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August 26, 2020

National Institutes of Health
9000 Rockville Pike
Bethesda, Maryland 20892

Re: Request for Information- Inviting Comments and Suggestions on University-Based Approaches for COVID-19 Surveillance Testing to Review the Current Landscape (NOT-OD-20-162)

The Association of American Medical Colleges (AAMC) appreciates the opportunity to comment to the National Institutes of Health (NIH) on current and potential COVID-19 surveillance testing capabilities at universities. The AAMC is a not-for-profit association dedicated to transforming health care through medical education, patient care, medical research, and community collaborations. Its members are all 155 accredited U.S. and 17 accredited Canadian medical schools; more than 400 teaching hospitals and health systems, including Department of Veterans Affairs medical centers; and more than 70 academic societies. Through these institutions and organizations, the AAMC leads and serves America's medical schools and teaching hospitals and their more than 179,000 full-time faculty members, 92,000 medical students, 115,000 resident physicians, and 60,000 graduate students and postdoctoral researchers in the biomedical sciences.

The AAMC is pleased to offer comments on the considerations for COVID-19 surveillance testing networks across academic institutions:

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 (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

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 to rapidly learn from protocols, approaches, and challenges to optimize operations

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 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 AAMC 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.

The risks and challenges that might impact the successful establishment and operations of a learning network such as that described above

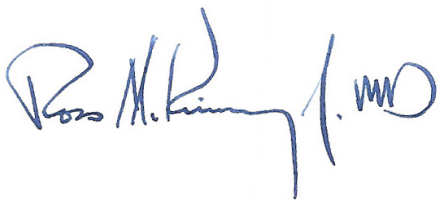
The challenges associated with large scale networks can be categorized as technological, disease-based, or policy based. Technological challenges that have been addressed herein include resources, space, available infrastructure, and communication mechanisms. All are addressable, but require

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 AAMC appreciates the NIH's engagement with the academic community on approaches to COVID-19 surveillance testing. Please feel free to contact me or my colleagues Anurupa Dev, PhD, Lead Specialist for Science Policy (adev@aamc.org) and Heather Pierce, Senior Director for Science Policy and Regulatory Counsel (hpierce@aamc.org), with any questions about these comments.

Sincerely,



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