

Snohomish School District Testing Study Design Overview

Background

The Seattle Flu Study is proposing a research study that aims to develop a SARS-CoV-2 testing strategy in schools to facilitate their reopening. This research study would allow the study and its collaborators to learn more about the transmission of SARS-CoV-2 in a school setting, specifically between adults and children, in order to help prevent future outbreaks and allow for the safe reopening of school districts. Weekly testing of children and staff could slow down the transmission of SARS-CoV-2 and decrease the risk of infection. Although COVID-19 vaccines are now available through FDA Emergency Use Authorization for priority groups, vaccination will not be available for younger children until the top three priority groups have been vaccinated and after data for completed vaccine clinical trials in children are available. Since a substantial proportion of children with SARS-CoV-2 infection are asymptomatic or have very mild illness, but can transmit to close contacts, current prevention of SARS-CoV-2 transmission in schools requires mitigation strategies, which may include regular testing, alongside research to inform prevention and control measures. This research study may help guide school reopening strategies for the future. The proposed research study would be conducted by the Seattle Flu Study group, which includes faculty and staff from the Brotman Baty Institute (BBI), University of Washington Department of Medicine and Department of Genome Sciences, Seattle Children’s Hospital, and the Fred Hutchinson Cancer Research Center.

Study Population

The study team proposes a pilot study that would focus on elementary schools of Snohomish School District (SSD), with the option of expanding to middle and high school sites for staff testing as funding allows. With approximately 1,100 students in the Snohomish School District attending Kindergarten through 2nd grade and plan on attending school for in-person instruction, we expect between 700 to 900 students to volunteer to participate in this study. We also estimate approximately 600 staff to be working in-person at elementary school sites with K-2 students, with an estimated 480 staff opting-in to participate in the study. A study coordinator will be available to visit a study site to provide an in-person orientation and answer questions if it would help engage the population and increase participation. A thermometer could be provided as a thank you for their participation.

Participant Workflow	
School Staff: K-2, option for 3-6 and 7-12	One swab self-collected each week and dropped off at school on scheduled day
K-2 children	Choice for parents: <ul style="list-style-type: none">● One swab collected each week and dropped off at school by parent/guardian on scheduled day, OR● Swab collected at school by a research staff member each week on the same day as the sample drop off
K-2 children and staff members staying home with symptoms	Swab mailed to home address. Swab is self- or parent-collected from home and picked up by courier.
Household members of SARS-CoV-2 positive cases	Consented to enroll in the study with a swab collected weekly for a total of two weeks

Study Design

The goal of this proposed study is to gain a better understanding of SARS-CoV-2 transmission in schools as they begin to reopen, specifically of asymptomatic children, and the viral load and transmission that can occur from those positive cases. Between February and June 2021, through regular symptom monitoring and weekly testing of children and school staff, the study aims to better understand the prevalence and impact of SARS-CoV-2 in children in a classroom setting. This study proposes once weekly testing of students attending Kindergarten through 2nd grade, and weekly testing of staff members working on elementary school campuses. Regular testing would be most effective, considering evidence suggests that approximately 45% of children infected with SARS-CoV-2 are asymptomatic, according to the Centers for Disease Control and Prevention (CDC).¹ In the event that an individual tests positive for SARS-CoV-2, the household contacts of that individual would be offered enrollment into a household transmission study with regular testing once per week over the course of two weeks. For SSD participants and for household contacts of positive cases, the research study would require informed consent and parental assent for minors, which could be obtained through email, text message, voicemail communication, or during child pick up one time at the beginning of the study period. English and Spanish translations of all study documents can be provided. An enrollment questionnaire would also be incorporated upon consent completion, which can be designed to collect important data including sanitization practices and masking, known health conditions, and willingness to receive COVID-19 vaccination for adults when eligible and available.

After enrollment, staff and parents would receive a welcome kit either onsite or shipped to their home with directions and all supplies needed for completing specimen collection for the study duration of 16 weeks. On one scheduled day per week, participating children and staff will be asked to return a collected sample to a school drop box. Parents may collect anterior nasal swab samples from their children before drop off, and then place the sample in a drop-box available on-site in a secure location. Alternatively, parents can request for their child's swab to be collected by a research staff member on campus on their scheduled day of the week. Staff may collect their own nasal swabs and place them in the same drop-box. The study team would then pick-up the sample kits and bring them back to the lab for testing. The pick-up time would be decided upon with each school and would fall on the same day each week for the duration of the study. If a staff or child participant is experiencing symptoms, home test kits can be delivered. Samples are tested in the laboratory using a standard CDC molecular based PCR test for SARS-CoV-2. Staff and parents would be able to look up their test results on the Seattle Flu Study's secure web-based portal approximately 24 to 48 hours after sample drop-off.

References

1. Centers for Disease Control and Prevention. Information for pediatric healthcare providers: infection among children. (2020). Available at: <https://www.cdc.gov/coronavirus/2019-ncov/hcp/pediatric-hcp.html>. (Accessed: 1st December 2020)