

GUIDANCE FOR RESUMING GI ENDOSCOPY AND PRACTICE OPERATIONS AFTER THE COVID-19 PANDEMIC

The rapid spread of COVID-19 has forced the temporary postponement of elective endoscopic procedures and non-essential GI office activity. As current containment measures take hold and the number of new COVID-19 cases is decreasing in some areas, GI practices need to plan for the gradual resumption of clinical operations. This must be achieved with the lowest possible risk of exposing patients, staff, and providers.

On April 19, the Centers for Medicare and Medicaid Services (CMS) provided guidance to facilities on restarting non-COVID care in accordance with a phased approach based upon criteria outlined in the White House Guidance to Opening up America Again. The decision to reopen ultimately rests with state and local authorities. Protocols should be followed and updated based on best available public health information.

The purpose of this document is to present recommendations to employ for mitigation of infection risks during the gradual reopening of endoscopy centers and GI clinics. It is anticipated that physician and facility readiness to resume clinical operations will vary based upon the status of the pandemic in a given geographic location and will evolve gradually based on local conditions and guidance from public authorities. Not all proposed measures will be applicable to all practice settings at all times. Gastroenterologists and their administrators need to exercise discretion in implementing individual suggestions, with the goal of supporting their reopening efforts while ensuring the safety of patients, staff, and providers.

TOP PRIORITY: SAFETY OF PATIENTS AND STAFF

Practices should consider the following:

1. Patients should be screened with a pre-procedure COVID-19 questionnaire within 72 hours of their visit, and responses updated, as needed, upon arrival to the clinic or endoscopy facility. Staff should be similarly screened prior to starting each workday. Although pre-procedure questionnaires are foundational, screening will evolve to include COVID-19 testing according to best available technology (see below). The supplemental use of telehealth services should be considered to further assess a patient's fitness. While there is continued debate about its utility, onsite forehead temperature measurement (of patients and staff) using, for example, a non-contact infrared thermometer can be considered as well².

- 2. Positive responses from patients or staff to any screening question should prompt their removal from care areas and, if clinically appropriate, self-quarantine. Resources and a defined workflow for care of anyone presenting with illness should be in place and will vary with institution and practice. Appropriate follow-up and repeat screening (commonly including testing) will determine suitability for rescheduling or return to work.
- 3. Potential exposure to infected individuals should be reported to the proper authorities (e.g., the Department of Health) to trigger contact tracing.
- 4. Room preparation and cleaning, as well as equipment reprocessing, should be performed in accordance with up-to-date requirements by licensing and society recommendations (see below).
- 5. All patients should be surveyed 1-2 weeks post-procedure to assess their satisfaction, to record potential adverse events and to assess for interval COVID-19 symptoms or positive test results. Contact tracing should be initiated if the interval between the encounter and new symptom onset is sufficiently short, or if, at any point, a staff member similarly tests positive.
- 6. Physical distancing rules (see below) need to be adhered to by patients and staff, except during intervals of close contact required by providers to prepare the patient for a procedure or conduct a physical exam.
- 7. When putting on or taking off PPE, proper hand hygiene needs to be practiced.^{3,4}
- 8. Staff should remove watches, rings, earrings, necklaces, and other forms of jewelry before entering the endoscopy unit. Facial cosmetic products should not be worn if PPE is being reprocessed, such as with N95 masks.
- 9. All staff and providers should be oriented and trained on the unit's COVID-19 protocol including proper hand hygiene, the required PPE in their designated work area, proper PPE don and doff technique, location within the unit of replacement PPE, and proper disposal. A "dry run" of the implemented protocol is suggested. New staff and providers who may rotate through the unit, such as anesthesia providers, must be properly oriented and trained prior to working in the unit for the first time. Training and orientation should be repeated as protocols change over time.

DISTANCING AND PPE CONSIDERATIONS FOR THE OFFICE

Distancing of 6 feet (2 meters) or more between individuals should be enforced as much as possible and the following measures considered:

- 1. Patients should come by themselves or with only one essential family member/caregiver.
- 2. Patients should wait off premises or in a vehicle until they are called for the visit.
- 3. Lobby/waiting room chairs should be redistributed for social distancing (which may reduce capacity by 50%-75%).
- 4. The check-in process should be reworked to limit direct contact with staff, and patients be roomed immediately after the initial screening.

5. Scheduling and check-out processes should be redesigned to ensure that distancing is maintained, preferably with separate entrance and exit. Staff performing pre-screening and follow-up assessments can take advantage of telehealth services and work remotely over a virtual private network (VPN). Telehealth can also be utilized for scheduling and relaying prep information or answering questions about any planned procedures. Physical barriers (e.g. plexiglass partitions) should be considered if sufficient physical distancing cannot be accomplished.

Patients and staff should be wearing washable cloth or surgical face masks at all times.

Resumption of minor office procedures should take into account the phased approach outlined in the introduction. PPE use for office procedures should follow PPE considerations for the endoscopy center (see below)³.

Whether such PPE requirements can be lessened will depend on the availability, accuracy and affordability of point-of-care viral tests and should await public authorities and professional society guidelines.

DISTANCING AND PPE CONSIDERATIONS FOR THE ENDOSCOPY CENTER

Distancing and entrance/exit considerations should follow parallel processes as described above for offices. The capacity of lobbies, admittance/recovery bays and foot traffic to leave the center may be substantially reduced, and substantial capacity decreases will be common as long as distancing is needed. Availability of reliable point-of-care testing may eventually allow for reduced distancing requirements.

All staff and patients should wear surgical/ear loop masks provided by the center. Only essential caregivers should accompany a patient into the center. Family members/responsible adult companions should return later or stay in vehicles until called. Staff in specific areas should wear the following:

- Pre-admission staff
 - Surgical/ear loop masks
 - Nitrile gloves

Physical barriers (e.g. plexiglass partitions) should be considered if sufficient physical distancing cannot be accomplished. If tablets are used for check-in, they should be cleaned and disinfected after each use. Use of devices in the lobby that cannot be easily disinfected should be discouraged.

- Pre- and post-operative area
 - Surgical/ear loop masks
 - Nitrile gloves

- N95 respirator or equivalent can be considered, depending on availability, if direct patient contact, e.g. helping patients gown or dress, conducting patients out of center for discharge
- Operative/procedure room
 - N95 respirator or equivalent
 - Nitrile gloves
 - Impervious gowns, if available. Laundered gowns have replaced lightweight disposable gowns in some centers
 - Face shields/eye protection
 - Head covering (hair net, bouffant type or surgical cap)

SCHEDULING OF PROCEDURES

Priority Tiering

Scheduling of patients should be prioritized as urgent (tier 1), semi-urgent (tier 2), or elective (tier 3), reflecting the potential of serious outcomes with delay of procedures. A detailed classification of symptoms and diagnoses by tier group can be found elsewhere⁵. Elective (tier 3), in this scheme, does not mean optional. If there are indications for the procedure, then inherently there are patient risks if it is not carried out. Patients should also be prioritized by the extent of their comorbidities, mainly to identify those whose physiological state might rapidly worsen if a procedure is deferred, or if their status might make them more vulnerable to COVID-19 adverse events. For example, a delayed evaluation of a colitis patient, may mandate empiric high dose corticosteroids.

The practice should follow a written policy outlining the priority protocol. In general, this parallels Phases 1-3 in the White House guidance document and other similar guidance. An affidavit should be included with all notes and telephone encounters declaring that the procedure meets prioritization criteria.

Providers should indicate the patient's procedural tier in their telehealth visit or telephone encounter note. Patients should notify the practice of any change in symptoms or condition that may occur between scheduling and the date of the procedure.

Timing of Procedures

Following a referral to the GI clinic, patients should be contacted and scheduled for a date appropriate to meet usual medical and COVID screening needs, and reflective of staff and provider availability. Offices or endoscopy facilities that have furloughed staff may find themselves unable to rapidly ramp back up, and staff will require training in detailed COVID-related processes. An extended work week, or extended hours, may be required in many cases during the ramp-up, particularly considering some of the

capacity issues imposed by distancing. Patients who require emergent or urgent care should be expeditiously handled without bypassing essential safety steps for screening and for safe completion of their procedures.

Pre-Visit COVID-19 Screening

A COVID-19 screening questionnaire (see Appendix A for suggested template) should be completed for all patients. The questionnaire should be completed at the time of scheduling and repeated within 72 hours of the procedure. Interpretation of answers to question #1 requires staff to have some knowledge about viral testing and its reliability. Reliance on viral testing becomes less important if all asymptomatic patients are treated as if they are potentially infected and contagious.

Pre-Procedure Evaluation

A telehealth visit or telephone consultation should be considered for each patient referred for endoscopy, to assess for co-morbidities and possible exposure to COVID-19. Expectations for the day of the procedure need to be explained during the same call. Specifically, the following process items need to be reviewed:

- 1. Endoscopy center intake process
- 2. Visitor policy
- 3. PPE policy
- 4. Consent form

Consideration should be given to including a paragraph in the procedure consent form regarding COVID-19 and the potential risk of infection transmission related to entering a medical facility and undergoing a medical procedure during the current pandemic. Following the pre-procedure evaluation, the consent form, procedure instructions, and procedure prep, as needed, can be mailed or emailed to the patient.

COVID TESTING

A significant number of COVID-19 infections are being transmitted from asymptomatic or pre-symptomatic individuals³. Ideally, efforts to mitigate viral transmission would require all patients to demonstrate either the presence of convalescent antibodies to SARS-CoV-2 or a negative molecular test within 48 hours of a scheduled procedure. Until such tests become widely available and assays have been standardized and their performance validated, GI practices will have to individualize their approach and will often have to rely on rigorous pre-procedure screening and universal use of protective equipment for all unit staff and patients.

DAY OF PROCEDURE

Specific steps for patient check-in, pre- and post-operative care and procedure room protocols will vary based on the availability of COVID-19 testing, and the type and size

of the endoscopic facility. The following are suggestions for endoscopy unit leadership to consider and adapt to local needs. They will need to be periodically revisited and modified as new information and additional COVID-19 management tools become available.

Endoscopy Center Check-in Process

- 1. Upon arrival, the COVID-19 questionnaire should be repeated, and the patient's temperature taken as noted above.
- 2. Cell phone numbers for patient and family/responsible adult should be recorded and questions answered.
- 3. If feasible, patients should wait in their vehicles/off premises until notified to come into the endoscopy unit.
- 4. Patients should proceed directly to the pre-operative bay. Family members/responsible adults should return or wait in the vehicle until they are notified for post-procedure pick-up.
- 5. Chairs in the waiting room should be spaced appropriately, and face masks worn by all family members/caregivers who are unable to wait in the car or offsite.
- 6. Form signatures, insurance verification, and payment details should be handled remotely if possible, at the time of initial screening and returned at check-in or provided to be completed in the vehicle before the patient enters the center.

Pre-operative/Post-operative Room Process

- 1. Patients should be admitted directly to their pre-operative room/bay. Using the same space for post-operative care, if feasible, will reduce the need for cleaning between individual patients.
- 2. Patients should continue to wear their surgical mask throughout their entire stay at the endoscopy center (with the mask being removed only for upper endoscopy).
- If a procedural oxygen mask is used during upper endoscopy and left in place for a portion of the post-operative recovery time, it should be replaced again with a face mask as soon as the procedural oxygen mask is being removed from the patient.
- 4. The family member/responsible adult should be notified by phone when the patient is ready for discharge. Procedure findings and follow-up plans can be discussed at that time if previously permitted by the patient.
- 5. The patient-provider discharge discussion can proceed as usual (with appropriate distancing and protective measures), including a conversation about endoscopy findings and follow-up plans.
- 6. The patient may ambulate to the vehicle or be transported by wheelchair at the nurse's discretion.
- 7. Follow-up phone calls will be made per unit policy.

- 8. Patient and family member/responsible adult should be instructed to call immediately if the patient has a positive COVID-19 test or develops any of the following symptoms within 14 days of the procedure:
 - a. Fever to 100.4 F (38C) or higher
 - b. Cough
 - c. Shortness of breath, difficulty breathing, chest pain
 - d. Sore throat
 - e. Loss of sense of smell or taste
 - f. New onset of fatigue or lack of energy
 - g. New onset nausea with or without vomiting
 - h. New onset diarrhea
 - i. Any other significant new or unusual symptom

Procedure Room Process

- 1. All members of the endoscopy team should wear a full set of PPE (gown, gloves, hair cover, eye protection), as noted above.³
- 2. The correct sequence of putting on and taking off PPE is critical and needs to be understood and practiced.³
- 3. All members of the endoscopy team should wear N95 respirators (or devices with equivalent or higher filtration rates) for all GI procedures. Given the high rate of infection transmission from pre-symptomatic or asymptomatic individuals, all patients should be considered potentially contagious. Negative COVID molecular testing within 48 hours of the procedure and/or convalescent anti-COVID antibodies may prove useful for procedural area management, but at present, the moderate negative predictive value of PCR testing done on nasal swab samples, and insufficient data regarding waning infectivity with antibody development make it hard to rely on either test for alteration in procedural area practices.
- 4. Reuse of N95 respirators may be necessary in the event of resource shortages.3 Guidance is available on how to wear, remove, decontaminate and store respirators for reuse.⁶
- 5. Patients with persistent coughing post-procedure should remain in the procedure room until their cough has subsided.
- 6. If nebulizer treatments are required, these should be administered in the procedure room rather than the pre-/post-operative area. Metered dose inhalers (MDI) are preferred over nebulizers. Patients with a history of nebulizer/MDI use should bring their own devices with them.

- 7. Procedural oxygen masks should be left in place until the patient is weaned off supplemental oxygen, as noted above.
- 8. Patients should be transported to the recovery area as soon as they are deemed safe and ready for transfer.
- 9. Procedure staff and proceduralist should remove PPE and perform proper hand hygiene before completing procedure reports. Computer terminal keyboards and computer mice will be disinfected regularly using appropriate wipes (see below).
- 10. Procedure room vacancy should be built into the schedule to allow for extended patient recovery and room cleaning times between individual procedures. Rooms lacking negative pressure benefit from additional aeration time for adequate clearance of droplets/aerosols.

CLEANING

- 1. No changes are recommended to established reprocessing procedures for endoscopes and accessories. Standard bedside pre-cleaning, followed by manual cleaning and high-level disinfection in the reprocessing facility should continue.^{7,8}
- 2. Reprocessing staff should be donning personal protective equipment (PPE) that includes gloves, gown, face shield, bonnet and mask. While there are no data to support a requirement for the use of N95 respirators in the reprocessing room, their use should be considered, if available.³
- 3. EPA-registered hospital-grade disinfectant solutions and wipes should be used in procedure rooms to clean all high-touch and horizontal surfaces.⁸
- 4. Clorox™/bleach wipes can be used for kitchen and personal desk spaces.8
- 5. Desks, counters, keyboards, computer mice, phones, doorknobs, faucets, etc. should be disinfected at least twice daily.
- 6. Restrooms should be cleaned frequently, ideally after each patient.
- 7. No changes are recommended to 'terminal cleaning' procedures for cleaning and disinfecting the endoscopy unit at the end of the day.⁷

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APPENDIX A

COVID-19 Questionnaire (suggested; adapt as needed)

- 1. Have you had testing for COVID-19? Clarify if this was a direct viral test (e.g., swab, saliva) or serologic (blood antibody) test.
 - a. Was your test positive or negative?
- 2. Do you have any of the following? (yes or no)
 - a. Fever to 100.4 degrees (38C) or higher
 - b. Cough
 - c. Shortness of breath, difficulty breathing, chest pain
 - d. Sore throat
 - e. Loss of sense of smell or taste
 - f. New onset of fatigue or lack of energy
- 3. Do you have nausea with or without vomiting?
- 4. Do you have diarrhea?
- 5. Have you recently traveled to any current COVID-19 hot spot? If so, where?

The top impacted states in the United States and hot spots around the world can be found in the New York Times Coronavirus Map: Tracking the Global Outbreak^a.

- 6. In the past 14 days, have you come into close contact (within 6 feet/2 meters) with someone who has a laboratory-confirmed COVID-19 diagnosis?
- 7. Are you a first responder, healthcare worker, or do you work or volunteer at a hospital or health care facility?
- 8. Are you an employee of a daycare facility, senior living location, adult daycare or extended care or rehabilitation care facility?

Answering "yes" to any of the above symptom questions (1-4) should result in referral to a primary care provider for assessment and possible testing. Answering "yes" to any other question should trigger COVID-19 testing performed less than 72 hours prior to the procedure.

^a Coronavirus Map: Tracking the Global Outbreak, *New York Times*, https://www.nytimes.com/interactive/2020/world/coronavirus-maps.html.