive-testing individual) should only be shared if there are no less intrusive means to protect public health.

Legal considerations are also important for HEIs in the design of data flows: HEIs must process the data fairly, lawfully, transparently and securely in accordance with privacy and confidentiality laws such as the General Data Protection Regulation (GDPR). For example, the University of Cambridge and its colleges completed a full data protection impact assessment and published Information Notices. The programme processed both standard personal data (including name, contact details, residence), and data concerning the health of participants (e.g. their COVID-19 tests results). Test results were held in databases with NHS-grade information security systems. The processing was permitted legally on several grounds in the GDPR. For instance, health data could be processed because the university was supporting the public interest in the area of public health (GDPR Art 9(2)(i)), preventative medicine (GDPR Art 9(2)(h)) and scientific research purposes in the public interest (GDPR Art 9(2)(j)).

Our consultation data suggest that stakeholders are likely to support some limited sharing of health data to facilitate the effectiveness of the testing programme. For example, there was overwhelming support for everyone in a household to be informed if a pool tests positive (99% of survey respondents agreed). Most (86% of survey respondents) also agreed that college staff who might have contact with that household should be informed. There was also wide support for anonymised data being used for scientific purposes. Stakeholders did, however, emphasise the importance of protecting individual privacy where possible. Interviews suggested that one important reason for respecting the privacy of those who test positive concerns stigma: for example, there could be a perception that they behaved recklessly or irresponsibly. Stigma has been recognised as a post-quarantine stressor, which might be addressed through education and messaging.

A minority of stakeholders in the consultation expressed serious concerns regarding issues of privacy or confidentiality – for example, around 25% of survey respondents were worried about who would know an individual student’s test result – but it should be noted that those who did discussed the potentially deleterious effects of poor data-handling on trust and support for the testing programme.

The framework thus recommends that a HEI should communicate clearly with students about who will be informed in the event of a positive test result, with clear justification for any sharing of health data. A HEI should acknowledge concerns that stakeholders might have about how information is used and shared, as such concerns have the potential to seriously undermine a testing programme and damage trust.

Communication

Main recommendation: Make clear communication with students and staff a priority, and put feedback and response mechanisms in place.

The framework recommends that HEIs should prioritise high quality communication, providing clear and understandable information in a range of accessible formats.

The public health literature is clear on the importance of transparency, openness, and effective communication. In the SAGE consensus statement on mass testing programmes, the need for engagement built on trust, shared goals and perceived fairness was emphasised, with recommendation for messaging to be “co-produced with target communities and include transparent rationales and benefits of testing, allayment of privacy concerns, and specified support for positive cases.” Concerns have recently been raised over the extent to which people have been adequately informed about and have understood information about false negatives in mass testing programmes.

Our consultation data indicated the importance of clear communication in addressing student concerns about the programme and in encouraging participation/compliance. Survey respondents supported provision of a wide range of information about the programme, including information about where and when testing is taking place, how students will be told about results, who else will be told, what support is available if students have to isolate, and regular updates about how many people test positive in the University. However, interviews identified the risk of information overload: students discussed getting a large volume of emails and at times struggling to pick out the important content. There is thus a requirement for HEIs to balance the need to provide adequate information to interested stakeholders with the need to avoid information overload, which compromises communication effectiveness.

Our consultation data also demonstrated support for a dedicated programme website as a channel for providing feedback about the testing programme. An effective communication mechanism is a way of demonstrating responsiveness; an important principle in ensuring a just procedure for healthcare decision-making.

Overall, both our consultation data and the existing public health literature emphasised the importance of high-quality two-way communication for asymptomatic testing in HEIs, to inform stakeholders, address concerns and build trust in a testing programme.

Discussion

The COVID-19 pandemic has seen calls for the coordinated development of transparent and publicly accessible ethical guidance based consultation with stakeholders. Mass testing
programmes for students in higher education is an area likely to benefit from such guidance, particularly if underpinned by engagement with stakeholders. Our consultation, using a mixed-methods design that enabled both quantification and in-depth exploration of a diverse range of views of undergraduates, postgraduates, and academic and non-academic staff, found very high levels of support for a university asymptomatic testing programme. Participants generally indicated that, at the time of our consultation, the burdens and benefits were acceptably balanced and that the goals of the programme were considered to be legitimate and worthy of pursuit. These and other findings, together with ethical, legal, and public health analysis, have informed the development of a 9-domain framework that identifies the range and nature of ethical issues to be considered by those considering or introducing higher education testing programmes. The framework largely avoids making recommendations as to “right” and “wrong” decisions, instead offering a tool for ethical discussion to assist organisational decision-makers with structured, systematic and reasonable assessments alert to the full range of relevant issues.

We note that the broad support for the testing programme – of the order of 99% – was tempered by a range of considerations that were important to stakeholders in considering the overall legitimacy and ethical standing of the programme. Legitimacy can be defined in various ways, but, for practical purposes, can be taken broadly to refer to how far the actions and values of an institution or organisation are perceived to be desirable, acceptable, proper and appropriate. One potential challenge to legitimacy for testing programmes concerns their effectiveness relative to the costs and burdens borne by the participants. In our consultation, stakeholders clearly saw a number of risks and possible harms for students, including isolation after a positive test. They also recognised that these harms might be legitimate in order to achieve collective benefit. Put simply, therefore, our analysis suggests that for testing programmes to be regarded as justified by the communities in which they intervene, they must be able to deliver on their goals. A programme needs to make a difference, and that difference needs to be positive.

Judgements of effectiveness in turn depend on the goals of the programme, and on how the thresholds for effectiveness are drawn. This is not straightforward, given that conclusive evidence on the effectiveness of asymptomatic student screening programmes has yet to appear. The challenges of assessing the effectiveness of a public health intervention, particularly in the context of emerging and incomplete evidence, have been discussed with reference to the need for a broader notion of effectiveness. Accordingly, it is important for HEIs to consider and engage with multiple perspectives in order to reach a reasonable and well-justified decision with regard to whether a testing programme is legitimate, acknowledging the relational and normative properties of ‘effectiveness’.

However, effectiveness is defined or operationalised, it is clear that as further evidence becomes available it may be necessary to re-evaluate student testing programmes, particularly with regard to the balancing and distribution of burdens and benefits. Those running the programme will need to be attentive to emerging evidence; the principle of regular review and responsiveness to changes in scientific knowledge or stakeholder concerns is accordingly prominent in our proposed framework. In the face of emerging infectious disease threats, the precautionary principle is often invoked. However, where technologies and pandemic conditions move rapidly, application of the precautionary principle in practice may generate further challenges, not least balancing risks and benefits of innovative infection control measures in the context of limited evidence.

Our work also identifies that the technical properties of testing regimens are a key ethical consideration. Given that the harms associated with false positives and false negatives are highly consequential, organisational decision-making should consider test options carefully. Although some might posit that the technical properties of tests – the sensitivity, specificity, positive and negative predictive values – are primarily a matter for scientific, as opposed to ethical discussion, we contend that it is necessary to consider them to make normative judgements about a testing programme. The scientific dimensions of a testing programme influence the ethical ones: ethical decision-making about testing programmes fundamentally requires “regular reassessment of a moral problem while science proceeds and offers new information”.

Another key consideration in the framework is the distinctive nature of relationship between students and their higher education institutions. The view that perceives the university as a producer of services and products and the student as a consumer has been criticised for emphasising individualism at the expense of community. As confirmed by our consultation, higher education institutions are better conceptualised as interconnected communities. We found evidence that the university as an institution is perceived to have a number of roles and responsibilities in relation to its students. For instance, although the university primarily acts as an educator, it also has welfare responsibilities and, for students living in its accommodation, it acts as a landlord. These relational characteristics were important in shaping some features of framework – in particular, reciprocal obligations exist between students and higher education institutions.

It is, of course, important to acknowledge the heterogeneity of higher education. It would be erroneous to assume that a testing programme suitable for one HEI will necessarily be useful in another. Though we expect our analysis to be useful, at the level of principle, to other higher education institutions in rest of the UK, it is important not to overstate the external validity of these results. We captured stakeholder views at a specific university, at a particular point in a rapidly changing pandemic. The collegiate nature of the University of Cambridge, which is relatively uncommon in UK higher education institutions, may have influenced some of our findings, particularly in areas relating to community ties and obligations. The programme we studied used nasal swab-based PCR testing and was based on a pooled testing approach. The generalisability of our consultation data to programmes using other technologies (e.g. lateral flow tests) and without
pooled testing are unclear. Moreover, the findings may not be directly applicable to programmes which test students living in privately-owned accommodation. We were unable to assess patterns of non-response to our consultation, and it is possible that our findings are not representative of the views of all students and staff.

A final consideration is the extent to which, if at all, our framework might be generalisable to asymptomatic testing programmes in other settings or populations, (e.g. schools or workplaces), or to asymptomatic testing programmes with different goals (e.g. ‘test-to-access’ to control access to sporting or culture mass events)\(^5\). Certain characteristics of HEIs and student populations might well limit the generalisability of our framework – for example, the relational context of HEIs (as discussed above), the logistics of supporting isolation in other settings, and the demographics and attitudes of typical student populations. This is not, however, to say that the principles discussed in our framework will have no relevance to other settings. For example, recommendations to assess possible benefits, costs, risks and harms and to explain the process of decision-making are likely to be relevant for the development of any asymptomatic testing programme (and indeed, any public health intervention). Thus, while we cannot be sure that our results would be replicated in other settings, it is likely that some features of our framework are transferable. However, we recommend further development and refinement before transplanting the framework into different settings (particularly in the context of a rapidly changing pandemic).

Conclusions
The framework we offer may, by identifying ethical considerations relevant to mass asymptomatic COVID-19 testing in higher education, facilitate deliberation and help inform decision-making about the introduction, design, delivery and evaluation of testing programmes.

Data availability
Underlying data
Because of the conditions of ethical approval for the project, the raw data (transcripts and survey responses) are not available for deposit. This is owing to the sensitive nature of the responses, including their possible political nature, and concerns that it would be difficult to completely de-identify participants (who often gave extensive and specific details about their college and own circumstances in answering questions).

Any requests for access to or use of the data should be made to director@thisinstitute.cam.ac.uk. Access to fully anonymised data for suitable purposes may be granted to bona fide researchers under a data sharing agreement, but must be approved by the relevant ethics committee.

Extended data
The study instruments (interview guide and questionnaire) are available:

Repository: Guiding organisational decision-making about Covid-19 asymptomatic testing in higher education institutions: mixed-method study to inform an ethical framework. DOI 10.17605/OSF.IO/D768T\(^6\)

This project contains the following extended data:
- Supplement 1 – Interview guide.
- Supplement 2 – questionnaire.

Data are available under the terms of the Creative Commons Attribution 4.0 International license (CC-BY 4.0).

Acknowledgements
We thank the participants – students and staff – in the consultation. We thank Dr Zoe Fritz for her support in the early development of this project. We thank those involved in the University of Cambridge testing programme for their support and advice, particularly Dr Ben Warne, Dr Nicholas Matheson, Professor Patrick Maxwell and Craig Brierley. We thank the Thiscovery and Communications teams at THIS Institute for enabling this project to happen. We thank Becky Kenny, Bethan Everson and Gwen Brierley for project management and governance support.

References

1. Gill M, Gray M: Mass testing for covid-19 in the UK. BMJ. 2020; 371: m4436. PubMed Abstract | Publisher Full Text
2. Mahase E: Covid-19: Mass testing is inaccurate and gives false sense of security, minister admits. BMJ. 2020; 371: m4916. Publisher Full Text
3. Raffles A: Screening the healthy population for covid-19 is of unknown value, but is being introduced nationwide. BMJ. 2020; 371: m4438. PubMed Abstract | Publisher Full Text
4. Childress JF, Faden RR, Gaare RD, et al.: Public Health Ethics: Mapping the Terrain. J Low Med Ethics. 2002; 30(2): 170-8. PubMed Abstract | Publisher Full Text
5. Marcxmann G, Schmidt H, Sofsar N, et al.: Putting public health ethics into practice: a systematic framework. Front Public Health. 2015; 3: 23. PubMed Abstract | Publisher Full Text
6. Thompson AK, Faith K, Gibson JL, et al.: Pandemic influenza preparedness: an ethical framework to guide decision-making. BMC Med Ethics. 2006; 7: E12. PubMed Abstract | Publisher Full Text | Free Full Text
7. Smith CB, Batten MP, Jacobson JA, et al.: Are there Characteristics of Infectious Diseases that Raise Special Ethical Issues? Dev World Bioeth. 2004; 4(1): 1-16. PubMed Abstract | Publisher Full Text
8. Beauchamp TL, Childress JF: Principles of Biomedical Ethics. New York: Oxford University Press; 2001; 454. Reference Source
Open Peer Review

Current Peer Review Status: ✗

Version 1

Reviewer Report 19 August 2021

https://doi.org/10.21956/wellcomeopenres.18540.r44912

© 2021 Buchan I. This is an open access peer review report distributed under the terms of the Creative Commons Attribution License, which permits unrestricted use, distribution, and reproduction in any medium, provided the original work is properly cited.

Iain E. Buchan

Chair in Public Health and Clinical Informatics, Department of Public Health and Policy, University of Liverpool, Liverpool, UK

The authors address the important and challenging topic of ethical planning and execution of testing for infectious diseases at pandemic pace and scale. They chose the community context of a UK, college-based university and sampled 213 volunteer staff and students in an iterative mixed-methods study using surveys and semi-structured interviews. They found that participants supported university-based testing for staff and students without symptoms of COVID-19, preferring voluntary, non-coercive, non-incentivised participation. They also uncovered mixed views on the need to know the (cost) effectiveness of testing on outcomes such as reduced transmission of SARS-CoV-2 in this (and the wider) community. A nine-element framework for ethical consideration of such testing was constructed from thematic analysis of responses and with reference to health (care) ethics and selected public health literature.

The framing of the research question in health protection literature, specifically outbreak prevention and control, and pandemic management, was unclear. The authors start from a position of assuming that university-driven testing for SARS-CoV-2 is a discrete community for health protection, and do not explore its interdependence with the surrounding civic communities. They do not consider the ethics of that arrangement versus an alternative that is driven by the local public health department for the geographically defined population most of the university staff and students reside within.

The relevant risk-mitigation interactions of individuals are not only with “healthcare systems” but also with wider civic systems where consequences of COVID-19 responses are social and economic as well as disease-related.

The rapid, often uncertain time course of pandemics also needs to be part of the framing. For example, asymptomatic testing has a different meaning as symptom-mix changes over time with vaccination by age group, natural immunity, and variants – see: https://www.bmj.com/content/bmj/374/bmj.n1625.full.pdf. Consequences of infection and
behavioural responses to risk-mitigations also change over this time-course – a fluid interplay of biology, behaviour and environments.

In calling to establish a transparent process for ‘mass testing’, it should be noted that many Local Resilience Forums run such processes for their COVID-19 responses. See for example the report from the national pilot of such testing in Liverpool:
https://www.gov.uk/government/publications/liverpool-coronavirus-covid-19-community-testing-pilot-full-evaluation-report-summary

Universities acting independently of civic systems might inflate inequalities for example by diverting testing capacity. This should feature in reflection on autonomy and non-maleficence.

Inappropriate translation of Wilson Junger clinical screening criteria to pandemic management was discussed recently in https://journals.sagepub.com/eprint/ZQKXHX2UTW66P9CTPFBV/full – the authors may wish to refer to this reasoning.

Misinformation over diagnostic test accuracy comparing lateral flow rapid antigen testing with RT-PCR needs to be considered in the ethical handling of the end-to-end treatment of testing – and not tests in isolation – which SAGE calls for. Testing aims to maximise utility (1/time to % appropriate action such as isolation) and not sensitivity, specificity and predictive values in isolation from that utility. See:
https://www.liverpool.ac.uk/coronavirus/research-and-analysis/covid-smart-pilot/
https://www.bmj.com/content/372/bmj.n208
https://www.thelancet.com/journals/lancet/article/PIIS0140-6736(21)00425-6/fulltext
https://www.ncbi.nlm.nih.gov/pmc/articles/PMC8203180/
https://science.sciencemag.org/content/372/6542/571

The statement that RT-PCR “offers much greater reliability and validity” is incorrect. The relationship between viral load, viral shedding and infectiousness is highly complex and not fully understood.

The autonomy afforded by self-testing with universal access lateral flow tests might be considered vs the clinical/lab dependency of RT-PCR testing. With that autonomy also comes risks of falsification, as demonstrated in schools (e.g. https://www.medrxiv.org/content/10.1101/2021.07.05.21260003v1). The authors may wish to expand on the self-organisation of student households/groups in collective participation that may minimise falsification.

The generalisability of (atypical) Cambridge college communities to other university settings may need raising as a limitation.

The agility of consultation/involvement in co-producing ideal testing, responding to different phases of epidemic curves, vaccination uptake, social and economic pressures on control measures, etc. could come out more in the manuscript.

Allusion to “effectiveness” of testing needs defining – effectiveness for what? – a specific level of transmission; consequence risk-mitigation; effective reopening with a certain level of testing in place? If the focus is on transmission reduction across student households and student classes
then it would be good to spell that out and note the difference between vaccinated and un/part-vaccinated contexts for students, staff and wider community. This brings in the ethics of dual certification for testing and vaccination – if this was covered in thematic analysis it could be brought out more in the paper.

Allusion to “benefits and burdens” needs to go further into mental health and economic ‘harms’ from isolation. Looking ahead, consider, for example, students with essential part-time jobs in a part-vaccinated population.

Contact-tracing interaction with testing could be discussed more – part of the utility for rapid isolation (of individual and contacts) – and now SMART release / Daily Contact Testing as an alternative to isolation could be discussed: https://www.gov.uk/government/news/daily-contact-testing-rolled-out-to-further-critical-sectors.

References
1. Crozier A, Dunning J, Rajan S, Semple M, et al.: Could expanding the covid-19 case definition improve the UK’s pandemic response?. BMJ. 2021. Publisher Full Text
2. Ashton J: When is a screening test not a screening test?. J R Soc Med. 2021; 114 (8): 411-413 PubMed Abstract | Publisher Full Text
3. Crozier A, Rajan S, Buchan I, McKee M: Put to the test: use of rapid testing technologies for covid-19. BMJ. 2021. Publisher Full Text
4. Mina M, Peto T, García-Fiñana M, Semple M, et al.: Clarifying the evidence on SARS-CoV-2 antigen rapid tests in public health responses to COVID-19. The Lancet. 2021; 397 (10283): 1425-1427 Publisher Full Text
5. Fearon E, Buchan I, Das R, Davis E, et al.: SARS-CoV-2 antigen testing: weighing the false positives against the costs of failing to control transmission. The Lancet Respiratory Medicine. 2021; 9 (7): 685-687 Publisher Full Text
6. García-Fiñana M, Buchan I: Rapid antigen testing in COVID-19 responses. Science. 2021; 372 (6542): 571-572 Publisher Full Text
7. Oni L, Hawcutt D, Buchan I, Semple M: Soft drinks can be misused to give false “false positive” SARS-CoV-2 lateral flow device results. medRxiv. 2021. Publisher Full Text

Is the work clearly and accurately presented and does it cite the current literature?
No

Is the study design appropriate and is the work technically sound?
Partly

Are sufficient details of methods and analysis provided to allow replication by others?
Yes

If applicable, is the statistical analysis and its interpretation appropriate?
Partly

Are all the source data underlying the results available to ensure full reproducibility?
Partly

Are the conclusions drawn adequately supported by the results?
No

**Competing Interests:** NIHR Senior Investigator; PI on Department of Health and Social Care national pilot of Community Testing; Chief Data Scientist Advisor for AstraZeneca

**Reviewer Expertise:** Public Health; Health Informatics and Data Science

I confirm that I have read this submission and believe that I have an appropriate level of expertise to state that I do not consider it to be of an acceptable scientific standard, for reasons outlined above.