National Institutes of Health

NIH Request for Information: Inviting Comments and Suggestions on University-Based Approaches for COVID-19 Surveillance Testing to Review the Current Landscape

Analysis of Public Comments

September 2020

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Executive Summary

The National Institutes of Health (NIH) has developed a multifaceted research framework to accelerate the creation of prevention strategies, diagnostics, treatments, and vaccines to mitigate the COVID-19 pandemic and stop the spread of SARS-CoV-2 (see the NIH-wide Strategic Plan for COVID-19 Research). Expediting the development, implementation, and wide-spread use of these medical countermeasures is paramount to ending the pandemic.

Frequent and reliable testing to detect SARS-CoV-2 infection will be critical to resolving the spread of COVID-19. Evidence has shown large assemblies, close contact, and indoor gatherings increase the risk of disease spread. These issues are particularly applicable to universities where students coming from across the country convene in small, communal living, and classroom spaces. Additionally, commuter student and faculty populations not limited to the university campus could facilitate the spread of COVID-19 to and from the local community. In response to these unique challenges, many universities have developed policies to limit viral spread and implemented testing procedures to track and prevent disease spread.

The NIH Request for Information (RFI) on university-based approaches for COVID-19 surveillance testing (NOT-OD-162) aimed to better understand the current testing capacity and protocols at universities, needed infrastructure and resources, their potential to serve within a learning network to align testing efforts and share resources, and possibly to serve as testing facilities for their local communities. The RFI gathered input from university members, private companies, and other interested stakeholders from across the country. A total of 27 responses were received during the submission window of August 12 to August 26, 2020.

The responses detailed a range of COVID-19 testing protocols, frequencies, and capacities. Some indicated established networks across campus locations or with other local organizations for testing or to share knowledge and resources. Others indicated a need for such networks to collect information on other testing systems, the success or needs of each system, and a need to support decision-making as the dynamics of COVID-19 or SARS-CoV-2 infection change. Overall, the majority of respondents felt setting up a university surveillance network was feasible (20 respondents), but some felt their participation in a network may be limited by difficulties such as shortages of trained technical staff and supply chains of materials and equipment. Some respondents suggested that creating a learning network with centrally governed logistics, data management, and communications and additional resources would be beneficial to a university-based COVID-19 surveillance effort (14 respondents).

Report on the Results of the RFI

Introduction

The coronavirus disease 2019 (COVID-19), caused by the virus SARS-CoV-2, has contributed to nearly 200,000 Americans deaths since its emergence in early 2020 (as of September 2020). Implementing consistent and thorough testing and surveillance practices will be critical to mitigating this disease, particularly in close contact university and other higher education environments where students from across the country are returning to campuses to live and study together. Leveraging existing materials and equipment and optimizing workflow processes could support robust testing protocols and increase testing capacity to control the spread of SARS-CoV-2 and protect university and surrounding communities.

NIH sought to better understand the COVID-19 testing and surveillance capacity across U.S. universities by requesting input from stakeholders on seven key topic areas (NOT-OD-20-162, see Appendix 1):

- The *feasibility* of carrying out such university-based network activities at scale,
- The *types and frequency* of testing including the technologies and approaches that could be utilized,
- The use of *alternative evidence-based approaches* to monitoring the level of COVID19 in the community (e.g., wastewater surveillance) and the development of methods to categorize and identify high-risk populations within a university system,
- The *resources* needed to jointly develop robust surveillance testing capabilities for students, faculty and staff and possibly for other critical institutions in their local communities,
- The *risks and challenges* that might impact the successful establishment and operations of a learning network such as that described above,
- Proposed *mitigation strategies* to address the potential risks and challenges, and
- Novel *network approaches* to efficiently manage testing capacity among institutions and collaborate with other university-based networks to rapidly learn from protocols approaches and challenges to optimize operations.

The process and outcomes of the analysis conducted by NIH staff are detailed below.

Analysis of the Results

NIH staff categorized the 27 responses on university surveillance testing approaches and considerations received from stakeholders during the submission window of August 12 to August 26, 2020, using standardized codes (Appendix 2). If the respondent did not address an area, no code was assigned. Additionally, codes were not exclusive; if responses included information relevant to more than one code, all were included in the analysis. Two responses were duplicative, submitted by two individuals from the same organization; these were coded identically, but as individual responses.

Characteristics of the Respondents

Responses were submitted from 12 U.S. states, the District of Columbia, and the U.S. Virgin Islands (Figure 1). Most responses were submitted by university stakeholders (88%, 24), including three responses from university systems (7%, 2) or collections (4%, 1) and one response from a Historically Black College or University (HBCU). There was diverse geographical spread in the responses, with representation from the Northeast (26%, 7 respondents), South (37%, 10 respondents), Midwest (4%, 1), and West (22%, 6). However, there was a dearth of respondents in states where vulnerable populations (e.g., Native American, Latino, African American, rural) reside in greater numbers and testing infrastructure may be more critical, including many Western states and the upper and lower Midwest. Responses included stakeholders from large institutions (>15,000 students, 13 responses), medium-sized institutions (5,001 to 14,999 students, 4), and small institutions (<5,000 students, 6). Sixteen responses were submitted from public institutions and 7 from private institutions. Other respondents were from private industry (4%, 1), a professional association (4%, 1), and an unaffiliated individual (4%, 1).

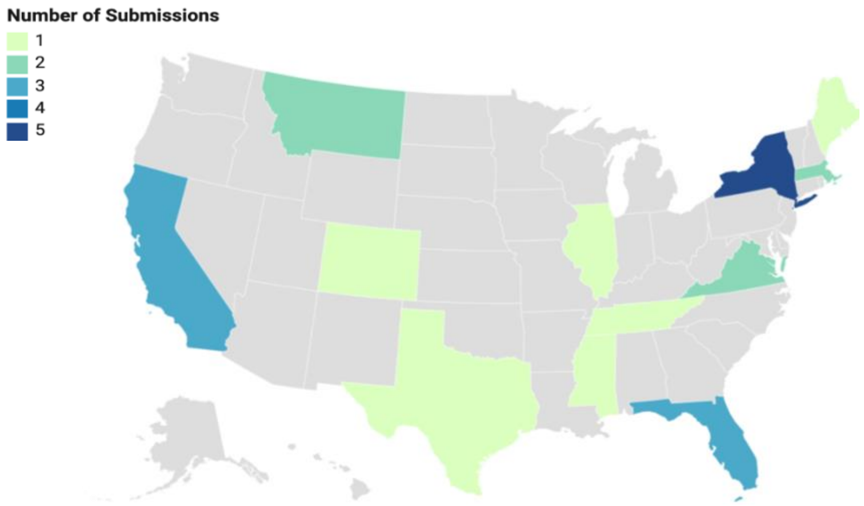

Figure 1. The geographical distribution of university-affiliated respondents was widespread across the United States. One response was from the U.S. Virgin Islands (not depicted).

Feasibility of Scaling University Network Testing

Overall, 74% (20) of respondents indicated that the feasibility of scaling university network testing activities was moderately or highly feasible (Figure 2). Only 15% (4) of responses indicated a perception of low feasibility and 7% (2) were unclear.

Factors most affecting the respondents' views of the feasibility of scaling up COVID-19 testing included infrastructure, logistics, and policies. Regardless of their perception of feasibility, respondents suggested that infrastructure, such as the availability of existing laboratories, quarantine spaces, and data management infrastructure factored into network feasibility (44%, 12). Those who responded that a network was highly feasible were influenced by the availability of human (e.g., expertise) and material resources (e.g., testing supplies).

Several respondents (41%, 11) suggested that logistical processes for sample collection, pooling, and tracking could be leveraged and shared across networks. Respondents from organizations with logistical processes already in place indicated this positively impacted the feasibility of scaling up testing. Respondents who indicated that a network was moderately feasible (33%, 9) or had low feasibility (15%, 4) often cited logistical impacts (26%, 7).

Policies, such as those affecting access to or obtaining a waiver for Clinical Laboratory Improvement Amendment (CLIA) lab access and testing requirements or federal approval of custom diagnostic tests and tools, were cited as a top factor for those with a low perception of feasibility (11%, 3 respondents). However, some respondents indicated CLIA labs within their existing networks positively impacted their testing capacity by providing a robust, ready infrastructure and trained staff along with the ability to perform individual testing in support of surveillance testing.

Other factors that negatively impacted feasibility included the need for trained staff to collect samples and perform diagnostic tests, the scarcity of material resources (e.g., swabs and test kits), and environmental factors (e.g., access to lab workspace).

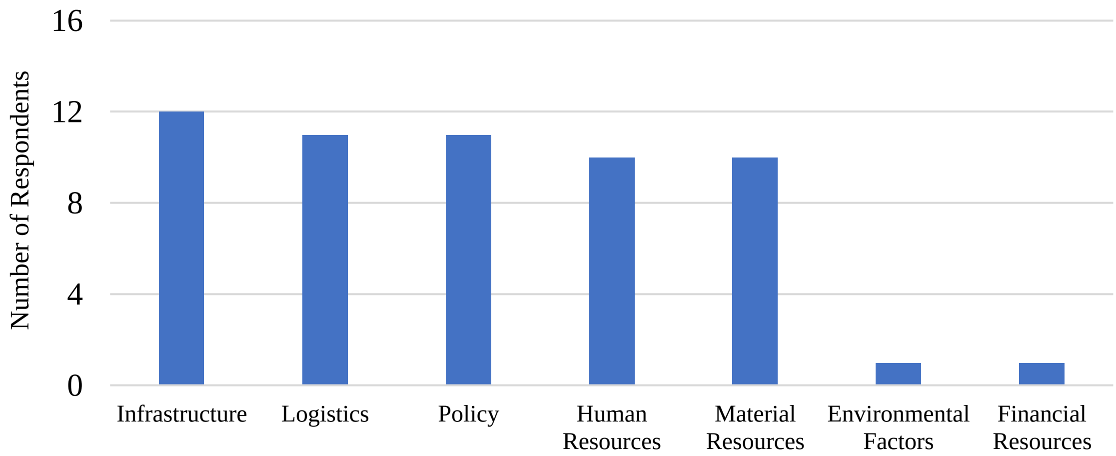

Figure 2. Factors Affecting Network Feasibility. Respondents identified factors that influenced their perception of the feasibility of setting up a university surveillance network. Top concerns affecting feasibility included infrastructure, logistics, and policy. Please see Appendix 2 for more information about the seven categories listed in the graph.

Testing: Types, Frequency, and Alternative Evidence-Based Approaches

Existing testing capabilities varied across responsive universities. Fourteen respondents indicated their institutions were testing students, faculty, and staff with high frequency (as identified by the respondent or every 1-6 days, 52%) (Figure 3). Of this group, capacity varied from 200 to 2,000 tests per day, with the turnaround time for returning results ranging from less than 24 hours to five days. Some respondents indicated medium (as identified by the respondent or every 7-14 days) or low (as identified by the respondent or greater than every 14 days) frequency testing (7%, 2) or did not clearly indicate how frequently their university was testing individuals (30%, 8).

Nucleic acid-based tests (67%, 18) represented the majority of the testing currently being performed by university respondents (Figure 3). Seventy percent of respondents also mentioned that they were considering or already using alternative testing strategies, including wastewater

(33%, 9), computational data-driven (33%, 9), or other environmental testing (15%, 4), breath analysis (7%, 2), and CRISPR (4%, 1), as well as screening surveys (7%, 2), automated temperature screening (4%, 1), and the SwabSeq high throughput pooled testing approach (4%, 1). Eight respondents indicated the ability to perform high-throughput screening (30%). Many respondents indicated that current testing frequency was affected by resource availability, including funding for test materials and staff able to perform testing. Several respondents were able to use a variety of testing techniques according to the university's approach to surveillance, such as pooling samples for initial testing followed by clinical testing in a CLIA lab for positive individuals.

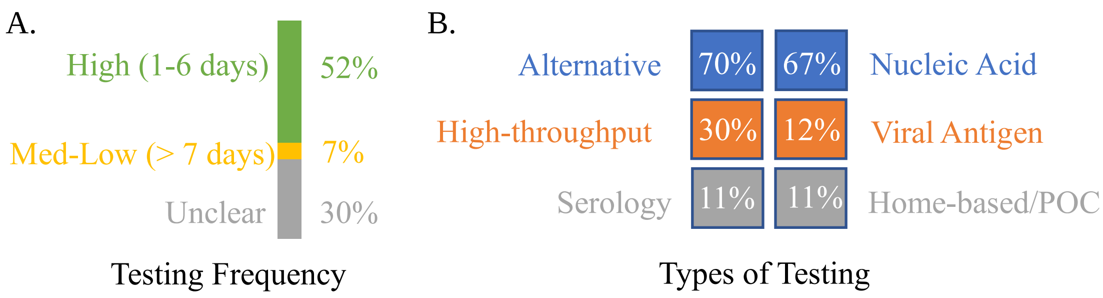

Figure 3. Testing Capabilities and Frequency. A: University-affiliated responses were categorized by testing frequency into high (testing every 1-6 days, 14 respondents), medium (testing every 7-14 days, 1 respondent), and low (testing greater than every 14 days, 1 respondent) categories. Eight respondents did not clearly indicate how frequently they were testing their university populations. Three respondents (11%) were not affiliated with a university (not depicted). B: Seventy percent of respondents indicated using or plans to use alternative testing approaches. Nucleic acid approaches (67%) included PCR and reverse-transcriptase PCR (60%) and loop-mediated isothermal amplification (7%) approaches. Home-based and point-of-care (POC) approaches (11%) were not specified.

Resources Needed

Top resource requirements for universities to develop robust surveillance programs and participate in a learning network included human (44%, 12), infrastructure-related (44%, 12), and equipment (41%, 11) resources (Figure 4). Human resource needs included trained staff to administer and process diagnostic tests and coordinate data management and experts capable of coordinating across university networks (4%, 1). One university respondent noted they lacked personnel to carry out testing, but had sufficient staff capabilities to coordinate a response. Top themes related to infrastructure (44%, 12) included the need for new laboratory spaces or to convert existing spaces for COVID-19 testing and sample processing or storage (22%, 6). Two respondents also noted a lack of quarantine space for individuals who test positive for SARS-CoV-2. Regarding equipment needs, many responses (41%, 11) noted that it was difficult to source and expensive. Relatedly, respondents identified a need for analysis and data management software and tools (22%, 6). Many respondents indicated that additional financial resources would be necessary to sustain or stand up testing programs (33%, 9), especially for those from small (<5000 students) universities (11%, 3). "Other Resources" not categorized (Figure 4) included analytical models for decision-making (7%, 2), uniformity across networking sites (4%, 1), test distribution support (4%, 1), and guidance on sample collection and handling (4%, 1).

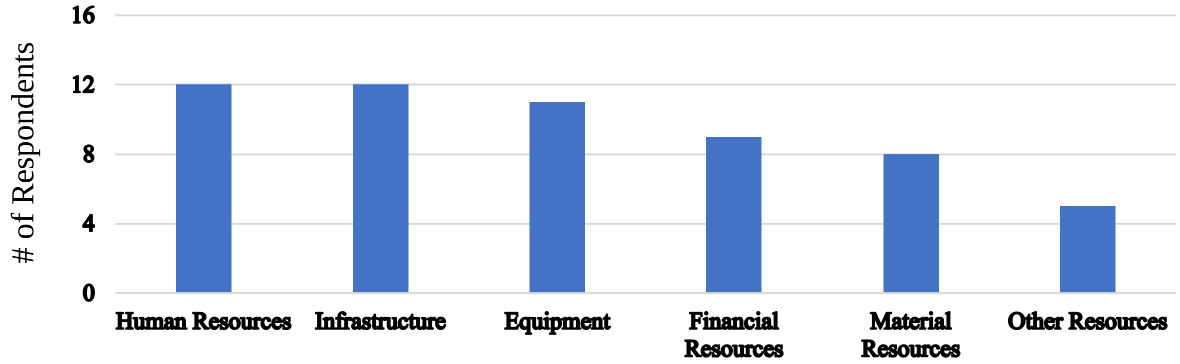

Figure 4. Resources Needed by Universities to Set Up COVID-19 Surveillance Network. The top three resources indicated as being needed by respondents were trained staff to administer and process tests and manage data (human resources, 44%), additional lab space or quarantine space (infrastructure, 44%), and testing equipment (40%).

Risks, Challenges, and Mitigation Strategies

A majority of respondent-identified risks and challenges associated with setting up a university-based surveillance network overlapped with factors that affected the feasibility of setting up a network, primarily financial (33%, 9) and logistical (33%, 9) risks (see Feasibility section above). The accountability of institutions participating in a university surveillance network for COVID-19 clusters or outbreaks in their testing populations and high-risk staff concerned other respondents (7%, 2). One response detailed apprehension about the security of medical records and the need for deployment of a robust, centralized electronic health record system to ensure the security of personal data.

Six respondents remarked on challenges related to testing populations, which included aversion to testing to avoid quarantine, stigmatization of individuals who test positive, and volunteer-only testing policies that result in low participation. A few respondents suggested mitigation strategies to boost voluntary participation (7%, 2), including extra credit points for students or excused absences from class. Challenges associated with CLIA policies were cited above in the "Feasibility of Scaling University Network Testing" section (11%, 3). Relatedly, one respondent cited logistical and policy concerns over return of results and suggested that additional measures be taken to provide regulatory relief to research laboratories at a state and federal level. Another response noted potential difficulties in extending university infrastructure, tests, data, and resources to populations with the highest risk of infection in resource-poor areas. Other challenges identified by respondents included transitioning the university research mission to a surveillance-based system (4%, 1) and translating positive test data into an effective decision-making framework (7%, 2).

Network Approaches and Opportunities

The RFI revealed several opportunities for universities to become "hubs" for testing throughout their university networks or local communities. A key theme that emerged from the responses was that sharing knowledge and resources through learning networks could be beneficial to participating universities. Many respondents (66%, 18) indicated that their university had already shared or wanted to share operational resources and infrastructure, such as testing protocols and supplies, or were sharing testing burdens across their networks. For example, in some cases, low resource universities or campuses are sending samples to high resource universities or campuses for testing. Along with shared operations, several respondents indicated the establishment or desire for open communications channels with other universities (41%, 11). Existing communication strategies included joint meetings of experts, online dashboards, and webinars or listservs. Finally, 37% of the responses described the use of or projected benefit from data-sharing and network computational approaches (10). Some respondents indicated sharing data to increase sample sized would aid modeling efforts and decision making (19%, 5). Respondents viewed utilizing network approaches to testing and scaling testing methods to larger communities as a way to share, assess, and implement effective approaches.

Conclusion

Responses from across the country indicated that many universities and stakeholders feel they would benefit from a coordinated, national university surveillance network to share approaches, resources, lessons learned, and infrastructure. Development of a surveillance learning network with centralized data, communication, and logistical process management could help alleviate the administrative, resource, and financial burdens cited by many respondents. Building open communication channels would allow universities to learn from each other and may inform planning and response strategies as the pandemic continues and the response evolves. Sharing of network-wide, pooled data and data analysis tools could also enable more highly powered analyses to support higher level decision-making and inform COVID-19 response efforts by universities and their local communities. Going forward, NIH is further considering the information and suggestions collected to determine next steps.

Appendices

Appendix 1: Request for Information

Request for Information (RFI): Inviting Comments and Suggestions on University-Based Approaches for COVID-19 Surveillance Testing to Review the Current Landscape)

Notice Number: NOT-OD-20-162

Key Dates

Release Date: August 12, 2020
Response Date: August 26, 2020

Issued by

National Institutes of Health (NIH)

Purpose

This Notice is a Request for Information (RFI) inviting information to understand the current surveillance testing capabilities at universities, and the potential for university-based networks (including universities, colleges, community colleges, satellite campuses, or other higher education institutions) to jointly deploy existing equipment and staff to develop robust SARS-CoV-2 surveillance testing for their students, faculty and staff, and possibly for other critical institutions in their local communities; share knowledge and testing infrastructure; efficiently distribute testing capacity among the institutions; and collaborate with other university-based networks to rapidly learn from protocols, approaches, and challenges, and optimize operations.

NOTE: It is important to read this entire RFI to ensure an adequate response is prepared and to have a full understanding of how your response will be utilized.

Background

Universities and other institutions of higher education may face unique challenges posed by the COVID-19 pandemic, in particular as students from varying geographical locations return to campus, reside in more confined living quarters and shared personal spaces, and participate in activities where the evidence as to the safest practices is still being generated. Optimally implementing surveillance testing could potentially benefit a generation of students and support the restoration of normal operations of institutions seeking to deliver learning in a safe environment for students, faculty, staff, and the local community.

Under CMS guidance, non-CLIA university laboratories are able to conduct surveillance under certain conditions. For the latest guidance, policies, and information on surveillance testing, please refer to the following resources:

- CMS Frequently Asked Questions: SARS-CoV-2 Surveillance Testing (https://www.cms.gov/files/document/06-19-2020-frequently-asked-questions-covid-surveillance-testing.pdf)

- CDC Interim Guidance for Use of Pooling Procedures in SARS-CoV-2 Diagnostic, Screening, and Surveillance Testing (https://www.cdc.gov/coronavirus/2019-ncov/lab/pooling-procedures.html)
- FDA FAQs on Testing for SARS-CoV-2 (https://www.fda.gov/medical-devices/coronavirus-covid-19-and-medical-devices/faqs-testing-sars-cov-2)

The production of new testing equipment and instruments is one factor currently limiting the expansion of national testing capacity; therefore, it may be advantageous to explore leveraging existing workflow processes and equipment that already reside in research laboratory settings, such as testing platforms for PCR and next-generation sequencing. Microfluidics platforms and other innovative technologies may provide additional opportunities to expand the national testing capacity as well.

Of particular interest are validated solutions that could be widely replicated throughout the Nation. Networks that include institutions serving underserved communities, could have an especially large impact on the sectors that are being disproportionately affected by COVID-19. The potential for university communities to access inclusive, frequent surveillance testing is significant and would provide increased support to control the spread of the virus and restore normal operations.

Request for Comments

This RFI invites input from stakeholders throughout the research community regarding the considerations for approaching surveillance testing across universities with different levels of infrastructure and resources.

Specifically, the NIH seeks comments on any or all of, but not limited to, the following topics:

- The feasibility of carrying out such university-based network activities at scale
- The resources (e.g., testing infrastructure and equipment and/or human and financial resources) needed to jointly develop robust surveillance testing capabilities for students, faculty and staff, and possibly for other critical institutions in their local communities
- Novel network approaches to efficiently manage testing capacity among institutions and collaborate with other university-based networks to rapidly learn from protocols, approaches, and challenges to optimize operations
- The types and frequency of testing, including the technologies and approaches that could be utilized
- The use of alternative evidence-based approaches to monitoring the level of COVID-19 in the community (e.g., wastewater surveillance) and the development of methods to categorize and identify high-risk populations within a university system
- The risks and challenges that might impact the successful establishment and operations of a learning network such as that described above
- Proposed mitigation strategies to address the potential risks and challenges

NIH encourages organizations (e.g., university systems, relevant professional organizations) to submit a single response reflective of the views of the organization or membership as a whole.

Appendix 2: Coding Scheme and Definitions

The analysis provided categorical information based on the response topics listed in the RFI. Each response was subject to the coding scheme detailed below for each main category. Where appropriate, the coding scheme was broken into multiple subcategories to provide additional depth to insights about the larger umbrella category.

Respondent Information Overview

- **Number of respondents**
- **Geographical distribution**—Based on organization name, since this information was not a collection field on the RFI
  Coding scheme—use state-based tags to code the location of each respondent's organization

Feasibility

- **Overall impressions of feasibility**—Coder's subjective impression of respondents' relative perception of the feasibility of carrying out university-based network activities at scale
  Coding scheme
    - **High feasibility—**Respondent indicated strong confidence that university-based network activities were feasible
    - **Moderate feasibility—**Respondent expressed some reservations regarding feasibility but suggested that university-based network activities were plausible
    - **Low feasibility—**Respondent had strong reservations about the feasibility of university
    - **N/A-feasibility—**Respondent did not provide input on feasibility
    - **Unclear-feasibility—**Respondent did not give a clear indication of how feasible they thought carrying out university-based network activities was
- **Factors influencing feasibility**—Strengths or barriers identified by respondents that influenced their perception of how feasible carrying out university-based network activities would be
  Coding scheme
    - **Financial resources**—Availability (or lack thereof) of funding
    - **Human resources—**Staff numbers or staff expertise/training
    - **Material resources—**Availability of supplies, equipment, or other physical resources
    - **Environmental factors—**Accessibility of physical workspace, capacity of physical workspace, etc.
    - **Logistics—**Sampling methodology and management to track samples and results, choose sub-populations for testing, or ensure compliance with testing
    - **Policy—**Federal, state, local, and university policies that help or restrict feasibility (e.g., restrictions in the number of staff allowed in physical workspaces)
    - **Infrastructure—**University/laboratory facilities necessary to perform testing function
    - **Other feasibility factors**—Other factors that influenced feasibility not identified above

Resources needed to develop surveillance capabilities

- **Top three resources**—The three resources identified most frequently by respondents as top needs for developing surveillance capabilities
- **Full list of resources**—The full range of resources needs expressed by respondents
  Coding scheme
  - **Financial resources**—Availability (or lack thereof) of funding
  - **Human resources—**Number of staff or staff with appropriate expertise/training
  - **Equipment—**Availability or accessibility of appropriate testing equipment that meet scale needs
  - **Material resources—**Availability of or ability to obtain non-equipment supplies such as PPE, reagents, plasticware, etc.
  - **Infrastructure**—Availability of university/laboratory facilities, cores, etc., necessary to perform testing function
  - **Other resources—**Other resources not identified in above categories

Network approaches to manage testing capacity among institutions

- **Low-hanging fruit**—Ideas for network approaches that are simple and easily implemented
- **High potential approaches**—Ideas for network approaches that could have the highest impact
- **Full list of approaches**—All suggestions from respondents that provided network approaches
  Coding scheme
  - **Communication strategies—**Proposed approaches that help facilitate communication with or among institutions in the network. (e.g., meetings, web-based platforms, etc.)
  - **Operation management—**Approaches for conducting operations, protocols, testing approaches, etc.
  - **Data management**—Proposed approaches that facilitate data sharing, real-time visualizations of testing data/capacity, data storage, etc.
  - **Other network approaches**—Other factors not identified above

Frequency of Testing

- **Testing frequency breakdown**—Number of respondents who mention approaches broken down by the frequency coding scheme below
- **Approaches by frequency**—Using the types of testing coding scheme combined with the frequency coding scheme, categorize approaches by how often a respondent says they need to be performed
  Frequency coding scheme
  - **High frequency—**Respondent stated that an approach was high frequency or that the approach was used to test every 1-6 days
  - **Medium frequency—**Respondent stated that an approach was moderately frequent or that the approach was used to test every 7 to 14 days
  - **Low frequency—**Respondent stated that an approach to testing was infrequent or that the approach was used to test at a frequency of greater than 14 days

N/A-frequency—Respondent did not provide input on how often testing should occur
Unclear-frequency—Respondent did not give a clear indication of how often testing should occur

Type of Testing

- **Most frequently mentioned types of testing—**Top three types of testing mentioned most frequently by respondents
- **Number of respondents with standard versus high-throughput capabilities—**as described
- **Full list of testing types/approaches**—as described
  Types of testing coding scheme
  - **High-throughput screening techniques—**Testing platforms that can process high volume samples with minimal manual labor (e.g., advanced microfluidics platforms, high-throughput PCR/RT-PCR machines)
  - **Standard screening techniques—**Traditional, labor-intensive techniques that require a high degree of manual processing (e.g., standard PCR/RT-PCR equipment)
  - **Viral antigen**
  - **Nucleic acid**
  - **Serology tests**
  - **PCR/RT-PCR**
  - **Microfluidics**
  - **Home-based/Point-of-Care**
  - **Chip- or platform-based testing**
  - **Non-traditional approaches**
  - **Pooled sampling approaches**
  - **Other testing approaches**
  - **N/A Testing Type -** No testing type indicated

Alternative evidence-based approaches to monitoring COVID-19

- **Low-hanging fruit**—Ideas for alternative approaches that are simple and easily implemented
- **High potential approaches**—Ideas for alternative approaches that could have the highest impact
- **Full list of approaches**—All suggestions from respondents that provided alternative testing approaches
  Coding scheme
  - **Community wastewater**
  - **Breath analysis**
  - **Biosensors**
  - **New analytics platforms with chemistries** (e.g., incorporates CRISPR)
  - **Tests that detect changes in sensory or other functions to predict disease early**
  - **Data analysis approaches—**including dashboards, AI/ML predictive algorithms
  - **Environmental testing (other than wastewater)—**air sampling, surface testing
  - **Other alternative testing approaches**

Risks and Challenges that Impact Establishment and Operations of Learning Network and Mitigation Strategies

- **Top identified risks/mitigation strategies**—Top three risks identified by respondents
- **Full list of risks/mitigation strategies**—All risks/mitigation strategies identified by respondents

<u>Coding scheme</u>

"Patient"-associated risks—physical and social factors that the participant weighs in deciding to get tested (e.g., fear of testing process, implications of testing/quarantine, risk of infection, etc.), stigmatization of areas/people who test positive, voluntary participation in testing programs
Communication barriers
Legal risks—Liability of the university for hosting test sites, potential for lawsuits, return of results, etc.
Staff Risks—physical and social risks to university staff involved with testing (e.g., risk of exposure), labor/time burden on staff
Emergency Use Authorization (EUA)
Clinical Laboratory Improvement Amendments (CLIA)
Logistical—Challenges pertaining to the availability of or access to testing supplies and equipment (supply chain issues), staff, sample collection issues, information dissemination, analysis of results
Financial risks—Risks associated with loss of revenue and financial burden due to expending university resources on testing
Outsourcing—Goods, services, testing, data analysis

<u>Mitigation strategies coding scheme</u>

Increased resources—PPE, cleaning supplies, resources for testing, etc., staffing to support testing (replaces increased staffing and access to supplies)
Policy—Includes items such as preventive policies and what sort of policies to enforce upon positive testing (what is the threshold for shutting down, etc.), network wide policies for data-sharing, protocols, and standards
Resource sharing—accessing network- or university-wide tools (dashboards, information systems, registration systems, etc.)
Increase prevention strategies—increase testing to detect issues sooner, additional PPE,
Communication strategies

Institution Characteristics

- **Public versus private**
- **Region**
- **Size**

Coding scheme

Public
Private
Large—–15,000 students and greater
Medium—–between 5,001~~0~~ and 15,000 students
Small—–5,000 or fewer students

University Network—part of large university system (e.g., a state system)
West—Alaska, Arizona, California, Colorado, Hawaii, Idaho, Montana, Nevada, New Mexico, Oregon, Utah, Washington, Wyoming
Midwest—Illinois, Indiana, Iowa, Kansas, Michigan, Minnesota, Missouri, Nebraska, North Dakota, Ohio, South Dakota, Wisconsin
South—Alabama, Arkansas, Delaware, District of Columbia, Florida, Georgia, Kentucky, Louisiana, Maryland, Mississippi, North Carolina, Oklahoma, South Carolina, Tennessee, Texas, Virginia, West Virginia
Northeast—Connecticut, Maine, Massachusetts, New Hampshire, New Jersey, New York, Pennsylvania, Rhode Island, Vermont

Appendix 3: Responses[1]

Response 1

The feasibility of carrying out such university-based network activities at scale
We have capabilities for this and have done some of it already

The resources needed to jointly develop robust surveillance testing capabilities for students, faculty, and staff, et. al. (e.g., other institutions in communities)
We have PCR and multi-modal antibody testing platforms including measuring neutralizing antibodies
We also have statisticians with the capacity for developing sampling methodologies
We are capable of doing whole genome sequencing which we have used with statewide collections to monitor variations in viral strains

Novel network approaches to efficiently manage testing capacity among institutions and collaborate with other university-based networks
We have partnered with the State Department of Health for a statewide strategy

The types and frequency of testing including the technologies and approaches that could be utilized
PCR testing, both commercial and LDT
Antibody testing, commerical, ELIZA and neutralizing antibody testing
Whole genome sequencing of the virus

The use of alternative evidence-based approaches to monitoring the level of COVID19 in the community (e.g., wastewater surveillance)
We developed a survey system to delineate risk levels and a sampling strategy for each of those groups

Risks and challenges that might impact the successful establishment and operations of a learning university-based surveillance network
bias in sampling due to willingness to participate
Testing positive usually means quarantine which some people want to avoid

Proposed mitigation strategies to address the potential risks and challenges
Strong mask mandates and availability of cleaning materials

Response 2

The feasibility of carrying out such university-based network activities at scale
The director of our molecular analysis core has developed a PCR-based, high-throughput, high accuracy, and quantitative test for SARS-CoV2 in saliva using an RNA-stabilizing solution swab kit that was previously developed for an FDA-approved saliva-based autism diagnostic (Clarifi ASD) in collaboration with a private company. This test is very close to EUA approval by the FDA for individualized testing and has been adapted to do pooled testing which is being done under a state department of health-approved surveillance protocol. The test uses 96 and 384 well PCR machines and our facility alone can test 500 pools of 12 per day. We are currently doing the opening testing of all students for 11 campuses and 2 private schools with another 8 under consideration. We have enough supplies currently to perform 250,000 tests.
In addition, in collaboration with another campus within the university system, a private university, and a private company, we are performing waste-water surveillance testing for early detain of community spread. Almost all state counties are participating in this work.
Also, our Department of Public Health has developed a sophisticated dashboard for all our campuses that shows where students are coming from to return to campus and the risk they present based on the current

[1] Responses may have been altered to deidentify respondents.

conditions in their home state or country. Testing results data could easily be incorporated into this dashboard.

The resources needed to jointly develop robust surveillance testing capabilities for students, faculty, and staff, et. al. (e.g., other institutions in communities)
The tests developed with the private company will be able to be licensed and require basic molecular biology expertise, PCR machines and reagent supply chains for master PCR mixes, swab kits and consumables (PCR plates etc). The team will be pursuing FDA EUA approval for the pooled test as well allowing it to be run in CLIA-certified labs. Note the pooled test can certainly go to larger pools of 24.

Novel network approaches to efficiently manage testing capacity among institutions and collaborate with other university-based networks
We have the advantage of being a part of the large university system with centralized administration which has facilitated developing the approaches to work with several campuses and to work out "the bugs". SOPs and videos have been developed for swabbing and registration using student ID numbers coupled to bar-coded swab kits and pooling of the samples prior to being transported back to our campus for testing. When a positive pool is obtained, campuses will be notified who will then tell their students in that pool that they must obtain an FDA approved test. Once the FDA approves our test, our and any CLIA lab will be able to do this individualized test.Testing data can also be aggregated in the dashboard I describe above.

The types and frequency of testing including the technologies and approaches that could be utilized
Working with our statisticians, we are developing guidance for campuses on how frequently they should test and what percent of their student body they should test to monitor covid-19 during the rest of the school year following the initial entry screening. If I recall, current indication is 5% per week.

The use of alternative evidence-based approaches to monitoring the level of COVID19 in the community (e.g., wastewater surveillance)
I mentioned the waste water testing program above and the dashboard for monitoring risk, also above.

Risks and challenges that might impact the successful establishment and operations of a learning university-based surveillance network
Supply chain issues and the availability of PCR machines. Getting more PCR machines to increase capacity has been a huge challenge. Also, when multiple students start testing positive in a pool, the cost-saving utility of the pooled approach goes away.

Proposed mitigation strategies to address the potential risks and challenges
There are plenty of people in Universities with the training to perform these fairly simple PCR-based tests. What needs to change is U.S. manufacturing bandwidth for PCR machines, reagents, and consumables. This requires federal leadership which is lacking right now.

Response 3

The feasibility of carrying out such university-based network activities at scale
The Center of which I am a co-director has the capability of carrying out pool screening for COVID19 and is planning to implement a random screening program on campus at the start of classes on August 24. We have four robotic RNA purification systems capable of processing up to 150 samples (e.g. pools each containing 4-5 individual specimens) an hour, and enough real time thermocyclers to run up to 300 samples per day. With sufficient reagents and technical support, we could process 1500 samples per week, or test up to 7500 individuals per week in pools of five. We also have a select agent certified BSL3 facility in our center where we have the capability (and currently are) culturing viral isolates.

The resources needed to jointly develop robust surveillance testing capabilities for students, faculty, and staff, et. al. (e.g., other institutions in communities)

The major bottlenecks we have experienced have been in obtaining reagents necessary for the PCR pool screening as well as the supplies necessary to collect the specimens. Swabs and PPE have been in short supply. Another issue is the need for manpower in the laboratory capable of processing the specimens. A major bottleneck here is in organizing the samples and preparing the pools. According to our Biosafety office we need to carry out the pooling and initial extractions under BSL2 conditions in a Biosafety cabinet, which slows down throughput. Finally, there is the cost of the reagents and supplies, which is not trivial, given the financial pressures that the university is facing. since this is surveillance and not diagnostics, insurance cannot be billed and all costs need to be borne by the institution.

Novel network approaches to efficiently manage testing capacity among institutions and collaborate with other university-based networks

Setting up a standard protocol file on one of the network servers such as protocols .io would be a good way to share tips and QA/QC information rapidly. This could be very useful when labs have different equipment and reagent sources. Being able to comment "I tried this on a Qiacube using the viral RNA mini kit and ran my positive controls in a BioRad real time thermocycler and it worked fine" would allow us to rapidly ensure that a given protocol worked on the equipment from different manufacturers.

The types and frequency of testing including the technologies and approaches that could be utilized

I see two rapid uses for this technology. The first will be to monitor prevalence of infectious individuals in the population as a whole. We would like to ensure that prevalence on campus in not significantly higher that in our surrounding community. A second use will be to be to rapidly test potentially exposed populations. For example, if an individual student tests positive, pool testing could be used to rapidly survey the infection status of anyone who was in a particular class with the positive student. If some of the pools came up positive, the individuals whose samples were positive could be directed to a clinical testing facility to be individually tested.

The use of alternative evidence-based approaches to monitoring the level of COVID19 in the community (e.g., wastewater surveillance)

We are also considering testing environmental samples collected from high traffic and frequently touched surfaces in the residence halls. This may allow us to localize residences where virus is circulating. We are planning to get students who are residents of the halls to volunteer to collect these samples for us. We considered using air sampling as well, but decided it would be too labor intensive and complex for the student volunteers to do on their own.

Risks and challenges that might impact the successful establishment and operations of a learning university-based surveillance network

A major challenge I foresee is getting the individuals randomly chosen to be tested in our surveillance strategy to actually show up and get tested. And a second major challenge will be deciding how to act upon the information we obtain. At what level of prevalence does the administration consider shutting down in class instruction? Do they consider shutting down the residence halls? Would it be safer to keep the students on campus where they might be more likely to become exposed and infected or send them home where they might infect their parents and grandparents, who are much more likely to become seriously ill?

Proposed mitigation strategies to address the potential risks and challenges

One can try to ensure compliance using a carrot or a stick. I feel that while a punishment based approach might be easier to envision (you must show up to be tested, or you will be sent home) is draconian and unlikely to be that effective. Perhaps a reward (congratulations, you have been chosen to be randomly tested for COVID19. Please proceed to X location to submit a sample. Once your sample is recorded in our system, you will be awarded five extra credit points to apply to the course of your choosing!) might be more effective.

Response 4

The feasibility of carrying out such university-based network activities at scale
Faculty within our university system are at an advanced stage of developing a method which involves high-throughput sequencing of bar-coded samples. A preprint describing the method and initial results has been posted on MedRxiv. This method can be scaled to enormous capacity at relatively low cost. An FDA EUA has been obtained to use this test under CLIA conditions. However, the test has not yet been developed in a CLIA setting. Instead, we currently are further developing and validating the test in our student health center under an IRB, with all samples tested in parallel by PCR in a CLIA lab. The test is accurate, sensitive, and robust. The next step is to expand its use for surveillance testing of students under an IRB, with positives confirmed in a CLIA lab by PCR.

The resources needed to jointly develop robust surveillance testing capabilities for students, faculty, and staff, et. al. (e.g., other institutions in communities)
The test can be scaled up dramatically and the equipment and personnel needs can be achieved. The main challenges are largely logistical, involving sample collection, supply chain, and analysis of results at large scale.

Novel network approaches to efficiently manage testing capacity among institutions and collaborate with other university-based networks
The method is under discussion with the University system and with the State Department of Public Health. Interest is high, but the first step is to implement broadly at our university to demonstrate that broad implementation can be achieved.

The types and frequency of testing including the technologies and approaches that could be utilized
Plans for testing students during the Fall quarter, which begins on October 1, are still under discussion.

The use of alternative evidence-based approaches to monitoring the level of COVID19 in the community (e.g., wastewater surveillance)
Not being actively pursued at this time.

Risks and challenges that might impact the successful establishment and operations of a learning university-based surveillance network
The challenges are largely logistical, as described above. Dissemination to other institutions would require careful validation and precautions are needed to prevent cross-contamination of samples, which can lead to false positives.

Response 5

The feasibility of carrying out such university-based network activities at scale
It is feasible for our institution to ramp up its testing capacity. While we are not a university-based laboratory, partnership with the local health department or regional institutions of higher learning is possible.

The resources needed to jointly develop robust surveillance testing capabilities for students, faculty, and staff, et. al. (e.g., other institutions in communities)
Space, equipment, interfacing and personnel are the limiting factors.

If these are overcome, with planned methodology under development we can scale up to 6,000-10,000. At this volume, reagent and consumable supplies should not become a chokepoint.

Space:
- At up to 6,000 specimens/day, additional BSL-2 space will need to be built out for specimen pre-processing.
- For more than 6,000 specimens, BSL-2 space will be needed for both processing and pre-processing.

Equipment:
- Liquid handling equipment must be added for every additional 2,000 specimens handled ($100-S150K). (These are in very short supply right now.)
- For every 1,500 specimens an additional PCR machine is needed ($75K).

Interfacing:
- PCR instrumentation must be directly interfaced with the Laboratory Information System in which the results will be reported.

Personnel:
- Technical personnel processing PCR (licensed CLSs):
  - Up to 3,000-4,000/day: Probably none needed
  - For every additional 1,000 per day: 2

- Specimen pre-processing personnel (MLA):
  - Per 1,000 specimens: 5-6

- Registration of patients into Epic (Hospital Information System) (clerical personnel):
  - Per 1,000 specimens: 13-15

Novel network approaches to efficiently manage testing capacity among institutions and collaborate with other university-based networks

Network collaboration: opportunities unclear
Information sharing: There is already robust information flow and sharing now via the Association of Pathology Chairs list-serv, many members of which are dealing with these same issues.

The types and frequency of testing including the technologies and approaches that could be utilized

Type/methodology: We are currently developing extractionless PCR using the A*Star Resolute system, which will greatly increase speed and volume throughput.
Frequency: This would be determined by the clinical/epidemiologic partner (e.g. local university, department of public health) utilizing our test results.

The use of alternative evidence-based approaches to monitoring the level of COVID19 in the community (e.g., wastewater surveillance)

As a CLIA laboratory in an urban free-standing hospital, some of these approaches are non-applicable, or would be determined by the clinical/epidemiologic partner:
- Surveillance tool example 1: Pooled specimens – adds great complexity to testing protocols, lowers analytic sensitivity, and not cost effective without very large volumes in a very low prevalence population
- Surveillance tool example 2: Wastewater surveillance – requires closed, static resident population like school dormitory. Could theoretically be used to monitor nursing homes/other SNFs, but similar cost effective issues to above
- Identification of high risk populations 3: testing strategy would be determined by clinical/epidemiologic partner, but informed by testing data

Risks and challenges that might impact the successful establishment and operations of a learning university-based surveillance network

Challenges:

- Pre- and post-analytic information sharing and transmission. (Patient registration/specimen ordering, results reporting)
- If testing is used for clinical purposes: CLIA, HIPAA, and public health reporting regulations apply.
- If testing is used for research: network-wide IRBs are required.

Proposed mitigation strategies to address the potential risks and challenges

Sharing of access to our Hospital Information System to pre-register patients into system would greatly reduce time and resources on the laboratory end.

Response 6

The feasibility of carrying out such university-based network activities at scale

An issue that has largely been ignored is that broad based testing of students or employees on public university campuses implicates the Fourth Amendment to the U.S. Constitution. The testing constitutes a search under the Fourth Amendment. If testing is mandatory, universities will have to show that the mandatory testing is reasonable under the Fourth Amendment. The more frequent the testing, the more invasive the test, the more likely it is that a court would find testing to be unreasonable, and therefore unconstitutional. Further, students will at some point stop coming to the university if they are constantly subjected to unreasonable searches. Voluntary testing would likely render the searches constitutional, but may not be sufficient from a surveillance testing standpoint. We need to be careful not to trample on the rights of people to be free from unreasonable searches, which would include mandatory disclosure of medical information and invasive medical tests.

Response 7

The feasibility of carrying out such university-based network activities at scale

Our college is actively working up a surveillance system using Saliva to LAMP detection. We will be using sample pooling (2-5samples/pool) which will scale to ~1500 samples/day. This would allow us to test our campus/faculty/staff community every 3-5days.

The resources needed to jointly develop robust surveillance testing capabilities for students, faculty, and staff, et. al. (e.g., other institutions in communities)

As a smaller liberal arts institution, we lack the liquid handler and robotics infrastructure. We will be using BSL2 trained PhD microbiologists for lab work, a full-time supervisor for the point of collection, and multiple undergraduate support lab-assistants/collection-interns. The college is providing financial support to deploy surveillance research and fund the work-study assistants/interns.

Novel network approaches to efficiently manage testing capacity among institutions and collaborate with other university-based networks

The college, a university, and a local hospital are in connection and informed of the work we are each attempting to accomplish. Both institutions are deploying pooled approaches to asymptomatic screening. A second, medically diagnostic, test is performed by the local hospital for any potential positive. All symptomatic testing is directed straight to the local hospital. The two universities are supplying spaces for quarantine and isolation.

The types and frequency of testing including the technologies and approaches that could be utilized

The college plans to test every 3-5 days, but no less than weekly. We will are planning to use saliva to LAMP assay. We will be using the SalivaDirect protocol for saliva collection. We will be performing a LAMP test analogous to approved COVID19 EUA for testing.

The use of alternative evidence-based approaches to monitoring the level of COVID19 in the community (e.g., wastewater surveillance)
We do not have any plans to monitor the community spread through other measures. We are using an anonymized survey tool, associated with our surveillance research, to identify high-risk populations based on behavioral attributes.

Risks and challenges that might impact the successful establishment and operations of a learning university-based surveillance network
Our college would be VERY excited to be part of a more extensive learning network. A huge risk is time management. Particularly for small schools, we have limited number of individuals attempting to fulfill multiple roles. Our college is looking at a considerable loss of revenue stream. Fiscally, everything is challenging as we attempt to scale up testing.

Proposed mitigation strategies to address the potential risks and challenges
We are considering hiring additional full-time personnel to assist in the surveillance research program.

Response 8

The feasibility of carrying out such university-based network activities at scale
The research team at our university has successfully demonstrated the feasibility of the sampler at healthcare facilities (see Alternative approach section below for details). Many other institutions also have programs in environmental engineering/science/health that can perform air sampling; several of them have inquired with us for how-to. The research team will also produce videos for others to learn and SOP for others to follow. Thus, sampling at scale is feasible.

The resources needed to jointly develop robust surveillance testing capabilities for students, faculty, and staff, et. al. (e.g., other institutions in communities)
There is a capital cost for purchasing the air samplers, but many other institutions also have programs in environmental engineering/science/health/safety that can perform such air sampling. Sample analysis can be carried out using RT-PCR, which is available in many institutions, or RT-LAMP that has been rapidly developed in several institutions.

Novel network approaches to efficiently manage testing capacity among institutions and collaborate with other university-based networks
Apps can be developed to wirelessly communicate the result from each sampler/analyzer, e.g. via small phone, then all data can be networked on campus. It can take advantage of the Internet of Things (IOT) movement.

The types and frequency of testing including the technologies and approaches that could be utilized
The proposed surveillance approach (see Alternative approach section below) allows continuous monitoring on an hourly basis. It can also be programmed to activate only during high traffic hours (e.g. during meal times at dining centers, or evening/late night hours at fraternity/sorority clubhouse).

The use of alternative evidence-based approaches to monitoring the level of COVID19 in the community (e.g., wastewater surveillance)
The conventional approach that relies on human specimens collected from sick patients reporting to clinics is outdated; furthermore, it can take days to weeks before the analysis results are returned, since reagent supplies are limited. At that moment, it has likely spread to other people on campus, and preventive public health measures are no longer useful. Importantly, that approach inherently misses individuals with no or mild symptoms, who are known to account for a significant fraction of infected individuals and who are "silent spreaders" that are fueling outbreaks. Without knowing they are infected

and can still shed viruses, these individuals are active in different corners on campus, thus missing hot spots in infection control.

An alternative approach that does not rely on this passive conventional approach is to surveil ambient air continuously in multiple spots for the presence of the virus of interest, similar to the use of air quality monitoring network used to monitor PM2.5 and ozone. This can be accomplished by combining a virus aerosol sampler that can efficiently capture airborne virus and an analyzer that can quickly detect its presence on the spot (within an hour). The research team has successfully demonstrated the feasibility of the sampler at healthcare facilities and the on-the-spot analyzer in vitro, respectively. An integrated system can be deployed strategically at places with high foot traffic, such as student union, dining centers during meal time, stadium during game time, gym, and fraternity/sorority clubhouse.

This approach is much more economically feasible than mandating all faculty/staff/students to conduct frequent testing (e.g. 3 times/week) which certain populations resist. It also avoids missed population on campuses that only ask for voluntary testing or for self-reporting. Once demonstrated, it can be implemented outside campus into communities (e.g. transportation hubs, shopping centers) since it's non-invasive (no need to retrieve samples from humans) and doesn't reveal individual identity (pooled samples).

Our approach surveils COVID-19 before an individual's symptom shows up (current standard) if there is a symptom. It is also ahead of wastewater surveillance because of additional time required to go through the digestive system and the time to accumulate detectable virus traces due to significant dilution.

In addition to what we have demonstrated that can be quickly deployed, investment should also be made to develop a wireless network wherein automated samplers can communicate with a data center their surveillance results. A vision is to ultimately develop low-cost personal samplers that would allow deployment of thousands of them on each campus that will enable citizen science.

Risks and challenges that might impact the successful establishment and operations of a learning university-based surveillance network

If the number of infected individuals is low, the probability of detecting it is also low. If not catching the virus for a while, people may then perceive it as a waste of money and want to terminate it before it catches the virus. Thus the key is to invest money to make the technology reliable and reproducible (should be added to the next question).

Also, there will be units on campus that are afraid of being labeled as "house of infection" and thus will not be willing to participate and to allow access.

Proposed mitigation strategies to address the potential risks and challenges

If a specific spot detects the presence of SARS-CoV-2, the university can quickly inform occupants of that place (e.g. fraternity/sorority, dorm) and investigate potential infected individuals (likely asymptomatic or mild symptoms). They may also be advised/requested to conduct individual testing, which will be on a much more feasible scale then all-campus testing. If it is from a public place (e.g. dining hall, student union), a reduced capacity with large distancing between diners may be advised in conjunction with additional mitigation measures (e.g. increasing air exchange rate of the HVAC system, add portable air filtration systems, open windows to increase natural ventilation).

Response 9

The feasibility of carrying out such university-based network activities at scale

We are performing pool testing using anterior nasal swabs followed by RNA extraction and RT-qPCR. We estimate that approx. 2,000 samples can be performed per day. We anticipate to double this in the next two weeks. Pools of 5-10 samples are being run. Samples are taken from the university community members based on a risk stratification, with undergraduates (living on or off campus but attending classes) being tested twice per week, master's students tested once or twice per week based on interactions with undergraduates, and Ph.D. students, postdoctoral scientists, staff researchers, and academic staff and faculty tested once every two weeks. Positive pools are then referred to antigen testing or other point-of-care or state/commercial laboratory testing. We are working with a local CLIA laboratory and the State to apply for state approval as an overflow laboratory, which would enable use to deconvolute the positive pools and identify positive individuals.

The resources needed to jointly develop robust surveillance testing capabilities for students, faculty, and staff, et. al. (e.g., other institutions in communities)

The testing infrastructure requires equipment, reagents, staff, IT infrastructure and scheduling infrastructure. Standard RNA extraction and RT-PCR needs to be replaced by non-RNA extraction capability and limits of detection (LOD) in pools of up to 10 samples compared with high specificity and sensitivity demonstrated. Higher-throughput antigen testing and ultimately test-strip home testing is needed to ensure that all university members are tested every 2 days. All of this has already and will continue to require substantial financial resources, including support for the tests and equipment, development of new testing strategies, and Health Center, Student Life and IT staff, which takes them away from other functions required for the university. Inter-university data transfer will complicate the testing of outside institutions, although testing volume should be available. It is critical to ensure that other institutions where students and other community members interact with our students, staff and faculty be able to undergo high frequency and rapid testing to ensure prevention of transmission to our university community members. Finally, there is a critical need for quarantine and isolation living facilities.

Novel network approaches to efficiently manage testing capacity among institutions and collaborate with other university-based networks

Many local universities, community colleges, and private organizations that interact among each other do not have the capacity for internal testing. Limited availability of community testing creates challenges to prevent viral spread and decrease (or maintain low) prevalence. Thus, there is a need to provide critical capacity at relevant universities to provide such a service to the community. Challenges include overall capacity to ensure no more than 24 hour turnaround, Sampling using nasal swabs is inefficient and can lead to variable sample quality. For entities outside of the university, this may result in significant delays in results. Furthermore, the ability to share results remains complex due to health privacy concerns and the often incompatible network systems that exist across a range of institutions.

The types and frequency of testing including the technologies and approaches that could be utilized

There is a need for high risk groups at universities (such as undergraduates) to be tested twice per week. Ideally, this can be done WITHOUT Health Center sampling, but critical training is required. The standard nasal swabs leading to RNA extraction and then RT-PCR is the gold standard approach. Replacing nasal swabs with saliva reduces the upstream complexity and enables faster sampling. Then, eliminating RNA extraction and lysis buffer, and doing viral inactivation and RNA isolation will increase throughput of samples. Finally, transitioning to point-of-use testing is critical, i.e., simple test strips, much like those used in pregnancy tests, would yield truly daily testing with high penetration in society.

The use of alternative evidence-based approaches to monitoring the level of COVID19 in the community (e.g., wastewater surveillance)

AI/machine learning and data analytics is being used to identify high transmission risk individuals, including onboarding at universities based on zip codes of the student. These analytics can then be used to model the likely prevalence at the university as a function of time and within specific segments of the university community. These models must be used in conjunction with testing protocols that provide information on positive/negative samples within 24 hours. In addition, as the prevalence of COVID-19 changes within the local community, this needs to be incorporated into a functional model.

Risks and challenges that might impact the successful establishment and operations of a learning university-based surveillance network

The models are only as good as the data, and in addition to university testing data, the ability to get local data is critical. This is likely negatively impacted by lack of testing in the non-university community. This further directly impacts students living off campus. However, secondarily, this impacts students living on campus due to mixing.

Proposed mitigation strategies to address the potential risks and challenges
Education and adherence of the entire university community is critical. However, that only goes so far. Diligence in testing (up to twice per week for highest risk individuals) with 1-day data turnaround is critical to ensure reduced overall transmission. Moreover, there is a need to form broader community networks. This includes local community testing through the university capability, as well as to ensure colleges and universities in the region to have similar testing capability. If the school is unable to do this themselves, then sufficient resources must be made available to ensure that universities in the region are able to absorb that additional capacity.

Response 10

The feasibility of carrying out such university-based network activities at scale
This may be possible here for surveillance of pooled samples depending on the technology. However, I do not believe there is currently an FDA authorized test for pooled samples. False positives/negatives might be an issue with testing pooled samples. For point-of-care (POC) testing, there would need to be a system developed to distribute tests (who gets tested? who pays for the tests?) and receive results. For individual samples, a CLIA certified lab is required. I believe our student health centers are CLIA certified. However, they would need to state whether or not their facilities could do the testing on-site or could collect samples for off-site testing.

The resources needed to jointly develop robust surveillance testing capabilities for students, faculty, and staff, et. al. (e.g., other institutions in communities)
Infrastructure: A secure, HIPAA compliant online system would need to be established for scheduling testing, keeping track of testing results and reporting results to individuals, DOH, and CDC (and NIH?). A dedicated area would be needed to house equipment and process samples. This lab would need to be CLIA certified. For point-of-care (POC) testing, there would need to be a system developed to distribute tests and receive results. A contract-tracing program would need to be established.

Equipment: Equipment would need to be purchased. If POC tests were used, equipment would still need to be purchased to validate results until reliable tests are developed.

Financial resources: PPE would have to be purchased for all involved in testing. Equipment and consumables would have to be purchased. Salaries for personnel involved.

Personnel resources: Personnel would be needed to conduct the testing and for contact tracing. Faculty could be involved in testing but would need course release time. Training and certification may be necessary.

Novel network approaches to efficiently manage testing capacity among institutions and collaborate with other university-based networks
Regional networks might work best. Individuals in each regional network could coordinate with other regions. An HBCU network could be established since COVID-19 is disproportionately affecting people of color. Networks would interact through videoconferencing and secure online systems for sharing information.

The types and frequency of testing including the technologies and approaches that could be utilized

POC testing for asymptomatic individuals should be done more frequently at the beginning of the semester and after breaks (Fall break, Spring break) due to student travel. DNA testing should be done for all symptomatic individuals and immediate contacts (i.e., roommates). Flu testing might also need to be done.

The use of alternative evidence-based approaches to monitoring the level of COVID19 in the community (e.g., wastewater surveillance)

Our department of natural resources entity collects water samples for monitoring the safety of beaches. Perhaps these samples could be tested for the virus.

Automated temperature screening in high-traffic areas (airports, ports, safaris, taxis, grocery stores, churches, tourist attractions, restrooms, restaurants, cafeterias, mail facilities). Results could be wirelessly transmitted to a central source for monitoring. Areas with spikes in temperatures could be tested for the virus (surface swabs, air sampling). Have used disposable masks collection sites. Persons could submit their disposable mask and be given a new one. Masks could be swabbed and tested. Surface testing of communal areas (computer labs, restrooms, gas pumps, grocery carts). Antibody testing could identify those previously exposed. This may help categorize individuals into low- and high-risk groups (positive versus negative, respectively) once we know more about if antibodies are protective and for how long.

Risks and challenges that might impact the successful establishment and operations of a learning university-based surveillance network

Lack of definitive studies on surface or air detection of the virus including how long the virus lasts and detection limits.

SOPs for testing of environmental samples.

Infrastructure for centralized remote monitoring.

Costs (personnel, facilities, equipment) associated with establishing infrastructure and testing.

Time to test results.

Keeping the public informed and mitigating mistrust and panic.

Social stigmatization of locations/people where positive test results are found.

Proposed mitigation strategies to address the potential risks and challenges

Low-cost POC testing that provides rapid, reliable results.

National or regional standardized testing protocols for direct comparison of results with different communities/regions.

Funding and training for personnel, equipment and supplies.

Education campaigns for the general population but tailored to unique characteristics of communities.

Community members that act as points-of-contact for information (that field questions, hold town halls, etc) from the public.

Response 11

The feasibility of carrying out such university-based network activities at scale

The University convened an interdisciplinary group with expertise in public health, epidemiology, and information resources, to assess the feasibility of the University to carry out a SARS-CoV-2 proactive testing program. This group determined that three factors made a testing program feasible:

1. The University has a Clinical Laboratory Improvement Amendments (CLIA) certified lab that is able to process 500 tests a day and results turnaround time within 24 to 48 hours.

2. The University had taken steps to reduce the on-campus population (students, faculty, and staff) by 80%. The University expects 7,200 students will come to campus at least once per week to take a face-to-face session.

3. The University is primarily an urban university with only a small portion of the student body in residence.

The resources needed to jointly develop robust surveillance testing capabilities for students, faculty, and staff, et. al. (e.g., other institutions in communities)

- People: 5 scientific staff for the lab and data analysis; 12 persons to administer the tests, collect personal data, and move the test swabs to the lab.
- Laboratory: 500 sq ft of dedicated laboratory working space.
- Collection sites: 4 outdoor testing sites on campus.
- Equipment and supplies: personal protective equipment, KingFisher flex (RNA extraction) and ABI 7500 Fst Dx system (RT0PCR), viral transport media vials, oropharyngeal swabs, and supplies (e.g. tables, ice chests, scanners, laptops)
- Total Funding (estimated): $1.6 million
- Data and analysis resources in-house.
- Redundant communication systems to reach the campus population.
- Close coordination with Community Health Authorities.

Novel network approaches to efficiently manage testing capacity among institutions and collaborate with other university-based networks

Approaches and testing strategies were informed by regular meetings with Community COVID-19 Health Task Forces, including the City and County Health Departments, Council of Research of the Association of Public & Land-Grant Universities, and special topic webinars from NIH and others.

To optimize the impact of testing, the program targets students, faculty, and staff at higher-risk for on-campus spreading, including:

- Students enrolled in face-to-face and hybrid courses
- Students enrolled that have a higher risk because of the nature of their educational experience (i.e., 3rd year Nursing, College of Health Science, and Pharmacy students that require clinical experience, music and arts students)
- Faculty and staff present on campus
- Students residing in dormitories
- Athletes

The types and frequency of testing including the technologies and approaches that could be utilized

The screening includes one or more of the following tests: collection of an upper respiratory nasopharyngeal swab or collection of an oropharyngeal swab.

Athletes are tested before the use of athletic facilities and upon starting their respective seasons. Students residing in dormitories are invited to be tested every 14 days. Asymptomatic students, faculty, and staff are invited to test through a statistical sampling process, weighted to time spent on campus. In addition, students may “walk-in” to one of the four (4) outdoor testing stations, with locations advertised on the university COVID-19 response website.

The equipment utilized to test the samples are the KingFisher flex (RNA extraction) and ABI 7500 Fst Dx (RT0PCR) system. For processing, the ThermoFisher Emergency Use Authorization protocol, KingFisher Flex are magnetic beads to capture viral RNA and using TaqPath COVID-19 high-throughput kit. Capacity is estimated at 500 tests per day and results turnaround time within 24 to 48 hours.

The use of alternative evidence-based approaches to monitoring the level of COVID19 in the community (e.g., wastewater surveillance)

Each day anyone will be visiting/attending campus, they are required to complete a web-based screening application asking for self-analysis of symptoms as well as potential exposure to COVID-19. People reporting no exposure or symptoms are cleared to come to campus. For University employees, using this tool will automatically send an email informing them that the employee completed the web application. If COVID-19 exposure or symptoms are reported thru the web application, the system will automatically report to the Environmental Health and Safety department, and that department will reach out with further instructions.

When positive tests or potential exposure, the University will identify which classes or offices the infected person has been in for sanitation. Asymptomatic individuals who may have been in contact with the individual testing positive are invited to be tested. Symptomatic individuals are encouraged to visit one of the City or County public testing facilities.

Risks and challenges that might impact the successful establishment and operations of a learning university-based surveillance network

The University's proactive testing program is strictly voluntary, with a completed one-time consent form required for all participants. Proper sampling of on-campus personnel requires that there is a high level of participation. Currently, we have consent forms from 50% of persons that are anticipated to be on-campus, and we are working to raise that number to 90% as classes start for the fall semester.

For optimal statistical sampling, as many of the consented, identified, and invited participants are required to actually participate in regular, multiple sampling.

The challenge is that people may choose to not take the tests.

Proposed mitigation strategies to address the potential risks and challenges

Proposed mitigation strategies to address the potential risks and challenges include:

- Making the testing process as easy and convenient as possible.
- Continue communications programs to encourage people on-campus to take part in the testing program.

Response 12

The feasibility of carrying out such university-based network activities at scale

This is quite achievable if the correct infrastructure is put in place and the universities partner with either companies or institutions who are well versed in scale. Carrying out 10s or 100s of tests per day is quite different than running 10,000s of tests per day. Issues arise in various parts of the supply chain and the data processing. Both of these are solved problems, yet the universities need to ensure they are getting help from organizations that know how to scale.

The resources needed to jointly develop robust surveillance testing capabilities for students, faculty, and staff, et. al. (e.g., other institutions in communities)

In an ideal situation, the laboratories would be models of each other. They would have the same machines, use the same reagents, and run the same accessioning and LIMS software. By standardizing on a platform, a few things can happen. First, training staff becomes easy and repeatable. Various training methods can be used and leveraged across all campuses. Second, all of the testing machines, or their associated systems, can be connected to a single cloud, allowing for real time results read out. As long as only testing data is captured, and not PHI, there are minimal HIPAA and FERPA issues. If this is a true Surveillance Testing workflow, PHI may not have to be collected at all? Not all universities have to have testing on site. There are hub and spoke models that can be set up, leveraging larger institutions that can accept samples from smaller ones. In addition, overflow testing capacity can be given to the community.

If similar instruments and reagents can not be used, this is OK, as long as the data is collected in a single place and transformed appropriately.

Novel network approaches to efficiently manage testing capacity among institutions and collaborate with other university-based networks

A standardized approach to testing should be established, with the machines and protocols aligned, and data being sent to a central cloud. If this is the case, data on testing locations, throughput, and excess capacity can be inferred through the number of machines, amount of reagent in stock, and number of tests currently being run. This centralized cloud of testing and excess capacity can inform various institutions where to send their samples in order to optimize turn around time. Using technologies such as machine learning and blockchain, we can also optimize and secure these networks. In addition, we can pick out labs which are running under capacity, or under performing, and target them for optimization. As long as the data is being sent to a central location, we can optimize supply chain and lab operations.

The types and frequency of testing including the technologies and approaches that could be utilized

This approach is quite agnostic to the type of testing. That said, it should be able to scale and connect back to a centralized data location.

The use of alternative evidence-based approaches to monitoring the level of COVID19 in the community (e.g., wastewater surveillance)

Various mobile apps could be developed to monitor behaviors and locations of individuals. Using this information, one could determine how to assess risk of infection. The same apps could use quick medical surveys to warn individuals if they are high risk. University health records can also be combined with machine learning to identify high-risk populations.

Risks and challenges that might impact the successful establishment and operations of a learning university-based surveillance network

One major challenge will be aligning on a common standard, preferably one that is already widely accepted in industry, and ensuring compliance with this standard. Data sharing using individually developed standards and ontologies makes learning quite hard. A second challenge, especially around identifying high risk individuals, would be access to PHI.

Proposed mitigation strategies to address the potential risks and challenges

For the issues of standardization and scale, set up an industry/academic working group to decide on a standard and ensure that this standard is followed throughout the university network. For the issues around patient data and data security, this should also be a working group, but one with a data centric focus.

Response 13

The feasibility of carrying out such university-based network activities at scale

Over the past 4 months our University has stood up an RT PCR lab, a system for collecting samples up to 7,000 samples a day, and a robust system for contact tracing and also isolation and quarantine housing for those who test positive. With these pieces in place, the University has now implemented a surveillance system for its entire on-campus population of approximately 30,000 faculty, staff, and students. The system is able to process up to 42,000 tests per week, with the potential to process an additional 15,000 tests with additional resources. Ensuring a short turn-around time between testing and availability of results allows for a rapid public health response. Individuals with positive test results are immediately isolated and contact traced and close contacts are put into quarantine, allowing us to isolate asymptomatic individuals who have been in close contact with COVID-19 positive members of the University community.

Our testing is done in coordination with multiple COVID-19 prevention strategies, such as reconfiguration of work and living spaces, required masking, improved air flow and filtration in buildings, and advertising campaigns aimed at promoting social distancing and safe choices. The advertising campaigns include a student-led and student-focused effort, as well as a University-sponsored campaign for the entire campus.

Our robust surveillance and testing protocols are most likely to be scalable for institutions who are able to develop rapid in-house testing and contact tracing capabilities with supply chains that do not rely on commercial labs.

Scalability is also helped by regional coordination with other institutions of higher education in the State. For example, we are part of a Collaborative PCR Testing Group. The institutions discuss protocols and have existing research collaborations, allowing us to benefit from the region's collective knowledge.

The resources needed to jointly develop robust surveillance testing capabilities for students, faculty, and staff, et. al. (e.g., other institutions in communities)

Significant data infrastructure resources would allow us to better coordinate with regional universities and hospitals. We have effectively shared information about our protocols and plans with these organizations, but to make the leap to collective prevention and surveillance we would need financial support for a robust data sharing network.

Internally, the University has devoted significant resources and management around testing, interventions, and surveillance. Our Medical Advisory Group meets regularly to review individual cases and recommend policies and procedures related to COVID. Our Community Health Oversight Group meets daily to track community health metrics, such as disease incidence & prevalence, the capacity & effectiveness of our campus COVID operations, compliance & disciplinary actions and to advise leadership of changes in health risk to the community and to propose actions. These groups are comprised of in-house experts from student health services, occupational health, human resources, research, public health (medical epidemiology and biostatistics), and various campus operations, such as housing. These individuals maintain full-time responsibilities in their respective units, in addition to the new responsibilities for COVID-19 surveillance.

We have thus far invested $3 million in equipment. We have hired 35 people to run the COVID-19 testing lab and more than 100 people to manage four collection sites which are open 14 hours a day, seven days a week. Additional resources have also been required for our medical team, contact tracing, and isolation and quarantine housing.

Novel network approaches to efficiently manage testing capacity among institutions and collaborate with other university-based networks

Given the large amount of data each institution in the region is collecting, joint activities would give us the opportunity to learn a tremendous amount about the time-course of the disease and collaboration across several institutions could provide a tremendous amount of data. As a university embedded in an urban environment that is shared with other institutions of higher education, we have the opportunity to conduct joint activities with a large data set. In addition, we have research collaboration structures in place among those institutions.

Resources for a formal shared data infrastructure would allow us to determine what intervention strategies are most effective to prevent the spread of COVID-19, as well as patterns in infection transmission, cross-campus outbreak detection, disease severity, and testing compliance.

Additional resources would also allow us to carry out additional testing which would shed light on the time course and nature of the disease. For example, repeated testing of students while in isolation would allow us to gain valuable insight into infection dynamics including the potential utility and safety of testing as a strategy to shorten the duration of quarantine. The addition of antibody testing at specific intervals post-disease, would provide important information about the body's immune response to the infection.

The types and frequency of testing including the technologies and approaches that could be utilized

The University currently carries out RT-PCR testing at the following frequencies:

- undergraduate students every three days;
- graduate students either every three days or one time per week, depending upon duties; and
- faculty and staff one time per week.

The data provide a tremendous opportunity to assess the efficacy of our surveillance strategy.

The use of alternative evidence-based approaches to monitoring the level of COVID19 in the community (e.g., wastewater surveillance)

We have developed open source software to create a detailed, institution-specific modeling and simulation system, incorporating key contact structures (e.g., classes, residence halls, etc.), exogenous drivers, and current understanding of COVID-19 dynamics [modified Susceptible - Exposed - Infectious – Recovered (SEIR)].

The data we are collecting provides an opportunity to extend the existing methodology for estimation of R_t, to allow for (i) separation of internal (e.g., within the university) versus external contributions, using uncertain labels gathered through contact tracing; and (ii) adaptive prediction or correction techniques from control theory (i.e., variations of Kalman filtering).

Our plan is to examine a set of comprehensive data around testing, self-attestation, contact tracing, and other measures, integrated with internal surveillance, external dashboard, and modeling workflow. We can use complex compartmental models to guide strategies for active surveillance on campus. Additional testing both with RT PCR and antibody testing could provide valuable data about the time course of the disease. We will also be able to assess viral load information over time – something commercial labs are unable to do. This is because we will have viral load data for all our samples and many of the individuals will have repeated tests over the course of a semester.

A central challenge in understanding the epidemiology of CV19 is determining what proportion of infections are symptomatic, pre-symptomatic vs. asymptomatic. The key barrier to determining these proportions has been the absence of longitudinal data sets with repeated testing of individuals over time. The university's COVID-19 response strategy creates just such a data set. To note, we have a fixed denominator of students/faculty/staff over the semester. All will be tested at least weekly and in the case of undergrads twice weekly. Symptom data are being harvested in parallel. And there is capacity for contact tracing and follow up of exposures. This could allow us not only to provide a cleaner estimate of the pre-symptomatic vs. asymptomatic fractions, but also a systematic means to identify secondary spread from those primary cases. This is a far superior way of measuring infectiousness of an asymptomatic vs. pre-symptomatic individuals than inferring levels of contagion risk based on cycle threshold values from PCR. It would also provide a way of validating infectiousness from CT values.

Finally, there is the opportunity to reconcile our data with both State and City data to look at how a large asymptomatic population behaves, affects, or interacts with the surrounding area.

Response 14

The feasibility of carrying out such university-based network activities at scale

This is very feasible and in some cases appears to have worked better than testing by commercial companies. The approach of using a research laboratory to screen pooled or individual samples at least partially circumvented the roadblock of available test kits that were reserved for critical case diagnosis in the beginning of the pandemic. We demonstrated that our university system laboratories represent a resource pool for special population surveillance testing that is currently underutilized and can be deployed to scale up and operationalize surveillance efforts.

The resources needed to jointly develop robust surveillance testing capabilities for students, faculty, and staff, et. al. (e.g., other institutions in communities)

Resources for database/sample management, ramp up and transition of laboratory infrastructure have been less of a bottleneck than supply chain reagents and supplies, which have presented challenges.

Novel network approaches to efficiently manage testing capacity among institutions and collaborate with other university-based networks

Our state is doing this well. The University has been in communication with labs at other research and medical institutions across the state and generally know what they are doing, although it would be useful to incentivize coordination so that the various institutions are not competing or repeating efforts, i.e., infrastructure grants that are regional and identify leads for different diagnostic platforms that make sense. The University, for example, is leading in serology and ddPCR tests while another university within the system has the largest CLIA infrastructure and access to patient samples for validation, and another university has technology for point of care diagnostics. The University system's School of Public Health could be a hub for modeling efforts within the state, with contributions by each campus.

The types and frequency of testing including the technologies and approaches that could be utilized

1. Serologic testing monthly and/or following outbreaks to assess asymptomatic shedders
2. Point of care PCR/viral detection that is cost effective and can be used daily by exposed or at risk workers and to identify shedders
3. ddPCR for environmental surveillance, frequency of which depends upon samples, units tested, and utility for prediction

The use of alternative evidence-based approaches to monitoring the level of COVID19 in the community (e.g., wastewater surveillance)

It is still to be determined as to the effectiveness of these approaches within university settings, but they may be very helpful for monitoring stand-alone units like skilled nursing facilities. Pooled samples with rapid testing for virus, or cheap individual testing platforms may be better for minimizing outbreaks. An outstanding group of scientists at the University have been leveraging the capacity and energy of research laboratories to provide surveillance screening to skilled nursing facilities (SNFs) quickly and inexpensively since early March. To protect the health of residents and workers in long-term care facilities in the state, we initiated a longitudinal surveillance program of workers in 32 SNFs. Nasopharyngeal swabs from consented asymptomatic workers were collected weekly by trained members of the SNFs and transported to the University's BSL-3 laboratories where they were aliquoted for biobanking and tested for SARSCoV- 2 RNA using qRT-PCR. Testing was performed in the laboratory of the director of animal and infectious disease and testing programs were initiated and managed by the University's director of its aging center, a catalyst institute for gross-disciplinary aging. Positive samples are confirmed by the University's CLIA-certified SARS CoV-2 testing center. The early work has been reported in MedRxIV preprint and the larger scale work is continuing. This effort has revealed that a high percentage of asymptomatic workers in SNFs that are positive for the COVID-19 virus as confirmed by PCR tests. Viral isolation and plaque assay results have further confirmed these tests correlate to the presence of live virus capable of infecting others. Further, our data suggest that longitudinal weekly testing and early identification of asymptomatic positive workers significantly decreased the number of incident cases among workers.

The success of early work, which has been entirely funded by the University's resources, led us to obtain funding to significantly scale up our efforts to include SNFs across the State to provide weekly surveillance testing and monitoring. Samples are continuing to be collected and archived at the University and we have now accumulated what we believe is the largest data and sample archive spanning March 2020 to current day of serial samples from this unique workplace environment. Further we have also collected serial serum from a large percentage of participants and have been analyzing binding and neutralizing antibodies in these cohorts. This effort underscores the potential for research labs at Universities to quickly and efficiently deploy both surveillance capacity in tandem with research activities to inform future health guidance.

In addition, the University is also using droplet digital PCR to test wastewater from residence halls in order to monitor SARS-CoV2 levels. Automated samplers have been placed in 17 locations and samples are tested twice a week. The goal is early detection of increases in the level of community infection. Potential outbreaks will be followed up via clinical pooled testing.

Risks and challenges that might impact the successful establishment and operations of a learning university-based surveillance network

There is a need to have a lead coordinating institute that is constantly communicating with partners to keep things organized. Also, attention needs to be given to the effort it will take to accurately manage samples, test results, and data. This management will not be trivial and Institutional Review Boards may have conflicting opinions.

Response 15

The feasibility of carrying out such university-based network activities at scale

With access to our consortium of 127 major Ph.D.-granting institutions, a national network of specialized teams of experts and unique laboratory capabilities, the Association is in a unique position to respond to this RFI. Among the full complement of the Association's member institutions are universities that comprise the Historically Black Colleges and Universities/Minority Educational Institutions (HBCU/MEI) Council. The University Partnerships Office has been actively working with its university partners to understand their capabilities, infrastructure and research on the topic of SARS-CoV-2, and to create opportunities for collaborations and information exchange. Of note, the Association recently convened an expert panel on the topic of Wastewater Surveillance. With our industry partner, we held a well-attended (150 university leaders and research faculty) webinar titled Surveillance for SARS-CoV-2 Using Wastewater—A Leading Edge Indicator with experts from several universities who shared their research, data, protocols and lessons learned specifically focused on Wastewater Surveillance. The goal of the webinar was to better define and develop the end-to-end process for implementation of sewage surveillance for relevant and priority use cases. Interactive discussions were focused on four critical areas where further work is needed: (1) define the preferred wastewater collection methods, (2) define the pre-testing sample processing methods, (3) develop methodologies for data interpretation in support of decision making, and (4) develop data sharing standards across multiple efforts.

The Association can easily scale up input from its member universities in a variety of mechanisms. Our relationship with our consortium members is well established and trusted. A University Councilor is appointed by the President/Chancellor at each university and is typically the Vice President for Research. The Association knows our university members and maintains a knowledge base of their capabilities, using that database to target universities for specific research opportunities. The Association also acts as convener and integrator, bringing together interdisciplinary teams to solve our nation's most complex problems. The Association frequently convenes "research clusters" of universities based on specific areas of interdisciplinary interest and expertise. Ensuring diversity of experience, geography, race, ethnicity and culture is paramount in the Association's university research engagement model and has proven to be a critical success factor in the creation of successful and sustainable research clusters.

The resources needed to jointly develop robust surveillance testing capabilities for students, faculty, and staff, et. al. (e.g., other institutions in communities)

The Association offers an existing and well-established university-based network and the tools, approaches and existing relationships that serve as key drivers for successful deployment. Based on the Association's in-depth knowledge of its member universities' capabilities (including resources such as testing infrastructure) and applied expertise, we have a well-established process for engaging experts within the academic community. The Association has a rich history in matching the right people with the right knowledge and skills to enable the effective collaboration that leads to rapid learning. We facilitate and convene our university members to build teaching and learning communities so that protocols, approaches and challenges are shared and disseminated effectively to support targeted outcomes.

Novel network approaches to efficiently manage testing capacity among institutions and collaborate with other university-based networks

As mentioned above, the Association recently held a well-attended webinar titled Surveillance for SARS-CoV-2 Using Wastewater—A Leading Edge Indicator with experts from several universities who shared their novel approaches, research, data, protocols and lessons learned on Wastewater Surveillance.

Similar to one university's COVID-19 national and global case map, a member university of the Association has developed a dashboard on wastewater monitoring. A city in collaboration with a local university has pioneered wastewater-informed public dashboards that have been used for over two years for public health decision-making and for tracking the impact of any given intervention implemented: e.g., Opioid epidemic response and COVID-19 epidemic response.

The Association is working with a private corporation to pilot the an academic surveillance tool with several of our member universities. The tool is a standards-based, open source tool that automates the process of public health monitoring and reporting of individuals exposed to or infected with COVID-19 or any infectious disease. The system allows contact tracing through remote monitoring of individuals who have been exposed, are ill, or at risk of developing a coronavirus infection (or any infectious disease). Using multiple access methods (web, text, email, phone), individuals enter their symptoms daily and results are immediately available to participating public health departments.

The types and frequency of testing including the technologies and approaches that could be utilized

The webinar referenced above includes valuable information on the types and frequency of testing, including technologies and approaches that could be utilized across a broader university network.

The various testing technologies and approaches conducted at 10 member universities range from:

1. How the virus responds to ultraviolet and solar light
2. Investigating the process for "enveloped" viruses like coronaviruses and influenza
3. Analyzing sewer sets looking for genetic material and validating the reliability of the data
4. Investigating contamination risk associated with sewage spills and flooding events, e.g., hurricanes
5. Evaluating health disparities and vulnerable populations and how geographic differences come into play

The use of alternative evidence-based approaches to monitoring the level of COVID19 in the community (e.g., wastewater surveillance)

Through the webinar referenced above, valuable information was shared across all parties on technical, legal/privacy, and data coordination techniques and lessons learned.

Risks and challenges that might impact the successful establishment and operations of a learning university-based surveillance network

The webinar referenced above includes information on risks, challenges and proposed mitigation strategies related to Wastewater Surveillance.

Proposed mitigation strategies to address the potential risks and challenges

The webinar referenced above includes information on risks, challenges and proposed mitigation strategies related to Wastewater Surveillance.

Response 16

The feasibility of carrying out such university-based network activities at scale

Leveraging the competencies of the university public health programs increases opportunities to more directly impact healthcare by integrating the three distinct areas of prevention as provided in the Center for Disease Control and Preventions' framework Public Health 3.0. The CDC developed this framework in response to a transforming system of healthcare that typically focused on episodic, non-integrated care towards one that integrates healthcare and public health to effect substantial change in lasting health for individuals, communities, and populations. The integration is conceptualized using three "buckets" of prevention–traditional clinical prevention interventions, interventions, and extend care outside the care setting, and total population or community-wide interventions. (Healthy People 2020, U.S. Department of Health and Human Services). The university's public health programs work in concert with this model as graduates are trained to develop non-clinical, community approaches using evidence-based research to help build sustainable, healthy communities outside of the clinical setting and that affect total populations.

The resources needed to jointly develop robust surveillance testing capabilities for students, faculty, and staff, et. al. (e.g., other institutions in communities)

Evidence of the university's public health programs that have directly impacted the public health sector can be seen in recent events in response to the global pandemic COVID-19. The university's public health faculty have been directly involved in state and local efforts to help combat the rapidly growing pandemic in the U.S. On April 25, 2020, the university opened its stadium as a walk-up COVID-19 testing site to assist the local community in the fight against the pandemic. The university, in partnership with a local Community Health Center organized the site, with logistical and other support from the state Department of Health, the state Division of Emergency Management and the National Guard. The local County Health Department is also a partner.

Since its opening, more than 36,000 people have been tested for COVID-19. Our community partners have noted its success and have been very pleased with the outcomes, particularly the services provided to the area, where the university is physically located. The site was initially scheduled to operate for only a few weeks, however, it remains open due to the demand to serve the county and its constituents. The site will remain open for the foreseeable future in an effort to combat the COVID-19 pandemic with essential services provided by the university Institute of Public Health, faculty, staff, and community partners.

Should the community testing site on campus be demobilized; testing for faculty, staff and students will be managed through the campus health clinic. The university continues to explore options for expanding laboratory capacity, including the possibility of opening a diagnostic laboratory on campus to provide a quick turnaround for test results.

Novel network approaches to efficiently manage testing capacity among institutions and collaborate with other university-based networks

State Directors of campus student health centers communicate frequently. We have shared varied approaches to address COVID-19, specifically in regard to testing for students. We readily share experiences on managing testing for students, faculty and staff, reporting, coping with difficulties in timeliness of reporting from diagnostic labs, and how we can provide support to students, faculty, and staff overall.

The types and frequency of testing including the technologies and approaches that could be utilized

The university COVID-19 Community Testing Site is open at 9 a.m. Monday through Saturday until we reach the daily quota for tests (500 PCR tests/200 antibody tests) or unless the site is closed due to inclement weather. Free testing is available without appointments and no physician referral is required. In addition to paid staff, we recruit volunteers to distribute educational materials and face coverings to individuals tested and provide verbal instructions regarding their next steps. This function occurs at the site's exit table, which is outside the testing area. All volunteers are trained and provided appropriate personal protective equipment.

The use of alternative evidence-based approaches to monitoring the level of COVID19 in the community (e.g., wastewater surveillance)

We are currently implementing scheduled testing of specific populations, including our resident advisors, student athletes, marching band, and members of fraternities and sororities. The university has also implemented a daily-symptom check that is on the university app. We are encouraging faculty, staff and students to utilize the app to check for and document symptoms at the start of each day. This information will help individuals determine if they should report to work or class. It will also aid campus surveillance activities.

Risks and challenges that might impact the successful establishment and operations of a learning university-based surveillance network

The university has established guidelines and protocols in response to COVID-19, which all members of the university community, vendors and visitors are expected to follow. The Centers for Disease Control and Prevention (CDC), state, and local social distancing guidelines that are in place at the time of Fall opening have been implemented in all campus facilities and include procedures for enforcement for all constituents. The university has surveyed all facilities to determine maximum capacity based on social/physical distancing requirements of at least 6 feet. The university continues to coordinate with student health services (SHS) and the Office of Human Resources to develop University-wide social/physical distancing guidelines, with tailored plans for higher risk areas. Plans include the following strategies (non-exhaustive):

- Required training on COIVD-19 disease for students, faculty and staff;
- Removing/rearranging seating to reduce capacity in used office/lounge/reception/ conference rooms to promote social/physical distancing;
- Adding panels to separate adjacent workspaces and within identified classrooms;
- Installing sneeze guards where needed;
- Removing or limiting shared workspaces;
- Designating small rooms as single occupancy only;
- Using floor decals and signage to direct traffic and maintain 6 feet distance
- Encouraging use of videoconferencing;
- Implementing elevator ridership limits: no more than 2 individuals in regular elevators;
- Prohibiting large gatherings of more than 10 people; meetings of 2-10 persons must be held in a location that will allow for a minimum of 6 feet distance between participants;
- Campus-based testing for COVID-19;
- Available campus units for isolation and quarantine for students; and
- Partnership with local health department for contact tracing on known positives.

In addition to the phased return of employees, on-campus housing capacity has been adjusted to adhere to social distancing guidelines. University shuttles, buses, and vans will reduce ridership capacity and use decals to demarcate distancing expectations, where possible. Passengers will be required to wear face coverings in transit.

Response 17

The feasibility of carrying out such university-based network activities at scale

It would be highly feasible to establish a testing facility for the university system if specialized federal funding were made available to do so.

We have identified a diagnostic research laboratory as a possible site or we could utilize existing or new molecular biology equipment in a BSL-2 research laboratory space on one campus as needed.

We applied for and received a CLIA Certificate of Waiver for the purpose of the proposal, but we would need full-time staff to establish an operational testing facility.

However, pooled or individual surveillance testing using an FDA- or EUA-approved test can be performed with a CLIA Waiver, if results are not being reported to an individual.

This level of surveillance would identify potentially positive cases, which would then be referred to a health care center or state facility for confirmatory tests.

Establishment of a laboratory would require ~1-2 months for hiring, laboratory set up, and test procedure validation.

If a CLIA-certified laboratory was required, the time frame would be at least 3 months to establish a laboratory.

The resources needed to jointly develop robust surveillance testing capabilities for students, faculty, and staff, et. al. (e.g., other institutions in communities)

Projected costs:
Staff:
a. Skilled technician: ~$60,000-80,000/year
b. Possibly 3 additional staff for laboratory and data management ~$50,000-65,000/year/position

Equipment:
Part 1 of test:
a. Kingfisher automated RNA extraction (magnetic bead technology)
  i. Lead Time: 3-months for ordering
  ii. Quote can be requested; could place a PO and cancel before shipment if needed
  iii. New equipment; full day on-site training with a field scientist and a lab demo (would be good for training our personnel).
  iv. Inquired about the tech support and service contract
  v. Run time: 50 mins total/96 well plate
  vi. Estimated price $70,000

Or

b. Alternate manual workflow for RNA extraction

i. EUA-approved manual magnet, but same RNA extraction kit
ii. Run time: 2-3 hrs/96 well plate
iii. Add a liquid handler to automate it (additional cost)

Part 2 of test: RT-PCR portion:
a. Testing platforms:
i. 3 approved machines in the EUA: ABI27s 7500 and 7500 Fast DX (both are 96w format) and ThermoFisher27s 384 well QuantStudio 5
ii. QuantStudio 5 estimated cost = ~$49,000 or utilize the 2 QuantStudio 5s at the DRL (may need increased capacity to serve current and new needs arise) (Available now)
iii. Quote for the ABI 7500 Fast DX 96-well workflow ($70,000) and ThermoFisher Quantstudio5 ($49,000)

c. Supplies and reagents:
i. Viral RNA isolation kits
ii. RT-PCR kits
iii. Other materials: plates, tips, tubes, and other consumables
iv. Estimated costs = ~$25-35/test x 3,000-21,000 tests/month depending upon required frequency of testing based upon incidence rate in the population and other public health metrics= $90,000/month - $630,000/month x 3 months = $270,000 - $1.89M. If this facility were to be established for Fall 2020, the projected costs would = 180,000 (3,000 tests x $30/test x 2 months)

*Costs could be less as new tests become available, i.e. Yale saliva test

d. Miscellaneous:
Costs and infrastructure for secure data storage and management currently unknown

Novel network approaches to efficiently manage testing capacity among institutions and collaborate with other university-based networks

We could support a partnership for the university system, comprising 7 university campuses with over 21,000 in-person students, faculty, and staff for the Fall 2020 semester. We could also work with other universities in the state, support smaller colleges and universities or neighboring state universities . We have already begun discussions with neighboring state university about developing a partnership to learn from their experiences in establishing a testing facility on their campus.

The types and frequency of testing including the technologies and approaches that could be utilized

The university system has enacted a three-phase testing plan that includes arrival testing for all students or staff from out-of-state, all residence hall students, and special populations; a second round of testing within 7-10 days for everyone required to have an arrival test; and on-going surveillance testing through individual and wastewater testing. The phase three individual testing strategy will include random sampling of ~10% of the population of faculty, students, and staff every 10 days throughout the remainder of the semester. The testing will be conducted through RT-PCR with established testing partnerships with local, private companies.

Future testing strategies to establish an in-house surveillance testing system could be used in place of the phase 3 testing approach. In this regard, we could establish a laboratory as outlined above.

The use of alternative evidence-based approaches to monitoring the level of COVID19 in the community (e.g., wastewater surveillance)

We have established a plan for wastewater surveillance on 3 of our 7 campuses in the university system, where wastewater testing is feasible. This captures ~75% of the population of our campuses, and will provide an early warning of a rise of cases on campuses. The incidence rate will be determined in Phases

1 and 2 of baseline testing of students as they return to campus. The community transmission rate and other metrics will be factored into the determinations for retesting and surveillance.

Risks and challenges that might impact the successful establishment and operations of a learning university-based surveillance network

Our current plan has risk due to the lack of frequency of testing due to limited resources. Resources could ultimately be saved if an independent testing laboratory were established and sustained. It would require resources to start a testing facility, hire staff, and it would be necessary to determine the long-term sustainability plan for such a testing laboratory. For example, if the University faces closure due to an outbreak, the resources would not be properly utilized. Additionally, testing resources have been a challenge for other laboratories due to supply chain issues.

Proposed mitigation strategies to address the potential risks and challenges

The laboratory could pre-order testing supplies to prepare for each semester. However, this may not be a prudent use of resources in a pandemic. The laboratory could be designated as a commercial laboratory to assist with state overflow testing or community surveillance testing if demand warranted or in the event of University closure.

Response 18

The feasibility of carrying out such university-based network activities at scale

Generally the actual assay capacity should not be the rate limiting step. For example, the university has a large number of PCR instruments in research labs which, in theory, could participate in a network of non-CLIA pooled surveillance testing. However, we would likely also need additional robotics in research labs to do massive pooled surveillance as doing this manually is likely not realistic and risks high error rates. The major feasibility challenges we believe are 1) the upstream collection and handling of specimens, 2) the maintenance of appropriate patient identity through the analytic process and 3) the downstream tracking and identification of positive individuals that present information system infrastructure. We would likely have a large number of professionals and professional trainees who could be dedicated to running surveillance testing, but setting up this workforce could be a major bottleneck. With the challenges around individual specimen collection and development of surveillance populations, at the university we have focused innovative surveillance efforts on wastewater testing of on-campus congregate settings (dorms, apartment buildings). This approach could compliment individual screening programs and perhaps greatly reduce the need for individual testing. We have stood up a team led by an Infectious Disease Physician-Clinical Microbiologist and Engineering faculty who are deploying wastewater surveillance techniques at the level of a building to understand the methods and approaches. Because of a prior collaboration between the Schools of Medicine and Engineering around wastewater surveillance, the university has expertise and knowledge around the logistics for accessing building level wastewater with a trained facilities team. Sample collection requires robotic samplers which can acquire wastewater multiple times an hour as SARS-CoV-2 is transient in wastewater. In current state, we are able to monitor 20 buildings every other day and process the composite samples with high sensitivity methods. The team has already done a sample collection and molecular method comparisons. This allowed for testing to use a very sensitive qualitative approach. We have the infrastructure for comparison and have validated results from buildings with both sample collection and molecular processing from known negative COVID-19 populations (from screening program results) and known positive/negative occupants. Ideally, if deployed at scale, a positive waste water result would then result in the screening of building occupants. We currently have the infrastructure to perform wastewater testing representing a composite collection from hundreds of individuals at a time, followed by individual point prevalence testing as prompted by positive waste water screens.

The resources needed to jointly develop robust surveillance testing capabilities for students, faculty, and staff, et. al. (e.g., other institutions in communities)

In the university's clinical laboratory, we have a large complex molecular SARS-CoV-2 testing which we estimate could perform roughly 2000 tests per day and potentially scale to 3000 per day under a CLIA certificate, given increases in personnel and reagent allocation. We are currently using four different testing platforms (Cepheid Infinity, Abbott m2000, Abbott Alinity and ABI7500 CDC method). We have validated multiple specimen types including wastewater. The limiting factor here has largely been supply chain on traditional diagnostic platforms which have EUA approval for sensitive molecular detection of SARS-CoV-2. With our extended capacity, we have also been acting as a contributor to the state Department of Health for expanded capacity around the state. We have been supporting testing in nursing home outbreaks, correctional facilities, and at risk communities. We have been using the expanded capacity to address unmet testing needs in Black and Latino communities which have been hard hit with the pandemic. We have set up recurring testing events in these communities for the state Department of Health. In addition we developed flocked swab manufacturing and registered the swabs with the Food and Drug Administration so they can be distributed. We are manufacturing 75,000 flocked per week and we provide the state Department of Health with 60,000 swabs per week. We could increase production but would need additional assistance with distribution. In addition, we have a facility which manufactures and distributes viral transport media to others around the state. We believe we will have the capacity to provide 24 hour turn around on symptomatic patients, community members students, faculty and staff with any on-campus surge in cases or patients. It is not as clear with our commitments to the state that we will be able to open this testing capacity up to other groups in a network. An advantage that we have is the presence of infectious disease physicians/epidemiologists which can help gating the testing and can eliminate lower priority screening testing in the setting of a surge of symptomatic cases and exposed individuals.

We also believe that we will have the ability to continue to do a pooled surveillance approach of wastewater monitoring of the dorms with the paired ability to perform a point prevalence if a dormitory wastewater tests newly positive. We have developed algorithms to trigger testing of students from on-campus congregate living situations to try to limit spread.

We do have a symptom checker app which asks students, faculty and staff to attest to being asymptomatic. This has been deployed across campus and will be published on a dashboard. This could help as an early warning system. Also we have a tracking system with dashboards of all tests run, number of hospitalized patients, number of daily positives. This data could be used to understand the impact of interventions especially in collaboration with other universities.

Novel network approaches to efficiently manage testing capacity among institutions and collaborate with other university-based networks

A small group of faculty at the university has already been working with a group of other researchers from two other institutions to determine the best approach to wastewater surveillance on campus. We have been sharing protocols and approaches as well as preliminary data. This has increased the development of the wastewater pilot project which the university has undertaken. We would be pleased to share methodology and approaches with other Universities on a larger scale as needed.
With a very active data science department, the university would also be able to participate in collaborative efforts to perform modeling to understand the emergence and control. We have individuals which could assess the impact of different interventions on the control. The Data Scientists would also be able to assist in participation in the development of data based alert systems which could indicate the need to enter different phases of restriction to limit transmission.

The types and frequency of testing including the technologies and approaches that could be utilized

The university could participate in frequent (daily) wastewater surveillance especially with additional personnel and equipment. Because of a prior collaboration between the Schools of Medicine and Engineering around wastewater surveillance the university has expertise and knowledge around the logistics and accessing building level wastewater with a trained facilities team. Sample collection requires robotic samplers which can acquire wastewater multiple times an hour as SARS-CoV-2 is transient in wastewater. In current state, we are able to monitor 20 buildings every other day and process the composite samples with high sensitivity methods qualitative methods. To continue and do it at full scale here and on other campuses will take additional equipment for collection and a knowledgeable team of the sanitary systems on campus and the knowledge of building occupants. The team has already done a sample collection and molecular method comparisons. We have the infrastructure for both sample collection and molecular processing to continue testing. Ideally, if deployed at scale and reliable once a building which had previously tested negative then tests positive further screening of occupants will occur. We have the infrastructure to perform wastewater testing using a composite collection followed by point prevalence tested as prompted by new positives. The team has an infectious disease physician-scientist who has led a number of point prevalence testing events in collaboration with the state Department of Health so we would be well positioned to support the execution of point prevalence testing in a dormitory.

The use of alternative evidence-based approaches to monitoring the level of COVID19 in the community (e.g., wastewater surveillance)

We felt that congregate living poses one of the greatest risks if students otherwise adhere to social distancing. Therefore, the university has provided $150,000 for a pilot program to evaluate the ability to do surveillance on building wastewater on congregate living situations in the dormitories. We have stood up a team of facility personnel, engineering faculty, infectious disease faculty and laboratory personnel. Many of the researchers had previously worked together in related wastewater infectious disease monitoring so there was less start-up time. We have successfully compared both collection and molecular methods and arrived at a sensitive method. We have been able to find buildings where occupants were frequently tested for other reasons and have institutional review board approval to compare known carriage to the wastewater results thus validating the methods. We are now deploying monitoring on campus dormitories in a limited capacity. We will need to hire additional personnel to expand the program to every other day on all congregate settings if students move back to campus. We have developed algorithms to trigger a point prevalence testing of the building occupants if the wastewater goes from negative to positive. This data could be used as early passive surveillance to detect asymptomatic carriage early. It would eliminate the need for frequent human surveillance and if a negative dormitory turns positives the action would be to test all occupants.

Risks and challenges that might impact the successful establishment and operations of a learning university-based surveillance network

The time it takes to share data can normally be slow and the systems are in need of rapid solutions. Another risk point will be an underestimate of the amount of resources needed to accomplish many of the potential solutions and to evaluate what is working. There are also unique situations at each University which may allow some solutions to work well at one institution and not well at another (rural versus urban or ready access to rapid sensitive testing versus not). For instance in the case of waste water monitoring the actual physical configuration of some sewage systems impacts this approach and the inability to isolate positive individuals away from a specific building will quickly hamper this approach. It will be critical to have University networks with enough dedicated staff to perform and document new surveillance methodologies and be given a resource that provides real time data to learn from others' experience.

Proposed mitigation strategies to address the potential risks and challenges

Funded programs and have realistic outlines of the number of personnel to both execute innovation but also review and share the findings so others in a network can learn. It would be helpful to have easily accessible funding to help support some of the network initiatives such as the NIH RADx with a rapid review and evaluation program. This could then require metrics for what is working and not working in different systems to prioritize different deployments.

Universities with Schools of Medicine and Schools of Engineering are uniquely positioned to lead some of the needed innovation to combat the pandemic and allow safer reopening. They could serve as testing grounds for new ideas to quickly succeed or fail. For example, at the university through collaboration we have been able to design and distribute FDA cleared swabs and viral transport media to supply to ourselves and other to address supply chain constrictions. Because we have a sophisticated clinical microbiology lab with a director with vast experience in viral molecular diagnostics we were the first laboratory to have testing in the state outside of public health. With a co-director who is a specialist in infectious disease and epidemiology we provide expanded testing not only to our patients but to at risk patients and communities. This epidemiologic expertise paired with clinical microbiology also allows for the direction of testing to where it is most needed adjusting for changing epidemiology and testing capacity. We have developed an innovative wastewater pooled surveillance method for congregate living with the capacity for point prevalence on those in the congregate living setting. Encouraging Universities to foster innovation, develop interventions and rigorously test strategies will create a knowledgebase critical to addressing the pandemic. This information and knowledge could then be shared and deployed more widely where needed.

Response 19

The feasibility of carrying out such university-based network activities at scale
Testing is the foundation for contagion management.

In its simplest form testing can be used to estimate the total number of individuals who are currently infected and who have recovered. These numbers are essential to developing and improving models for the pandemic and to the overall response efforts.

Testing can also be used to detect all active and recovered cases. While it is substantially more difficult, comprehensive testing has enormous benefits. It grounds the models and the policies in reality and thereby makes them much more effective. It makes it possible to institute quarantines and other social distancing measures in an optimal manner.

Organized and planned testing is an obvious and essential prerequisite to large scale epidemic management. We have unprecedented computational interconnectivities and powerful computing capacities. It is critical that we come to grips with the full value and use of these capabilities to manage our way through the pandemic. It starts with sensing the world through testing.

The resources needed to jointly develop robust surveillance testing capabilities for students, faculty, and staff, et. al. (e.g., other institutions in communities)
We need complex decision analytics that integrates sensing, state assessment, and decisions across multiple scales.

The COVID-19 pandemic is an emergent example of the need for modern computational extension of human perceptual and cognitive capacities for very large scale, complex situation interpretation and coordinated rational decision making. The COVID-19 environment is extremely distributed, much is unknown and the effects are, from most local perspectives in the pandemic, very diffuse and rare; hard to see and interpret. Without the Information and communications technology (ICT) environment, it would be nearly impossible to accurately perceive and reason about, much less manage this event in "real time".

“Model fatigue” or “model shopping” is not a realistic option. Model-driven testing and data-driven modeling for such distributed system decision making is necessary.

Testing drives decisions that are made at the individual, family, group, and national levels.

While testing is done at the individual level, all levels are connected by the need for the best decisions and the best outcomes across levels. A decision may require a test or a test may lead to a decision. Testing technology, sampling protocols and data are integral to the decision technologies, including modeling for locally relevant, yet connected, state assessments. Testing technology, accessible testing technical infrastructure, and effective/responsive information coordinating policies across levels are necessary, interconnected issues.

Novel network approaches to efficiently manage testing capacity among institutions and collaborate with other university-based networks

The need to optimize testing is an ongoing requirement.

Testing can be optimized through a model-driven approach, and it turn testing can help develop better models. Overall testing protocols can be made more efficient by using models. The simulation based models can be used in an active sensing and querying loop to lead to improved outcomes. For example, a model might suggest that more cases are likely to be present in one dormitory versus another, or that certain groups of individuals are more likely be infected.

Testing can be amplified using contact tracing and isolation strategies. Using contact tracing strategies and modeling to optimize where to test and how to manage costs and maximize information will require the use of combined model-driven and statistical science approaches in a distributed, computationally enabled management decision environment. Testing, modeling and mitigating actions- from optimized test, to isolation or other decisions, to vaccination- are in a loop, not isolated activities.

The types and frequency of testing including the technologies and approaches that could be utilized

For novel contagions, in the absence of immunity, prompt physical isolation is the only interim strategy.

As noted at the outset, contagion management begins with testing support and policy. Without integrated testing and delivery of test information, prompt and effective isolation management is not possible. ICT networks are critical and will allow significant economic productivity even during physical isolation at scale. Integration of these virtualized work/everyday life organizations with testing and testing-driven contagion management would be very valuable. Given global interconnectivity, population size and infectious disease experience, the current COVID-19 pandemic is not the last event of its kind and routine testing based re-isolation should probably be a priority.

Response 20

The feasibility of carrying out such university-based network activities at scale

The university is well positioned to provide the means and the mechanisms to assist its host cities to return to a pre-pandemic economy, beginning with re-opening schools and allowing parents to return to work. As part of the Massachusetts Higher Education Working Group, the University President joined 13 other University Presidents to deliver a “framework for reopening colleges and universities” to the Governor’s Reopening Advisory Board. The document offered specific details for how colleges and universities can reopen based on a four-phase plan for reopening the state.

These strategies leverage the university’s existing relationship with an independently governed and supported as a 501(c)(3) nonprofit research organization including over 3,000 scientists. With the the nonprofit's expertise and infrastructure, the university has implemented a comprehensive SARS-CoV2 (COVID-19) dry swab testing program in partnership with the nonprofit testing lab which serves all four of the university's campuses, creating nuanced models that serve the urban, suburban, and rural communities where its four campuses are located.

We have realized we can make the greatest impact on public health and safety on our main campus, in which the vast majority of our undergraduate population resides in on- and off-campus housing. The university's operational protocol and available technology allows us to schedule and support the administration of 18,800 tests per week to provide the university with information about the spread of the disease on our campuses. The university's surveillance testing covers our faculty, staff, and student population, giving us confidence to reopen with the ability to quickly isolate positive cases and trace associated contacts to minimize COVID-19 transmission. The telemetry provided informs decisions about campus operations, allowing real-time adjustments in response to any change in campus infection rates.

Working closely with local government and school officials, the university can support local K-12 schools in developing modeling, surveillance testing, and creating actionable information as they begin to reopen in the fall of this year. The university has the expertise and infrastructure to test local members of the community, while simultaneously training local officials, healthcare professionals, and nearby K-12 school faculty and staff on best practice processes developed at the university. Ultimately, this university-community partnership will help limit the spread of COVID-19 in the greater metropolitan area.

The resources needed to jointly develop robust surveillance testing capabilities for students, faculty, and staff, et. al. (e.g., other institutions in communities)

The university and the nonprofit research organization have adequate expertise, equipment and facilities to successfully carry out this work, though additional resources (test kits, dedicated personnel for testing and training, additional funding) would greatly enhance our ability to test a larger population including K-12 schools. The university plans to implement a two-phased approach, with cost projections (for easy extrapolation) listed below in Table 2.

Phase 1: Piloting Pooled and Individual Testing
Beginning on September 8, the university will pilot different pooling schemes to assess specificity/sensitivity and operability ranging from 10-1 (maximum possible according to research). The sample testing will use 900 subjects drawn from the university population. Each subject will provide 2 samples—one for individual testing, and the other to be pooled along with 7 other samples in accordance with existing Food and Drug Administration (FDA) published guidance for testing: https://www.fda.gov/medical-devices/coronavirus-covid-19-and-medical-devices/faqs-testing-sars-cov-2. The university will adhere to Molecular Diagnostic Template for Laboratories and will draw upon the existing FDA guidance for both individual and pooled testing. Based on published research (JAMA Network Open. 2020;3(7):e2016818. doi:10.1001/jamanetworkopen.2020.16818), pooling testing is reliable, safe, and according to our calculations, cost-effective. We are assuming that an 8-1 pooling scheme will be verified in this pilot.

Phase 2: Focus on K-12 students, faculty, and staff in two local Public School Systems.Once the pooling protocol has been proven to be a reliable and safe method for screening and surveillance testing, the university will begin Phase 2, working with K-12 schools within the local communities to expand pooled testing into schools to support a hybrid reopening.

The university intends to train local public school nurses to perform screening and surveillance testing. These healthcare staffers will be trained using the innovative anterior nares "dry swab" method pioneered by the university's nonprofit partner. By using simple aggregate pooled testing, The University estimates that it will add testing capacity for the 12,000 students, faculty, and staff in the local public-school systems at a 2X/week schedule. This provides adequate surveillance data to contain transmission while only requiring 2500 pooled samples to be processed per week, demonstrating a scalable and replicable method for supporting broad-scale surveillance testing programs. Similar to the university's existing testing protocol established in Phase 1, samples will be bar-coded for pool identification, and sent to the nonprofit research organization located 5 miles away. Results are expected within 24 hours. If a pooled sample is COVID-19 positive, the 8 individuals will be contacted by phone and given instructions to isolate until an individual surveillance test is completed and results are returned. A clinician will contact individual positive cases with instructions for isolation and medical guidance. In addition, we can take swab samples from other immediate family/household members in close contact with the individual positive student for testing, as we know spread within households is frequent. Therefore, our surveillance strategy in schools will have positive health impact on the larger community by testing all close contacts of positive individuals, including family members.

Novel network approaches to efficiently manage testing capacity among institutions and collaborate with other university-based networks

The university has four campuses: two in a city, one in suburban areas, and one a largely rural community. In response to urgent requests from the Mayors of the suburban areas, the two municipalities upon which the university's main campus sits, the university will scale up its own reopening plans based on rigorous screening and surveillance protocols. This will enhance and extend the strong link between the university and its community and ensure that the university continues to fulfill its mission of active civic engagement. The university has been at the forefront of the COVID+ pandemic in the state. For example, prior to this specific request for information, the university: hosted police officers and firefighters in residence halls over the summer; provided housing for local healthcare workers and COVID-19 patients from a local hospital; and allowed a large cafeteria to be used by a local nonprofit organization to store food before it was distributed to local food pantries. Because we onboarded in phases, we are able to use excess testing capacity to assist our local neighbors. Though there have been the expected concerns raised by some in our host communities, the mayors of both cities have been supportive of our reopening plans. We continue to have productive conversations with them and are working on plans to assist both communities based on their needs.

In addition, the university has partnered with a research facility that is providing 106 colleges and universities with a comprehensive COVID-19 testing and surveillance program. Together with the research facility, we can create nuanced models to serve the urban, suburban, and rural communities where its four campuses are located.

As a member of a local association that is the leading voice on public policy issues affecting independent higher education in the state, the university is well positioned to extend its relationship model and innovative practices beyond the city area to the region via this network. The Association is comprised of 60 degree-granting, accredited, independent (private) colleges and universities across the state. The Association promotes increased awareness of the significant contributions by colleges and universities to the cultural, economic, and knowledge-based reputation of the state. As such, this network will be able to rapidly benefit from protocols and approaches identified here to optimize operations and return the region to a pre-pandemic economy.

The types and frequency of testing including the technologies and approaches that could be utilized

Our partners at the nonprofit research organization developed a Covid-19 testing capability in March 2020 in response to the growing public need in their city, in response to the pandemic. Since launch, the nonprofit has achieved EUA approval for its test and has processed nearly 800,000 Covid-19 diagnostic tests. The nonprofit has implemented a dry swab testing protocol that is scalable and addressed numerous supply chain and biosafety concerns.

In response to need for a pooled testing approach the nonprofit is developing a multi-swab dry testing method as summarized below:

Multi-swab Dry Testing
Multiple swabs placed into a single dry tube for transport to off-site facility, minimizing risk of leaking tubes.
No additional risk of personnel exposure in pooled sample preparation
Minimal need for personnel, equipment and supplies: lysis (inactivating buffer) added immediately upon receipt of multi-swab tube. Single transfer of reconstituted buffer into plates for downstream RNA extraction. Uses Biosafety hoods already in-place for standard testing.

Traditional Pooled-Liquid Transfer Method
Wet samples manually combined and added to liquid transport medium
Requires courier transport to a BSL2 lab from collection site and to diagnostic facilities to address the safety risks
Requires trained personnel and is supply intensive requiring: viral transport medium, pipets and pipet tips, biosafety cabinets, modified centrifuges, PPE (lab coats, double gloves, face shields/safety glasses/goggles), and disinfectant

The university has developed its own scalable technology platform to support the scheduling, order submission, labeling, and results monitoring of large-scale testing operations. This software platform is presently in use at the university and at 3 other colleges in the state. The software has reduced the cycle time from arrival to sample collection to departure to approximately two minutes. Direct integration with the nonprofit's systems enables the university to submit orders directly and monitor results in near-real-time as they are fed back from the processing line.

This testing platform, already proven as a multi-institutional ordering system, integrates directly with institutional systems for biographic and demographic information on testing participants, and is readily extensible to support pooled test samples while also preserving patient confidentiality.

Our comprehensive arrival and asymptomatic testing regimen has proven to be a distinctive advantage in assuring that we keep infection rates at a minimum. At the university we are doing both arrival testing and comprehensive surveillance testing of all students (both on- and off-campus), faculty and academic staff, which is a pillar of our testing model.

The use of alternative evidence-based approaches to monitoring the level of COVID19 in the community (e.g., wastewater surveillance)

The university is unique in that it has campuses in four separate municipalities. In fact, our main campus is located on the border of two separate cities. Of greatest concern to our host communities are our undergraduate students that live off campus. Approximately 33% of our undergraduate students live off campus in some of the most densely populated urban areas in the country. Local school districts are finding it difficult to reopen K-12 schools without surveillance testing. Offering surveillance testing to local students, teachers and staff will allow our host communities to reopen their schools. Working closely with local municipalities, the university has been able to create a cooperative plan wherein human, physical, and scientific resources are effectively shared. For example, to address logistical and regulatory requirements that come with administering tests within the K-12 school system, will use school spaces as test sites and train school nurses to carry out the tests. Screening and surveillance testing will be administered on school grounds by local public school nurses to perform the innovative anterior nares "dry swab" method pioneered by the university's nonprofit partner.

The university and the nonprofit have adequate expertise, equipment and facilities to successfully carry out this work, though additional resources (test kits, dedicated personnel for testing and training, additional funding) would greatly enhance our ability to test a larger population including K-12 schools. What is lacking is the funding to finance these efforts.

The budget for the university's planned pooled COVID-19 19 surveillance testing for local schools includes the following: transportation of samples, facilities collection personnel, ordering provider costs, tubes, swabs and processing costs, individual retests, and technology support.
Total: $3,447,900

Despite the cost-saving innovation of pool testing, leveraging the physical and human resources of the school system, there is no existing budget at the university, the nonprofit, or the local cities to cover the 3 million-dollar expenditure these efforts require.

Risks and challenges that might impact the successful establishment and operations of a learning university-based surveillance network

The university proposes to share its screening and surveillance testing model to minimize the risk of infection through the state college and university network to assist the region's school-aged children to return to a regular schedule of classes, extra-curricular activities, and school-based support services, bringing the region back to a pre-pandemic economy.

Response 21

The feasibility of carrying out such university-based network activities at scale

With sustained national investment, a testing network composed of institutions of higher education, working in partnership with state and local departments of public health and other stakeholders, could address unmet coronavirus surveillance needs for students, staff, faculty, other campus users, and surrounding communities. Despite considerable progress in the U.S.'s testing capacity since the novel coronavirus outbreak last Spring, case identification for surveillance and clinical management remains insufficient to meet the need. The Association of American Medical Colleges (AAMC) has recommended that the US set a testing goal of 2.3 million tests per day. Similarly, the Rockefeller Foundation has called for the expansion of diagnostic testing capacity to 4.3 million tests per day by October 2020. As of mid-August, the COVID Tracking Project estimated that the US is conducting only 700,000 tests per day(1). Our state has faced similar challenges: As of mid-August, the Harvard Global Health Institute(2) estimated that it met only 62% and 18% of its targets for coronavirus outbreak mitigation (564 tests per 100k population, defined as obtaining a ≤10% test positivity rate) and suppression (2088 per 100k population; ≤3% positivity rate), respectively. The challenges of scaling up widespread testing in the U.S. context have been well-documented.

With sufficient resources, institutions of higher education could contribute meaningfully to coronavirus surveillance by collaborating with local and state departments of public health, community based organizations, and the private sector to expand testing on their campuses and surrounding communities. In recent months, the campuses and national laboratories comprising the university system have pivoted to perform real-time reverse transcription polymerase chain reaction (rRT-PCR) tests for surveillance and clinical management of novel coronavirus (SARS-COV-2) infection. Although much of the focus has been on diagnosing new infections, new collaborations between university system research labs and medical campuses have created "pop-up" CLIA-certified labs to ramp up testing on campus and in nearby communities. For example, one non-medical campus with insufficient onsite diagnostic testing capacity partnered with an academic lab at anothercampus with an academic medical center to expand testing. New collaborations at another campus have resulted in the temporary extension of CLIA certification through its student health services to permit secondary, on-campus testing through an academic research lab. These examples offer proof of concept that, with sufficient resources, new surveillance testing networks can be launched that both fill existing gaps and identify best practices and workflow improvements that can benefit local, state, and national surveillance activities.

Further, a university-based surveillance network could enhance case detection and outbreak mitigation in underserved communities. In the state, as elsewhere, communities surrounding university campuses have high proportions of low-income, racially/ethnically-diverse communities and essential frontline workers. Leveraging new or established research partnerships with local community-based organizations could prove vital to ensuring the availability of epidemiological data for persons most vulnerable to the adverse consequences of coronavirus infection.

(1) https://coronavirus.jhu.edu/testing/individual-states
(2) https://globalepidemics.org/july-6-2020-state-testing-targets/

The resources needed to jointly develop robust surveillance testing capabilities for students, faculty, and staff, et. al. (e.g., other institutions in communities)

Over the course of the pandemic, university researchers have transitioned their academic labs to address capacity limitations through the provision of laboratory-based diagnostic testing. These “pop-up” labs can serve as the foundation of a unique operational and scientific capability that uses available equipment to scale up testing capacity, and enables researchers to develop innovative tests with higher quality and accuracy.

Although these facilities operate independently, connecting them could result in the creation of a national network uniting university research lab-based testing facilities in every state. This network would enable the sharing of best practices and knowledge to further accelerate testing capacity and to develop better tests. It would also serve as a strong foundation for effective response to future pandemics.
Over time, adequate funding and programmatic support can support the development of these centers into a network of interconnected, mixed operational and research facilities:

*Immediate term: Fund operational use to scale up testing
*Near term: Fund infrastructure development and construction of replica facilities to provide a leading-edge, national-scale testing and research capability
*Long term: After the current emergency is over, re-purpose the operational and scientific infrastructure to advance research while continuing to support operational capability in standby mode.

One university academic laboratory converted its lab space for testing needs early in the pandemic, pivoting from academic research to processing diagnostic tests within days. At an estimated $14 million to operate at full capacity(1), the following are key diagnostic lab costs:
*Purchase and configure laboratory equipment: $3 million
*Operational personnel costs: $1.5M - $1.9M per y*ear, depending on staffing levels
*Consumables (swabs, reagents, etc.): $9 million

Similarly, regular weekly pooled surveillance testing for 45,000 individuals at a single campus is estimated to cost a minimum $10-15 million annually(2). Assuming an average of three such facilities per state, we can estimate costs in the range of $2.1 billion. It should be noted that this is an incomplete assessment of costs: a true calculation of resources required for the full life cycle of the test should incorporate costs for communication; IT, physical, and technical infrastructure and data storage; sample acquisition, transport, and processing; results distribution to individuals, campuses, and communities; contact tracing; and behavior management.

With economies of scale and introduction of emergent technologies, we expect the cost per test to decrease as more tests and different kinds of surveillance and screening innovations are performed (antigen, gene-editing assays, oral-saliva, wastewater, etc.). Funding sources could be provided on a Federal interagency basis, including BARDA (new pandemic response research) and others, in addition to state-level support as funded via Federal CARES Act. (1) The estimate assumes 1,200 tests/day, 5 days/week, 52 weeks/year: 300k tests/year, at roughly $30/test). (2) The estimate assumes 10:1 pooled testing is conducted, at a 5% prevalence rate, with 6,750 tests per week conducted per week totaling $270k, at a per-test cost of $40. Costs associated with personnel, equipment, data systems, and other expenses are additional.

Novel network approaches to efficiently manage testing capacity among institutions and collaborate with other university-based networks

We suggest the establishment of a collaborative innovation network (CoIN) encompassing testing inventory capacity, expertise, infrastructure, and equipment and supplies in individual testing centers across the country. This network would connect expert researchers and institutional stakeholders who can share best practices and accelerate research and capabilities faster and better than any individual testing node could achieve on its own.

The network will build on the combined expertise of researchers who have stepped up to transition their academic labs into testing facilities (both CLIA-certified and non-CLIA-certified). Their labs have pivoted to explore novel, cost-effective, and more comprehensive approaches to testing and contact tracing, and to develop models that can aid in economic and societal pandemic recovery. The collaborative network could consist of testing laboratories and intellectual communities of practice who can nimbly contribute to specific, cutting-edge expertise-focused topics—e.g., exchange of knowledge on Next Generation Sequencers, on software compatibility and interoperability, and on supply chain protection, logistics, and regulatory requests and challenges.

Promising practices can be amplified and scaled across higher education associations nationwide, e.g., APLU and AAU, and should include traditionally under-represented minority-serving institutions such as HBCUs and HSIs. Additionally, existing networks that link universities with their surrounding communities can be further leveraged to span urban metropolises, suburban regions, and rural and farming communities. For example, one university campus tests faculty, students and staff through its health service, as well as essential workers in the community, including utility workers in a region undergoing weather extremes and rolling energy blackouts. Meanwhile, another campus is utilizing its combined qPCR and surveillance testing capacity to serve both the campus and members of the surrounding community. Working in partnership with local public health authorities, this campus is now the largest testing provider in the county.

The creation of multiple networks, each comprised of universities with similar challenges and resources, also holds promise. For example, at campuses with medical schools but lacking hospital infrastructure, testing labs have faced challenges specific to building diagnostic testing facilities from the ground up without the ability to fully integrate within an affiliated hospital. Networks that can address shared challenges through deep dive analyses and operational coordination would be valuable and could assist each other in addressing limitations such as limited claims departments and lack of access to CLIA-certified laboratories. Strategies for building a scalable surveillance program will, by necessity, vary across institutions with different available resources and infrastructure. Developing multiple frameworks and strategies would allow shared approaches to be appropriately tailored to the needs and resources available at different types of institutions.

Operationally, a national testing network would provide testing assistance and support when natural (flooding, hurricanes, fires, earthquakes) disasters, human-made disruptions (cybersecurity threats) and/or surges arise. At the university recently, one campus has had to cease their symptomatic testing for the campus and the county as well as halt plans for asymptomatic testing, due to natural disasters. A robust network could support the campus's testing needs until they are able to recommence testing activities.

The types and frequency of testing including the technologies and approaches that could be utilized

Coronavirus testing within the proposed university-based, surveillance network could facilitate or inform mathematical modeling, adaptive testing, and other innovations to optimize case-detection, contact tracing, and outbreak mitigation and suppression strategies. Currently, COVID-19 diagnostic testing for surveillance, diagnosis, and clinical management is provided in the university system by CLIA-certified laboratories at five academic medical centers. Although capacity varies, some campuses can conduct nearly 2,000 diagnostic tests per day with rapid result turnaround (<24 hour) for patients. Throughout the university system, the general consensus is that implementing testing strategies using frequent, rapid, low-cost, and modest sensitivity tests would permit the implementation of an effective surveillance system to curb onward transmission. As noted, partnerships with CLIA-certified labs has enabled the development of "pop-up labs" throughout the system to conduct standard and quantitative RT-PCR testing using samples derived from saliva, tracheal aspirate, bronchial washing fluid, and mid-turbinate, nasopharyngeal, and oropharyngeal swabs.

Additionally, select campuses are developing new CRISPR-based diagnostics to detect known genetic sequences from coronavirus DNA; these methods are faster and use less reagent material than traditional PCR-based tests. Other campuses are conducting serology testing to better understand coronavirus transmission dynamics and to identify groups at elevated risk for infection and associated disease. One health science campus is testing employees using a home-grown method to detect the presence of coronavirus-specific antigens and has expanded its on-site testing programming in partnership with its local public health department and other agencies to augment testing capacity in local communities.

Yet a recurring challenge is to understand the type and frequency of surveillance testing necessary to identify and stem coronavirus clusters and outbreaks on campuses, particularly those sparked by "super-seeding" events resulting in an unusually large number of incident infections. Consistent with the evidence suggesting that up to 40 percent of new infections are associated with pre- or asymptomatic persons, a recent modeling study suggested that symptom-based screening alone was insufficient to stem a campus outbreak. Instead, the study concluded that screening campus users every two days with low-cost, moderate sensitivity tests may help campuses to safely reopen (1).

A university-based network for surveillance testing should invest in such mathematical modeling studies, particularly that offer interactive tools and share lessons learned, to optimize resource allocation for greatest impact. A robust surveillance testing network could facilitate mathematical modeling, adaptive testing, and other innovations to optimize case-detection, contact tracing, and outbreak mitigation strategies. Although PCR-based testing remains the gold standard for diagnosis, its utility for disease transmission surveillance and outbreak control has been limited by shortages of reagents and test kits, delays in sample transportation, lacking data systems and infrastructure, and limited personnel and fiscal resources. The Rockefeller Foundation has noted that to re-open all sectors of societies, the US must develop fast, inexpensive tests for asymptomatic screening. This is important for campuses and communities, which have essential workers most at risk for adverse health outcomes associated with coronavirus infection (2).

(1) https://jamanetwork.com/journals/jamanetworkopen/fullarticle/2768923

(2) https://www.rockefellerfoundation.org/national-covid-19-testing-action-plan/

The use of alternative evidence-based approaches to monitoring the level of COVID19 in the community (e.g., wastewater surveillance)

Improved epidemiological data collection are needed to understand how surveillance networks could enable return to campus and community life, particularly for ensuring the health of those most vulnerable to adverse health outcomes. Improved data for groups disproportionately impacted by the epidemic is a key consideration for building surveillance networks(1), particularly for race/ethnicity groups missing from coronavirus surveillance surveys in the US(2), despite accounting for significant variability in incident infections and adverse health outcomes(3). A robust surveillance network would provide the evidence and data to inform policy interventions addressing the social determinants of health, interrupting recurring health disparities exacerbated by the coronavirus(4).

A collaborative innovation network (CoIN) led by university campuses could be organized around key problems and novel solution combinations:

*Antigen testing: Antigen testing may support new therapies or vaccines for coronavirus infection. One university campus is in the process of acquiring equipment that can run up to 10,000 qPCR reactions per day and plans to screen 5,000 saliva samples daily, with follow-up diagnostic testing for those testing positive.

*Pooled testing: Pooled PCR testing may be a viable alternative strategy to detect asymptomatic coronavirus infections in low-prevalence, limited-testing settings. Several campuses are assessing the use of pooling as part of a multi-component strategy to identify individuals with asymptomatic or pre-symptomatic infections and confirm diagnosis of symptomatic individuals and their close contacts.

*Wastewater surveillance: Sewage systems monitoring for the SARS-CoV-2 virus can provide early-warning, low-cost surveillance strategy to identify outbreaks days or weeks before new cases appear in diagnostic testing or surveillance data. The utility of this approach, currently underway at several university campuses, varies depending on campus age, infrastructure, layout, and topography, etc.

*Emergent innovations: Novel technologies under development may help to improve testing, screening and surveillance capacity, accuracy, and uptake. In particular, point-of-care rapid diagnostic testing could revolutionize mass testing at speed and scale. University labs are developing combined technological innovations ("CRISPR meets smartphone") to facilitate:

**Lab-based mass testing: short of developing accurate and effective point-of-care rapid diagnostics, more work is needed on home-based saliva testing, gene-editing, and other lab-based innovations.

**AI-powered adaptive surveillance: by using machine learning, researchers can more efficiently and effectively sift through syndromic, behavioral, environmental, public health, and prior testing data to identify geographic hotspots, target testing, and warn of impending outbreaks.

**Environmental surveillance testing: effluent wastewater testing and air sample testing for SARS-CoV-2 (including use of mobile air sampling and other innovations in environmental surveillance).

**Next-generation diagnostics or platforms: enabling fast, cheap high throughput are needed to conduct surveillance at scale and to leverage resources at institutions that can build platforms to make capacity sharing feasible. One innovation for pooled testing has been advanced by one campus to augment traditional clinical diagnostics to increase capacity for diagnostic and surveillance testing needed to safely reopen all sectors of society, including institutions of higher education.

(1) https://www.sciencemag.org/news/2020/07/huge-hole-covid-19-testing-data-makes-it-harder-study-racial-disparities
(2) https://coronavirus.jhu.edu/data/racial-data-transparency
(3) https://jamanetwork.com/journals/jamanetworkopen/article-abstract/2768723
(4) https://www.healthaffairs.org/do/10.1377/hblog20200716.620294/full/

Risks and challenges that might impact the successful establishment and operations of a learning university-based surveillance network

Successful establishment and maintenance of a university-based surveillance network would face major challenges, including liability risks, financial (upfront and sustained) and other costs. Additional challenges include data system interoperability, coordination and stewardship, logistics, and ensuring commitment to distributive justice. A primary concern about the establishment of such a network is whether institutions would be held liable for clusters or outbreaks, particularly for individuals infected on campus. This is particularly true for higher-risk essential staff and faculty.

Next, financial challenges may limit the establishment of a university-based surveillance network. Even at the university's modest levels of testing for asymptomatic infections, it is unclear how to support associated costs, particularly given recent Federal clarification that surveillance testing for coronavirus infection is not covered under the FFCRA and CARES Acts(1). Hence, universities must cover these costs. Further, maintaining a networked, university-based surveillance system for current and future pandemic response will require more than revenue-generating approaches like bond issuances that may be unique to public institutions(2). A sustainable response will require the commitment of Federal resources.

Third, establishing a surveillance network will require development and deployment of interoperable, secure medical records systems that facilitate timely, secure information exchange between laboratories, clinical care, and state and local public health departments. These systems may also require hardening against external pressures that may influence rapid, transparent, and accountable data collection and reporting. Further, streamlined systems logistics would facilitate the exchange of data, samples, and lessons learned.

Fourth, a recent survey of higher education institutions underscores the necessity of establishing common, evidence-based testing plans, even in the absence of clear Federal guidance(3). The importance of effective coordination of key stakeholders when establishing and maintaining a university-based surveillance network with common goals, data safety protocols, strategies, and metrics can not be overstated. Additionally, such a network should incorporate an interdisciplinary approach to address individual, social, and structural factors that undermine the efficacy of an evidence-based public health approach to mitigating and suppressing the coronavirus epidemic.

Fifth, delays in turnaround times associated with PCR tests have rendered a substantial fraction of the results useless for public health action. Ensuring robust supply chains will be essential to the success of a college and university-based coronavirus surveillance network with excess capacity to serve their surrounding communities.

A final challenge to network establishment is in ensuring that principles of distributive justice are observed, particularly for making surveillance tests, data, and resources available to segments of society at highest risk for infection and associated adverse health outcomes. Likewise, caution will be needed to ensure that resources, risks, and benefits do not disproportionately favor locations with greater abilities to leverage existing resources. University networks, such as the university's, are responsible for community needs, broadly defined, and have amplified their role in response to a wide range of needs, ranging from deployment of organized support for their university members to outlying communities including local American Indian and Alaska Native populations.

(1) https://www.cms.gov/files/document/FFCRA-Part-43-FAQs.pdf
(2) https://www.bloomberg.com/news/articles/2020-07-09/university-of-california-faces-hardship-and-eager-bond-buyers
(3) https://doi.org/10.1101/2020.08.09.20171223

Proposed mitigation strategies to address the potential risks and challenges

We suggest funding a network of university-based pandemic surveillance centers, linked and distributed across the nation to share new knowledge and best practices in the transition to early detection and monitoring, enabling faster operational surveillance of universities' faculty, staff, and students while serving their local communities. Under this networked model, local labs would maintain a stand-by reserve function and scalable capability when needed, while also providing a foundation for future research and mitigation efforts. This approach will better prepare the nation to face the current pandemic and its potential aftershocks, as well as inevitable future pandemics. The proposed approach leverages a diverse coalition of universities throughout the country while offering a practical framework for advancing an entirely new model for virus surveillance testing and early detection.

Regulatory relief should be provided to research labs during the Public Health emergency period, by 1) permitting enforcement discretion for research laboratories that perform COVID testing and want to return results to research subjects, 2) encouraging consideration of Emergency Use Authorization applications from unregistered research laboratories, provided that they adhere to applicable requirements and performance standards, and 3) encouraging state public health agencies to follow suit with respect to applicable state laws that, like CLIA, preclude full reporting and utilization of research test results.

Key to network success is the provision of ongoing funding and programmatic support to evolve and extend these emerging centers into a network of interconnected mixed operational and research facilities:

*Invest immediately in operational capacity to provide scaled-up testing in the near term.
*Invest in extension and duplication of the best facility designs across the nation, to grow cutting-edge testing and research capability in every state or region.
*Utilize the operational and scientific infrastructure thus established as a national facility for immediate need; and maintain it in standby mode for when it is needed for future emergencies.
*Provide funding for accelerated research on new and better testing regimes, while utilizing the national network as essential research infrastructure to deepen our understanding of the fundamental science of viruses and possible scientific responses to future pandemics.
*Foster public-private-government partnerships to ensure that network engagement is fully inclusive of universities, county and State departments of public health, industry partners, and community and civic organizations. Effective engagement and partnership with these non-academic sectors is an essential component of information exchange and networked technical collaboration opportunities, particularly when establishing communities of practice and harmonized data platforms.
*Create a central repository where instructions and step-by-step guidance are easily available. A networked surveillance system will require coordinated oversight of capacities and functions to design, monitor, and accelerate the scale-up of coronavirus testing capacity sufficient to interrupt transmission dynamics and mitigate outbreaks on campuses and in their surrounding communities(1).

(1) https://www.rockefellerfoundation.org/national-covid-19-testing-action-plan/

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The feasibility of carrying out such university-based network activities at scale

It is feasible; however, It is important to standard several things within the network. For example, a key component would be to ensure that assay performance across different universities meet a set criteria, that there are attempts to also apply some minimum criteria for sample collection.

The resources needed to jointly develop robust surveillance testing capabilities for students, faculty, and staff, et. al. (e.g., other institutions in communities)

Human resource is a huge component, process engineer to help each site identify and solve their unique bottlenecks and for integrating sites into a network. A key resource will also be the different types of technology that is needed, such as software for scheduling, sample collection, laboratory information management, results reporting, and also the software to support how results will be used and reported to the testee, provider, responsible parties, and department of health. If there could be a single app that all sites could use to interface with testees and testee institutions that would be incredibly helpful.

Novel network approaches to efficiently manage testing capacity among institutions and collaborate with other university-based networks

Standardization of how patient data are collected and reported is very imporotant, as well as specific metrics and SOP components for the test sites will be important and helpful for rapid learning. However, the goal isn't necessarily to apply an identical solution to every site.

The types and frequency of testing including the technologies and approaches that could be utilized

PCR test remains the gold standard and can be used for re-opening workplace, campuses, etc., whereby individuals are cleared to go back to work/school with a PCR test (Self-collected anterior nasal swab) that will be reported in 24 hours. The individuals should quarantine and then tested again by PCR test in 3-5 days. The two consecutive tests will clear the individual, who should then be tested every 5-7 days. Although there is a lot of interest in saliva test, it is rather challenging for labs to implement at a large scale, so that should be a consideration in specimen type recommendation. Additionally, the FDA at this time does not allow use the saliva for SARS-CoV-2 testing. for individuals without symptoms.

The use of alternative evidence-based approaches to monitoring the level of COVID19 in the community (e.g., wastewater surveillance)

n/a

Risks and challenges that might impact the successful establishment and operations of a learning university-based surveillance network

Risks and challenges are that it is expected that at baseline, there would be substantial variations across universities, and that a subset of the universities would be using commercial tests for which they have very little ability to tweak. Therefore, it would be helpful to clarify if, how much, and how feasible is it for testing lab a specific university to modify it's existing testing method--if it is deemed a critical component, then that could be used to screen out sites that may be less suited in the learning network. Another potential issue is the variation in testing volume and testing population across university and even within the university. One could argue that it is important to include smaller labs since most labs are relatively small, while larger labs with greater expertise may be better able to develop and test ideas.

Proposed mitigation strategies to address the potential risks and challenges

To ensure that the learning network is successful, it is useful to develop a clear infrastructure for how the members within the network will work with each other, and clear/minimum variables for tracking each site's technical approach and performance metric. It will be important to thoughtfully curate a geographically-representative and qualified network members. The members can then work together to identify: 1) key areas for improvements in COVID-19 testing , 2) brainstorm/discussion solutions, 3) test proposed solutions, 4) report back to network.

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The feasibility of carrying out such university-based network activities at scale

As hubs of innovation that are also facing the imminent return of thousands of students, staff, and faculty from across the country and the world, academic institutions have risen to the challenge to address the evolving situation presented by the COVID-19 pandemic, from developing and validating new diagnostic tests to manufacturing or finding alternatives to key resources during the continual testing supply chain bottlenecks. The key to understanding and scaling broad university-based networks will require a comprehensive understanding of the approaches that academic institutions, in close partnership with medical schools, hospitals, communities, and public health departments have developed to assess the impact and spread of the virus. Teaching hospitals routinely utilize surveillance testing strategies in infection control protocols and are invaluable partners in both strategy development and in running the tests themselves through associated high-capacity academic labs.

Such activities are not only feasible, they are already happening. Campus reopening plans routinely include broad testing operations and diverse institutions such as the University of California system, University of Illinois, Stanford, Oregon Health and Sciences University, Duke and many others are implementing different but extensive testing strategies. Learning networks should seek to gather, assess, and disseminate the most effective strategies employed.

When discussing surveillance testing in any community, it is critical to distinguish the broad testing of individuals as a tool to monitor infections and make decisions about opening or restricting campuses and community gathering places from the environmental surveillance testing approaches that do not require interaction with a specific individual. Testing components are still a scarce resource, and so increasing testing by 10- or 20-fold through surveillance testing of individuals may require the use of samples, reagents, and testing methodologies that result in a less sensitive or specific test than the gold standard RT-PCR tests. If less sensitive tests are used for surveillance testing, those tests may provide an institution with a good sense of the infection rate when administered to thousands or tens of thousands of people but could give individuals with presumptive negative results a false sense of security, allowing the virus to spread through social interactions. Surveillance testing plans need to account for the fact that each time an individual is given a test, whether through a nasal swab or saliva sample, that person expects to get results back and to be able to take action based on what they learn. In virtually all cases, presumptive positive results from less sensitive surveillance tests conducted outside of a lab that has been certified to perform high complexity tests by the Centers for Medicare and Medicaid Services through the Clinical Laboratory Improvement Act (CLIA) process will be referred to a CLIA lab for a confirmatory test. However, individuals who do not receive a positive test will be less likely to follow up with a test done for diagnostic purposes prior to engaging in riskier behaviors. This highlights the need for clear and precise education efforts.

The resources needed to jointly develop robust surveillance testing capabilities for students, faculty, and staff, et. al. (e.g., other institutions in communities)

The resources to set up and administer robust surveillance testing capabilities are significant. Financial costs are high to roll out these initiatives, and there are few sources of funding that will cover the entirety of the costs. Some of these resources can be shared across communities, but many are borne equally by each institution that takes on these efforts. The costs of setting up new labs, adapting existing lab space, or contracting for the lab services to run the tests can be prohibitive, and institutions seeking to build new testing capacities have found that virtually all equipment needed to set up labs is in short supply. The acquisition of hoods, high-capacity testing machines, and all testing equipment is hampered by delays or backorders of weeks or months. Costs to run each test have typically been paid for by the institution itself, and if a surveillance testing strategy is used that relies on running some tests through campus research labs that have not been CLIA certified, additional costs may need to be allocated for running confirmatory tests for presumptive positive results for students and essential workers as well as faculty and staff. Personnel are also a key consideration in testing, and the types of tests being conducted will determine those resource needs. Any test steps that can be automated or performed without the aid of a healthcare worker or university staff member can act as a cost-saving mechanism (e.g. self-collection of samples, tests that do not require an extraction step, streamlined or app-based notification of test results). This requires up-front investment to set up the necessary infrastructure. Human capital is also required to maintain and analyze the data obtained through testing and utilize it for evidence-based decision-making. Smaller institutions may have difficulty coming up with these additional resources. Academic medical centers in particular play a key role in testing capacity not only for staff and students but also for the surrounding community. Partnerships to bring testing to communities should follow principles of community-based participatory research to maximize the efforts' effectiveness. (For specific examples of how engagement with at-risk communities can be improved by approaching the issue with a health equity lens see: Michener L, Aguilar-Gaxiola S, Alberti PM, Castaneda MJ, Castrucci BC, Harrison LM, et al. Engaging With Communities — Lessons (Re)Learned From COVID-19. Prev Chronic Dis 2020;17:200250. DOI: http://dx.doi.org/10.5888/pcd17.200250.)

Community engagement could also enhance the potential role of Community Health Needs Assessments and leverage Clinical and Translational Science Awards (CTSA) community engagement cores.

Novel network approaches to efficiently manage testing capacity among institutions and collaborate with other university-based networks

Unsurprisingly, in the face of this pandemic academic institutions have been very willing to share their approaches, technologies, partnerships, and success stories with other institutions as well as with the general public. Learning networks will require open sharing of information, challenges, and technologies, especially in the quickly changing environment of the COVID-19 pandemic. We recommend the adoption of open science principles with respect to not only technical details such as testing protocols, but also operational practices for public health messaging and education, and institutional policies.

Many institutions have established testing dashboards and other communication vehicles intended to enhance transparency and facilitate rapid communication efforts for the academic community as well as the public. Federal facilitation of the many ongoing collaborations and communication efforts could be enhanced by hosting or providing links to information hubs where these many efforts, dashboards, and successful methods are housed.

Some institutions looking to expanding in-house testing capacity have demonstrated success in pairing research labs with CLIA-certified clinical labs to expand testing capacity rather than working to convert research labs into stand alone labs that can do high capacity screening or surveillance testing with results that can be relied upon for individual diagnostic results. In addition to the startup challenges described previously, supply chain issues can lead to labs from the same institution to compete for reagents, extraction kits, or other critical components, capping the testing capacity of both labs.

The types and frequency of testing including the technologies and approaches that could be utilized

Institutions have taken different approaches to surveillance testing including variations in: the type of samples used (nasal swabs or saliva); utilization of pooled testing; testing frequency; and which segments of the university population are included in testing. In developing surveillance networks, it is not essential that each institution adopt the same approach. In fact, a diversity of approaches has contributed to the success of the increases in testing capacity that have been accomplished so far. Without the wide range of testing approaches, the supply chain bottle necks would have capped our national testing capacity far below what it is today. Institutions must also find a testing process that works for their existing infrastructure, level of resources, state and local regulations, and the local COVID-19 infection rates, and that supports their specific plans for re-opening.

Institutions that are working on novel approaches to surveillance testing are collecting data on sampling protocols, novel pooled testing approaches including those that could test very large pools without the need for retesting entire pools (see, e.g. https://www.medrxiv.org/content/10.1101/2020.08.04.20167874v1), and self-collection protocols under direct or remote observation. Any new technology that creates an alternative supply chain can expand and scale up testing to make surveillance more feasible and more cost effective.

The use of alternative evidence-based approaches to monitoring the level of COVID19 in the community (e.g., wastewater surveillance)

This association agrees that true community surveillance methods such as wastewater, air, and surface testing will be an important component of monitoring the virus' impact and identifying areas of continued infection. We encourage the continued incentivizing of new technologies to develop and validate these testing approaches without diverting supplies and resources from the critical shortages of testing components needed to test individuals. The NIH RADx program could be an effective vehicle for such incentives. Once proven, these monitoring approaches and protocols should be widely available, with accessible information in a single resource hub, rather than contained on individual university websites.

Risks and challenges that might impact the successful establishment and operations of a learning university-based surveillance network

The challenges associated with large scale networks can be categorized as technological, disease-based, or policy based.

Technological challenges that have been addressed herein include resources, space, available infrastructure, and communication mechanisms. All are addressable, but require resources that may be tied up in responding to other COVID-19 related challenges on campus such as research lab reopening, responding to outbreaks on campus, or managing remote learning challenges.

Disease-based challenges describe those that follow from the evolution of our understanding of the disease and its transmission rates, threat of aerosolized spread, reinfection capabilities, and the development of one or more vaccine candidates. As the science provides more information, the surveillance testing strategies and approaches must adapt.

Policy-based challenges to surveillance learning networks include both government and institutional policies. The decision to leave resource allocation, testing plans, and reopening criteria to states rather than setting federal policies means that institutions in different states may be subject to different expectations, infection rates, and access to resources.

Proposed mitigation strategies to address the potential risks and challenges

Building a network of institutional knowledge and infrastructure will require some level of central coordination. Currently, sampling, modeling, and other surveillance testing elements are either not being shared publicly or are difficult to locate and compare. We can enhance and better disseminate these approaches by first identifying the evaluation metrics which would be most useful to establish which of them can be most readily scaled and replicated. Particularly effective and efficient methods could then be readily available to other institutions in order to expand the surveillance networks. Most critically, any such effort should leverage existing efforts, collaborations, and partnerships and not seek to create a surveillance testing network from the ground up using a new of single strategy for all institutions. A federal-academic partnership could both enhance the existing approaches and frameworks as well as scale up the testing capacity, using the lessons and intellectual resources from the academic community that is innovating to keep their campuses and communities safe.

The association appreciates the NIH's engagement with the academic community on approaches to COVID-19 surveillance testing.

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The feasibility of carrying out such university-based network activities at scale

The college created a Coronavirus Task Force to monitor the situation, with subgroups focused on Infrastructure; Testing, Tracking, Tracing; Academics; and Student Experience. Each group monitored guidance provided by CDC and the state, while collaborating with college departments to develop readiness and response plans; and communicated updates to the campus.

The resources needed to jointly develop robust surveillance testing capabilities for students, faculty, and staff, et. al. (e.g., other institutions in communities)

Campus 1: All faculty, staff and students returning to the campus by personal vehicle from less than 300 miles from campus are required to have a COVID-19 diagnostic test between August 12 and August 26. We are requiring this testing be done no more than two weeks before students return to campus to ensure we are starting the semester with a "clean slate." Everyone will be required to provide documentation of their test result.

State residents are encouraged to get their free COVID-19 diagnostic testing done at one of the state testing centers. To get a testing appointment, a quick assessment must be completed. Residents are called within 24-48 hours to set up an appointment, and test results are provided in 2-5 days. People may also contact their primary care provider to get tested, though insurance may not cover the cost of the test.

Students returning to campus using public transportation, from other countries, or from areas on the travel advisory must be tested within 24 hours of arrival on campus, quarantine for 7 days, and get retested on day 7.

On our Campus 1, we will have free point of care testing for anyone who is symptomatic or considered at risk to exposure. The testing site is in a building carport. Test results will be available within 45 minutes. If someone tests positive, we will immediately follow an isolation protocol. There are quarantine and isolation rooms designated on campus.

Testing is provided Monday through Friday from 8:00 am to 4:00 pm. The testing center is staffed by faculty and staff from the related college departments. The tests are administered with the SOFIA device.

Campus 2: All faculty, staff and students returning to our Campus 2 are required to have an on-campus COVID-19 diagnostic test between August 28 and August 30. All faculty, staff and students will be tested on the campus and documentation will be collected through the on-campus testing process.

Students returning to the campus using public transportation (i.e., train, plane), from states on the state's list of states with quarantine restrictions, must follow all state Department of Health quarantine guidelines.

Infrastructure and Air Quality

To help us evaluate the HVAC systems in our diverse infrastructure, we worked with two expert firms, our occupational health, safety, and environmental consultants. Over the past couple months, representatives from both firms have evaluated our campus spaces.

Daily Health Assessment

Everyone is required to complete a brief daily health assessment before coming to campus. This survey is sent via text message. Answers to this assessment determine if the individual needs to schedule a test on campus.

Face Coverings and Social Distancing Required
Face coverings are required by anyone on campus in any area other than personal dorm room or office. Additionally, social distancing is properly marked and enforced in shared areas on campus.

Novel network approaches to efficiently manage testing capacity among institutions and collaborate with other university-based networks
Building upon our campus' expertise in healthcare and in conjunction with the state Executive Order signed by the Governor authorizing pharmacists to administer CLIA-waived point-of-care diagnostic COVID-19 testing, our campus is serving as a testing site for four other college campuses in our central vicinity. The college's CLIA-waived Limited Service laboratory is the central testing location for other local colleges to rapid testing students and employees from each of the closely located campuses. The college is a uniquely situated health sciences school with both clinical laboratory scientists, public health scientists, experts in infectious diseases, and pharmacists and had already established a Limited Service Laboratory based in the the area. Due to the Governor's Executive Order authorizing pharmacists to administer CLIA-waived point-of-care diagnostic COVID-19 testing, this has allowed our Pharmacist to serve as the Medical Director of our Limited Service Laboratory on campus providing point-of-care diagnostic testing services to our five campus collaboration.

The point-of-care testing is utilized for students arriving from areas with travel advisories, or who arrived using public transportation or traveled over 300 miles, or who need test results to begin clinical rotations. After this initial round of diagnostic testing, point-of-care testing will be utilized for students and employees who are symptomatic or who are a close contact of a known positive case. The turnaround time is less than an hour for each test. The campuses are affiliated with a Memorandum of Understanding clearly delineating the responsibilities of each campus. The college functions as the specimen collection and testing center and lab and expenses are shared between the colleges for PPE (personal protective equipment), testing cartridges and materials, and staff time for operationalizing the lab. Given the limitations of point of care testing, we have also contracted with an outside lab completing a PCR test for COVID-19. The college is responsible for doing the saliva specimen collection and sends out the samples with an average turnaround time of 24-36 hours. All symptomatic patients, who receive a negative result with point-of-care testing, will also have the PCR test completed. Additionally, protocols have been established for small scale campus sweeps of COVID-19 testing, if there are cases on our campuses throughout the fall semester. Given the scale of these, they would be conducted in partnership with our outsourced lab for expediency. The college also has an out-of-state campus and collaborated with a medical center to provide on campus testing to our students and employees during the first weekend of classes. This partnership will allow for a campus sweep if that is necessary during the semester as well. This partnership also entails a clinically trained pharmacist as the provider ordering tests and counseling patients, due to a state Executive Order. The partnership with the medical center allows for a turnaround time of 24-48 hours for most samples collected at the the college's main campus.

The types and frequency of testing including the technologies and approaches that could be utilized
Utilizing our state approved, CLIA-waived Limited Service Laboratory (LSL) we are conducting campus screening by employing multiple testing methodologies; viral antigen detection assays using a point-of-care (POC) testing system and nucleic acid amplification techniques completed offsite at a contracted laboratory. Our campus community, including all employees and students are required to complete a COVID nucleic acid test before arrival to campus, ensuring campus will be free from infection to begin the academic year. Additionally, following state Travel Advisory and essential health care student

guidelines we are requesting individuals arriving from these states to complete an on-campus virus test, quarantine for seven days followed by a second virus assay. After completion of this quarantine period and upon receipt of two negative tests, only then individuals can join our campus community. Additional established policies tests students arriving to campus after travel that has included public transportation such as bus, train, or airplane. This on campus POC testing system provides flexibility to quickly screen individuals, ensuring campus safety. Lastly, if an increase in COVID case numbers are detected or if there is an occurrence that involved the potential for significant viral exposures, we can conduct a campus-wide specimen collection and testing event. Our offsite, contracted laboratory was chosen as they can assure COVID-19 SARS2 results within twenty-four hours of specimen arrival at the testing location.

Regarding our second campus location, we have established testing protocols to effectively screen all students and employees to begin the academic year. Working in conjunction with a local university medical center and a research nonprofit, a campus testing event has been established which will require all campus associated individuals to be tested potential infection.

To complete a daily assessment of campus health and potential testing needs we have contracted with a company specializing in the sharing of health data utilizing a Population Health platform. This platform provides daily health questionnaires for screening and data collection. Utilizing an easily interpretable dashboard system campus can easily track the results campus-wide, required daily assessments and the need for immediate COVID testing. This electronic health record has allowed us to automate data collection and consent for services, ultimately streamlining our COVID-19 monitoring on campus.

Overall, the processes that have been established allows for an accurate assessment of the campus population for possible COVID-19 infection.

The use of alternative evidence-based approaches to monitoring the level of COVID19 in the community (e.g., wastewater surveillance)

Currently the college and collaborating campuses are not testing for viral loads in wastewater or virus on inanimate objects associated with campus buildings; both considered experimental in the ability to assess potential campus exposures. However, we have developed and implemented procedures for identifying high-risk populations on campus and improving our screening and testing capacity over the summer in order to facilitate a return to campus this fall for any student who wanted to be on campus. Utilizing the latest scientific understanding of COVID-19, its' epidemiology, and infectious disease properties, our task force has developed protocols for seeking out high risk community members and improving protection for them to mitigate their risk. Our first strategy was to require all students, faculty, and staff to have a COVID-19 test and report the results to the campus prior to returning to campus buildings or moving into on campus residences. Next, we built upon the state mandated isolation and quarantine requirements for those traveling from restricted states, but also to include those traveling more than 300 miles to campus, traveling by airplane or mass transit. Thus, everyone who met this criterion was required to have an on campus COVID-19 test with the SOFIA2 before being allowed to move onto campus or attend classes. All students from the state's travel advisory states completed a rapid test, then quarantined for 7 days, and then had a second rapid test. Only if both tests were negative and the student complied with the quarantine restrictions could a student move into their planned dorm room and begin attending classes in person.

All students were given the opportunity to choose remote or in person learning for the fall semester and to adjust their decision during the semester. We also want to utilize our daily screening questions to help us monitor the health of our campus community. To do this we added several questions to the mandatory questions from the state to assess the prevalence of mask wearing and compliance with social distancing requirements. We hope to utilize this data to educate the campus community and improve adherence with designed protocols.

Finally, we are integrating students, at every level, to the procedures. We have student volunteers overseeing the specimen collection and testing center operations on campus. We are also working with about 15 public health third year students completing a service learning course to assist in 2 critical tasks. First utilizing internal and externally available data to analyze high risk populations on campus and to target educational campaigns and/or programming to those key groups. Another group of these students will work on educational messaging around face mask utilization, improving social distancing, and reminding people to stay home when sick with culturally relevant and timely health education campaigns executed by students for the student population on campus and to focus on mitigating risk.

Risks and challenges that might impact the successful establishment and operations of a learning university-based surveillance network

The goal of our collaborative partnership is to harness the unique skills and resources available to the college to assist our community, to be a good neighbor, and to reduce COVID-19 risk in our community, while ensuring students at all our colleges maintain access to in person education and the high quality experiences the students and employees have come to expect from our colleges. Importantly this allows for health professions focused students, who otherwise may have limited opportunities to obtain direct patient care experience to work in a real world setting on a timely topic and build expertise, while learning and training with seasoned professionals.

The clear first challenge is that we are in the midst of a global pandemic and the city and the region have experienced high rates of COVID-19 early in the pandemic. While we have managed to reduce infections and deaths, reintroducing thousands of young adults to our community for the local colleges will create new opportunities for the virus and challenges to risk reduction in our community.

Outside of the global spread of disease, academic partnerships face challenges in administration and management, given differing campus communities and cultures. In our case, we have slight variations in the policies across the campuses, unique student populations, and varying levels of enforcement in the campus policies and procedures.

Perhaps the largest challenge is the financial costs of this pandemic response. There are large financial commitments for PPE, testing, personnel, disinfectant materials, campus wide air handling assessments, and modifications of classrooms and office spaces to accommodate social distancing. Launching a limited service laboratory on campus has high associated costs including information technology to collect, aggregate, and maintain personal health information for each member of our community.

Proposed mitigation strategies to address the potential risks and challenges

All the policies presented here describe our good faith efforts towards mitigation of COVID-19 impact on our collaborative campuses. We can limit outside personnel costs due to our health science focus and access to a wide range of expertise. We were able to secure a point of care testing instrument and cartridges for testing on campus to reduce external lab costs. Finally, we outsourced our daily assessments of campus health and population assessments with the population health platform. This platform focuses on privacy and empowering campuses and students to bring our community back on campus this fall semester.

Response 25

The feasibility of carrying out such university-based network activities at scale

The university has developed a program to mitigate the spread of SAR-CoV-2 on its campus. The program is being implemented now for our entire campus with twice weekly testing of all students (~40k), faculty and staff (~15k). The approach could be adopted at other universities as well as more broadly. We are currently working with other universities, communities, and companies in the state and across the country to help them deploy the mitigation program for the good of those in their communities. In brief, the mitigation program involves masking, social distancing, hygiene, and frequent testing such that infectious individuals and their close contacts are isolated and quarantined so as to mitigate viral transmission.

As background, in March a team was formed and continues to evolve to develop a strategy for the mitigation of the spread of SARS-CoV-2. The team is implementing that strategy first at one campus and across the other two universities in the university system, then across the state and beyond. The team identified the suite of components necessary to achieve the goal of mitigating coronavirus spread such that the original campus could open and remain open. The team quickly began the implementation of these components. The effort has required the convergence of chemists, physicists, biologists, engineers, social scientists, medical and veterinary scientists, computer scientists, and data scientists, as well as deep collaboration with administrators at all levels, a wide range of university staff, community partners, regional medical hospitals, and local, regional, state, and federal government officials and agencies. The effort aligns perfectly with our land-grant mission. The mitigation program has three components: modeling to determining who to test and when, so we can identify and isolate those who are infectious, and communicating with individuals and health officials regarding results and actions to be taken.
The implementation of the mitigation program at one university campus requires the execution of every aspect of the comprehensive solution to virus spread – this is not just a testing program. Modeling was needed to understand the conditions related to the spread of this virus. While the most comprehensive deployment of the program in a new community would include a modeling component, many communities will fall under a particular archetype (e.g., a university, a company, a K-12 school, etc) and thus modeling-informed solutions applicable in one instance are likely transferable to other instances. E.g., twice weekly testing at a university with semi-porous boundaries will likely be applicable broadly to other semi-contained communities. The means to communicate test results to individuals and public health officials was implemented at the original campus and is being scaled across the state.

There is every indication that the mitigation program can be deployed widely; indeed, we are in the process of doing so in collaboration with universities, companies, and communities across the state and the US.

The resources needed to jointly develop robust surveillance testing capabilities for students, faculty, and staff, et. al. (e.g., other institutions in communities)

The university mitigation program is based upon three components. The first component is founded upon mechanistic and agent-based modeling that drives the determination of who to test and when. For the large semi-contained campus, models suggest twice weekly testing for everyone on campus to catch infections before they are further transmitted. The precise time of testing for each person is in part determined based upon their self-reported activities such as their schedule. The infrastructure necessary includes access to computing facilities to conduct the modeling and the expertise to model the circumstances that impact viral transmission. The testing of individuals requires sample collection sites, a laboratory to conduct the testing, and the data management infrastructure to follow the sample from collection to delivery of results to individuals and public health officials. The collections sites on the main campus include ~20 tents where up to ~20k people provide saliva samples each day. The laboratory facilities are staffed with 3 shifts/day with technical staff running samples using robotics and RT-qPCR systems. One component of the mitigation requires IT infrastructure so that results can be reported quickly to individuals and public health officials. That IT infrastructure is nontrivial to standup. On the main campus, results are reported to individuals via a smartphone based app where the results are transmitted in an encrypted fashion or to individuals at a website that can be accessed with the person's university netID and password. An important aspect of the mitigation program is information that is sent to individuals so they know what to do when they get their results. More broadly, the communications to faculty, staff, and students regarding the entire program is a robust and evolving program. For the entire program, a manual is being developed so others can be guided in the implementation of the mitigation program; the manual includes a list of supplies and equipment that are needed. The University has stood up two groups to deploy the mitigation program beyond the campuses. The state mitigation program is working with institutions, companies, and communities in the state to deploy the mitigation program across the state. We anticipate having ~10 testing sites across the state within a few months. Major equipment has been ordered, supply chains are being developed, labs are being identified, hiring is in process, and data management solutions being stood up. Conversations with companies and diverse communities are underway. We are particularly cognizant of the needs of underserved regions of our state. The next phase of the mitigation program is working to deploy the program beyond the borders of our state. The larger scope of the next phase requires solutions for a wide range of challenges. For both the state mitigation program and the next phase, supply chain issues, personnel issues, and the ability to provide service for each instance of the mitigation program in the time frame demanded by the pandemic is a challenge. Partnering with communities and businesses has proven helpful.

Novel network approaches to efficiently manage testing capacity among institutions and collaborate with other university-based networks

We are standing up the mitigation program on the main campus. Building a program that can process up to ~20k samples per day has provided us a template to scale the mitigation program. During the scale up, we also stood up testing at the other two universities in the system. Each is different. One has ~5k students and is in a community of ~175k people. It is collecting its own samples, then driving them ~1hr to labs containing the PCRs. The other is in a cit, population ~3M (~9.5M in the metro region). It collects its own samples and has a lab on campus at which tests are run. Both use university ID's and run their results via the same data management system that is used at the main campus. This method streamlines data management and speeds reporting of results.

We also partnered with another University (~700 students) in a rural county (population ~16.5k) to test the mitigation program under very different circumstances. The university is collecting its own saliva samples and delivering them to the main campus for testing. We stoodup a different data management system for the rural university so results could flow to individuals and health officials appropriately. One week into the semester, the process works well and positive returning students are being isolated and contacts quarantined at that university.

For the state mitigation program, we are collaborating closely with the public universities that are located around the state. Given the need for rapid turnaround to properly mitigate viral spread – our goal is ~6 hrs from saliva collection to test result — we need testing labs geographically dispersed across the state. We are partnering with sister public universities and geographically co-located companies outside the city. Within the city, we are building from our base at the campus hospital and medical centers; we are also in discussions with other potential partners.

To increase the efficiency of testing, we recognize the need to load-balance testing across the network of testing sites that we are developing. Further, to mitigate the challenges associated with data management, we are standing up an instance of an EMR within a HIPAA compliant environment to handle test results from any of our labs across the state. We expect the EMR system to be functional within a few weeks. We expect our first lab outside the university system to be started within a couple of weeks, and then validated and operational within six or so weeks. Our goal is to make each instance of the testing site as similar as possible. The EMR will be identical for all. Our goal is to work with community partners to have them standup collection sites according to a template. We are in close collaboration with the state Department of Public Health throughout this process so that rapid test results lead to quick action, i.e., isolation, contact tracing and quarantining.

The types and frequency of testing including the technologies and approaches that could be utilized

Sample Collection

A saliva-based test is used because it is noninvasive, thus individuals will agree to high frequency testing, and does not require trained personnel or special PPE during sample collection, thereby decreasing collection costs. All faculty, staff, and students on campus are required to test twice per week. Each person responds to a survey concerning typical activities and is assigned two days per week to provide a saliva sample. We have ~20 tents on campus, each with two lines for testing. Each individual scans their ID, answers several required questions, receives a bar-coded test tube, moves to an isolated area of the tent to dribble saliva in the tube, puts the tube in a plastic bag, seals the bag, deposits it, and leaves. The time from ID scan to departure is typically <90s. Everyone attests to being npo for 60 minutes prior to dribbling saliva. The ID scan links personal data with the sample. The samples are collected every hour and delivered to the testing lab.

Testing Laboratory

The saliva samples are received at the CLIA-approved lab, a converted veterinary diagnostic laboratory, where chain-of-custody checks regarding the samples are done. Each test tube is put in a rack and in a 95C water bath for 30 min; this process removes the need for reagents necessary for RNA isolation, thereby bypassing supply chain bottlenecks, and inactivates the virus, thereby mitigating infection risks to lab workers. Then a saliva aliquot is mixed with reagents (TaqPathCovidComboKit and TaqPath Multiplex 1 step MasterMix), and transferred into a 384 well plate for analysis in a Thermo Fisher QuantStudio RT-qPCR system. The results are analyzed and transferred into a folder that is securely sent to a HIPAA compliant electronic health record.

The test is FDA authorized for use in our CLIA lab based upon a bridging study that verified the assay being used is not inferior to the SalivaDirect process that recently received an FDA EUA (https://www.fda.gov/media/141194/download).

The use of alternative evidence-based approaches to monitoring the level of COVID19 in the community (e.g., wastewater surveillance)

At the university other, complementary approaches to mitigating the spread of SARS-CoV-2 are being investigated. For example, wastewater based epidemiology (WBE)—monitoring potential pathogens in sewers and waterways—provides a rapid and cost-effective means to monitor COVID-19 infections in dorms, cities, and regions. Sewers and treatment plants collect wastewater from entire urban regions and provide a means to monitor COVID-19 across large geographic areas. Waste water can also be collected more locally, e.g. at individual dorms, allowing determination of coronavirus at these locations. Because SARS-CoV-2 RNA is excreted by pre- and asymptomatic individuals, WBE provides advance warning and more complete assessments of the COVID-19 epidemic than traditional testing. We have initiated collaboration between the city health and water management departments and research institutions, each contributing complementary and unique resources. In this partnership, we will develop and demonstrate city-scale COVID-19 wastewater surveillance, and facilitate regional and national exchange of surveillance methods. The goal is to increase the precision of tracking SARS-CoV-2 and assessing its geographic distribution within a region thereby allowed more targeted testing of individuals suspected of carrying the virus.

Risks and challenges that might impact the successful establishment and operations of a learning university-based surveillance network

Based on the extensive momentum we have already generated, we feel confident that the individual components of the mitigation program platform, the three components, will each be able to achieve their individual goals. Indeed, over the past three months we have effectively stood-up the implementation of the mitigation on the main campus. We expect scale up on university campuses elsewhere will be challenging, but do-able. Standing up the mitigation program at companies, K-12 schools, rural communities, and in urban environments will be a significant challenge. For example, we need to develop a model for an urban neighborhood whose residents commute daily by public transportation, living in high density environments with others similarly exposed to the virus regularly. Thus, the biggest risk we face to making this solution available in a scalable way.

We plan to manage these risks by performing a series of increasingly large and complex pilot studies over the next few months with specific subsets of our communities across the state. We expect to uncover the challenges inherent in such integration and have ample opportunities to learn how to overcome these challenges. A second risk that we face is not getting sufficient voluntary participation from community members, and thus missing the chance to be maximally effective. This could be due to a lack of trust. To mitigate this risk we plan to pursue a privacy-first and fully transparent approach, communicate effectively and often, listen and learn from our pilot study participants, and constantly evolve our approach based on continuing feedback from our community. We also plan to partner closely with community members in the implementation of the mitigation program in their community.

Response 26

The feasibility of carrying out such university-based network activities at scale

For the purposes of this response, surveillance is assumed to use rapid, population-level testing to quickly identify asymptomatic or infected individuals early in disease presentation, isolate them and stop the chain of transmission. Surveillance of the population can be thought of as a routine screen necessary to identify resurgence of the virus in infected individuals and to halt localized outbreaks. Surveillance testing is deployed in concert with clinical testing using an FDA EUA method in a CLIA certified laboratory. In order for university-based networks to function at scale, universities need clear and consistent guidance on using surveillance positives in decision-making structures. Initial requirements articulating the need for CLIA certification of labs providing surveillance testing significantly slowed our ability to respond and build capacity. This guidance should also make recommendations upon the allocation and spending of federal funding to the state for building a surveillance capability. State institutions are seeing hiring freezes that limit the ability to recruit in the needed workforce to establish coordinated surveillance capacity (often requires numerous FTE). Many university research programs are not readily equipped to handing the logistics of thousands of samples and often lack the data collection and results reporting infrastructure required to implement a surveillance capacity. Best practices for decision-making frameworks that articulate how positive results are reported, integrated into the testing paradigms, coordinated with local public health and clinical systems would make a network more likely to succeed.

The resources needed to jointly develop robust surveillance testing capabilities for students, faculty, and staff, et. al. (e.g., other institutions in communities)

Processing thousands of samples per day requires resource investment, including staff to provide the capacity, equipment, reagents, data handling, as well as the fundamental capacity building support for assay development and validation. Research institutions are not necessarily equipped for routine, rapid, large-scale, high-throughput assay implementation. Equipment resources (liquid handling, RT qPCR, plate readers, etc.) reallocated from research programs to support the building of diagnostic testing capacity will eventually need to be returned to complete other federally funded, non-COVID-19 research projects. The University houses the expertise to rapidly pivot to support surveillance capacity building including existing CLIA laboratories, BSL3 laboratories and highly trained research faculty. However, pivoting from a research mission to building a surveillance capacity requires confidence in decision-making frameworks, epidemiological models to guide routine and targeting testing strategies, and confidence when handling IRB issues. This poses challenges in the transition from research to an institutional decision-making framework. Informed and experienced leadership is required to effectively make this transition with confidence. Leadership at the state and institution level can be empowered through coordinated national guidance and best practices implemented through federal funding agencies such as NIH, CDC, HHS, and FDA.

Novel network approaches to efficiently manage testing capacity among institutions and collaborate with other university-based networks

Development of a network to share data, assays, protocols, best practices, lessons-learned, resource allocation strategies, testing strategies and decision-making frameworks would be highly beneficial for institutional support of surveillance capacity development. Widespread distribution of the information through a coordinated network would be beneficial to institutions of all sizes. Equitable information distribution mechanisms are strongly recommended so institution size, historical resource allocation, grant success and current funding support does not preclude an institution from receiving data and information. Coordinating protocols and assays also provides an opportunity to standardize and compare capabilities nationally and build confidence in the data repository that can be developed through a network. Also needed are standardized apps for rapid detection of symptoms as well as contact tracing in order to sustain coordinated surveillance.

The types and frequency of testing including the technologies and approaches that could be utilized

We have already optimized EUA assays for routine testing and diagnostics, wastewater surveillance of the city and neighboring communities, a testing service agreement with the State for overflow samples (infrastructure for qPCR), RT-LAMP capabilities, and epidemiology modeling. We have demonstrated the use of pooled sampling in order to create capacity scale-up if required.

The use of alternative evidence-based approaches to monitoring the level of COVID19 in the community (e.g., wastewater surveillance)

Research faculty have instituted wastewater monitoring capabilities in the community and wastewater streams leaving from campus buildings. We have developed a rapid LAMP-based assay for increased surveillance testing capacity with the intent to send positives from the screen for CLIA testing. We are also performing pilot studies with detection dogs in order to investigate whether trained dogs can be used to identify breath samples from SARS-CoV-2 infected subjects. Groups at other institutions have successfully trained detection dogs on a variety of sample types from COVID-19 patients, including sweat samples, which could be useful for screening of large crowds at sporting events or other large gatherings.

Risks and challenges that might impact the successful establishment and operations of a learning university-based surveillance network

Many of the challenges have already been described. Logistics, lab space and equipment, personnel, funding, reporting/privacy/legal around data are all critical to implementing a successful surveillance capacity.

Proposed mitigation strategies to address the potential risks and challenges

Institutions are outsourcing some of the testing to companies and in turn can take advantage of the platform and app development by these companies. Some institutions have developed their own app that displays recent test results and allows entry into buildings. Coordination or transfer of apps, protocols, assays and data integration will aid other universities. The data generated from these protocols and reduced risks associated with assay performance challenges, compliance, data integration, modeling constraints or limitations can be mitigated with a coordinated effort.

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