Scientific evidence is highly supportive that SARS-CoV-2 (COVID-19 virus) transferred to humans from animals sold at a Wuhan China market in the November-December 2019 time. The World Health Organization (WHO) declared a public health emergency in January 2020 and on March 13, 2020, the President of the United States declared the outbreak a public health national emergency retroactive to 1 March 2020. At a time with no vaccination or therapeutic capabilities against the virus, multiple nonpharmaceutical interventions were implemented. Over a 10-day period in March 2020, all 50 states closed kindergarten—grade 12 schools and childcare centers along with nearly all colleges and universities. Online web-based home instruction was rapidly implemented. Only essential service workers (ie, grocery stores, health care) were allowed to engage in on-site employment, specifically bars, indoor dining, and entertainment venues were closed. School opening guidance from the American Academy of Pediatrics in June 2020 stated, “all policy considerations for the coming school year should start with a goal of having students physically present in school.” In this time without vaccine, testing for asymptomatic COVID-19-infected children in the K-12 classroom environment with subsequent isolation of the infected student and quarantine of exposed students/staff was a significant public health intervention. The first COVID-19 vaccine for students 16 years and older became available in December 2020 when Pfizer-BioNTech COVID-19 received FDA Emergency Use Authorization.

This policy and practice description shares the experience of two San Diego County socio-economically diverse school districts with pilot-testing a rapid antigen test (BinaxNOW™ card system) amongst students and staff from December 2020 to May 2021. The process is shared as an example for the implementation of onsite rapid antigen testing. Multiple publications on rapid antigen K-12 school testing exist that support the efficacy of this mitigation strategy. While COVID-19 vaccination remains a cornerstone of intervention and rapid antigen home testing for COVID-19 is now possible with less institutional expense, routine testing (especially for close contact athletic teams) can be highly effective at reducing within-school COVID-19 transmission. Ongoing support of community leaders and parents for testing as well as coordinated guidance and resources from state and local public health authorities is essential for success.

Multiple challenges exist for school systems implementing weekly screening testing, especially those that are chronically underfunded, and/or serve lower socioeconomic students. Laboratory costs, inclusive of test kits, reagents, and laboratory staff expenses are compounded with personnel costs of obtaining
parental permission, staff training, test conduction, and implementation of isolation, and quarantine policies for those who test positive, and results reporting to parents and Public Health Departments. Pilot development of in school rapid antigen testing in two diverse San Diego County Public Schools was the focus of this project.

Unvaccinated asymptomatic and pre-symptomatic persons with COVID-19 infection are highly capable of transmitting the virus, including at the elementary school level. Many COVID-19 infected children have minimal symptoms or have common childhood illness symptoms that overlap with COVID-19 infection. A significant challenge exists for school nurses on returning a child with the mild symptoms (ie, headache, nausea) that may be related to non-COVID-19 viral infections to the classroom or calling the parent/caretaker that is likely required to leave employment to return the child to home. Parents/caretakers may then be required to obtain medical clearance from a health care provider or a negative laboratory test to confirm no detectable COVID-19 virus is present for the child to return to class in the less than 10-day isolation period that was in effect at the time. Even with rapid COVID-19 test turnaround times, this often results in several days absence from in-class instruction along with locating at-home supervision for an elementary school child with employed parents/caregivers.

This policy and practice description shares the experience of two San Diego County socio-economically diverse school districts with pilot-testing a rapid antigen test (BinaxNOW™ card system) amongst students, staff and students from December 2020 to May 2021. As for advocacy, these school districts partnered with Public Health Services (PHS) departments, County of San Diego, Health and Human Services Agency, as well as the California State Department of Public Health (CDPH). The two pilot schools were in different school districts in San Diego County (population 3.38 million). One school is suburban and located in a high-socio economic area (median home price $1.7 M). The other is in a rural remote setting, approximately 2-hour drive from the urban center, with the median home price of $245 K.

Later in the process, CDPH provided the ordering physician, addressed administrative obligations, and contracted with a third party (Primary Health, Inc.) for recording of results. The rapid antigen test cards were supplied by PHS to school districts at no cost. Test card accountability is required to document utilization and recording of results.

**COVID-19 SCREENING TESTING METHODS IMPLEMENTATION**

The initial decision point for a school is to determine the specific population to test. Those that are fully vaccinated or recovered from COVID infection in the last 90 days are less likely to become infected and transmit COVID-19 to others, especially if asymptomatic for COVID-19 infection. Testing this “low prevalence” (likelihood of COVID-19 infection) may lead to “false positive” tests resulting in isolation periods for the individual and quarantine for unvaccinated close contacts. The other major decision is to determine frequency of testing. Frequency of rapid antigen testing is related to the level of acceptable risk and prevalence of disease in the community population. Once-weekly screening is most appropriate in many settings; twice weekly screening in times of high transmission is most beneficial to extracurricular activities of athletics, cheer, band (especially trumpet players), and performing arts of song and dance. Twice weekly screening while most effective to reduce in school transmission between students and staff many of whom are asymptomatic during times of high community transmission, is disruptive and taxes time and personnel resources; every-other-week more easily allows an asymptomatic infected individual to expose others over the course of multiple days but is still better than no testing. Significant predictive mathematical analytics on frequency of rapid antigen testing was available from the local nationally recognized University of California San Diego indicating that twice weekly antigen testing would capture the largest number of asymptomatic students based on the sensitivity of rapid antigen testing to detect early infection. Once weekly testing balanced cost, especially for school staff testing time and classroom disruption. This was compared to more sensitive once weekly PCR molecular testing. A weekly teleconference was held with the San Diego Office of Education, including interested local school officials and school health care staff on the most recent science advances and school policy issues. Initially, the rapid antigen tests were supplied to the County for distribution to the schools, with onsite training for educational staff supplied by San Diego County, Health and Human Services Agency (County Public Health personnel). Of interest, the rural district included multiple Hispanic families routinely crossing the US/Mexico border; the weekly testing decreased concerns for possible exposure from cross border travel.

The second decision is the type of COVID-19 testing platform. COVID-19 laboratory testing is complex and nuanced, but for the purposes of this commentary, will be reduced to a choice of a “Point of care” rapid antigen test which utilizes a similar process as a home pregnancy test. The other option is the polymerase chain reaction (PCR) molecular test that is sent to a major clinical laboratory, with results returned ideally within 24-48 hours. The PCR testing method is available through multiple commercial laboratories often at cost of $50/test. In many urban settings, turnaround
time is 24-48 hours, but in remote settings with courier or mailing required time can be prolonged. Both tests have received Emergency Use Authorization (EUA) from the U.S. Food and Drug Administration (FDA). Both rapid antigen and PCR tests usually involve insertion of a flocculated swab to the anterior nares in the first inch of the nose. Children of all ages reported a tickling sensation that is not painful.

Earlier produced rapid antigen tests (eg, Quidel Sophia II™, BD Veritor™) that were distributed by the federal government required a small on-site machine to read the immunofluorescent results. The card-based BinaxNOW™ system employed here does not require a machine reader and may be more accurate in the hands of trained personnel than the earlier rapid antigen tests. Multiple other rapid antigen test platforms have been FDA EUA approved and are expected to be of similar efficacy to the BinaxNOW™ system.

Point of care, rapid antigen testing can theoretically be effectively implemented in any school situation and determining feasibility was the purpose of the pilot in these two diverse districts. Initial administrative hurdles usually are finding an ordering physician or credentialed health care provider, such as a nurse practitioner or physician assistant, for this rapid antigen test. A Clinical Laboratory Improvement Amendments (CLIA) waiver is necessary to ensure laboratory standards which requires a clinically credentialed provider. The ordering provider can also be the CLIA certifying official in California.

As CLIA on school site testing (not home tests) requires positive antigen tests to be reported to local public health authorities and negative antigen tests might require reporting, an administrative tracking system is highly desirable. While the reporting of positive antigen cases is of highest priority and handled by the local health jurisdictions as “probable” cases per the Council of State and Territorial Epidemiologists (CSTE) definition, many health departments request the reporting of negative tests to provide a complete picture for the significance of infection in the local school population. Since December 2021, rapid antigen at home testing has been an invaluable resource for K-12 schools. Reporting of home results vary by public health jurisdictions. Currently, reporting at home positive results to local public health authorities from school districts is required in California. As a home test, there is no requirement for credentialed health care provider involvement. Credentialed health care provider involvement is required for CLIA regulated on-site school testing, this does not imply that the credentialed individual must be on site, but is held responsible for testing process, results, and notification, that is, health technician working under the supervision of the school district RN. On 27 December 2021, based on knowledge of COVID-19 and the Omicron variant that a majority of SARS-CoV-2 transmission occurs early in the course of illness, the CDC shortened the recommended time for isolation and quarantine for the public to 5 days with mask wearing recommended for 10 days after exposure. In our area, recent guidelines from the California Department of Public Health (CDPH) no longer require individual contact tracing, unidentified individual group notification of a classroom case is sent to classroom parents through their local school. Exposed individuals are encouraged to be tested, COVID-19 symptomatic individuals require negative testing prior to classroom entry (antigen now acceptable). Quarantine is no longer required for classroom members, while masks are strongly encouraged along with MERV 13 classroom air filtration.

Rapid Antigen School Testing Teams

In both school districts the BinaxNow™ card-based, rapid antigen test was found to be ably performed on-site by trained school staff. The testing team was comprised of approximately 5-6 individuals. Staff training was primarily accomplished by online web-based videos with a knowledge test coupled with onsite training by external nursing/physician staff. Onsite training ensures appropriate infection control and prevention measures are in place and personal protective equipment (PPE) is utilized. Moreover, the accuracy of the test result may be related to the operator’s expertise. Specifically, detection of any evidence of a second “positive” colored line, no matter how faint, is essential. Photos can be obtained on site and sent to the ordering physician or other outside experts for evaluation of questionable cases. Positive or suspect positive antigen tests generated a same-day additional PCR/molecular nasal swab for that student or staff member to confirm that the antigen test was truly positive. The antigen tests can be performed in a low prevalence setting of community COVID-19 transmission which have a higher probability of “false positive” results.

A school testing team involves 5-6 individuals in the following roles: (1) “Greeter” and enroller. In the suburban district with a high socio-economic and higher educated English-speaking population, preregistration, and parental consent via cell phone was found to be feasible for a significant portion of the school population. (2) Self-administered nasal swab test supervisor. The experience in these 2 schools showed that, with training, students as young as those in the first grade can self-swab under supervision. Kindergarten children initially required direct swabbing assistance but were able to self-swab over time. Short instructional age-appropriate videos were made available from one school site and shared with the other pilot school site. Children are returned to class after the initial swab, an optional small prize for testing at the elementary school level was found to be
material designated "infectious medical waste" requires specific PPE. Infectious waste requirements vary. In this Southern California County, the only negligible nasal swabs. No other individuals require specific PPE. Infectious waste requirements vary. In this Southern California County, the only material designated "infectious medical waste" requiring "red bag" specialized environmental handling were the cards with swabs for positive tests.

**RAPID ANTIGEN TESTING ASSESSMENT**

Notification of a positive result is performed with confidentiality and sensitivity, usually by the classroom teacher who has direct contact with the positive tested student, especially in schools with minimal on-site health care staff. During this time frame, the student reported back for a same day confirmatory PCR nasal swab testing. These confirmatory PCR tests were sent to the County of San Diego Public Health Laboratory for analysis. In the current paradigm, PCR testing of a positive antigen test for confirmation is no longer necessary. This is based upon results of over 20K Binax™ rapid antigen tests by CDPH showing a specificity of over 98%, meaning less than 2 in 100 are false-positive results. Close interactions with the CDPH school rapid antigen testing team were maintained in the process, with suggestions "from the field" eagerly accepted by the higher authority policy team. During this pilot program, a positive antigen student or staff member was be managed as a "presumptive positive" case, with removal from class until the confirmatory PCR test results were returned in 24 to 48 hours. If negative, the student/staff returned; if positive, the student/staff continued in isolation. School-based tracing, in conjunction with the County, identified close contacts requiring quarantine for 10 to 14 days.

The suburban school had 14 antigen-positive results out of approximately 1800 tests during the December 2020 to May 2021 time frame, with most positives occurring in February 2021, when COVID-19 transmission was highly prevalent in the community. A month later, the rural location conducted over 400 antigen tests with no confirmed positives, coinciding with a community prevalence of infection that had fallen. All BinaxNow™ antigen-positive tests were confirmed as positive in 24 hours, when the same day obtained, samples were sent to the County Public Health Laboratory for PCR testing. These school districts' senior leadership and nursing staff became valuable resources to the broader community by providing supportive technical information and encouragement for the antigen testing program to other school districts in the County and throughout the State.

BinaxNow™ cards are designated by quick response (QR) codes, therefore, a digitalized information system is highly beneficial to ensure accuracy when recording results for reporting to local health jurisdictions. Two commercial systems merged—Color.Com and Primary. Health—all products are effective in assisting with data management systems. CDPH contracted with Primary. Health to supply services to any interested school system free of charge. Fees for services usually involve a monthly stipend and then a per card cost—with costs varying with volume of tests. In other states, noncommercial sourced spread sheets are potential substitutes, but onerous in high volume situations.

A "rapid" molecular RNA "loop'' amplification test (Cue™), which is based on similar genetic amplification technology as a PCR has also been evaluated by these two school systems. This test received FDA/EUA approval for rapid point of care testing. The sample is placed in a cartridge in a very small test machine platform that performs an onsite sensitive and specific molecular test in 20 minutes. The cartridge is synchronized to a cell phone application which reports the result. An ordering physician, CLIA coverage, and trained staff are required. A clinically credentialed individual on site (RN or LVN) is also recommended to be responsible for the test. At the time, the test could not be utilized for confirmation of point of care rapid antigen testing, laboratory based molecular PCR type confirmation was required. This sensitive and specific rapid molecular test may be of great benefit...
to also delineate COVID-19 infection in symptomatic individuals that present with sudden onset infectious COVID-19 symptoms in a school setting.

Conclusions
In K-12 schools, on-site rapid COVID-19 testing was shown to be feasible, in partnership with local and state health departments. Two socio-economically and geographically diverse schools successfully implemented an onsite rapid COVID-19 testing procedure. Since then, these schools have functioned as mentors for other school systems. COVID-19 rapid testing technology has quickly advanced and offers school systems additional risk mitigation efforts to address appropriate COVID-19 concerns of students, parents, teachers, support staff, school administrators, and community leaders. On site, rapid same-day school testing results of will be beneficial to identify asymptomatic infected individuals and mitigate the risk of COVID-19 transmission within the school setting.

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