Feasibility and Functionality of SARS-CoV-2 Rapid Testing in K-12 School Health Offices

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ABSTRACT

Introduction: The COVID-19 pandemic created unprecedented opportunities to introduce rapid SARS-CoV-2 antigen testing (RSAT) into kindergarten through 12th grade (K-12) school settings. We evaluated the feasibility and functionality of Sofia Fluorescent Immunoassay Flu + SARS in 1 school district across the 2021-2022 academic year.

Methods: Seven schools in the Oregon School District (Oregon, Wisconsin) were supplied with RSAT analyzers and test kits, along with minimal training of health office staff. We assessed RSAT utilization among schools, rate of invalid results, and comparability to 952 190 reverse transcription-polymerase chain reaction tests performed countywide during the same time period. A feedback survey was distributed to all 13 health office staff to assess respondents' perceptions regarding the feasibility and acceptability of RSAT in the Oregon School District.

Results: Over the school year, 1226 RSATs were performed; SARS-CoV-2 was detected in 103 specimens. Percent positivity was similar to the county level (8.4 vs 9.2%; chi-square = 0.74; P= 0.39). Cross-correlation of weekly positive tests between the Oregon School District and Dane County was maximal with no lag (r_s=0.69; P<0.001). Health office staff indicated Sofia2 RSAT was easy to perform, and 92.3% reported interest in continuing to utilize RSAT in the upcoming school year.

Conclusions: Implementing a RSAT protocol is feasible and acceptable for monitoring SARS-CoV-2 cases in K-12 school settings. High rates of compliance and confidence in results demonstrate program effectiveness. Continuing to use RSAT in school settings after the urgency of the pandemic subsides could help address future outbreaks of SARS-CoV-2 and other respiratory viruses within schools and in the larger community.

INTRODUCTION

Increased social contact, through physical proximity and across ages, in kindergarten through 12th grade (K-12) school settings is associated with outbreaks of acute respiratory infection and became a major concern during the COVID-19 pandemic.1 Although literature describing incidence and clinical presentation of COVID-19 in school-age children is still limited, pediatric infections of SARS-CoV-2 are generally milder than those in adults and often include fever, cough, and fatigue.² According to the Centers for Disease Control and Prevention, pediatric infections currently account for approximately 17.2% of diagnosed COVID-19 cases.3 K-12 schools deployed several tactics to disrupt transmission of SARS-CoV-2 among students and staff, including the use of rapid antigen tests. Federal policy changes and funding created unprecedented opportunities to introduce rapid

SARS-CoV-2 antigen testing (RSAT) into the K-12 environment. $\!\!^4$

Author Affiliations: Department of Family Medicine and Community Health, University of Wisconsin, Madison, Wisconsin (Temte J, Barlow, Temte E, Goss, Bell); Department of Biostatistics and Medical Informatics, University of Wisconsin, Madison, Wis (Norton, Chen).

Corresponding Author: Maureen Goss, MPH, Department of Family Medicine and Community Health, University of Wisconsin School of Medicine and Public Health, 1100 Delaplaine Ct, Madison, WI 53715; phone 608.301.7730; email Maureen.Landsverk@fammed.wisc.edu; ORCID ID 0000-0002-7062-1916 Several studies have demonstrated that testing asymptomatic students and staff who were exposed to SARS-CoV-2 was an effective alternative to quarantine and resulted in fewer disruptions in education.⁵⁻⁷ School and community testing sites also improved the accuracy of disease surveillance by capturing cases that were not seen by a health care provider and may not have been reported otherwise. Little is known about the feasibility and functionality of RSAT for symptomatic children and staff in K-12 schools.

Prior to the pandemic, rapid antigen tests were traditionally

limited to clinical and public health settings. The SARS-CoV-2 pandemic, however, provided an opportunity to expand the use of rapid diagnostic technologies. K-12 schools are a prime location for rapid testing because of the proximity to students and immediacy of results that enable near real-time decision-making. Continuing to use rapid tests in school settings after the urgency of the pandemic subsides could help address future outbreaks of SARS-CoV-2 and other respiratory viruses that have long-plagued communities.

Drawing on a longstanding relationship with a school district⁸ and years of experience evaluating rapid influenza diagnostic tests in clinical and community settings,^{9,10} we conducted a retrospective evaluation and quality improvement program to assess (1) the feasibility and functionality of a district-wide rapid testing protocol in 7 schools and (2) whether school testing was correlated with local SARS-CoV-2 trends.

METHODS

The program was part of a Wisconsin Department of Health Services (WDHS) statewide initiative and was originally developed as a nonresearch service to the Oregon School District (OSD) (Oregon, Dane County, Wisconsin). The OSD serves over 4000 K-12 students and comprises 7 schools, including 3 elementary schools (grades K-4), 1 expanded elementary school (K-6), 1 intermediate school (5-6), 1 middle school (7-8), and 1 high school (9-12). The health office at each school was supplied with a Sofia2 Fluorescent Immunoassay (FIA) analyzer,11 equipped with wireless reporting capability,10,12 and received Sofia2 Flu+SARS Antigen FIA test kits as needed throughout the school year. Parental consent for rapid antigen testing of students was obtained at the beginning of the academic year during the school registration process. The WDHS provided funding for and oversight of the statewide rapid antigen testing program, thus the institutional review board (IRB) deemed our involvement was restricted to consultation, technical support, and training relevant to specimen acquisition and testing and did not require a formal review. The survey distributed to school nursing staff was granted a waiver from the UW Health and Sciences IRB.

Implementation and Reporting

The OSD health offices were staffed by 13 individuals, including 4 nurses and 9 health aides. Due to our longstanding relationship with the school district, we provided—prior to the start of the 2021-2022 academic year—technical support and trained health office staff on: (1) screening students for rapid testing eligibility, (2) nasal swab collection technique, (3) Quidel Sofia2 FIA analyzer operation, and (4) reporting SARS-CoV-2 results via the COVID Connect platform, the WDHS web-based portal for managing COVID-19 test results.¹³ Rapid testing was performed under a Clinical Laboratory Improvement Amendments (CLIA) Certificate of Waiver obtained by the OSD superintendent. Deidentified rapid results were transmitted wirelessly to Virena, a service that collects test results from Quidel instruments and makes them accessible for analysis.¹² For all specimens with a negative SARS-CoV-2 rapid result, health office staff collected a second nasal swab and placed it into a 3 mL tube of viral transport medium, which was labeled appropriately for reverse transcription-polymerase chain reaction (RT-PCR) SARS-CoV-2 molecular testing at Exact Sciences in Madison, Wisconsin, per WDHS protocol. Specimens were transported to Exact Sciences by Fitchburg Pharmacy staff (contracted by the WDHS), and results were communicated to the lead school nurse within 7 days.

Recruitment

Parents/guardians of minor students provided their consent to the school district for on-site testing at the beginning of the academic year. School health office staff selected students and staff for rapid testing according to inclusion criteria that we suggested based on other research activities within the school district. Students and staff were eligible for testing if they presented to the school health office while at school and had at least 2 of the following symptoms: fever, chills, cough, shortness of breath/difficulty breathing, fatigue, muscle or body aches, headache, new loss of taste or smell, sore throat, nasal congestion or runny nose, nausea or vomiting, and diarrhea. Students and staff were swabbed and tested in a designated isolation room at each school to reduce the risk of transmission.

RSAT Performance

We used anonymous data obtained from Virena to assess the numbers of tests performed per week; the number of positive, negative, and invalid results; and the utilization across schools. Percent positivity for SARS-CoV-2 within the OSD was calculated as the number of positive tests divided by the total number of valid tests performed. For community comparison, we used SARS-CoV-2 testing data provided by Public Health Madison and Dane County,¹⁴ covering the same time period, with 87183 positive results out of a total of 952190 tests.

Feedback Survey

We designed and distributed a 40-question post-program feedback survey as part of a quality improvement effort via Qualtrics XM survey software (Qualtrics; Utah, USA) to school health office staff. The survey was intended to assess respondents' perceptions regarding the feasibility, ease of use, and overall acceptance of rapid testing in the OSD health offices. The survey included basic demographic questions and questions assessing knowledge and experience with Sofia2 FIA analyzer technology, swab collection, specimen preparation for RT-PCR testing, and utilization of COVID Connect. For questions related to potential effects of training, we relied on respondents' recall for the pre- and post-training experiences. The survey was delivered by email over the course of one week in June 2022.

Statistical Analysis

Descriptive statistics were used to evaluate the rates of invalid tests, percent positivity, and responses to survey questions. Changes in survey responses, pre- and post-training, were assessed using Wilcoxon signed-rank test. The percent positivity of OSD and Dane County data were compared using the chi-square statistic. Spearman rankbased cross-correlation was used to determine an association between weekly counts of SARS-Co-2 detections for Dane County and the OSD. In addition, we accounted for time-dependency using a generalized additive model (GAM) structure, where Dane County counts were the outcome of the model, OSD counts were a covariate, and a smoother was used to estimate and account for the week-to-week timedependency. We examined 5 scenarios: one where the Dane County/OSD count pairs were from the same week (no lag or lead), 2 versions where the OSD counts lagged the Dane County counts by 1 or 2 weeks, and 2 versions where the OSD counts led the Dane County counts by 1 or 2 weeks. All analyses were performed in R 4.2.0 using the mgcv package and the GAM

function defaults for all smoothing parameter settings. Statistical significance was assessed at the 5% level.

RESULTS

RSAT Performance

Over the course of the 2021-2022 school year (September 1, 2021 through June 6, 2022), a total of 1226 Sofia2 Flu+SARS rapid antigen tests were performed at the 7 schools in the OSD (Table 1). A total of 940 students (77%) and 286 OSD staff (23%) were tested, and SARS-CoV-2 was detected in 103 specimens (84 students, 19 staff). There were 6 invalid results (0.5%). Influenza was detected in 55 specimens (35 influenza A, 20 influenza B). The average age of a tested student was 10.9 years (SD±3.8 years). Although the district's 4 elementary schools enrolled 38% of students, they accounted for 51% of completed rapid tests. The 2 schools with the highest SARS-CoV-2 positivity rates, at 12.2% and 11.9%, also conducted the lowest number of rapid tests (82 and 109, respectively). Six specimens tested positive for both SARS-CoV-2 and influenza A. Families of students who tested positive for COVID-19 or influenza were notified immediately

 Table 1. Enrollment Data and Sofia Rapid SARS-CoV-2 and Influenza Test Results by School

| School | Enrollment (2021-22) | Total Tests | Student Tests (≤18 years) n (%) | Staff Tests (>18 years) | SARS-CoV-2 (+) tests n (%) | Influenza (+) tests |
|---------------------|-------------------------|----------------|---------------------------------------|----------------------------|----------------------------------|------------------------|
| Elementary 1 (K-4) | 382 | 139 | 96 (25) | 43 | 7 (5.0) | 5A, 1B |
| Elementary 2 (K-4) | 397 | 191 | 129 (32) | 62 | 17ª (8.9) | 9Aª, 6B |
| Elementary 3 (K-4) | 367 | 82 | 69 (19) | 13 | 10ª (12.2) | 4Aª, 1B |
| Elementary 4 (K-6) | 426 | 214 | 161 (38) | 53 | 15 (7.0) | 5A, 4B |
| Intermediate (5-6) | 476 | 197 | 160 (34) | 37 | 15ª (7.6) | 4Aª, 6B |
| Middle school (7-8) | 631 | 109 | 74 (12) | 35 | 13 ^b (11.9) | 6A ^b , 1B |
| High school (9-12) | 1251 | 294 | 251 (20) | 43 | 26 (8.8) | 2A, 1B |
| Total | 4159 | 1226 | 940 (23) | | 103 (8.4) | 35A, 20B |

a1 dual SARS-CoV-2/Influenza A positive.

b3 dual SARS-CoV-2/Influenza A positives.

Enrollment numbers are for students only. Total tests include those for students and staff. The percentage of students tested (number of student tests/number of students) is provided for each school. The overall percent positivity is shown in the SARS-CoV-2 (+) column, based on the number of positive tests divided by the total number of tests at each school.

 Table 2.
 Comparability of the Temporal Trends in Weekly SARS-CoV-2 Detections From the Oregon School
 District (OSD) and Dane County, Wisonsin Over the 2021-2022 Academic Year

| OSD Lag/Lead | Spearman's C | Correlation | Generalized Additive Model Results for the OSD Count Relationship With Dane County Count, After Accounting for the Estimated Time-Form | | | |
|--------------|-----------------------------|-------------|--|------|---------|--|
| | Estimated Spearman's rho | P value | Estimate | SE | P value | |
| 2-week lag | 0.55 | < 0.001 | -66.2 | 61.2 | 0.289 | |
| 1-week lag | 0.66 | < 0.001 | 96.8 | 59.5 | 0.115 | |
| None | 0.69 | < 0.001 | 247.5 | 49.6 | < 0.001 | |
| 1-week lead | 0.63 | < 0.001 | 280.6 | 45.8 | < 0.001 | |
| 2-week lead | 0.57 | < 0.001 | 92.0 | 66.2 | 0.176 | |

and advised of school policy regarding testing and returning after illness. They were also given information on local testing locations.

While Family Educational Rights and Privacy Act (FERPA) guidelines did not allow us to match RSAT results with corresponding RT-PCR results, the Sofia Flu+SARS Antigen FIA is reported to have a sensitivity of 95.2% for SARS-CoV-2, compared with an average of 50% to 77% for comparable at-home SARS-CoV-2 tests.^{11,15}

Comparability of Results

The overall percent positivity for RSAT at OSD was 8.4% (103/1220), which compared closely to the overall countywide percent positivity of 9.2% for RT-PCR (chi-square = 0.74; P=0.39) over the same time period. The temporal patterns of weekly positive specimens from OSD and Dane County demonstrated similar trends (Figure). In the Spearman correlation analyses, all 5 versions displayed statistically significant positive correlations between Dane County and OSD counts, with all estimated Spearman's rho (r_s) tests between 0.55 and 0.69 (Table 2). The analysis without any lag or lead displayed the largest estimated rho and the smallest P value, with smaller rho estimates and larger P values exhibited for greater leads or lags away from zero. It should be noted that differences in these estimates was not assessed statistically.

In the GAM analyses, both the 1-week lead and the no lag models had statistically significant positive associations between the OSD counts and Dane County counts. Both lag models and the 2-week lead model did not detect a statistically significant association between OSD and Dane County counts. These results are after the models accounted for the nonlinear time-dependent form of Dane County counts. The 1-week lead model had the smallest standard error of the estimate and the smallest P value but, similar to the Spearman correlation, the differences in

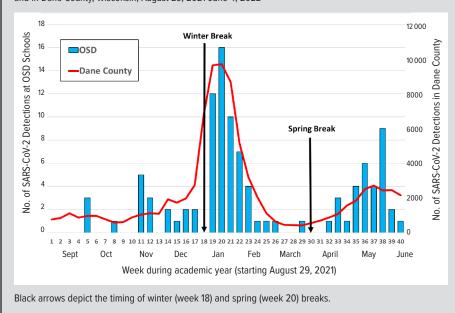


Figure. Number of SARS-CoV-2 Detections per Week Within K-12 Schools of the Oregon School District (OSD) and in Dane County, Wisconsin, August 29, 2021-June 4, 2022

these estimates and P values have not been assessed statistically.

Feedback Survey

The end-of-year feedback survey was completed by 100% (n = 13) of respondents (Table 3). Respondents rated their level of confidence in measures critical to performing and reporting SARS-CoV-2 testing before and after training on a 5-point Likert scale (1 = not at all confident, 5 = very confident). Health office staff reported significant improvement (P < 0.05) post-training on the following measures: registering a student in COVID Connect, collecting a nasal swab, performing a Sofia rapid test, and reporting test results to a parent. Staff noted an improvement in identifying COVID-like symptoms, though this change was not significant (P = 0.054). On the same Likert scale, respondents rated feasibility measures related to utilization of Sofia rapid testing, PCR testing, and COVID Connect (Table 4). On average, staff reported ease of use for Sofia rapid testing at 4.62/5 and ease of nasal swab collection for Sofia rapid testing and PCR testing at 4.77 and 4.45, respectively. On a scale of 1 (not at all confident) to 5 (very confident), staff reported confidence in the accuracy of Sofia rapid testing and PCR testing results at 4.23 and 4.92 on average, respectively. Respondents rated usefulness of Sofia rapid testing and PCR testing for detecting cases of COVID-19 at 4.54 and 4.85, respectively, on a scale of 1 (not at all useful) to 5 (very useful). A majority of health office staff (12/13, 92.3%) indicated interest in continuing to use Sofia rapid testing and COVID Connect in OSD health offices the following year.

DISCUSSION

Use of RSAT in a K-12 school environment was feasible, acceptable, and performed comparably to county-wide SARS-CoV-2 testing. Individuals collecting specimens and running the rapid tests within school health offices rated the RSAT highly and indicated willingness to continue this service into the following year. A low rate of invalid testing was noted (<1%). In addition, high similarities in percent positivity and temporal patterns of positive results were noted between the RSAT and the reference testing program.

We found that brief, in-person training resulted in improvements in tasks related to testing students for SARS-CoV-2 including (1) registering students in the state's COVID-19 result reporting system, (2) collecting a nasal specimen, (3) performing the RSAT, and (4) reporting results to parents. Most of the health office personnel reported an appreciation for on-site rapid testing, reduction in the need to help families navigate testing elsewhere, and the ability to test staff members. They also noted challenges with time demands required for in-school testing and concerns with false negative results.

We were unable to provide a formal assessment of performance characteristics of Sofia2 in this quality improvement report, as we did not have access to the RT-PCR results from negative RSAT specimens. In addition, we did not assess the utility of testing for influenza. We did note a very low rate of invalid tests in this CLIA-waived environment where tests were performed by nonlaboratorians. In addition, the overall percent positivity closely matched that for the surrounding county, and the temporal trends of positive specimens per week closely reflected the ambient level of SARS-CoV-2 in the community.

Compared to screening of asymptomatic students, the testing of symptomatic students appeared to work well. In contrast, a recent report from Wisconsin detailed low yield, high cost, and high burden of a screening program for asymptomatic individuals in the setting of relatively high student masking compliance and physical distancing.¹⁶

Strengths and Limitations

There were a number of strengths to this evaluation. First, this was a pragmatic assessment of the introduction of rapid antigen testing into a K-12 environment. As such, setup and our review of quality required minimal input. Accordingly, it represents a real-life experience with RSAT in K-12 settings. The health office staff made testing available to students (77% of tests) and staff (23%) who developed symptoms at school and were able to receive accurate test results within 15 minutes. Those who tested positive for SARS-CoV-2 were sent home immediately, thus avoiding the potential for transmission during the school day had testing been delayed until after school. Second, we were able to combine external assessments of performance and staff level experiences. Third, this was conducted within a county that had very active SARS-CoV-2 testing activity. During the

evaluation period, almost 1 million SARS-CoV-2 tests were performed, yielding a detailed assessment of background SARS-CoV-2 activity for comparison. Finally, the OSD used an available, easy-to-use, and inexpensive RSAT, enhanced by a wireless reporting system that can be used for public health measures. Accordingly, this approach is replicable elsewhere.

There were also significant limitations. First, we worked with the manufacturer of Sofia to provide the OSD with analyzers and test kits. Other school districts may use other technologies and may not have the same level of support. Second, rapid test results were not labeled as student or school staff, so our staff used the provided age to delineate the tested individual (>18 years old labeled as staff, ≤18 years old labeled as student). Third, because of FERPA guidelines, secondary swabs taken from individuals with a negative rapid test and submitted for RT-PCR testing were unable to be paired with the corresponding rapid results, so study case numbers are based on rapid results without confirmatory testing. Rapid tests generally have high specificity, but only moderate sensitivity, so the true positivity may be greater than reported data suggest.17 Furthermore, we were unable to evaluate influenza data, as current surveillance for influenza has been disrupted by the pandemic. Fourth, the reasons and process for RSAT testing is clear; however, the reasons and process for individuals seeking

 Table 3. Self-rated Average Level of Confidence in Performing Activities Involved in Testing for SARS-CoV-2 and Reporting Results Before and After Training

| | Before Training | After Training | Mean Change | <i>P</i> value |
|--|------------------------|---------------------|----------------|----------------|
| How confident are you in your ability to: | | | | |
| Identify COVID-like symptoms | 3.85 | 4.46 | +0.62 | 0.054 |
| Register a student in COVID Connect | 1.54 | 4.46 | +2.92 | 0.001 |
| Collect a nasal swab | 3.54 | 4.77 | +1.23 | 0.008 |
| Perform a Sofia rapid test | 1.69 | 4.69 | +3.00 | 0.002 |
| Report test results to parent | 3.38 | 4.69 | +1.31 | 0.014 |
| Ratings were reported on a Likert scale (1 | = not at all confident | 2 = slightly confic | ent 3=somewhat | confident |

Ratings were reported on a Likert scale (1= not at all confident, 2=slightly confident, 3=somewhat confident, 4=fairly confident, 5=very confident).

 Table 4. Comparisons Between Use of Sofia Rapid Testing, Polymerase Chain Reaction (PCR) Testing, and

 COVID Connect (Wisconsin Department of Health Services Reporting Portal)

| | Sofia Rapid Testing | PCR Testing | COVID Connect |
|--|------------------------|----------------|------------------|
| How easy was this resource to use? | 4.62 | _ | 3.46 |
| How easy was it to collect a nasal swab for this test? | 4.77 | 4.45 | - |
| Would you like to utilize this resource next year? | 12/13 | 11/13 | 12/13 |
| How helpful was in-person training? | 4.83 | 4.58 | 4.67 |
| How confident were you in the accuracy of these results? | 4.23 | 4.92 | - |
| How useful was this resource for detecting cases of COVID-19? | 4.54 | 4.85 | - |
| How useful was this resource for detecting cases of Influenza? | 4.46 | - | - |
| How easy was it to select students and staff for testing? | 3.83 | - | - |

Each question was scored on a 5-point Likert scale, from 1 (very difficult, not at all helpful, not at all useful, or not at all confident) to 5 (very easy, very helpful, very useful, or very confident).

testing in the Dane County data are less known and likely more variable. Moreover, we lacked the ability to enumerate invalid tests for Dane County. Fifth, we relied on recall to assess the value of training provided. Finally, this evaluation was conducted in a small school district with an annual enrollment of 4159 students, with a racially and ethnically homogeneous student population (86.1% White non-Hispanic).¹⁸ Accordingly, the findings may not be generalizable.

CONCLUSIONS

We found that implementing a district-wide K-12 SARS-CoV-2 rapid testing protocol is feasible, widely accepted, and reflective of local trends. With minimal training, 13 health office staff members were able to successfully implement a rapid testing protocol for symptomatic students and staff in 7 schools during the 2021-2022 academic year. Testing was performed continuously throughout the school year with an invalid result rate of less than 0.5%, and positive rapid testing data correlated highly with county rates of SARS-CoV-2. Twelve of 13 participating health office staff indicated interest in continuing this program of rapid testing in the coming school year.

Rapid tests are relatively inexpensive and have the added benefit of being performed on-site, with results that are available in near real-time. Cause-specific illness episode data emanating from K-12 schools has the potential of providing a community-based data stream for more accurate estimates of local SARS-CoV-2 trends, especially when there is a potential for underreporting of at-home tests.¹⁹ The SARS-CoV-2 pandemic has opened the door for the introduction of rapid antigen testing in K-12 schools. In the future, schools may serve as an ideal location for testing and surveillance of other pathogens.

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