Health Resources Task Group Executive Summary

Submitted 7/2/20

Task Force Charge: On June 2, 2020, the Health Resources Task Group was charged to provide options and recommend potential approaches available to the University regarding structured testing and contact tracing of all Penn State students, faculty, and staff across the Commonwealth for COVID-19, including molecular and serologic testing. This also would include consideration of testing of students prior to arrival on campus as well as inventory of testing options and modalities. In addition to a seven-person steering committee, the task force included a group of over thirty individuals that are representative of University Park, the College of Medicine and the Commonwealth Campuses. Our analysis prioritized minimizing risk of disease transmission within the faculty, staff and students of the university and throughout each of the campuses, and avoidance of overwhelming the local health care systems and quarantine/isolation facilities. No option will completely eliminate risk, and feasibility will play a role in which strategies are ultimately pursued.

Flattening the Curve: While coronavirus testing and contact tracing are strategies that must be employed to potentially minimize the prevalence of disease when the campuses reopen in August, they will not be successful in the absence of strict adherence to principles recommended by the CDC regarding appropriate face covering, physical distancing and hand hygiene, or, if initial prevalence on campus is too high. The epidemic curve can be flattened by isolating infectious cases, tracing and testing contacts, and behavior change including varying degrees of operational performance from full operation (with consistent appropriate safety measures) to complete closure of operations, as occurred in March of this year. The curve is primarily a function of (1) the number of infectious people at the start (e.g. 5 vs 500 vs 1500) and, (2) rate of increase of infectious people (outbreak doubling time). A fraction of the cases will result in hospitalization and if this number is high enough will overcome health care resources.

Diagnostic vs. Antibody Testing: Testing encompasses assays looking for acute infection (molecular and antigen) and serologic testing to assess for prior infection. Molecular testing is currently believed to offer the greatest sensitivity (up to 97%) and specificity (>99%) for the diagnosis of COVID-19. The sensitivity of this testing is highly dependent on the type of sample obtained and the quality of specimen collection. The CDC recommends using authorized nucleic acid assays that have received an FDA EUA to test persons with symptoms when there is a concern of potential COVID-19. Antigen testing is far less sensitive and antibody testing is not helpful in the diagnosis of acute infection. Tests should be used in accordance with the authorized labeling; providers should be familiar with the tests’ performance characteristics.
and limitations. Less is known about testing of asymptomatic individuals (both close contacts of infected patients and individuals with no known exposure), however, utilizing asymptomatic testing to establish baseline and detect rising prevalence within a community may help inform community policies. In addition, results can be utilized to identify currently asymptomatic individuals with the potential to spread COVID-19 to others, allowing early isolation and contact tracing in hopes of preventing or controlling a larger outbreak.

**Pre-Arrival, Arrival and Post-Arrival Testing Options:** In this report, testing is divided into three main categories: pre-arrival, arrival, and post-arrival testing. For each of these testing categories testing of symptomatic and asymptomatic close contacts is assumed. Options are then presented for asymptomatic surveillance. Both pre-arrival testing and arrival testing of a large number of individuals is associated with significant expense and many logistical challenges. Our analysis highlights two potential strategies for pre-arrival and arrival testing. Comprehensive testing provides the greatest opportunity to prevent infected individuals from arriving on campus and achieving our intended goals. Testing a subset of these two categories will provide actionable prevalence information but will have less impact on outbreak management. Our analysis highlights that post-arrival testing should focus primarily on the testing of symptomatic individuals and close contacts of COVID-19 cases. Our analysis of the number of symptomatic patients to be tested includes historical baseline “flu season” data from Employee Health and University Health Service, as well as projections for actual, symptomatic coronavirus infected individuals. Post-arrival testing would also ideally include testing a subset of asymptomatic individuals for surveillance over time. Our recommendations related to surveillance testing of asymptomatic individuals allow for identification of trends in disease prevalence before outbreaks occur, providing the opportunity for additional mitigation efforts in advance. We advocate for fulfilling the testing needs of the university with a combination of reference laboratory contracting, hospital facilities in each region if appropriate and, possibly, utilization of FDA authorized experimental screening. Finally, wastewater screening can potentially identify early disease outbreaks but requires further analysis.

**Contact Tracing:** Our recommendations related to contact tracing are based upon currently available literature, past experiences of the University in caring for viral outbreaks, and the recent experiences of the College of Medicine and University related to COVID-19. We believe there is a significant gap related to the staffing resources available to the university at present and what we project will be needed to effectively trace contacts in the future. We advocate in this document for a contact tracing hub and spoke model that compliments that traditional manual contract tracing process with related technologies.
Factors Beyond the Direct Control of the University: While the options and recommendations as presented will contribute to disease mitigation, their impacts may be limited by the many external factors outside of the direct control of the University. These include: the status of COVID-19 rates in the communities before and during the semester, 3rd party capacities to enable pre-arrival, arrival and post-arrival testing on scale and within necessary time frames, user compliance with self-quarantine prior to returning to a campus, location, degree of willingness to comply with social and behavioral norms related to social distancing, symptom monitoring by individuals and their acceptance of testing and reporting contacts, compliance with quarantine and isolation and possible legal challenge related to mandatory student testing - though the risk of a potential legal challenge should not dissuade the University from adopting measures aimed to protect the health and safety of its students, staff, and faculty.

Specific data follows in the full report, yet the authors of this report wish to draw specific attention to the scenario data on pages 6 and 8, and the chart on pages 13-15 that presents pro/con details of options. The report also contains four Appendices for your review.
Task Force Overview

Who are we? The Health Resources Task Group, we are working collaboratively with the broader Public Health and Scientific Advisory Group.

What is our charge? Our charge is to provide options to the university regarding structured testing and contact tracing as a part of a strategy to re-open Penn State University as safely as possible.

How are we organized? We have a seven-person steering committee (Dr. Kevin Black, Dr. Melissa George, Prof. Kevin Harter, Dr. Catharine Paules, Dr. Andrew Read, Dr. Kelly Wolgast, and Prof. Steve Tracey,) that supports and provides direction to a larger task force of more than 30 highly qualified multi-disciplinary professionals across the university and healthcare system.

Who are our key stakeholders? Our key stakeholders are students, faculty and staff, the communities in which we operate and reside, and the healthcare institutions that support those constituencies.

What tasks were asked of us?

1. Determine the level and type of testing that will identify a baseline prevalence of COVID-19 in the incoming Penn State University population where re-opening would pose unacceptable risk to students, faculty, staff, and the surrounding community
2. How to utilize testing and contact tracing as an adjunct to social distancing measures to minimize the potential risks for COVID-19 related:
   A. Mortality,
   B. Morbidity,
   C. Healthcare capacity overload,
   D. Operational disruption to the key stakeholders.
3. Employ testing to provide actionable insight to leadership to take proactive measures regarding re-opening and maintaining operations:
   A. If current epidemiology allows, be able to open campuses (based upon the dates the university announced on 6/15).
   B. If ongoing epidemiology allows, keep campuses open until the fall semester concludes successfully.
4. Design a well-reasoned, data-based, systems solution to testing that addresses the needs of key stakeholders (Students/Faculty/Staff/Community/Local & Regional Health Administration)
Definitions

- **Testing**: In this document testing will refer to molecular (PCR testing) for viral RNA to identify individuals who have COVID-19 and have the potential to transmit the virus to others. Molecular testing sample collection strategies, including the use of pooled samples, are further described in Appendix A. Other types of tests, such as antigen testing and serological testing, are not considered here for the reasons considered in Appendix A.

- **Pre-arrival testing**: Individuals receive a COVID-19 test prior to returning to their workplace, classroom or, other campus related activity.

- **Entry testing**: Individuals receive a COVID-19 test as they return to their workplace, classroom or, other campus related activity.

- **Post-arrival testing**: Individuals receive a COVID-19 test at predetermined time-points while integrated in their workplace, classroom or, other campus related activity.

- **Symptomatic testing**: Individual receives a COVID-19 test when they present with symptoms commonly associated with COVID-19. This requires a clinical evaluation (virtual or in person depending upon severity of symptoms) and is associated with a recommendation to isolate until a negative test result has been returned and a clinical assessment has been made to ensure the individual does not pose an infectious risk to others.

- **Close contact testing**: Testing of asymptomatic close contacts identified through contact tracing or self-report. This will result in quarantine from the community until they have completed a quarantine period of 14 days or until a test result is positive and they require isolation for COVID-19.

- **Asymptomatic surveillance testing**: Testing of individuals who are not self-reporting symptoms and without a known COVID-19 contact. This can be comprehensive (e.g. all students) or done on a stratified sample of a population. Asymptomatic testing may be accomplished as an individual test or, as part of a pooled sample (see Appendix A).

- **Wastewater testing**: Testing of localized waste streams to identify virus within a particular geographic area (e.g. campus, collective domicile). Detection of virus may then warrant further detailed human sampling as mentioned above.

- **Contact Tracing**: The identification of persons who may have come into contact with an infected person (“contacts”) and subsequent collection of further information about these contacts. Contact tracing is generally followed by quarantine of identified contacts for a pre-defined period, in this case 14 days.

- **Isolation**: Separates sick people with a contagious disease from people who are not sick.

- **Quarantine**: Separates and restricts the movement of people who were exposed to a contagious disease to see if they become sick.

Background:

*Why does COVID-19 pose a challenge to re-opening Penn State University and maintaining operations throughout the fall semester?*

Since COVID-19 was described in December of 2019, it has caused >10M cases worldwide and 507,014 deaths. The United States has experienced a substantial outbreak, one of the worst worldwide, with 2.6M cases and 128,000 deaths as of June 30, 2020. Large outbreaks in California, Washington, and New York City prompted a nationwide shut down in March 2020 as health care systems in heavily impacted areas surged past capacity. In Pennsylvania and other areas of the northeastern United States, cases
have fallen substantially in May and June 2020 and states are re-opening at various rates while attempting to control further epidemic surges. This is not the case in other states in the United States; for example, Texas, Arizona, and Florida, who are experiencing high numbers of COVID-19 cases and approaching maximum health care capacity in several major cities. While healthy students of traditional college age are unlikely to have severe cases of COVID-19, approximately 1.2% of symptomatic individuals age 20-29 will require hospitalization and 0.03% will die. In addition, faculty, staff and individuals in the surrounding community with risk factors are more likely to manifest a more severe case of the virus, requiring hospitalization and resulting in severe complications or deaths.

Figure 1: Predicted hospitalizations and infection fatality ratio from a modeling group at the Imperial College of London:¹

<table>
<thead>
<tr>
<th>Age-group (years)</th>
<th>% symptomatic cases requiring hospitalisation</th>
<th>% hospitalised cases requiring critical care</th>
<th>Infection Fatality Ratio</th>
</tr>
</thead>
<tbody>
<tr>
<td>0 to 9</td>
<td>0.1%</td>
<td>5.0%</td>
<td>0.002%</td>
</tr>
<tr>
<td>10 to 19</td>
<td>0.3%</td>
<td>5.0%</td>
<td>0.006%</td>
</tr>
<tr>
<td>20 to 29</td>
<td>1.2%</td>
<td>5.0%</td>
<td>0.03%</td>
</tr>
<tr>
<td>30 to 39</td>
<td>3.2%</td>
<td>5.0%</td>
<td>0.08%</td>
</tr>
<tr>
<td>40 to 49</td>
<td>4.9%</td>
<td>6.3%</td>
<td>0.15%</td>
</tr>
<tr>
<td>50 to 59</td>
<td>10.2%</td>
<td>12.2%</td>
<td>0.60%</td>
</tr>
<tr>
<td>60 to 69</td>
<td>16.6%</td>
<td>27.4%</td>
<td>2.2%</td>
</tr>
<tr>
<td>70 to 79</td>
<td>24.3%</td>
<td>43.2%</td>
<td>5.1%</td>
</tr>
<tr>
<td>80+</td>
<td>27.3%</td>
<td>70.9%</td>
<td>9.3%</td>
</tr>
</tbody>
</table>

*Note: U.S. numbers reported in MMWR² are higher than those in the above table.

Penn State University, with over 46,000 students at the University Park campus, and over 81,000 students combined across the Commonwealth is at risk for a COVID-19 outbreak when students return from areas around the country and internationally where COVID-19 outbreaks are occurring. Given the communal nature of college life, and a recent survey indicating that returning students are unlikely to fully comply with masks, social distancing, and refraining from high risk activities, this environment poses a particular risk for epidemic spread. Depending upon the epidemiology at the time of re-entry to Penn State University, it may be possible to safely reopen the college campus with health and safety

¹ https://www.imperial.ac.uk/media/imperial-college/medicine/sph/ide/gida-fellowships/Imperial-College-COVID19-NPI-modelling-16-03-2020.pdf?fbclid=IwAR3CzyyB6eTJsulOpGLvdO1_ALR3k-54jKEWjyp6EGSc1h6qJB6as

² https://www.cdc.gov/mmwr/volumes/69/wr/pdfs/mm6924e2-H.pdf
efforts in place. However, no strategy, including broad testing and contact tracing efforts, will completely eliminate the risk of COVID-19 spread on campus and the possibility of cases occurring that result in hospitalization and/or death. This risk, which cannot be quantified given current knowledge gaps, should be communicated broadly to all of our key stakeholders identified above. If outbreaks occur on campus, college students will also pose a risk to their home communities when they return.

Why incorporate testing and contact tracing into a larger health and safety effort?

An epidemic curve is the projected number of cases of an infectious disease over time and is primarily a function of (1) the number of infectious people at the start (e.g. 5 vs 500 vs 1500), (2) rate of increase of infectious people (outbreak doubling time). A fraction of the cases will result in hospitalization. If cases occur over a short time period the slope of the curve will be steep and if enough cases require medical care this will stress overall health care capability lading to unnecessary deaths from the infection and over consumption of resources such as personal protective equipment, putting healthcare workers at undo risk as they attempt to care for infected patients. Figure 2 (above) illustrates the importance of the peak of an epidemiologic curve in allowing adequate health care responses.

During an epidemic, the epidemic curve can be flattened by spreading cases out over time. This involves behavior changes that slow the spread of cases throughout the community (i.e., masking, social distancing, or even complete closure of operations) and implementing testing and contact/tracing strategies as an adjunct to these behavior changes.

Testing can help flatten the epidemiologic curve in two ways:

1. Find infectious individuals and their contacts, isolate the infected individuals and quarantine the contacts. This will directly impact outbreak size. The more infectious individuals that can be found, the bigger the impact.

2. Provide data to enable rational operational decisions about the need for, and extent of, further protective measures needed to flatten the curve, including enhanced distancing measures and GO/NO GO points for university operations. Testing can also allow the detection of declining prevalence, which might enable the relaxation of protective measures later in semester or in subsequent semesters.

No strategy will completely eliminate the risk of cases at Penn State University. Instead we have defined a ‘tolerable threshold’ of cases as the point beyond which local health care COVID facilities
become overwhelmed. This needs to be determined for each campus location. For University Park as an example, this currently means less than 1 hospitalization per day at Mt. Nittany Medical Center, assuming an average length of hospital stay of 21 days. This number is based upon the current capacity of Mt. Nittany Medical Center to care for these patients (regular and intensive care unit beds, negative pressure room capacity, ventilators, health care staff.) Our tolerable threshold may rise over time if hospital stays shorten and morbidity is less severe, but this is unpredictable. Note that isolation/quarantine facilities may be overwhelmed below this ‘tolerable threshold’ if contact tracing and asymptomatic testing programs are working well. Mathematical modelling (Appendix B) indicates that the ‘tolerable threshold’ could be exceeded when 4% of the population is infected.

Two illustrative scenarios.
Using the modelling approach summarized in Appendix B, we can summarize the outcome of two scenarios for University Park. The first case is with testing used only for diagnostic purposes of symptomatic individuals (no contact tracing, no asymptomatic testing etc.). The initial number of positives (5, 50, 500 people) dramatically impacts the number of hospitalizations (both the subset due to students, and the total), as well as the time when Mt. Nittany Medical Center is overwhelmed (as soon as three weeks, as late as 12 weeks).

Table 1: Scenario 1 - No testing:

<table>
<thead>
<tr>
<th># infected students at semester start</th>
<th>Total # student hospitalizations</th>
<th>total hospitalizations</th>
<th>days to MNH overwhelmed</th>
</tr>
</thead>
<tbody>
<tr>
<td>5</td>
<td>5-9</td>
<td>17-32</td>
<td>80</td>
</tr>
<tr>
<td>50</td>
<td>24-28</td>
<td>82-92</td>
<td>50</td>
</tr>
<tr>
<td>500</td>
<td>40-42</td>
<td>134-138</td>
<td>20</td>
</tr>
</tbody>
</table>

Scenario 1 corresponds to the ‘Do Nothing’ strategy in the Table 3, Options, and ‘None’ in Table 4, Costs, below. The second scenario we consider is when there is a highly effective contract tracing and quarantining program and asymptomatic testing at 1% of the population per day. Again, the number of cases at the start is important, but this time there are scenarios where it is possible to stay below the ‘tolerable threshold’ all the way to Thanksgiving. (Note (Appendix B) that in all cases, quarantine facilities can become overrun even if 1000 beds are available.)

Table 2: Scenario 2 -with testing (1%/day, highly effective contract tracing and quarantining)

<table>
<thead>
<tr>
<th># infected students at semester start</th>
<th>Total # student hospitalizations</th>
<th>total community hospitalizations</th>
<th>days to MNH overwhelmed</th>
</tr>
</thead>
<tbody>
<tr>
<td>5</td>
<td>1-2</td>
<td>3-6</td>
<td>never</td>
</tr>
<tr>
<td>50</td>
<td>5-7</td>
<td>16-22</td>
<td>&gt;90</td>
</tr>
<tr>
<td>500</td>
<td>14-16</td>
<td>48-52</td>
<td>40</td>
</tr>
</tbody>
</table>
This second scenario corresponds to ‘Post-arrival Sampling Option’ in Table 3, and the ‘Low’ cost option in Table 4. Note that the calculations in Scenario 2 assume nothing else is done beyond the quarantining and contact tracing of positives. In reality, that level of testing would also give early warning indicators of underlying outbreak dynamics which could trigger additional mitigation efforts such as intensified social distancing and operational shut down, all of which could further help keep the curve under the ‘tolerable threshold’. With no asymptomatic sampling (scenario 1), the only warning of outbreaks would be rising number of people seeking health care, by which time it would likely be too late to flatten the curve sufficiently to prevent the ‘tolerable threshold’ being passed.

Who should be tested?

In Appendix C, we schematically outline the proposed Testing-Tracing system. A range of different testing strategies are available. Most obviously, anyone with symptoms of COVID-19, even if symptoms are mild, should be tested. This is the highest priority group to test and will have the highest yield of positive results. Second, all contacts of COVID-19 cases should be tested.

There are additional options involving testing of asymptomatic people. There are also options for testing wastewater for the presence of virus. These options and the reasons for them, are laid out below.

Why test asymptomatic individuals, who have not had a close contact with a COVID-19 patient?

A significant challenge with controlling COVID-19 epidemics is transmission from individuals shedding virus but without reported symptoms. This will include truly asymptomatic individuals (those that will never develop symptoms), pre-symptomatic individuals (those who will develop symptoms in the next few days), mildly symptomatic individuals (those in whom symptoms were not noticeable enough to self-identify), and post-symptomatic individuals (those who did have symptoms but they are now resolved). Any of these groups may unwittingly infect others. Thus, testing asymptomatic populations has two measurable benefits:

1. Asymptomatic testing can identify individuals with high risk of transmission (because they will behave as though uninfected) as early as possible. These individuals can be isolated or removed from the types of personal contact and activities that could lead to significant transmission to others.
2. Asymptomatic testing can help estimate prevalence of infection and trends in prevalence. Symptomatic testing also generates prevalence estimates, but there are two important reasons to add asymptomatic testing:
   a. To identify outbreaks while there is still time to take interventional actions. Young adults are significantly less likely to show symptoms than older people. This means there is significant risk that outbreaks in student populations can grow to sizes that will inevitably overwhelm local health facilities before increases in health-seeking behavior are observed at student health services or before sufficient spill-over to non-student populations has resulted in cases in high-risk individuals
   b. Early in outbreaks, hotspots and super-spreader events can lead to erratic numbers of individuals seeking health care. For instance, none on one day, 5 on the next, 3 on the third need not be evidence of rising curve that requires more stringent distancing measures. Formal estimates of prevalence from a systematic surveillance system
provide evidence that such fluctuations are due to random events rather than true trends.

Why test wastewater?

There are media reports and at least one scientific paper claiming that viral RNA can be detected in wastewater. This could provide potentially one of the earliest indications that outbreaks are occurring, for example, if virus negative wastewater becomes virus positive after student return, or if virus concentrations in wastewater start to double as the semester proceeds. Equally, it could provide early evidence that enhanced mitigation strategies are working and extreme social distancing measures could be relaxed. Thus, wastewater sampling has the potential to provide an important data stream for decision-making. It is also possible that targeted sampling across campuses might identify sources (e.g. particular dorm buildings, sports facilities) which could be targeted for isolation, behavioral avoidance or disinfecting etc.

A second reason for testing wastewater is that it is inexpensive per sample (see below), and so a wastewater surveillance program is more efficient than surveillance of asymptomatic, especially the marginal costs for subsequent semesters. There are also currently zero legal regulatory issues, in contrast to asymptomatic testing, and so it could become standard practice in universities and municipalities nationwide in the future.

A third reason is that an asymptomatic testing program is very logistically complex and may not be adequately delivered, especially early in semester when it really matters. Therefore, it is a backstop to potential gaps in an individual symptomatic surveillance system.

Testing and Contact Tracing Options:

The options are summarized in Table 1 below. Broadly speaking, three options (none, comprehensive testing or sample testing) are available at each of three time points (pre-arrival, at arrival, post-arrival).

1. Pre-arrival testing: Testing performed prior to returning to the workplace, classroom or, other campus related activity.

   A. Symptomatic Testing: We recommend that all individuals with COVID-19 symptoms not return to any campus community until they have been tested and, if a positive test occurs or clinical suspicion for COVID-19 is high after their community medical evaluation, released by a medical professional to return to their community.

   B. Close contact testing: We recommend that all individuals known to be in contact with a COVID-19 positive person within fourteen days prior to scheduled campus arrival should not return to campus until they have been released by a medical professional to return to their

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3 https://www.medrxiv.org/content/10.1101/2020.04.05.20051540v1
community. If they develop symptoms prior to completion of their 14-day quarantine they must be evaluated by their community medical provider and managed as in symptomatic testing above.

C. Asymptomatic Surveillance testing:

a. Comprehensive testing (ideally everyone coming to campus): This is aimed at reducing the number of positive individuals at the start of semester and preventing outbreaks on the college campus. Positives will not be allowed to return to campus until evaluated by a medical provider and deemed to not pose a risk of infection to others. In addition, this allows for a prevalence assessment prior to arrival. Prevalence above a pre-determined threshold at pre-arrival testing suggests COVID-19 is uncontrolled in multiple areas around the United States and re-opening at full (or partial) capacity may not be safe. Comprehensive asymptomatic pre-arrival testing would inform Penn State University re-opening Go/No Go decisions and would allow exclusion of the maximum number of COVID-19 infected individuals from re-entry into the Penn State University campus environment.

b. Sample testing: This is aimed at determining baseline disease prevalence. If prevalence in sample testing is above a pre-determined threshold the predicted stress on Mt Nittany Medical Center in coming weeks would be too high to re-open safely. The number of initial positives is also a key determinant of the slope outbreak curve if the institution is able to safely reopen (see ongoing testing below). Although sample testing will provide actionable information to guide Go-No Go decisions it has far less impact on outbreak control than comprehensive pre-arrival testing and is a less desirable strategy than comprehensive testing in terms of outbreak control.

2. Arrival Testing: This testing occurs immediately prior to/right at start of the semester (i.e. in week 1, if there is no phased opening, or, if there is phased re-entry (which we advocate for), in week 1 of each entry cohort). Tests could be performed on or near a campus (ideal) or remotely.

A. Symptomatic Testing: We recommend testing of any individual presenting with symptoms consistent with COVID-19. Individuals will self-identify as having COVID-19 like symptoms. We recommend providing meaningful guidance on what symptoms to look for and enabling self-identification through a mobile application (commonly referred to as an ‘APP’) on a smartphone or, other web enabled technology. The IT workstream is looking at several options to accomplish this. Once a person has self-identified with symptoms, we recommend that their health care provider will conduct a clinical evaluation (which may be done remotely or, in-person depending on circumstances) and direct them to a location nearest to their point of identification for sample collection and test processing. We recommend that individuals be asked to self-isolate until the results are returned and they are cleared by a medical provider. We recommend that persons presenting as symptomatic immediately initiate the contact tracing process as detailed below, ahead of their test results.

B. Close contact testing: We recommend that any individual who has had close contact with someone with COVID-19 be tested. Individuals may self-identify (goal to add this to the IT
solution above for symptomatic patients) or be identified through contact tracing efforts. If their test result is positive they will be isolated, and their contacts will be traced. If their test is negative they will be quarantined for 14 days and monitored daily for symptoms. If symptoms develop we recommend that they be tested as above.

C. Asymptomatic Surveillance testing:

a. Comprehensive testing: This is aimed at reducing the number of positive individuals on campus at any given time and can be used to contain/control outbreaks by identifying and isolating positive individuals. Contacts can also be identified, tested, and quarantined or isolated as needed based on their test results. Prevalence above a pre-determined threshold during arrival testing will require either partial or complete shutdown to avoid stress on Mt. Nittany. This is the best option to minimize outbreaks at Penn State University but poses many logistical challenges.
b. Sample Testing: This is essential to determine baseline disease prevalence if individuals after return to campus. If prevalence is above a pre-determined threshold the predicted stress on Mt Nittany in coming weeks would be too high to open safely. The number of initial positives is also a key determinant of the slope outbreak curve if the institution is able to safely reopen (see ongoing testing below). Test positives are isolated, and contacts traced and quarantined. Prevalence above a pre-determined threshold at arrival testing will require either partial or complete shutdown to avoid stress on Mt. Nittany. Although comprehensive arrival testing would have the most impact on outbreak control, sample arrival testing coupled with comprehensive pre-arrival testing is a valid alternative strategy if comprehensive arrival testing cannot be performed due to logistical challenges.

3. Post-arrival testing: This testing happens in subsequent weeks throughout the semester. Tests will be performed on campus.

A. Symptomatic Testing: We recommend testing of any individual presenting with symptoms consistent with COVID-19. Individuals will self-identify as having COVID-19 like symptoms. We recommend providing meaningful guidance on what symptoms to look for and enabling self-identification through a mobile application (commonly referred to as an ‘APP’) on a smartphone or, other web enabled technology. The IT workstream is looking at several options to accomplish this. Once a person has self-identified with symptoms, we recommend that their designated health care provider (to be determined) conduct a clinical evaluation (which may be done remotely or, in-person depending on circumstances) and direct them to a location nearest to their point of identification for sample collection and test processing. We recommend that individuals be asked to self-isolate until the results are returned and they are cleared by a medical provider. We recommend that persons presenting as symptomatic immediately initiate the contact tracing process as detailed below, ahead of their test results.

B. Close contact testing: We recommend that any individual who has had close contact with someone with COVID-19 be tested. Individuals may self-identify (goal to add this to the IT
solution above for symptomatic patients) or be identified through contact tracing efforts. If their test result is positive they will be isolated, and their contacts will be traced. If their test is negative they will be quarantined for 14 days and monitored daily for symptoms. If symptoms develop we recommend that they be tested as above.

C. Asymptomatic Surveillance testing:

a. Comprehensive testing: Weekly testing of the majority of the Penn State University community is aimed at reducing the number of positive individuals on campus at any given time and can be used to contain/control outbreaks by identifying and isolating positive individuals. Contacts can also be identified, tested, and quarantined or isolated as needed based on their test results. Prevalence above a pre-determined threshold during arrival testing will require either partial or complete shutdown to avoid stress on Mt. Nittany. This option, while attractive for controlling outbreaks, is felt by the group to be logistically impossible.

b. Sample Testing: Daily testing of 1% of the Penn State University population each day would provide sufficient power to get prevalence estimates and, over a week, detect upward trends. This would allow actionable information to employ more stringent social distancing measures or proceed to university shut down if prevalence increases to levels where case volumes are predicted to overwhelm Mt. Nittany’s capacity. It will provide some benefit to outbreak control although not as much as a comprehensive testing approach.
<table>
<thead>
<tr>
<th>None</th>
<th>Comprehensive (aim to test everyone)</th>
<th>Sample</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Pre-entry</strong> (&lt;72 hours before arrival to campus location, State College, Altoona etc.)</td>
<td><strong>Pros</strong></td>
<td><strong>Pros</strong></td>
</tr>
<tr>
<td></td>
<td>• No cost</td>
<td>• Provides initial estimate of number of infectious people. That estimate can be used in operational decisions regarding social distancing, GO/NOGO decisions.</td>
</tr>
<tr>
<td></td>
<td><strong>Cons</strong></td>
<td>• Cheaper and logistically simpler than comprehensive testing</td>
</tr>
<tr>
<td></td>
<td>• No reduction in risk of serious outbreaks</td>
<td>• Could be focused on students from high risk county of origin. This would give upper bound on prevalence estimate as well as reduce number of infected individuals coming to campus.</td>
</tr>
<tr>
<td></td>
<td>• No estimate of size of initial risk. Semester planning blind</td>
<td><strong>Cons</strong></td>
</tr>
<tr>
<td></td>
<td><strong>Cons</strong></td>
<td>• Expense, logistic complexity</td>
</tr>
<tr>
<td></td>
<td>• Very expensive, substantial logistic complexity</td>
<td>• Unknown number of students could become infected after testing</td>
</tr>
<tr>
<td></td>
<td>• Possible issues with fairness, equity, cost</td>
<td><strong>Pros</strong></td>
</tr>
<tr>
<td></td>
<td>• False negative rate hard to estimate, might lead to complacency</td>
<td>• 1% provides initial estimate of number of infectious people. That estimate can be used in operational decisions regarding social distancing, GO/NOGO decisions.</td>
</tr>
<tr>
<td></td>
<td>• There could be a meaningful false positive rate</td>
<td>• Provides reliable estimate of how well any pre-entry testing worked</td>
</tr>
<tr>
<td></td>
<td>• Unknown number of students could become infected after testing</td>
<td>• Cheaper and logistically simpler than comprehensive testing</td>
</tr>
<tr>
<td></td>
<td><strong>Entry</strong> (&lt;72 hours after arrival on campus)</td>
<td><strong>Cons</strong></td>
</tr>
<tr>
<td></td>
<td><strong>Pros</strong></td>
<td>• Infectious individuals will have already relocated to campus area</td>
</tr>
<tr>
<td></td>
<td></td>
<td>• Very expensive, substantial logistic complexity (technically likely infeasible)</td>
</tr>
<tr>
<td></td>
<td></td>
<td>• False negative rate hard to estimate, might lead to complacency</td>
</tr>
<tr>
<td></td>
<td></td>
<td>• There could be a meaningful false positive rate</td>
</tr>
<tr>
<td></td>
<td><strong>Cons</strong></td>
<td>• Could be focused on students from high risk county of origin. This would give upper bound on prevalence estimate as well as reduce number of infected individuals coming to campus. Larger samples would enhance that.</td>
</tr>
<tr>
<td></td>
<td><strong>Pros</strong></td>
<td><strong>Cons</strong></td>
</tr>
<tr>
<td></td>
<td>• No cost</td>
<td>• Expense, logistic complexity</td>
</tr>
<tr>
<td></td>
<td><strong>Cons</strong></td>
<td>• No reduction in risk of serious outbreaks</td>
</tr>
<tr>
<td></td>
<td>• No estimate of size of initial risk; semester planning blind</td>
<td>• No estimate of size of initial risk; semester planning blind</td>
</tr>
<tr>
<td></td>
<td><strong>Pros</strong></td>
<td>• Reduces number of infected individuals coming to campus in first place, thus potentially very substantially flattening the curve, reducing mortality, morbidity and could enable operations to Thanksgiving and beyond.</td>
</tr>
<tr>
<td></td>
<td><strong>Cons</strong></td>
<td><strong>Cons</strong></td>
</tr>
<tr>
<td></td>
<td>• Reduces number of infected individuals coming to campus thus potentially very substantially flattening the curve, reducing mortality, morbidity and could enable operations to Thanksgiving and beyond.</td>
<td>• Expense, logistic complexity</td>
</tr>
<tr>
<td></td>
<td><strong>Pros</strong></td>
<td>• 1% provides initial estimate of number of infectious people. That estimate can be used in operational decisions regarding social distancing, GO/NOGO decisions.</td>
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<td></td>
<td></td>
<td>• Provides reliable estimate of how well any pre-entry testing worked</td>
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<td></td>
<td></td>
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<tr>
<td></td>
<td><strong>Cons</strong></td>
<td><strong>Cons</strong></td>
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<tr>
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</tr>
<tr>
<td></td>
<td><strong>Cons</strong></td>
<td><strong>Cons</strong></td>
</tr>
<tr>
<td></td>
<td>• No estimate of size of initial risk; semester planning blind</td>
<td>• No reduction in risk of serious outbreaks</td>
</tr>
</tbody>
</table>

Table 1: Pros and Cons of Asymptomatic Testing Options.
(important assumptions listed below table)
Table Assumptions:
- No options completely eliminate risk. It is impossible to estimate absolute risk. Some options reduce risk more than others.
- Assume this is in addition to risk reduction measures such as masks, social distancing; symptomatic and contact testing (and resulting isolation/quarantine)
- Assume the 1% per day is justified elsewhere.
- Recognize that the sampling strategy has yet to be fully developed and that it will depend on initial results. But will likely involve stratification by risk.
- Don’t muddy the water by distinguishing employees and students.
- Assume all positives detected by asymptomatic testing are isolated until cleared by medical provider - and contact traced.
- “Serious outbreak” is shorthand for threatens local medical centers, quarantine facilities, requires operational shut-down before Thanksgiving.
- All testing is vulnerable to supply chain problems, but proportionate to amount of testing.
- Assume there is no problem with mandating tests/compliance etc.
- Assume testing programs can be put in place at this late stage.
- Assume a prevalence cut-off will be set at which definitive action is taken, up to and including campus shutdown.

4. Wastewater sampling

 Composite samples are taken (small amounts of water over 24 hours to make up a 500ml sample from which RNA is concentrated). This sampling is done automatically by sampler machines. Labor is required to collect these samples. Samples would be collected 2-3 times/week from main wastewater facilities (at campus and municipalities) and key locations across campus. This would be tailored for each PENN State campus.
STATE campus. Thus, few samples need to be tested each week. Testing costs are low (currently $450/sample from vendors, but since sample volumes are small can be done in-house for <$100).

There are up-front capital costs for the machines (composite samplers) that do sample collection. We estimate that <$1m would cover all capital costs for all PENN STATE campuses. Once this investment has been made, marginal costs would be low and could provide early warning of risk for many years to come.

The main uncertainty is whether the wastewater RNA tests are sufficiently quantitative to generate useful data. Current published validation data are inadequate. We strongly recommend this be investigated in-house right now. We estimate that $100k, we could run this issue down (experiments spiking waste water with SARS-2 in the BSL3 lab, send spiked samples to vendors to sees if the tests truly are quantitative, spiking waste water from a variety of different sources, getting background samples now from campuses across the state, tracing water flows and rates across campus). Strongly recommend this investment.

5. Contact Tracing: Contact tracing is an effective method for identifying individuals who may have been exposed to an infectious pathogen when local transmission is low. Chains of transmission are broken by isolating infected individuals, quarantining exposed individuals, testing contacts for infection, and monitoring contacts for the development of symptoms. Contact tracing aims to identify individuals who had close contact (<6 feet) for a period of 15 minutes or longer with a confirmed case (CDC guidance) beginning 2 days prior to the onset of symptoms or 2 days prior to the test in asymptomatic cases. Contact tracing is often conducted in an interview with a trained contact tracer. Recently developed digital tools can help support those interview-based efforts. See Appendix D for full details of the contact tracing plans. We recommend implementation of a “Hub and Spoke” model to achieve appropriate contact tracing throughout all the university campuses. While the hub will be in University Park, communication and support resources must exist at each spoke to achieve the necessary goals. In addition, while UHS and Employee Health have worked independently historically, we believe a single contact tracing program that provides oversight of these components is optimal.

CHALLENGES:

- Disease prevalence in relevant communities at or near the time of pre-arrival to campuses. If prevalence is high enough, safe re-opening may not be feasible regardless of outbreak prevention measures.
- A negative test reflects a snapshot in time. The negative test indicates that virus was not detected in the sample, but does not rule out infectiousness subsequent to testing.
- There remain uncertainties in the relationship between the molecular test, symptomology, and infectiousness.
- Capacities to enable pre-arrival testing on scale and in limited time frames.
  - Pre-arrival, arrival, and initial interval sampling will require contracting with commercial laboratories with capacity for high volume testing
  - Commercial lab testing will be costly
- Turn-around-times for test results are likely to increase as commercial laboratory capacity becomes strained
- Other institutions are likely pursuing similar options and we may be in a queue to contract with the commercial laboratories
- One commercial laboratory may not be enough to handle the institution’s needs (initial or throughout the semester), making contracting with more than one entity a strong possibility

- User compliance with self-quarantine prior to returning to a campus location.
- Ability of the university to control, for users who do not test or test-positive prior to campus arrival, to remain off campus until they are either re-tested or cleared by medical professionals.
- Our ability to create and enable a point-of-interaction (Smart phone APP) for faculty, staff and students that is: fully functional, user friendly, universally adopted and, incentivizes connection with the testing and contract tracing capabilities of the university.
- User access to systems or facilities.
- Users compliance with social and behavioral recommendations related to: social distancing, symptoms monitoring, desire to access the testing and contract tracing capabilities of the university, reporting of a positive (or, negative) test result obtained outside the university systems, contact tracing participation and, compliance with quarantine or isolation as warranted.
- Legal issues and challenges related to mandated testing or mandated compliance with quarantine or isolation.
- User willingness to comply with surveillance testing
- 3rd party capabilities to provide adequate capacities for: test-collection, shipping, test processing, prompt turn-around-time for test processing and reporting.
- Adequate staffing for managing, delivering and analyzing results from this system.
- Data management – commercial vendors will not have an interface with University Health Services, but rather have their own patient information portals.
  - Process would be reliant on student compliance with accessing their information and acting accordingly.
  - University Health Services may need to maintain a manual database for tracking, isolation, and quarantine purposes
- Feasibility of hiring requirements to perform sample collection, data management, oversight of isolation/quarantine
- Expenditure constraints; illustrated below.

## Estimated costs

Note that for sample testing (here, the ‘Low’ cost option), number of tests required is set by the need to estimate prevalence and trends in prevalence. Calculations show that 1% per day/time point will provide robust estimates and so we have costed the ‘Low’ option on this basis. There may be scope to reduce this sampling further, but with corresponding decreases in confidence. Detailed calculations are available on request.
Table 4. Estimated costs of the testing options in Table 3.

Variable Cost Range estimates for each component:
All numbers expressed in $M USD$\(^1\)

<table>
<thead>
<tr>
<th>Component</th>
<th>MIDDLE</th>
<th>HIGH</th>
<th>LOW</th>
</tr>
</thead>
<tbody>
<tr>
<td>None</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Pre-entry</td>
<td>$0</td>
<td>$11-12</td>
<td>$11-12</td>
</tr>
<tr>
<td>Entry (&lt;72 hours after arrival on campus)</td>
<td>$0</td>
<td>$0</td>
<td>$11-12</td>
</tr>
<tr>
<td>Post-arrival (includes symptomatic and surveillance)</td>
<td>$0</td>
<td>$4.7</td>
<td>$5.9</td>
</tr>
<tr>
<td>Waste-Water</td>
<td>$0</td>
<td>$0.1</td>
<td>$0.1</td>
</tr>
<tr>
<td>Contact Tracing</td>
<td>$0</td>
<td>$2.5</td>
<td>$3</td>
</tr>
<tr>
<td><strong>TOTALS</strong></td>
<td>$0</td>
<td>$31.7-32.7</td>
<td>$44.4-46.4</td>
</tr>
</tbody>
</table>

**Capital Expenditures**\(^2\)

<table>
<thead>
<tr>
<th>Component</th>
<th>Pre-Entry</th>
<th>Symptomatic testing(^2)</th>
<th>Surveillance testing(^2)</th>
<th>Waste-Water</th>
<th>Contact Tracing</th>
<th><strong>TOTALS</strong></th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>$</td>
<td>Post-arrival</td>
<td></td>
<td>$0.90</td>
<td>$</td>
<td>$0.97</td>
</tr>
<tr>
<td><strong>TOTALS</strong></td>
<td>$</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

\(^1\) excludes PPE expenditures
\(^2\) capital for sample collection(s) has not been estimated
Appendix A: Overview of SARS-CoV2 (COVID-19 virus) Testing Options

Melissa George, DO & Catharine Paules, MD

Authorized assays for viral testing include those that detect SARS-CoV-2 nucleic acid (molecular testing), antigen, or antibodies.

**Basic test methods:**

- Molecular testing
- Antigen detection
- Antibody detection

**Molecular testing (most commonly PCR):**

Molecular testing looks for the presence of viral genetic material and is primarily performed using polymerase chain reaction (PCR). The goal of this type of testing is to identify patients that are currently infected with COVID-19. It will not tell us whether someone had COVID-19 in the past and has now recovered. The results of this type of testing help us to manage the patient appropriately, take steps to isolate the patient to prevent the spread of the virus to others, and quarantine close contacts who are at risk of developing infection.

Molecular testing is currently believed to offer the greatest sensitivity (up to 97%) and specificity (>99%) for the diagnosis of COVID-19. The sensitivity of this testing is highly dependent on the type of sample obtained and the quality of specimen collection. A well collected nasopharyngeal swab (deep sample) is the most sensitive type of specimen that does not require a deeper respiratory sample (obtained by sputum collection or bronchoscopy). A sample can also be obtained using oropharyngeal swabs for which, at our institution, we have observed a lower sensitivity than a properly obtained nasopharyngeal swab. Utilization of saliva samples, tongue swabs, anterior nares swabs, and nose swabs have all been proposed but will require further data and validation prior to being used as a substitute for a nasopharyngeal swab.

Molecular testing samples are generally collected by a health care provider and require personal protective equipment to be worn by the provider and appropriate infection prevention/isolation procedures to be taken. Recently, patient collection of samples has received interest as an alternative to provider collection. A study published in June in NEJM suggests that self-collected samples, particularly of the anterior nares, may be a feasible option in the pandemic setting when resources are limited. However, health care provider collected nasopharyngeal samples remain the preferred mechanism of sample collection when feasible.

Molecular testing samples are generally sent to a high complexity laboratory for processing with a results turn-around-time of 1-4 days. There are tests that can be done at bedside/in the clinic with results available in less than one hour (“point-of-care testing”). However, the sensitivity of the currently available point of care tests, like the Abbott ID Now (advertised widely on the news), are quite poor.
(~65%) and, particularly in high prevalence areas, will miss many cases of COVID-19 (false negative results). In addition, testing is available in a very limited quantity, essentially negating its usefulness.

Pooled testing is being explored for testing large quantities of asymptomatic patient samples. Pooled testing involves taking the genetic material from multiple samples, running the samples in aggregate through a molecular assay. If the pool tests negative, all samples within the pool are deemed negative. If the pool tests positive, tests must be performed on each individual sample comprising the pool separately. Pooled testing can be an effective strategy to screen large numbers of people, when the disease prevalence is low (and therefore the likelihood of the pooled sample testing positive and needing to be repeated is low).

**Antigen testing (not likely to be helpful here):**

Antigen testing, detection of viral proteins present in a sample without an amplification step, is far less sensitive than PCR based molecular testing (only ~80-85%). These tests are more likely to be point-of-care tests performed on plastic card-based assays. At present, only one antigen test (Quidel Sofia) has FDA Emergency Use Authorization (EUA), and is only available in small volumes.

**Antibody Testing (not likely to be helpful here):**

Antibody testing (from a blood sample) detects an individual’s immune response to a pathogen, it does not detect the pathogen itself. Antibodies typically do not appear until the second week after infection with COVID-19 and thus antibody testing has limited utility in diagnosing acutely ill COVID-19 patients. Rather, antibody testing may be used to identify people that have been infected with COVID-19 in the past and are now recovered/recovering. Antibody tests can NOT currently be used to assess immunity against reinfection as correlates and longevity of immunity have not been established for COVID-19.

The United States’ Centers for Disease Control and Prevention (CDC) does not currently recommend antibody testing from a blood sample as the sole basis for diagnosis of acute infection, and antibody tests are not authorized by FDA for such diagnostic purposes. Many of these tests have potential cross reactivity with antibodies against other less dangerous strains of coronavirus which may impact test specificity.

**General guidance:**

CDC recommends using authorized molecular assays that have received an FDA EUA to test persons with symptoms when there is a concern of potential COVID-19. Tests should be used in accordance with the authorized labeling; providers should be familiar with the tests’ performance characteristics and limitations. Less is known about testing of asymptomatic individuals (both close contacts of infected patients and individuals with no known exposure), however, utilizing asymptomatic testing to establish baseline prevalence within a community may help inform community policies. In addition, results can be utilized to identify currently asymptomatic individuals with the potential to spread COVID-19 to others allowing early isolation and contact tracing in hopes of preventing or controlling a larger outbreak.
Appendix B. Preliminary Simulations of Possible Infection Scenarios at University Park

Modelling by Matt Ferrari, preliminary summary by Andrew Read.

The analysis is based on an SEI$_1$I$_2$R model of SARS-COV-2 transmission at University Park with 45,000 students.

Here:

$S$ = susceptible individuals; assumed to decrease due to infection with no inputs or “births”

$E$ = individuals who are exposed but not yet infectious, these individuals are assumed to be asymptomatic, average duration of this period is 4-6 days.

$I_1$ = pre-symptomatic individuals who are infectious but not yet symptomatic, average duration of this period is 2 days.

$I_2$ = potentially symptomatic individuals who are infectious, average duration of this period is 7 days. The proportion of individuals in this class who present symptoms varied but a baseline assumption of 5% symptomatic is assumed to reflect the low rate of symptomatic infection in young adult populations consistent with a student population

$R$ = individuals who are recovered from infection and assumed to have short-term protective immunity.

Assumptions

$R_0 = 2.5$, consistent with conservative estimates around the world.

Students in the $I_2$ class develop symptoms with probability $1/20$ and seek care 2-4 days after the onset of symptoms (consistent with epidemiological observations).

All symptomatic individuals are assumed to be tested with results available instantly.

For simplicity, we assume 100% sensitivity and specificity of the test.

Consistent with flu data, 1 symptomatic student case is matched by one symptomatic community (non-student) case.

Consistent with data (see main text), assume 1/33 symptomatic students are hospitalized, and 1/10 symptomatic non-student cases are hospitalized.

Semester start for students is synchronous (no phased re-entry).

Outputs are from 1000 stochastic simulations.
The first figure below is the scenario for no testing (that is, testing for diagnostic purposes maybe occurring and there is isolation of symptomatic cases, but there is no contract tracing/testing and no testing of asymptomatic). This can be thought of as the worst-case scenario. If there are more than 5 infected students at the start of semester, we fail to get to Thanksgiving without passing the tolerable threshold of one hospitalized case per day, but the time to failure is shorter the more students infected at the start. The tolerable threshold is passed when prevalence in the entire population reaches about 4%.

The second figure (below) is the scenario for asymptomatic testing of 1% per day, with highly effective contact tracing and quarantining. Note that for the most part, the tolerable threshold is not passed, but because of contact tracing and the cases found by asymptomatic testing, it is easy to overwhelm the quarantine facility (here assumed to be 300 hotel rooms).
Note that the level of testing in the second scenario (1% asymptomatic testing per day) would also give data on the dynamics of the outbreak that would otherwise be invisible (since it is in the asymptomatic population). This data would provide early warning indicators of underlying outbreak dynamics which could trigger additional mitigation efforts such as intensified social distancing, closing of bars and/or operational shut down, all of which could further help keep the curve under the ‘tolerable threshold’. For instance, 4% prevalence will cause MNHC to be overwhelmed, so 2% prevalence should trigger operational shut down, given the lags involved. With no asymptomatic sampling (scenario 1), the only warning of outbreaks would be rising number of people seeking health care, by which time it would likely be too late to flatten the curve sufficiently to prevent the ‘tolerable threshold’ being passed.

Summary of calculations for daily asymptomatic sampling required.

Since 4% prevalence would lead hospitalizations exceeding the tolerable threshold, we want to know earlier than 4% - assume one doubling period early = 2%. At 500 tested individuals per day, that is 15 positives, which gives a ~5% chance of a thinking we’re above 2% when were not and a 1% chance of thinking we’re below 4% when we are over (i.e. false positive and false negative calls). Those calculations can be used to estimate the marginal gains of more or fewer tests.
Processes of investigating the infected cases and identifying "close contacts" defined as those within 6 feet of the infected individuals for more than 15 minutes during infectious period:

- Symptomatic cases – two days before symptom onset until the case was isolated.
- Asymptomatic cases – 48 hours from before the test was taken.

**Symptomatic cases**:
- **Tw days before symptom onset until the case was isolated.**

**Asymptomatic cases**:
- **48 hours from before the test was taken.**

**Close contacts** notified and verified via text, email, or phone

**Case Investigation and Tracing Approaches**

**Conventional Approaches**

- Infected individuals interviewed by contact tracer via phone and web-based questionnaire
- REDCap to support data capture
- Sara Alert to support monitoring and reporting for public health

**Web-Based Support Tools**

- REDCap to support data capture
- Sara Alert to support monitoring and reporting for public health

**Testing for COVID-19**

- **Diagnostic / screening test for active infections ("PCR").**
- **Antibody / serology (blood) test for immune response.**

**Specimen Sample Collection**

- **Self-Administered**
  - **ASYMPTOMATIC TEST ONLY**
  - **ALL TESTS**
  - Physician prescribes test kit
  - Kit delivered to home
  - Sample collected
  - Sample delivered to lab
  - Lab test results notification

- **Health Professional–Administered**
  - Physician prescribes test kit
  - Medical staff collect sample from pre-registered customers
  - Sample delivered to lab
  - Lab test results notification

**Sample Processing and Analysis**

- **Public labs (national, state, local labs)**
- **Commercial labs**
- **In-house hospital labs (satellite labs within health systems, on-premise hospital labs)**
- **NGO labs (academic labs)**
  - **ASYMPTOMATIC TEST ONLY**

**Contact Tracing**

- **Contact tracing triggered**
- **Isolation, symptom treatment and monitoring**
- **Physician prescription for testing**
- **Blanket script for testing**
- **Quarantine and daily symptom monitoring**
- **Sample collected**
- **Sample delivered to lab**
- **Lab test results notification**

**Inconclusive result**

- **COVID-19 positive case management**
- **Clinically high suspicion symptomatic cases**
- **Other negative cases**

- **COVID-19 negative case management**

- **Isolation discontinued based on clinical evaluation**

- **Re-test for COVID-19 with continued quarantine / isolation**

**Pre-Entry Screening**

- **Symptomatic Individuals**
  - Contact tracing triggered
  - Isolation, symptom treatment and monitoring
  - Physician prescription for testing
  - Blanket script for testing
  - Quarantine and daily symptom monitoring
  - Sample collected
  - Sample delivered to lab
  - Lab test results notification

- **Asymptomatic Individuals**
  - Contact tracing triggered
  - Isolation, symptom treatment and monitoring
  - Physician prescription for testing
  - Blanket script for testing
  - Quarantine and daily symptom monitoring
  - Sample collected
  - Sample delivered to lab
  - Lab test results notification

- **High Risk**
  - Symptomatic Individuals
  - Asymptomatic individuals stratified sampled for surveillance
  - Blanket script for testing
  - Quarantine and daily symptom monitoring
  - Sample collected
  - Sample delivered to lab
  - Lab test results notification

- **Medium Risk**
  - Symptomatic Individuals
  - Asymptomatic individuals stratified sampled for surveillance
  - Blanket script for testing
  - Quarantine and daily symptom monitoring
  - Sample collected
  - Sample delivered to lab
  - Lab test results notification

- **Low Risk**
  - Symptomatic Individuals
  - Asymptomatic individuals stratified sampled for surveillance
  - Blanket script for testing
  - Quarantine and daily symptom monitoring
  - Sample collected
  - Sample delivered to lab
  - Lab test results notification

**Tracking and Monitoring**

- **Penn State Customers**
  - Students
  - Staffs
  - Faculties

- **Web-based questionnaire tracking and monitoring of COVID-19 symptoms and exposure**

- **Practice social distancing and daily precaution**

**COVID-19 Testing and Contact Tracing System**

**Health Resources Task Group**

**Close Contacts**

- **Symptomatic cases** – two days before symptom onset until the case was isolated.
- **Asymptomatic cases** – 48 hours from before the test was taken.
Executive summary

We assume that prior to the return of the student body, in any capacity or at any time, COVID-19 testing would be widely accessible with the rapid return of results. Following the confirmation of a positive case, contract tracing, when integrated with basic public health measures, is an effective method for identifying individuals who may have been exposed to an infectious pathogen when local transmission is low. Chains of transmission are broken by isolating infections and quarantining exposed individuals, testing contacts for infection, and monitoring contacts for the development of symptoms. Universal testing helps reduce data skewed towards symptomatic cases because asymptomatic cases can transmit the virus widely.

When local transmission is high, contact tracing as a containment strategy requires a massive effort and a lot of resources. Disease management would then benefit from a broader mitigation approach. If high levels of local transmission precede the development of pharmaceutical interventions, which seems likely, control strategies would require a return to moderate behavioral interventions (large classes online, shared enclosed spaces like the HUB shut down, dorms at partial capacity) or strong behavioral interventions (stay at home, remote learning, dorm occupancy further reduced). With those restrictions in place, transmission rates would drop, and contact tracing would become more feasible.

In this brief report, we provide a general overview of both traditional contact tracing and digital contact tracing. Considering cost, privacy, and coronavirus experiences in other places, we recommend traditional contact tracing integrated with digital support from a decentralized data storage platform. These integrated efforts will be particularly useful in the first few weeks of a semester when students may not yet know their classmates’ names or have an established routine for behaviors and contact patterns, making recall more difficult. We also note that uptake may be low and even with participation in digital contact tracing, the technology is easy for users to temporarily disable or abandon. We stress that digital contact tracing and even integrated contact tracing are not effective stand-alone strategies. Effective disease management requires significant investment in and adoption of contact tracing, testing, and isolation.

I. Summary of Traditional Contact Tracing Methods with Benefits and Limitations

Contact tracing is a disease control measure that has been used by public health agencies for decades and has been identified as a key strategy for controlling the spread of COVID-19 (CDC).

The process of contact tracing with emphasis on quarantine and isolation, has been previously used to control tuberculosis (TB), the Middle East respiratory syndrome (MERS), severe acute respiratory syndrome coronavirus (SARS), and Ebola virus disease. In the United States (US), contact tracing is routinely used for sexually transmitted disease such as syphilis and human immunodeficiency virus (HIV) (Fox et al, 2015; Ki et al, 2019; Glasser et al, 2011; Macke & Maher, 1999).

The key concepts of traditional contact tracing include interviewing all identified cases; tracing, notifying, and monitoring the contacts of infected people; providing necessary medical
and counseling services, and supporting the quarantine of contacts to prevent additional transmission.

1. Limitations
   1. Rolls out relatively quickly and with high uptake, but requires a lot of human hours for training of contact tracers and application per patient
   2. Relies on recall accuracy, in this case 2.3 days (95% CI, 0.8–3.0 days) before symptom onset; 44% of secondary cases were infected during the pre-symptomatic stage of infection (95% confidence interval, 25–69%) (He et al. 2020)
      i. Recall bias, this can be reduced by using technology:
         a. Contact tracing may be supported by patient provided voluntary review of their own stored data without data transfer: records of purchases, events in calendar, recent communications, etc. Contact tracers can help suggest consulting this information.
         b. Student contact tracing may be supported by: proximity in university housing (neighbors, shared dorm bathrooms, etc.), class schedules (lab partners, seat neighbors), dining hall swipes.
         c. GPS records can link to an individual’s activities and contacts (see below for examples on China and South Korea experience).
   3. Relies on recall honesty: contacts from risky or prohibited activities may be intentionally withheld
      i. This can be mitigated if restrictions are thoughtful and disclosure of critical information is exempt from punishment. Well trained contact tracers can gain patients’ trust and trigger recall.
   4. Concerns about privacy, confidentiality and social stigma
      i. These concerns exist when personal information is collected.
   5. Resource intensive
      i. Workforce required: Estimates vary with respect to the number of the contact tracers needed. The U.S. will likely need 15-30 contact tracers per 100,000 population (Watson et al. 2020). This may vary slightly with transmission rates or prevalence.
      ii. Cost: Average pay for community health worker is $17 per hour (Watson et al. 2020), which equates to an annual salary of $35,360. University campuses are in unique position to access out of work or furloughed university and community members who may be able to take on contact tracing. Hiring for contact tracing would create local jobs and contribute to the local economy.

2. Benefits
   1. Information is disclosed voluntarily and directly to a person
   2. There is no large-scale passive surveillance, data collection and initial storage is decentralized, and misuse is less likely
   3. Likely to capture most contacts of significant length (>10 min), which account for majority of known transmission, brief encounters are less likely to lead to
transmission ("Public Health Recommendations for Community-Related Exposure" 2020)

4. Enormously successful in prior outbreak management efforts (smallpox eradication, Ebola elimination) when linked with pharmaceutical interventions (vaccination) or epidemiological interventions (patient monitoring, isolation)

3. All contact tracing must be paired with testing, isolation/quarantine or movement restrictions, monitoring
   1. Preparedness: Tools and tests must be available well in advance of student return, quarantine and isolation plans must be clearly laid out
   2. Scalability: all of the above resources must be available and functional for large numbers of infections and exposures

4. Example of traditional contact tracing implemented for COVID-19: Overview of Contact Tracing Program collaboration between Hershey Medical Center and PENN STATE

In the early weeks of the pandemic, a contact tracing program was rapidly developed at the Penn State College of Medicine. Currently the program includes ninety-eight students (medical, nurse practitioner, and public health), one physician, two epidemiologists, and a research team. All team members have received training in HIPAA compliance and human subject protection.

This program received approval from the College of Medicine leadership and the legal department to ensure HIPAA compliance, protection of confidentiality and privacy, and data security. The physician leader received information about each confirmed COVID-19 case at Hershey Medical Center and then initiated the call to the case. If the case was willing to participate in contact tracing, a team member called the patient and conducted phone-based contact tracing. The case information was captured in a secure REDCap database designed for this program and be passed to the student team. Students were tasked with calling the cases to interview them and obtain information on potential contacts who may have been exposed during the case’s infectious period. For this contact tracing effort, the infectious period is defined as 2 days prior to symptom onset until the date the contact tracers reached the case. Contacts were called and notified of their exposure (with no identifying information of case revealed) and were informed and encouraged to use proper isolation and quarantine measures. Case callers and contact callers were separate groups, such that contact tracers had no knowledge of original case information, which ensured confidentiality of the case patient. Student tracers also assisted those who were struggling to quarantine, via behavioral counseling and troubleshooting (e.g. provision of resources that might assist with meal or medication delivery). An extensive workflow and standard operating procedure were developed, and students divided into subcommittees including Intervention, Quality Assurance, Operations, Oversight, Data Management and Onboarding.

See Figure 1 for Appendix D for Expanded Team Structure.

II. Mobile Application Technology for Enhancing Contact Tracing

   a. Examples of technology in current use or development
1. Bluetooth-based Apps for Proximity Tracking can track an individual’s exposure to cases: Use Bluetooth proximity between mobile devices to monitor and record encounters that present potential transmission based on duration (variable) and distance of contact (<6 feet) between two Bluetooth devices that present transmission risk. Locational data are not necessarily collected.
   i. Data on proximity between Bluetooth devices may be stored on a central server and be accessible to contract tracing teams as soon as the data are collected.
   ii. Data on proximity between Bluetooth devices may be stored in a decentralized location, such as each user’s device, and volunteered to assist traditional contact tracing.
   iii. Action is taken when a case is diagnosed,
      i. Contact tracing via centrally stored Bluetooth proximity data can trigger automatic notifications to devices that were in proximity of patient’s device during the infectious period.
      ii. Diagnosed case is contacted for traditional contact tracing, patient has the option to provide locally stored Bluetooth proximity data to send notifications to devices that were in proximity of patient’s device during the infectious period.
   iv. These apps often assist in public health education; many provide personalized and general advice about COVID-19, e.g. hygiene reminders
   v. Apps often include self-reporting of symptoms
   vi. Previously used mobile application technology and contact tracing for COVID-19:
      i. Corona100m was used in the Republic of Korea along with a massive testing effort and broad, intrusive surveillance system.
      ii. TraceTogether was used in Singapore, in conjunction with additional surveillance measures, to support contact tracing conducted by the Ministry of Health. The app uses centralized data storage but data older than three weeks are permanently deleted.
      iii. TraceCovid was used by the Department of Health in UAE, uses mobile device location services (GPS) and Bluetooth technology to log locations and mutual app users in proximity. Data are stored on users’ devices but once an infection is detected, authorities “request” contact data and upload it to their server.
    vii. Bluetooth based mobile apps under development for contact tracing for COVID-19. US based efforts that prioritize privacy and focus on the protection of individual identity (Chan et al. 2020) and reduction of stigmas that could be assigned to specific geographic locations:
      i. COVID-19 Watch from Stanford University (https://www.covid-watch.org/article#aboutUs) is an anonymous exposure notification system
ii. **CovidSafe** from UW & Microsoft is an anonymous exposure notification system with proximity data stored on each Bluetooth device for two weeks ([https://covidsafe.cs.washington.edu/](https://covidsafe.cs.washington.edu/))

iii. **CoEpi**: Community Epidemiology in Action ([https://www.coepi.org/](https://www.coepi.org/)) is an anonymous Bluetooth proximity-based exposure alerting based on voluntary symptom sharing that targets social networks, not necessarily large scale populations.

viii. Digital initiatives that rely on users logging their own information. Based on logged locations, users who were in close proximity to the same location at the same time can be notified.

i. For example, Private Kit: Safe Paths from MIT logs GPS locations for 28 days. It also uses Bluetooth technology to log proximity between mutual app users for 14 days; pairing transmission and locations, the app aims to identify spatial hotspots of infection ([https://www.media.mit.edu/projects/safepaths/overview/](https://www.media.mit.edu/projects/safepaths/overview/))

ix. Finally, other programs are being developed that are designed to ease single steps of contact tracing. For example, “Tell Your Contacts”, funded in part by the National Coalition of STD Directors ([https://tellyourcontacts.org/](https://tellyourcontacts.org/)) is designed to ease one step of contact tracing (contact notification). This program allows users (e.g. cases) to send anonymous notification to up to 10 people at once notifying them of potential exposure and encouraging them to follow CDC guidelines. The program directs message recipients to a self-assessment tool where they can get recommendations for testing, isolation, etc.

b. Benefits of Incorporation of Mobile Technology
   1. High Accuracy in detecting device proximity
   2. Communication between health providers and app users
   3. Rapid Contract notification
      i. Characteristics of COVID-19 suggest that digital contact tracing may be advantageous for intervention in transmission due to rapid link between case diagnosis and Bluetooth devices in proximity of diagnosed patient during presumed infectious period (Ferretti et al. 2020).

c. Challenges Associated with Mobile Technology Incorporation in Contact Tracing Protocols
   1. As with traditional contact tracing, all contact tracing must be paired with testing, isolation/quarantine or movement restrictions, monitoring
      i. Preparedness: Tools and tests must be available well in advance of student return, quarantine and isolation plans must be clearly laid out
      ii. Scalability: all of the above resources must be available and functional for large numbers of infections and exposures
   2. Low uptake; must be in used in conjunction with other contact tracing methods—Assume R0 is 2.5. It can be estimated that reducing the reproductive number R0 below 1, must discover and isolate 60% of contacts before they spread elsewhere
To reach 60% of contacts – need 60-77.5% of population to download and run proximity protocols
-Singapore enrolled 1 in 6

3. Biased uptake; A recent survey suggests that approximately 40% of public in the US would “definitely install” an automatic contact tracing app on their phone (Milsom et al. 2020). A national study of health app usage among US mobile phone owners found use of health apps to be significantly associated with education beyond high school, household income greater than $50,000, and younger age (Krebs and Duncan 2015). While biased in a general population, this suggests that college populations may be a viable target population for health app usage.

4. Based on phone proximity, not human proximity

   Given that tracing is based on Bluetooth signals, tracing will be phone-specific and not person-specific. For example, if Individual A leaves their phone at home while they go out to a party for the evening, and a case comes to the home to visit a roommate, then tracing will erroneously indicate that Individual A may have been exposed. However, if a case is at the party that Individual A attends, Individual A will not be identified as potential contact because their phone was not in proximity.

   Proximity detection does not always correctly account for physical barriers; users on opposite sides of a window have been logged as contacts, forcing some into unnecessary quarantines.

5. Phones must be on with Bluetooth enabled

   Closely related to the issue raised above regarding phone proximity vs person proximity, digital contact tracing relies on the phone being on with Bluetooth enabled. If students opt to turn their phone off or turn Bluetooth off, Bluetooth dependent proximity logging cannot occur. It is possible that students will opt to turn off their phones or disable Bluetooth if they are engaging in prohibited activities, such as crowded events.

6. Privacy concerns (real and perceived) (Raskar et al. 2020)
   i. Singapore’s TraceTogether: deleted data older than three weeks
   ii. Some European nations are working towards de-centralization of data storage, shifting from Pan-European Privacy-Preserving Proximity Tracing (PEPP-PT) to Decentralized Privacy-Preserving Proximity Tracing (DP3T)
   iii. Israel’s internal security agency tapped into a vast and previously undisclosed trove of cellphone data to retrace the movements of people who contracted the coronavirus and identify others who should be quarantined because their paths crossed. In doing so, the government used data secretly gathered to combat terrorism for public health efforts (Halbfinger, Kershner, and Bergman 2020).

7. Equity and Socioeconomic Factors: representation in data (Raskar et al. 2020)
   i. Eighty-one percent of Americans own a smartphone, according to a 2019 report authored by Pew Research Center. However, there are substantial differences across demographics, such that only 53% of Americans over the age of 65, 71% of rural Americans, and 66% of those without a high school diploma own a smartphone (“Mobile Phone Ownership over Time” 2019).
Bluetooth technology dependent approaches exclude many populations’ most vulnerable to COVID-19.

ii. On a college campus, these differences are less likely to be relevant. A 2015 report indicated that 86% of college students regularly use a smartphone (“Pearson Student Mobile Device Survey 2015” 2015). A larger 2017 study found that 97% of college students owned a smartphone (Brooks and Pomerantz 2017).

   i. Consent is given but it is not informed consent, it is overlooked: students are being tracked on ~60 campuses with Bluetooth technology and university wireless networks with locations transmitted at high granularity (“How Colleges Are Using Tech To Keep Track Of Students” 2019)

9. Misinformation & Panic (Raskar et al. 2020)
10. Risky Behavior (Raskar et al. 2020)
11. Fraud & Abuse (Raskar et al. 2020)
12. Security of Information (Raskar et al. 2020) and data access

13. Little/no data on the effectiveness of digital contact tracing, even when coupled with additional highly invasive surveillance measures. This was done in several Asian countries but it is not clear whether it actually helped control spread (Branswell 2020, interview with Tom Frieden). Notably, many of these nations had been hit hard by SARS and their outbreak preparedness for this coronavirus included digital contact tracing tools, pervasive surveillance, and stringent isolation/quarantine protocols. Singapore believed digital contact tracing was ineffective for a number of reasons even though their platform was technically sound and rolled out without glitches. *They felt the app missed things a trained contact tracer would have caught.*
   i. Both China and South Korea achieved sustained epidemic suppression. However, without strict isolation/quarantine/move restriction measures, contact tracing would not be successful. *Per China’s protocol, the digital technology supports traditional contact tracing, but it is not the main approach: based on coronavirus diagnosis, movement restrictions are relaxed or enforced.*

Additional considerations for contact tracing protocol under development:

- Contact tracing staff – who will serve these roles? Collaboration with DOH? PENN STATE managed?
- HIPAA
- Medical services for testing/isolation
- IT Support for data collection
- Support staff for quarantine
- Facilities for quarantine/isolation
Figure 1 for Appendix D. Expanded Team Structure from PENN STATE College of Medicine Tracing Collaborative

Acknowledgements: Paige Koetter and Matt Pelton, Students at PENN STATE College of Medicine.

References


Appendix E

Penn State University Ramp-up of COVID-19 Testing Execution
April – August 2020

In late April 2020, Dr. Lora Weiss requested that a small focused group of individuals develop a proposal to present to the Commonwealth of Pennsylvania in anticipation of their $303 million allocation from the Federal testing pool allocated as part of the CARES act. While this proposal was not successful, the established group, and its acquired expertise, became the foundation of the Testing Task Force created by Dr. Nick Jones in late May 2020. This Testing Task Force (TTF) was co-chaired by Dr. Kevin Black of the College of Medicine and Professor Steven Tracey of the Smeal College.

The TTF leadership created several teams to perform the work of the task force, these teams included:
  - Testing Strategy, led by Dr. Andrew Read
  - Test Collection, Isolation and Contact Tracing, led by Dr. Robin Oliver-Veronesi
  - Test Execution, led by Professor Kevin Harter and the subject of this document
  - Legal, Regulatory and Government Affairs led by Michael Brignati
  - Other teams were planned but generally operated as part of another team (e.g., Commonwealth Campuses participation in Test Execution team)

Testing Strategy, Collection and Execution teams developed strategy and execution plans and presented several times per week to the overall TTF. The Legal team provide broad support for each of these teams. Throughout the process, multiple strategies and variations on the strategy were presented, rejected and modified. A strategy was approved by leadership for the PADL/TASC strategy on July 16, 2020 and for the overall testing plan on July 30, 2020. Operating plans and execution began for some options as early as June. Other operating plans remain in development in early August 2020.

Process

The testing alternatives and ultimately the selected options were developed simultaneously with the strategy and impacted by the constantly evolved regulatory strategy. Several options were rejected or dropped during the process. For example, UHS was initially selected as the home for the Kuchipudi test, but due to the lack of a molecular PCR certification, it was dropped as a viable alternative. Penn State Health and other providers did not have volume available due to increasing demand and supply chain issues with both instruments and reagents. Ultimately, one internal technology (Kuchipudi) was selected and two external reference laboratories were selected through an RFP process to generate the proposed solution.

The chart on the next page depicts the matrixed approach taken in the development of the alternatives and provides a framework for the project management portion of the effort.
TASC - Kuchipudi Technology (referred to as PADL in numerous older documents)

In this option, the Pennsylvania Animal Diagnostic Lab (TASC/PADL) will be utilized to provide testing of 500-700 samples per day using an assay developed at the CDC, approved by the FDA under an Emergency Use Authorization (EUA), and validated at Penn State by Dr. Suresh Kuchipudi in this lab. The initial plan for this project anticipates utilization of the test as a surveillance tool which, based on recent FDA guidance, does not require CLIA-certification for the laboratory. To increase volume and lower per sample cost given the expected low number of positive samples, sample pools of 5 samples will be processed together. The following plan was approved by the Provost on July 22, 2020.

Tasks and Milestones Required for Project Ramp-Up

Purchasing of Required Equipment, Reagents and Sample Collection Kits

As soon as possible, required purchases should be identified and approved. Concerns about supply chain remain and efforts to acquire the semester’s needed supplies should be undertaken quickly, and deficiencies rectified as soon as possible.

Next Steps/Decisions [Duane Elmore, PADL TEAM]:

- Orders placed for equipment and supplies
- Adjustments made for unavailable items
- Plans made for receipt and storage of materials
Selection of Students and Staff for Testing

Student and staff databases will be used to create a pool of testing candidates. It is expected that 1% of the student/staff population tested per day will result in approximately 100% of these groups being tested during the fall semester.

This database will be queried in a random or risk-adjusted manner to create the proposed population for testing each day. In advance, the individuals will be notified via text and email that they are to be tested in the coming days.

Next Steps/Decisions [I/T Lead]:

- TBD

Sample Collection

Sample collection locations will be set up at four-five locations around campus and be operational 8 -10 hours per day, 7 days per week. This estimate is based on similar plans at UHS. This number of collection stations assumes that samples will be taken using a supervised, self-collected approach. Staff at testing location will handle data and sample collection and prepare samples to be transported to PADL.

Next Steps/Decisions [Task Force, Sample Collection Supervisor]:

- Hire/assign a sample collection supervisor
- Finalize hours of operation
- Identify sample collection locations and configuration requirements
- Determine need for electric, computer access, printing
- Develop SOPs
- Review staff and federal requirements for staff credentials and training
- Hire needed staff [12-16 required]
- Identify needed PPE
- Train staff

Transportation

Samples will be transported twice per day from collection sites to PADL to coincide with the testing schedule at PADL. Transportation will be performed using existing protocols for handling hazardous waste.

Next Steps/Decisions [OPP, Sample Collection Supervisor]:

- Identify needed PPE
- Finalize handling details
- Develop SOP for sample transport
Lab Processing

Samples will be processed as received at PADL on the next available cycle. Samples will be pooled and processed. Clear identification of sample pools will be maintained throughout the process. The process will be governed by the SOP’s of the laboratory and in compliance with the FDA EUA for this test.

Positive pools will be identified. Individuals within those pools (initially five individuals) will be identified. These individuals will be contacted, immediate isolation will be stressed, and they will be referred to UHS for students Occupational Medicine for staff. UHS or Occupational Medicine will then take over care and data management for these individuals. The testing database will be updated to identify those referred for further testing. Follow-up results will be entered into the testing database by UHS and OccMed.

Individuals who did not show up for testing will be rescheduled for testing, or other action as deemed appropriate by University leadership.

Next Steps/Decisions [PADL Team, Task Force]:

- Configure PADL to receive equipment and establish testing line
- Validate process fully
- Finalize SOPs
- Hire staff
- Finalize data element collection and hand-off responsibilities

Data Analysis

Results of follow-on testing will be updated in the testing database by UHS/OccMed. These results, when combined with symptom tracking and contact tracing will provide a valuable tool for surveillance at the incident command center. [I/T Lead]

Billing/Reimbursement

It is expected that no tests performed for surveillance will be reimbursed by insurance companies.

General

Time needs to be built into the schedule to test the entire system at a lower volume prior to the beginning of the semester.

Cost

The current estimate for 75,000 samples to be processed in 15,000 pools is approximately $2.37 million, or $31.66 per sample.

Risks

A number of risks remain to this strategy, including:
• Ability to hire adequate staff in available time
• Ability to develop data systems to support operation in adequate time
• Ability to acquire necessary equipment and supplies
• Federal or Commonwealth action that would reduce our ability to deliver test volume
• Student, faculty and staff compliance

RFP

On July 1st, an RFP was issued to six reference laboratories with a deadline of July 10th. Four of these reference labs responded and two labs were selected by the evaluation team on July 14th. From July 14th to July 22nd, testing parameters were discussed at the senior leadership level to result in the projected amount of testing to be performed – see chart below.

**Fall Semester Testing**

<table>
<thead>
<tr>
<th></th>
<th>Pre-arrival</th>
<th>Surveillance</th>
<th>Symptomatic</th>
<th>Contacts</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>University Park</strong></td>
<td>Vault</td>
<td>TASC</td>
<td>UHS</td>
<td>UHS</td>
</tr>
<tr>
<td><strong>Format</strong></td>
<td>Oral</td>
<td>Nasal (Nares)</td>
<td>Nasal (NP)</td>
<td>Nasal (NP)</td>
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<tr>
<td><strong>Expected Volume</strong></td>
<td>24,000</td>
<td>70,000</td>
<td>30,000</td>
<td>15,000</td>
</tr>
<tr>
<td><strong>Commonwealth</strong></td>
<td>Vault</td>
<td>Vault</td>
<td>Quest</td>
<td>Quest</td>
</tr>
<tr>
<td><strong>Campuses</strong></td>
<td>Oral</td>
<td>Oral</td>
<td>Nasal (Mult)</td>
<td>Nasal (Mult)</td>
</tr>
<tr>
<td><strong>Expected Volume</strong></td>
<td>6,000</td>
<td>35,000</td>
<td>20,000</td>
<td>15,000</td>
</tr>
</tbody>
</table>

Contract notifications and negotiations began at this time. Vault completed negotiations on July 29th. Quest negotiations will be completed on approximately August 6th.

**Other Resources Considered**

A large number of options were considered, including external labs, internal technologies, capacity from Penn State Health, Geisinger, Mt Nittany Health and others, and expansion plans at UHS and Penn State Health in Hershey. No viable options emerged, generally for supply chain reasons.

A summary of the Testing Options as of August 5, 2020 appears on the next page.
<table>
<thead>
<tr>
<th><strong>Testing Vendor</strong></th>
<th><strong>Quest</strong></th>
<th><strong>Vault</strong></th>
<th><strong>TASC</strong></th>
<th><strong>Notes</strong></th>
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<tbody>
<tr>
<td><strong>Volume</strong></td>
<td></td>
<td></td>
<td></td>
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</tr>
<tr>
<td>Testing Capacity per day</td>
<td>150,000 (200,000 by September)</td>
<td>100,000 (160,000 by September)</td>
<td>700 when operational</td>
<td></td>
</tr>
<tr>
<td>Maximum available to Penn State</td>
<td>NA</td>
<td>NA</td>
<td>700 when operational</td>
<td></td>
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<tr>
<td>Expectation set with vendor</td>
<td>550/day</td>
<td>30,000 pre-arrival; 350/day thereafter</td>
<td>700 when operational</td>
<td></td>
</tr>
<tr>
<td><strong>Format</strong></td>
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<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Primary option</td>
<td>Custom anterior nares collection strategy for UP and CC’s using blended on-site, tele-med and retail location collection strategy</td>
<td>Oral sample at home, supervised via tele-med</td>
<td>On-campus supervised, self-collection of anterior nares swab</td>
<td>Quest uses on-campus resources, telemedicine resources or establishes agreements with local retail locations (e.g. Walmart)</td>
</tr>
<tr>
<td>Alternative option</td>
<td>Oral sample taken at campus location by Vault provider</td>
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<td></td>
<td></td>
</tr>
<tr>
<td>Alternative option</td>
<td>Oral sample taken at campus location by campus provider</td>
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<td></td>
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<tr>
<td><strong>Test Processing</strong></td>
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<td>Transportation</td>
<td>Courier</td>
<td>UPS</td>
<td>On-campus courier</td>
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<td>Processing time</td>
<td>24-48 after receipt</td>
<td>24-48 hours after receipt</td>
<td>12-24 hours from sample acquisition</td>
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<td>Results</td>
<td>Portal and data transfer</td>
<td>Portal and Data transfer</td>
<td>Database update</td>
<td></td>
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<tr>
<td><strong>Target Populations Anticipated</strong></td>
<td>Symptomatic and contact tracing at all locations (including backup at UP)</td>
<td>Pre-arrival testing, CC surveillance</td>
<td>University Park surveillance</td>
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<td>-----------------------------------</td>
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