A Surveillance Testing Protocol for Safely Re-opening Schools During the COVID-19 Pandemic

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Abstract

Schools and universities around the world are facing a daunting challenge as they attempt to re-open their campuses while protecting the health of students and faculty during the COVID-19 pandemic. Confusion persists over how to control the SARS-CoV-2 virus. This article describes three methods of testing for SARS-CoV-2, along with the benefits and drawbacks of each method. Several K-12 schools, colleges, and universities are moving away from *diagnostic* testing to *surveillance* testing of students and personnel. The advantages of surveillance testing are described. For the fall semester, 2020, the American School of Warsaw (ASW) has implemented a layered protocol that includes weekly (and sometimes twice-weekly) surveillance testing. The testing protocol is described along with the procedure ASW follows when responding to positive cases. ASW hired a health care advisory company to provide oversight of the testing protocol. Lessons learned and future challenges are described.

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Background

Over the summer of 2020, a group of faculty members and students from the California Institute of Technology and elsewhere analyzed reopening plans from about 500 colleges and universities. They reported on 11 August 2020 that 27 percent of schools were planning to test undergraduates as they enter the campus. About 20 percent planned "to test their communities regularly to some extent." The vast majority, in other words, did not. [4]

Lior Pachter, a professor of computational biology at Caltech who participated in the analysis, called those findings "very troubling." He said the data suggested many colleges were clinging to "an unrealistic belief, a kind of fiction, that people would come back to campus and not get sick."

In late June, the Centers for Disease Control and Prevention said it did not recommend that colleges test all students, faculty, and staff for the virus upon entry to campus because there were no systematic studies to show the effectiveness of that policy. However, the CDC added that colleges in areas with "moderate to substantial community transmission" of the virus might consider testing some or all asymptomatic students to identify outbreaks.

Oberlin College recently announced its reopening plans and weekly testing using a pooled sampling approach as one of the key measures taken to ensure safety in the College. Similar measures are being introduced by Syracuse University, which recently announced pooled testing will be used to regularly test all its 20,000 students.

The Massachusetts Institute of Technology (MIT) also announced that all students, faculty, and staff will be tested when they arrive on campus. MIT will also be conducting frequent testing and screening. Community members will have to file a daily health attestation to help identify those who may have COVID-19 symptoms. Wearing masks on campus will continue to be a requirement. Compliance with these protocols will be a critical part of campus life.

The Broad Institute has launched a screening program for universities and colleges in Massachusetts. It was developed for institutions in Massachusetts and surrounding regions, including the rest of New England and eastern New York state, with support from the Association of Independent Colleges and Universities in Massachusetts. In the fall of 2020, Broad is providing COVID-19 screening support for more than 100 public and private colleges and universities. The program supports these institutions of higher education, while allowing Broad to continue to serve critical public health needs in the Commonwealth of Massachusetts, especially for at-risk communities. Participating colleges and universities, working with their healthcare providers, determine who is eligible to be tested (students, faculty, and/or staff, with physician approval) and how often (twice weekly, weekly, or once every two weeks).

The University of Illinois at Urbana Champaign (UIUC) has been touted as a role model with respect to testing - they developed their own test kit based on saliva samples and set out to test all students and staff twice a week. Hundreds of employees were redeployed to labs and testing centers as UIUC started performing from ten to fifteen thousand tests per day - or 2% of all United States tests. Their testing program is discussed at the end of this article.

In early September 2020, the University of Cambridge announced it will offer all students living in college accommodations a weekly test for infection with SARS-CoV-2 even if they show no symptoms. While the testing of asymptomatic students is not national guidance, the university will be launching this program as part of their 'Stay Safe Cambridge Uni' public health initiative. Harvard University, Babson College, Emerson College, Clark University, Stanford University, and the

[4] Booeshaghi, A. S., Tan, F. H., Renton, B., Berger, Z., & Pachter, L. (2020). Markedly heterogeneous COVID-19 testing plans among US colleges and universities. medRxiv, 1–7. http://doi.org/10.1101/2020.08.09.20171223

University of Maryland also have implemented a surveillance testing protocol.

Children and COVID-19

There has been an ongoing debate about whether children are or are not infectious to others. Early evidence from New South Wales in Australia pointed to limited child-child or even child-adult transmission. However, more recent evidence points to children as potentially being important transmission vectors of SARS-CoV-2 infection. The U.S. Centers for Disease Control and Prevention in Atlanta, Georgia, investigated outbreaks at three childcare centers in Salt Lake County, Utah.[5] At all three centers, the first identified case was a staff member. Two had gone to work even though a person in their household had shown COVID-19 symptoms. Twelve children infected with the new coronavirus at the centers passed the virus on to at least twelve other people according to an analysis. All 12 infected children, ages 8 months to 10 years, had either mild or no symptoms. Among the resulting cases was a woman who was hospitalized after presumptive infection by her child. Among the children's close contacts who tested positive were six mothers and three siblings: one eight-month-old baby infected both parents. Not all close contacts were tested, meaning that infections associated with the childcare centers might have been missed, the authors say.

A study from Ann & Robert H. Lurie Children's Hospital of Chicago discovered that children younger than 5 years with mild to moderate COVID-19 have much higher levels of genetic material for the virus in the nose compared to older children and adults. Findings, published in JAMA Pediatrics, point to the possibility that the youngest children transmit the virus as much as other age groups.[6] The ability of younger children to spread COVID-19 may have been under-recognized given the rapid and sustained closure of schools and daycare during the pandemic.

COVID-19 tests

There are three types of tests currently used in the diagnosis and screening for infectious diseases, including SARS-CoV-2:

- Antibody tests
- Antigen tests
- Nucleic Acid Tests - PCR and LAMP Genetic/molecular tests

Antibody Tests are an indirect test of viral infection as they detect — qualitatively or quantitatively — the presence or concentration of antibodies against a given virus (or to be precise, against a given part of the outer protein shell of the virus) in our blood (or serum, to be precise — serum is the liquid part of the blood, so everything other than red blood cells — hence another name for antibody tests are "serology tests"). Antibodies are part of the body's natural defense mechanism — the humoral defense system. Our body (or to be precise the B Lymphocytes) produce specific antibodies to this given protein (also known as "antigen").

Antibody tests could potentially be useful in determining whether an individual had exposure to SARS-CoV-2 although their relatively poor specificity (false negatives) limits their widespread use. There are

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[5] Lopez AS, Hill M, Antezano J, et al. Transmission Dynamics of COVID-19 Outbreaks Associated with Child Care Facilities — Salt Lake City, Utah, April–July 2020. MMWR Morb Mortal Wkly Rep 2020;69:1319–1323. DOI: http://dx.doi.org/10.15585/mmwr.mm6937e3external icon

[6] Heald-Sargent T, Muller WJ, Zheng X, Rippe J, Patel AB, Kociolek LK. Age-Related Differences in Nasopharyngeal Severe Acute Respiratory Syndrome Coronavirus 2 (SARS-CoV-2) Levels in Patients with Mild to Moderate Coronavirus Disease 2019 (COVID-19). *JAMA Pediatr.* 2020;174(9):902–903. doi:10.1001/jamapediatrics.2020.3651

various methods for determining the presence of antibodies — ranging from rapid diagnostic tests from a finger prick to laboratory tests of venous blood.

Antigen tests are tests that detect the presence of viral protein (again, also known as “antigen”) in upper respiratory tract mucosa. These tests are done using swabs taken from the nose or throat. They can be performed in point of care (read “anywhere”) settings as they do not require lab equipment. They are mainly used in screening. They have a relatively high sensitivity at over 95% and essentially a 100% specificity (i.e., false negatives). Their limits of detection vary and are usually smaller than Nucleic Acid Tests. There are only a handful of manufacturers producing antigen tests as the technology is more challenging and expensive in terms of R&D and manufacturing. But, once developed, the scaling up and production are relatively simple, and costs decline with full production. In addition, the point-of-care setting requires no lab resources or sophisticated lab equipment.

Nucleic Acid Tests are laboratory tests that detect the presence of viral genetic material (in the case of SARS-CoV-2 — RNA) in the mucosal secretions of the upper respiratory tract. They are done on material taken from the nose or throat. There are two types of tests most often used — RT-PCR and RT-LAMP. These are lab-based tests and require trained personnel, sophisticated and expensive equipment, and time for results (which varies). Their limits of detection vary widely between 100 and 100,000 copies/ml. There are hundreds of manufacturers of test kits, and many labs make their own test kits from commercially available reagents (which are quite inexpensive). However, the actual testing requires trained personnel, sophisticated lab equipment, and infrastructure as well as time - all of which make the testing relatively more expensive.

Table 1, adapted from the CDC, provides a simple yet powerful overview of the key differences between nucleic acid tests and antigen tests.

	RT-PCR Tests	**Antigen Tests**
Intended Use	Detects current infection	Detects current infection
Analyte Detected	Viral RNA	Viral antigens
Specimen Type(s)	Nasal swab, sputum, saliva	Nasal swab
Sensitivity (% truly positive)	High	Moderate
Specificity (% truly negative)	High	High
Test Complexity	Varies	Relatively easy to use
Authorized for Use at Point-of-Care	Most devices are not, some are	Yes
Turnaround Time	From 15 minutes to >2 days	About 15 minutes
Cost/Test	Moderate	Low

Table 1. Differences between RT-PCR tests and antigen tests

Testing Strategies

Tests are just tools. It is more important to understand how these tools can be used in a strategy and how different strategies have different protocols and outcomes.

Clinical diagnostic testing is the current approach to control COVID-19. It uses the most sensitive and labor/resource-intensive methodology, the lab-based Polymerase Chain Reaction (PCR) test, to diagnose symptomatic individuals. The PCR test was invented in 1983 and is a time-tested method. This is accompanied by contact tracing — a very imprecise tool and clearly reactive. Based on various estimations, this approach identifies <5% of infected individuals. This low percentage is

understandable because:

- Tests are done at a single point in time
- Only a few people are tested (some symptomatic individuals and some contacts)
- Results can come days later, depending on transport to laboratories, the backlog in processing, and false-positive rates, especially in the recovery phase where the PCR is positive, but the person is no longer infectious).

A 24 July 2020 preprint underscored the downsides of slow tests. Shixiong Hu, a researcher with the Hunan Provincial Center for Disease Control and Prevention, and his colleagues followed 1178 people who tested positive for SARS-CoV-2 from January to April and tested their 15,648 contacts, defined as people who had been within 1 meter of a positive person between 2 days before and 14 days after the person's symptoms began. The researchers estimated that people were most likely to spread the virus 1.8 days before the onset of symptoms. The finding suggests that testing people only when they show symptoms and giving them test results days later does little to slow the viral spread.[7]

Diagnostics experts, public health officials, and epidemiologists are calling for a radical shift in testing strategy away from diagnostic testing of those who have symptoms or were exposed to surveillance **screening of whole populations** using faster, cheaper, sometimes slightly less accurate tests. By making it possible to identify and isolate infected individuals more quickly, proponents say, the shift would slow the spread of the virus, which is the key to safely reopening schools, factories, and offices.

An analogy to this shift is blood glucose testing in patients with pre-diabetes and diabetes. Before home glucometers were available, individuals with diabetes were managed poorly because their blood glucose was only tested every few months using HbA1c as a proxy.[8] Then, home glucometers started appearing and despite their inaccuracy (+/- 15% of a lab test), they became the gold standard because tests could be done frequently with immediate results, thus allowing for quick decision making.

Asymptomatic Screening

When the COVID-19 pandemic started, the FDA and many other regulatory agencies around the world approved tests for diagnostic purposes - i.e., to test symptomatic individuals. This was the priority in the test and trace strategies that were deployed by countries in the immediate aftermath of the dramatic events in China, Italy and Spain. Decisions about testing asymptomatic individuals could be taken by healthcare professionals depending on their specific situations.

This is a typical situation in medicine because science usually is faster than regulatory processes. Physicians using available scientific evidence may order tests (or prescribe medicines) in other uses than those specified in the manufacturer's leaflet. The regulatory protocol for approving tests for diagnostic purposes used by the FDA in the Emergency Use Authorization involves using the test in 30 confirmed positive individuals and 30 confirmed negative individuals and comparing the results obtained by the specific test with actuals. If the alignment is 95%, it is considered adequate by the

[7] Hu, S., Wang, W., Wang, Y., Litvinova, M., Luo, K., Ren, L., et al. (2020). Infectivity, susceptibility, and risk factors associated with SARS-CoV-2 transmission under intensive contact tracing in Hunan, China. medRxiv, 2020.07.23.20160317.

[8] The HbA1c test measures what percentage of hemoglobin in red blood cells is coated with sugar. Three months is the average lifespan of a red blood cell. That percentage can change only when new red blood cells appear. As the A1c percentage increases, one's risk of diabetes increases.

FDA in late June, the FDA issued guidelines for test developers who wished to receive specific approval for their tests to be used broadly for asymptomatic screening. In this protocol, a post-authorization test can be performed using 20 confirmed positive samples and 100 confirmed negative samples and confirming the test results with a known method. Again, a 95% alignment is considered adequate.

There is also significant experience that has come from other pandemics — the HIV pandemic is a good case example. It is quite like COVID-19 in that most people in the early stages of the HIV disease do not have AIDS. After decades of experience with HIV, a consensus protocol is screening at-risk communities with an inexpensive, quick, point-of-care antigen test.

A recent population-level effort in Slovakia points to weekly asymptomatic screening on a population level as being an important factor in significantly reducing infection rates. Over the course of three weekends in November, Slovakia performed over 5 million rapid antigen tests, effectively testing over 60% of its population three times. As a result, the number of infections in the third round of testing was reduced by 82% vs first round of testing.[9]

Rapid Antigen Tests in Asymptomatic Screening

Experts are now touting antigen tests as the future of surveillance testing. They are fast, point-of-care, relatively inexpensive, relatively sensitive, and can give results in 20 minutes. What does "relatively sensitive" mean? In broad terms, it means sensitive enough to detect persons who are about to be or who are infectious and not sensitive enough to detect those who are only infected but not infectious or who are no longer infectious. What does that mean exactly?

Not everyone who is infected is infectious. One needs to have a certain concentration of the virus in their upper respiratory tract mucosa to start shedding and become infectious. At the beginning of the infection, this viral concentration increases rapidly and then falls as the infection wanes and levels off (sometimes for months after recovery). Based on various studies, the level at which an infected person becomes infectious is when the virus reaches a concentration of between 100,000 and 1,000,000 copies per milliliter of blood. Hence to be effective in diagnosing the infected/infectious, we need a test with at least this Limit of Detection (LoD) — 10^5–10^6 copies/ml. Going below would not make a difference in reducing transmission because those individuals are not yet or no longer infectious.

This is supported by the Hunan Province study, in which increasing test sensitivity by 100 times (from LoD 10^5 to 10^3 copies/ml) had little to no impact (5–10%) on reducing transmission, whereas weekly testing reduced transmission by 3 to 4-fold vs a single-test and isolation strategy. Increasing frequency from weekly to every three days reduced transmission by a further 60–70%. Interestingly, increasing testing frequency from every three days to everyday had only a marginal impact. These concepts are explained in layman terms in an article by Powell (2020)[10] and in more scientific detail in the article from Larremore, et al (2020).[11]

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[9] Pavelka M et al. The effectiveness of population-wide, rapid antigen test-based screening in reducing SARS-CoV-2 infection prevalence in Slovakia. Retrieved on December 3, https://cmmid.github.io/topics/covid19/reports/Slovak_full.pdf

[10] Powell, A. (2020, September 02). Cheap, frequent COVID tests could be 'akin to vaccine,' professor says. Retrieved November 21, 2020, from https://news.harvard.edu/gazette/story/2020/08/cheap-daily-covid-tests-could-be-akin-to-vaccine/

[11] Larremore, D., Wilder, B., Lester, E., Shehata, S., Burke, J., Hay, J., Tambe, M., Mina, M., Parker, R. (2020). Test sensitivity is secondary to frequency and turnaround time for COVID-19 surveillance medRxiv : the preprint server for health sciences https://dx.doi.org/10.1101/2020.06.22.20136309

In early September 2020, the CDC issued specific guidance on using rapid antigen tests for SARS-CoV-2. One of the key areas in this guidance related to screening and surveillance testing. The guidance states that...

> *When used for screening testing, test results for SARS-CoV-2 should be considered presumptive. Confirmatory nucleic acid testing following a positive antigen test may not be necessary when the pretest probability is high, especially if the person is symptomatic or has a known exposure. When the pretest probability is low, those persons who receive a positive antigen test should isolate until they can be confirmed by RT-PCR.*

Confirmatory nucleic acid testing following a negative antigen test used for screening testing may not be necessary if the pretest probability is low, the person is asymptomatic, or has no known exposures, or is part of a cohort that will receive rapid antigen tests on a recurring basis. Nucleic acid testing is also considered presumptive when screening asymptomatic persons, the potential benefits of confirmatory testing should be carefully considered in the context of a person's clinical presentation**.** Additionally, the FDA in its guidelines provided similar recommendations clearly stating that it is not necessary to perform confirmatory high-sensitivity molecular tests on individuals with negative antigen tests or other point-of-care test results if they are obtained during routine screening or surveillance. In the same month, Polish medical experts expressed similar opinions that the availability of rapid antigen tests in Poland would be a breakthrough in the management of the pandemic.

Barriers in Using Antigen Testing

One might ask why antigen tests are not used more broadly. Among the hurdles facing widespread, repeat screening is the scarcity of such tests. Quidel and Becton Dickinson - two of the manufacturers of rapid antigen tests - together manufacture about 3 million antigen tests per week. A national screening strategy would likely require 25 million tests or more, says Jonathan Quick, who heads pandemic response for the Rockefeller Foundation.

Quick says companies are reluctant to ramp up production dramatically if they are unsure of the market for the products. One solution, he adds, could be a promise by the U.S. federal government to buy tens of millions of tests, much as it has done with vaccine doses. In one such effort, the governors of six U.S. states announced in September 2020 they are banding together to ask Quidel and BD for a total of 3 million antigen tests.[12]

Pooled Testing Protocol

One of the main issues facing surveillance testing is the large populations involved and the effective utilization of available resources. Using the proposals from multiple colleges noted above as a guide and through work regarding pooled testing, the primary methodology of the overall approach includes a validated 5:1 sampling protocol using the chosen antigen test. Whenever a test is identified as positive under this protocol, the 5 members of the pool are then tested individually to identify the infected individual. Pooled testing has been utilized for screening of large populations since the military used this protocol for screening under the syphilis outbreak of the 1940's.[13]

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[12] Weixel, N. (2020, August 05). 6 states band together to secure rapid COVID testing. Retrieved November 21, 2020, from https://thehill.com/policy/healthcare/510552-six-states-band-together-to-secure-rapid-covid-testing

[13] Mandavilli, A. (2020, July 01). Federal Officials Turn to a New Testing Strategy as Infections Surge. Retrieved November 21, 2020, from https://www.nytimes.com/2020/07/01/health/coronavirus-pooled-testing.html

ASW Protocols in Practice

Choosing Protocols

ASW reviewed literature and mitigation protocols being developed around the world in their plans for opening school in August 2020 after 15 weeks in virtual instruction between March and June of 2020. Diagnostic testing was considered as part of this opening plan, but dialog with local test providers found they were still, at that time, expensive and time lags continued to frustrate consideration of how results could guide decisions as these were still largely PCR based and laboratory evaluated. Turnaround time for results in late May was still 6 hours given transport and expedited lab time. No discussion of pooling strategies was suggested at that time.

As government requirements slowly relaxed, we reviewed corporate and adult setting mitigation for groups that were starting to consider opening. ASW initially found EpiXpert through this review as the only local company working in the corporate environment to provide both facility and policy audits and plans for safe opening. ASW contracted with EpiXpert for this comprehensive audit in June 2020. As part of that overall discussion, EpiXpert recommended surveillance screening was part of a comprehensive set of facility and policy recommendations. ASW used these recommendations in two Requests for Proposal that yielded 15 bids for testing and data management relative to the recommendations. EpiXpert was the winning bidder and their offer included population surveillance testing, data management, and ongoing consulting in a comprehensive proposal.

The weekly surveillance testing protocol has been based on all the above premises. EpiXpert is using antigen tests that have a Limit of Detection under the threshold considered as infectious. Their sensitivity and specificity are remarkably high at 96,5% and 99,7%. Such an alignment is well above the minimum threshold considered by the FDA as adequate for Emergency Use Authorization

We settled on a weekly testing protocol based on discussions and consensus from institutions using this approach. We also built into the protocol an increased frequency of testing after a positive case — to twice per week in a defined cohort in which the positive case was identified and for a defined period (or until no positive cases were detected) and settled on a pooled protocol utilizing a 5:1 sampling approach as described above.

Pooled Testing

The FDA is the only regulatory agency that issued specific guidelines for test developers wishing to receive Emergency Use Authorization for asymptomatic screening. Based on the FDA protocol, EpiXpert validated the antigen tests in asymptomatic screening using pooled sampling. In July 2020, a sample of 900 asymptomatic individuals was tested using a pooled sampling approach. A total of 180 pools of 5 nasal swabs were tested. Of these, 19 pools and 21 individuals tested positive. There were 161 pools and 879 individuals who tested negative. A confirmatory PCR test was performed on the 21 individuals who tested positive - all these tests were confirmed positive by PCR for 100% alignment.

Swabbing Technique

In the first weeks after the COVID-19 outbreak, the prevailing consensus was to use nasopharyngeal swabs. This is often referred to as the “brain swab” because of the invasive nature of the depth of sample collection. This is uncomfortable for many individuals given the sensitive nature of the area involved. This location was based on initial evidence that the virus attacked the upper respiratory airways. All tests that were initially approved in the emergency authorization protocol used nasopharyngeal as the swabbing methodology and had been approved with that specific methodology. In the meantime, new evidence started emerging that showed the virus is present in

the entire upper respiratory tract. The FDA more recently approved four sites for swabbing: (1) nasopharyngeal, (2) oropharyngeal, (3) mid-turbinate, and (4) anterior nares.[14]

ASW chose anterior nares sample collection as the least invasive methodology for broad range of age levels. For small children with changing practitioners, this location proved easiest for quick collection and, from a social/emotional point of view, is now commonly referred to as the "tickle test."

Manpower implications

Between this collection method and the use of a pooled approach, the school can complete 60 tests per hour on average leading to either 20% of each cohort per day or 33% per day on off-cycle testing. In certain instances, the school is also able to achieve 50% of each cohort per day when holidays or modified schedules require it. Total manpower per cohort is two to three individuals for a 90-minute period. These sessions overlap to match cohort schedules, but testing is largely complete by early afternoon each day. Staff connected to each cohort are distributed over the same schedule and included in the same pooling approach.

Frequency of Testing

The clinical consensus around COVID-19 provides the first layer of validation: incubation period or the time between exposure to the virus and appearance of first symptoms. This time has been defined for COVID-19 as approximately 5 days (median) with a range of 3 to 12 days. This is a broad range but let's stick to 5 days as the median. The second layer of evidence comes from a study cited above that an individual becomes infectious approximately 1.8 days before becoming symptomatic. This means that between exposure and being infectious, we have about 3 days. So, clearly, the optimal testing frequency would be every 3 days. There are many institutions that implemented a twice-weekly screening frequency or even a three times per week schedule as is being one at Harvard University.

Indeed, twice-weekly testing reduced the viral transmission factor by up to 95% (not much less than daily testing that reduces it by 99%). So why does everyone, including ASW, use weekly testing instead of testing every 3 days? In the absence of infections, we do not need to reduce the viral transmission factor because there is no virus. It is only when we detect an infection that a twice-weekly protocol should be initiated to stop transmission. This is exactly the protocol we are using at ASW — the twice-weekly frequency of testing is initiated for the cohort in which an infection has been detected. This is exactly how the first outbreak was managed and how within a week, using that approach, the outbreak was stopped with only minimal community transmission (three cases in one grade, one case of a sibling in another grade). No further local transmission has been identified to date of writing of this article, although 61 cases in total have been identified.

Assessing the horizon of research and development efforts of various tests, it is likely that in the next few months we will have access to at-home tests performed on saliva samples. Before that happens, we believe the weekly screening protocol with twice-weekly pulses whenever an infection is detected provides the best level of protection.

Additional Protocols

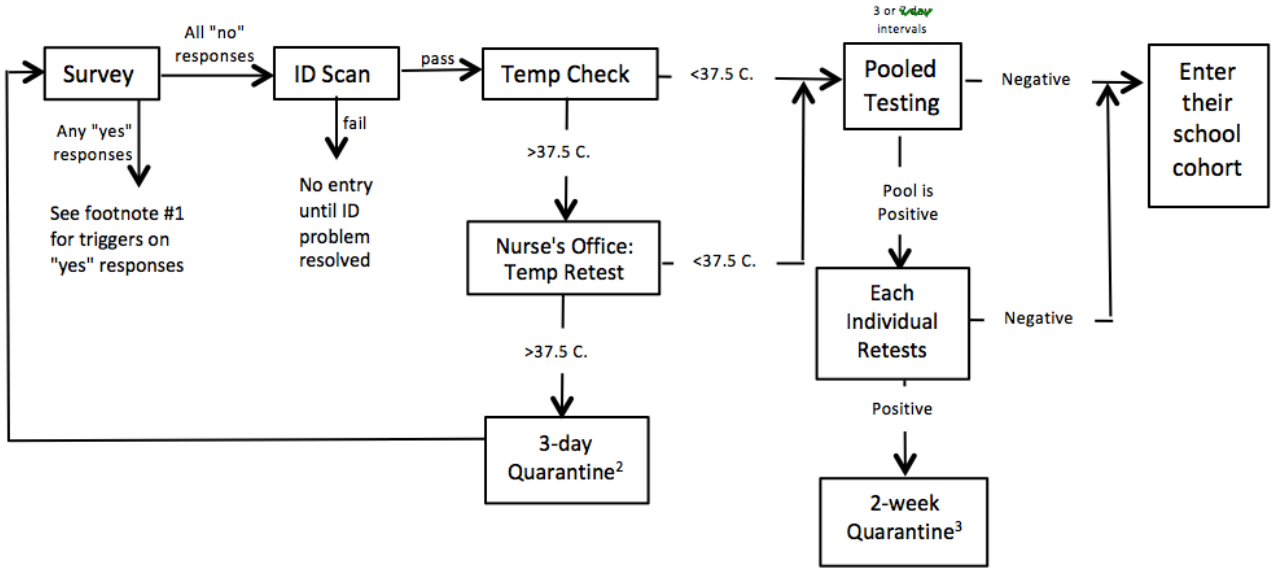
The protocol described below does not include other well-documented aspects of controlling Covid-19 on the campus such as temperature checks, masking, reducing the footprint of students and personnel on campus, and an extensive contract tracing program. The testing strategy we chose is designed to

[14] In layman's language: (1) the upper part of the throat, (2) the back of the tongue and soft palate, (3) the back of the nose, and (4) the opening of the nostrils.

break the COVID-19 chain of transmission. This protocol takes a substantial, coordinated commitment from the school administrators as well as everyone else in the school. ASW created a Crisis Team that uses this protocol to respond to each case with appropriate mitigation. The protocol puts into place several precautions that have been shown to stop the disease from spreading from person to person. It uses surveillance testing, personal hygiene, good ventilation, social distancing, good contact tracing and the avoidance as much as possible of clusters of individuals over a sustained period. Everyone is encouraged to be their own disease manager.

Flowchart of ASW's Protocol

Here is the process we use to implement the protocols.



[1] A "yes" response to a high temperature triggers exclusion of entire family from school until temperature is resolved and retesting is negative.
A "yes" response to symptoms triggers exclusion of whole family until the individual tests negative.
A "yes" response for close contact (no mask, within 1.5 meters, more than 15 minutes) with a person *outside the family* having symptoms but no diagnosis triggers a three-day exclusion and a negative test.
A "yes" response to close contact with a person diagnosed with COVID-19 means a 10-day quarantine before retesting.
A "yes" response to travel to high-risk areas means a 7-day exclusion from the date of return and a negative test.
A "yes" response to any family member engaging in high-risk activities triggers a three-day exclusion and a negative test.

[2] A positive re-test triggers an automatic 3-day exclusion from school and schedules a new test date and return date. The quarantine includes all family members at the school.

[3] The COVID Crisis Team meets each time a person is found to be positive on the retest and conducts contact tracing to determine the extent of primary and secondary infections. If circumstances warrant, an entire grade can be sent home early or for one day followed by drive-through testing on the following day. Testing schedules for that grade can be moved to every three days and families encouraged to monitor their members for symptoms.

Figure 3. The Implementation of the SW Protocol

Process Flow

The day begins at home with the daily attestation of health condition. Parents and students complete a survey that includes checking and recording temperature at home. This is entered into an online survey for each child in the family. Questions include general symptom check, temperature, and contact issues including travel, notification of close contact, and general assessment of risk since the

last survey (e.g., use of public transport, attend gathering, etc.).

When students arrive at school, they swipe their badge which determines whether the survey is completed and if they have a valid test that is less than 7-days old. If students flash as not OK4School, they are interviewed by waiting staff members who help resolve survey issues by calling home or referring students for testing at our main entrance testing station. If students are clear, they wash their hands at sanitization stands and look up at high-snsitivity temperature checking cameras. If temperatures are below 100.4 F (or 38 C.), they are then admitted to their cohort in school.

Weekly regular testing is done during the school day with regular appointments where students report to testing stations for their swab antigen test. The students are scheduled as cross sections of the cohort with about 20% of the cohort tested each day, Monday through Friday. If students are off schedule or have allowed a test to expire because of missing their appointment or being absent from school, they report in the morning to the main entrance testing station and remain there until they receive a test results which is their pass to enter the cohort.

Once in school, all students wear masks throughout their day while inside the building and generally observe distancing wherever feasible. Students are encouraged to wash their hands during the day. Students are allowed breaks outside where masks are not required, but distancing is still monitored.

Crisis Team

The Crisis Team is composed of lead administrators for each division along with EpiXpert medical liaison, The School Director, two Associate Directors, the Nursing Lead, the Security Coordinator, the Communications Director, and the HR Director. The team has a designated time scheduled each day to meet and discuss any cases that emerge from testing, either in the morning or through the day. Case management during the day, including identification, isolation, and referral is independent of this process. During the time between case identification and Crisis Team consideration, investigation is completed to determine degree of exposure and contact tracing. When the Crisis Team meets, the discussion generally follows this outline:

- Identification of timeframe between last negative test and current positive result
- Identification and exclusion of siblings and assessment of family members
- Identification of potential outside exposure (family interview, student interview)
- Identification of potential internal exposure (student and staff interview, assessment against other cases)
- Identification of close contacts with students outside of school
- Identification of close contacts with students inside of school (including bus, activities, etc.)
- Identification of close contacts with staff inside of school
- Identification of mitigation for all of the above, including off-cycle testing, exclusions, and/or virtual school for class, grade, or cohort and re-entry testing

Crisis Team mitigation decisions are binding and implemented with immediate effect. Communication follows to the entire ASW Community within hours of these decisions.

Reporting and Compliance

To provide for clarity in a complicated landscape of legal and health services requirements, a health care advisory company was contracted to provide oversight and advisory services, while implementing the surveillance testing protocols underpinning the entire program. In the context of this, a partnered relationship with an accredited lab (SANEPID) under health care oversight provides for the necessary linkage between reporting entities. ASW is, therefore, compliant with emergency regulations and sanitary guidelines. This relationship between entities can be seen in Figure 2 below.

By maintaining these relationships, we comply with all necessary requirements and build necessary lines of communication while relying on our key partner in maintaining health management protocols

as needed and adjusted over time.

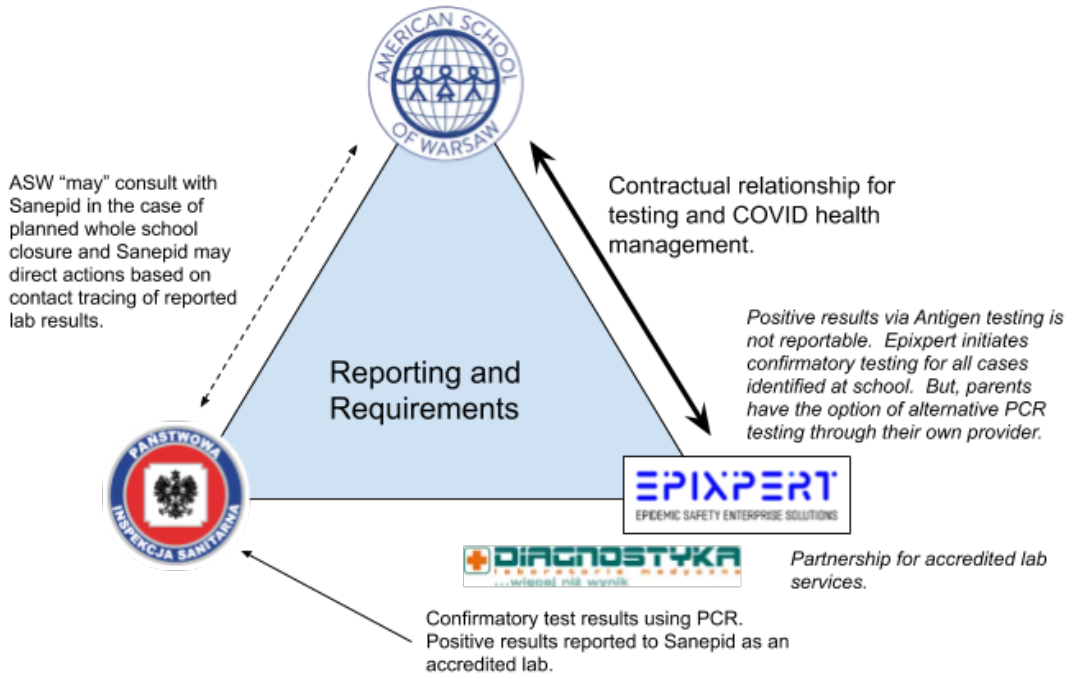


Figure 2. Reporting and Requirements Relationships

General guidelines published by the Polish Bureau of Education prescribe a set of general standards that were published in August 2020. Final planning was delegated to Directors of individual schools and their governing bodies. Our review of our protocol suggests that we meet or exceed all published guidelines available at that time.

The Future of Managing the Pandemic

As discussed above, COVID-19 has brought unprecedented speed to the science of testing, treatments, and vaccine development. Typical multi-year timelines of clinical studies were shortened to weeks or months. So how will we manage the pandemic going forward?

Without sounding overly simplistic, and in the absence of a safe and fully effective vaccine, the HIV pandemic is a good analogy. We will have three pillars: protection, testing, and treatment. The first pillar of protection is paramount because we will never test everyone, nor will we ever vaccinate everyone nor will the vaccine ever be 100% efficacious.

A cautionary tale comes from the University of Illinois at Urbana Champaign (UIUC) that introduced a comprehensive testing program for all students and faculty even more aggressive than the one at ASW. UIUC had to go into a two-week lockdown after a surge in infections. In an interview for *Nature*, Prof Martin Burke, the chemist responsible for developing the UIUC testing protocol, admitted the model did not anticipate that students who tested positive would be going to parties. The students have now been suspended, but UIUC modified its protocol based on key learning that testing frequently is not sufficient. Of equal importance is acting quickly on the results.

> *It's not just a matter of getting the test done fast; it's a matter of acting on the results as fast as possible. We didn't appreciate how powerful it could be if we were the ones to reach out immediately, as opposed to waiting for the*

standard process through public-health authorities.[15]

The ASW strategic plan encompasses other elements of prevention in the three-layer defense mechanism — STOP, PROTECT, REACT. All these elements protect our community. Undoubtedly this is an evolving protocol. We encourage you to evaluate this protocol for your specific situation and determine whether it is feasible to implement each of the elements. Use the same approach at home, at work, and with friends. Remember, we are all accountable to one another in the fight against this virus and need to remember that our practices must be consistent and sustainable. Every challenge brings opportunities, and this pandemic is no exception.

[15] Guglielmi, G. (2020, September 11). 'We didn't model that people would go to a party if they tested positive'. Retrieved November 21, 2020, from https://www.nature.com/articles/d41586-020-02611-y

References

Akw/kg. (2020, September 03). "Możemy mówić o kompletnej porażce programu szczepień przeciw grypie, zanim ona się jeszcze pojawiła". Retrieved September 15, 2020, from https://tvn24.pl/polska/koronawirus-w-polsce-dr-pawel-grzesiowski-o-nowej-strategii-walki-z-covid-19-i-testach-antygenowych-4682766

Booeshaghi, A. S., Tan, F. H., Renton, B., Berger, Z., & Pachter, L. (2020). Markedly heterogeneous COVID-19 testing plans among US colleges and universities. medRxiv, 2020.08.09.20171223.

Center for Devices and Radiological Health. (2020). FAQs on Testing for SARS-CoV-2. Retrieved September 15, 2020, from https://www.fda.gov/medical-devices/coronavirus-covid-19-and-medical-devices/faqs-testing-sars-cov-2

Centers for Disease Control and Prevention. (2020). Transmission Dynamics of COVID-19 Outbreaks Associated with Child Care Facilities — Salt Lake City, Utah, April–July 2020, 1–5.

Fall 2020 College and University Screening. (2020, September 02). Retrieved September 15, 2020, from https://www.broadinstitute.org/covid-19-testing/fall-2020-college-and-university-screening

Guglielmi, G. (2020, September 11). 'We didn't model that people would go to a party if they tested positive'. Retrieved September 15, 2020, from https://www.nature.com/articles/d41586-020-02611-y

Heald-Sargent T, Muller WJ, Zheng X, Rippe J, Patel AB, Kociolek LK. Age-Related Differences in Nasopharyngeal Severe Acute Respiratory Syndrome Coronavirus 2 (SARS-CoV-2) Levels in Patients with Mild to Moderate Coronavirus Disease 2019 (COVID-19). *JAMA Pediatr.* 2020;174(9):902–903. doi:10.1001/jamapediatrics.2020.3651

Hu, S., Wang, W., Wang, Y., Litvinova, M., Luo, K., Ren, L., et al. (2020). Infectivity, susceptibility, and risk factors associated with SARS-CoV-2 transmission under intensive contact tracing in Hunan, China. medRxiv, 2020.07.23.20160317.

Interim Considerations for Institutions of Higher Education Administrators for SARS-CoV-2 Testing. (2020, June 30). Retrieved September 1, 2020, from https://www.cdc.gov/coronavirus/2019-ncov/community/colleges-universities/ihe-testing.html

Interim Guidance for Rapid Antigen Testing for SARS-CoV-2. (n.d.). Retrieved September 15, 2020, from https://www.cdc.gov/coronavirus/2019-ncov/lab/resources/antigen-tests-guidelines.html

Larremore, D. B., Wilder, B., Lester, E., Shehata, S., Burke, J. M., Hay, J. A., et al. (2020). Test sensitivity is secondary to frequency and turnaround time for COVID-19 surveillance, 1–22. http://doi.org/10.1101/2020.06.22.20136309

Lopez AS, Hill M, Antezano J, et al. Transmission Dynamics of COVID-19 Outbreaks Associated with Child Care Facilities — Salt Lake City, Utah, April–July 2020. MMWR Morb Mortal Wkly Rep 2020;69:1319–1323. DOI: http://dx.doi.org/10.15585/mmwr.mm6937e3external icon

Mandavilli, A. (2020, July 01). Federal Officials Turn to a New Testing Strategy as Infections Surge. Retrieved November 21, 2020, from https://www.nytimes.com/2020/07/01/health/coronavirus-pooled-testing.html

O'Donnell, C. (2020, July 14). 3M, MIT partner to make rapid COVID-19 antigen test. Retrieved September 15, 2020, from https://www.reuters.com/article/us-health-coronavirus-3m-test-idUSKCN24F191

Powell, A. (2020, September 02). Cheap, frequent COVID tests could be 'akin to vaccine,' professor says. Retrieved September 15, 2020, from https://news.harvard.edu/gazette/story/2020/08/cheap-daily-covid-tests-could-be-akin-to-vaccine/

Service, R. F. (2020, August 04). Radical shift in COVID-19 testing needed to reopen schools and businesses, researchers say. Retrieved September 15, 2020, from https://www.sciencemag.org/news/2020/08/radical-shift-testing-strategy-needed-reopen-schools-and-businesses-researchers-say

Weixel, N. (2020, August 05). 6 states band together to secure rapid COVID testing. Retrieved November 21, 2020, from https://thehill.com/policy/healthcare/510552-six-states-band-together-to-secure-rapid-covid-testing

White House Coronavirus Task Force visits USF to address Florida's spike in COVID-19. (2020, July 2). Retrieved September 15, 2020, from https://www.usf.edu/news/2020/white-house-coronavirus-task-force-visits-usf-to-address-floridas-spike-in-covid19.aspx

HIV Endnote

Patients at the early stages of HIV, but not AIDS, are infectious but are asymptomatic. Based on this, the CDC recommends everyone between the age of 13 and 64 get tested for HIV at least once, and more often if they are in a risk category. Here is an excerpt from the CDC guidelines related to types of tests:

Antibody/antigen Combination Tests

The CDC recommends these blood tests. They can detect HIV earlier than antibody screening tests. They check for HIV antigen, a protein called p24 that's part of the virus and shows up 2 to 4 weeks after infection. They also check for HIV antibodies.

SUGGESTED

A rapid antibody/antigen test can give results in 20 minutes.

Nucleic acid test

This is also known as an RNA test. It looks for the virus itself and can diagnose HIV about 10 days after exposure. It's expensive, so it's usually not the first choice. But if you're at high risk and you have flu-like symptoms, your doctor may want to use it.