Addendum to: Risk Stratification and Personal Protective Equipment Use in Pediatric Endoscopy During the COVID-19 Outbreak: A Single-center Protocol

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OVID-19 is a rapidly evolving global challenge. In our rapid communication, "Risk Stratification and protective equipment (PPE) Use in Pediatric Endoscopy During the COVID-19 Outbreak: A Single Center Protocol," we discussed measures taken by our institution to reduce dissemination of severe acute respiratory syndrome coronavirus 2(SARS-CoV-2) infection and preserve PPE resources while maintaining a patient-centered focus on the care of children who require specialized gastroenterology evaluation. Since the initial publication of our report in March 2020, the medical community's understanding of the mechanisms of transmission, clinical course, and duration of infectivity, particularly in pediatric patients, has grown. Availability of testing for viral infection also continues to expand. To this end, we wish to highlight the following amendments to our institution's protocol:

- We continue to perform all previously scheduled and new 1. outpatient endoscopic procedures that are deemed "essential" (defined as procedures that, if delayed more than 8-12 weeks, could lead to harm or injury). Final decisions regarding scheduling and timing of endoscopy will be made through shared decision making between the individual gastroenterologist, patient, and family.
- We recognize that screening for COVID-19 infection based 2 solely on symptoms may not be reliable. We now recommend (although do not yet require) that all patients be screened for COVID-19 infection within 24 hours of the patient's scheduled procedure. Our institution tests nasopharyngeal swabs from patients before their procedure with our lab-developed test for SARS-CoV-2 nucleic acid using the ROCHE cobas 6800 automated platform. This is a dual target assay, with specific target unique to SARS-CoV-2 along with a conserved region of the E-gene from the Sarbecovirus subgenus that includes SARS-CoV-2. At our laboratory, in-house validation reports 99% sensitivity and 99.9% specificity using clinically obtained samples spanning a range of viral loads. The false-negative rate

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DOI: 10.1097/MPG.000000000002762

of our test is approximately 1%. Turnaround time is estimated at 6 to 8 hours (Fig. 1).

- We acknowledge the significant logistic difficulties that 3 "universal" screening can create. If the patient and family decline testing or if the test result is not readily available, the gastroenterologist may choose to either reschedule the procedure until COVID-19 status is known or proceed as "COVID-19 status unknown." It is very likely that preprocedure testing will soon be mandated at our institution as testing capabilities continue to expand.
- 4. For patients with positive preprocedure COVID-19 testing where endoscopy could not be safely delayed until after COVID-19 recovery, our endoscopists will use N95 respirators, double layer gloves, water-resistant gowns, eye protection, and hair coverings for any and all endoscopic procedures.
- 5. For patients with "COVID-19 status unknown" whose procedures cannot be safely postponed, our endoscopists will proceed as if these patients are COVID-19 positive.
- 6. For patients with negative preprocedure COVID-19 testing who present for endoscopy, our endoscopists will use a surgical face mask, single layer gloves, water-resistant gowns, eye protection, and hair coverings for any and all endoscopic procedures. Use of an N95 respirator is not required at our institution when patients test negative. Individual providers are, however, permitted to use an N95 respiratory in lieu of a surgical face mask based on their personal preference or risk factors.
- 7. We continue to perform all endoscopic procedures in negative pressure rooms.
- We are planning serological testing of all providers in the 8. near future. These results may further modify our approach to preprocedure screening and PPE utilization during endoscopy.

We recognize the fast-moving nature of the pandemic is such that our center's preprocedure screening protocol may be updated again soon based on new evidence, changes in resource availability, and the potential surge in local community infection rates. In areas of community spread, we affirm that all pediatric patients should be presumed positive for COVID-19 infection, even if asymptomatic. Viral testing should only be considered reliable if the sensitivity and specificity of the test used are known and validated. We caution that false-negative results of viral testing have been reported in up to 30% of patients (1–3). Institutions who conduct tests with high false-negative rates should consider employing strict airborne precautions, with universal use of N95 respirators, even if viral screening is negative. We are also sensitive to the risks of PPE shortages during this crisis. We allow for reuse of N95 respirators in the setting of aerosol-generating procedures if a long face shield

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Received April 17, 2020; accepted April 21, 2020.

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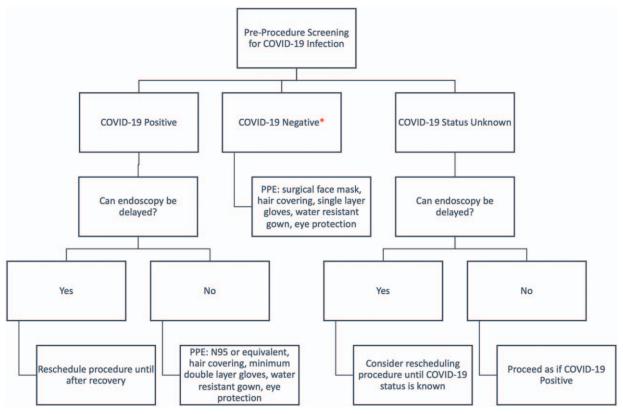


FIGURE 1. PPE utilization algorithm for pediatric endoscopists. *Confirmed negative using a validated test with high sensitivity and specificity within 24 hours of endoscopy; in areas of community spread, all patients should be presumed positive.

protected the mask during use, the mask is not damaged, and fit can be maintained. Storage of the N95 mask is allowed only in a brown paper bag that must be properly labeled with the date and the provider's name. Our institution is developing a technique for disinfection and sterilization of used N95 masks. We hope to share details of this process as it is validated and refined. We ultimately strive to prioritize the safety of ourselves, our anesthesiology and endoscopy staff, and our patients during this crisis, whereas balancing the need to conserve PPE and provision of care for the children who need us.

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