POST-COVID-19 RESUMING ENDOSCOPY

The ACG Endoscopy Resumption Task Force: GUIDANCE ON SAFELY REOPENING YOUR ENDOSCOPY CENTER

Dear Colleagues: May 12, 2020

As our profession faces the COVID-19 pandemic, it's critical at this time that all endoscopy units provide a safe environment for patients and staff. In order to care for our patients, we must resume endoscopic services for our patients and local communities as soon as it is feasible.

In response to the tremendous challenges of resuming or ramping up endoscopy during the pandemic and navigating a deluge of clinical information, regulations, and recommendations by the GI societies, the College's immediate objective was to provide insight and guidance. In late April, we convened the ACG Endoscopic Resumption Task Force, co-chaired by Dr. Neil Stollman and Dr. Costas Kefalas. On April 27th, this group presented a webinar attended by thousands of your colleagues, "COVID-19: A Roadmap to Safely Resuming Endoscopy."

Growing out of that invaluable session is this guidance document in which the Task Force provides a practical overview of reopening or ramping up endoscopy including when, who, what, where and how to succeed safely.

Even at a time when so much remains uncertain during the COVID-19 pandemic—and data to support decisions may be limited—the Task Force offers expert consensus opinion based upon the available data.

As a summary, the Task Force notes:

- The impact of the pandemic is substantial, with only one-third of GIs doing endoscopy in their ambulatory surgical center (ASC), and less than one-quarter having adequate personal protective equipment (PPE).
- There are patient consequences to delayed care, and this should inform resumption planning.
- Federal guidance is extensive, but local regulations and conditions dominate.
- Every aspect of ASC patient flow and operations needs thoughtful attention.
- PPE recommendations are fluid and dependent on local conditions and availability; we propose a flexible algorithm, the ACG "PPE Decision Tree."
- Highly sensitive rapid polymerase chain reaction (PCR) tests are recommended when and where available.

It's an understatement that gastroenterologists performing endoscopy now, and in the days ahead, are practicing during an uncertain time when recommendations are likely to change as this pandemic evolves. For this reason, the Task Force will continue to monitor and communicate any necessary changes in the coming weeks and months. We are so grateful to the members of the Endoscopic Resumption Task Force for providing a clear roadmap to support ACG members as they formulate plans to reopen or ramp up endoscopy that are as safe, flexible and practical as possible.

Stay safe and thank you for your commitment to the care of our patients,

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The American College of Gastroenterology (ACG) Roadmap for Safely Resuming or Ramping-Up Endoscopy in the COVID-19 Pandemic

Updated as of May 12, 2020

American College of Gastroenterology Task Force on Endoscopic Resumption

→ INTRODUCTION

Unprecedented Disruption in GI Practices

The COVID-19 global pandemic has led to millions of infections worldwide with tragic loss of life. Lockdown measures necessary to mitigate the spread of the infection have also caused extensive economic damage, resulted in millions of lost jobs, and marked disruption of our healthcare system. A survey done by the American College of Gastroenterology Practice Management Committee (PMC) (Table 1) revealed important changes to practice operations, severe reductions in revenue across all gastroenterology practice models, and a significant impact on patient access to endoscopy (details in Appendix A).

TABLE 1. KEY FINDINGS: ACG PMC COVID-19 CRISIS BUSINESS SURVEY (APRIL 7-21, 2020) – 335 RESPONDENTS

1. Reached a broad cross-section of practice types and communities in 42 states and Puerto Rico
2. Severe revenue reductions in every practice type: 86% reported at least a 50% income reduction and 38% expecting negative income
3. 39% of gastroenterologists were seeing patients face to face
4. 33% of gastroenterologists were performing endoscopy in an ambulatory surgical center (ASC)
5. A dramatic transition to telemedicine (67% doing >75% of encounters)
6. A widespread shortage of facial personal protective equipment (PPE) (only 23.5% reported adequate supply of N95 masks)

Weighing Unintended Consequences of the COVID-19 Response:

The profound attention during this crisis to infection control and mitigation efforts has left significant health care needs unmet, with potential negative consequences of prolonged delays to care. Causes for these delays include widespread closure of medical offices, cancellation of procedures deemed non-emergent and the loss of health insurance by millions. Telemedicine represents a significant change from traditional care and is a partial solution applicable only to cognitive care. Although colonoscopy for cancer screening has been categorized as 'elective,' it is likely that a prolonged delay will result in real harm. The IQVIA Institute for Human Data Science (1) has reported that the pandemic response has resulted in a reduction of mammograms, colonoscopies, and pap smears by 87%, 90% and 83% respectively since February 2020. Furthermore, if these trends continue in the U.S. through June 2020, it will translate to a delay in the diagnosis of over 80,000 cancers. According to another recent report, a suspension of elective colonoscopy for 6 months will result in the delayed diagnosis of over 2,800 colorectal cancers and 22,000 high-grade adenomatous polyps in the United States alone. The 6-month mortality rate for those eventually diagnosed with colorectal cancer would increase by 6.5% (2). Although determining how to weigh these issues in decision-making about expanding access to endoscopy is problematic, the importance of potential increases in cancer risk cannot be ignored. We believe that recommendations that significantly reduce access to the benefits of endoscopy must be firmly evidence-based and of clear net benefit.

Need for a Roadmap

Resuming endoscopy during this pandemic is a tremendous challenge, with a daily deluge of new information, regulatory guidelines, expert opinions, and society recommendations. The American College of Gastroenterology established the Task Force on Endoscopic Resumption to critically review the available information and offer practical guidance for our members. The Task Force presented a webinar on this topic on April 27, 2020 which can be accessed here. In follow up, the Task Force now presents this Road Map for Safely Resuming or Ramping-Up Endoscopy in the COVID-19 Pandemic, the goals of which are listed in Table 2.

TABLE 2. GOALS OF THE ACG ROADMAP FOR SAFELY RESUMING OR RAMPING-UP ENDOSCOPY

1. To summarize the current regulatory framework on reopening endoscopy
2. To base recommendations on available data, when available, and to provide expert consensus opinion as to best practices when data are inadequate
3. To provide plans to reopen endoscopy that are as safe, flexible, and practical as possible

Sections of the Roadmap

1. **The Regulatory Framework:** Summarizes the numerous orders, directives and regulations from the White House, the Centers for Disease Control and Prevention (CDC), and other governmental agencies. Specific CDC documents and society guidelines are made easily accessible via links.
2. **A Practical Overview of Reopening or Ramping-Up:** Outlines the "who, what, where, when and how" necessary to resume endoscopy operations. Attention is given to the processes of patient selection, minimizing infection risk, and many other practical imperatives.
3. **Making Sense of PPE and Patient Safety:** Reviews the equipment and processes needed for personal protection and patient safety. Specific attention is given to facial PPE and includes a practical "PPE Decision Tree" for choosing PPE appropriate for endoscopy in a variety of clinical settings.
4. **The Role of Testing:** Reviews available testing methods and summarizes options to test for COVID-19, placing each into appropriate clinical context.
5. **Restoring Endoscopy in the Hospital:** Reviews issues of resuming endoscopy operations unique to the in-patient setting.
6. **The Business of Reopening or Ramping-Up:** Outlines important financial and business considerations to reopening an ASC during this pandemic. Special attention is given to the challenges of reopening after shutting down and furloughing staff.

→ THE REGULATORY FRAMEWORK

Professional Society Guidance

- From the onset of the COVID-19 pandemic, new information has been rapidly assessed in real time and made widely available
- Professional societies, including ACG, have released recommendations pertinent to gastroenterologists and endoscopists
- Some of these recommendations have been conflicting due to many factors including the fast-changing situation, lack of valid data, geographic differences in prevalence, and the availability of personal protective equipment lab testing, and other resources
- A summary of pertinent professional society COVID-19 guidance documents released in 2020 is listed in Appendix B (3-11); ACG continues to monitor this fluid situation to inform its membership appropriately

The White House/CDC Recommendations – Opening Up America Again

- Three-phased approach based on public health experts' recommendations
- Guide to assist state/local officials when reopening economies
- **State or Regional Gating Criteria** (may be modified by state or local officials based on local circumstances) (Table 3) and **Core State Preparedness Responsibilities** (Table 4) must all be met, prior to re-opening (12)
- Includes both **General Guidelines for All Phases** (Table 5) and **Guidelines for Specific Phases** (Table 6 lists guidelines only for Phase 1); Phase 1 permits elective surgeries, including endoscopic procedures (12)

TABLE 3. WHITE HOUSE/CDC – STATE OR REGIONAL GATING CRITERIA

Symptoms	Cases	Hospitals
2-week ↓ trajectory of influenza-like illnesses ***AND*** 2-week ↓ trajectory of COVID-like syndromes	2-week ↓ trajectory of documented cases ***OR*** 2-week ↓ trajectory of positive tests as % of total tests (flat or increasing volume of tests)	Treat all patients without crisis care ***AND*** Robust testing program for at-risk healthcare workers, including emerging antibody testing

TABLE 4. WHITE HOUSE/CDC – CORE STATE PREPAREDNESS RESPONSIBILITIES

Testing and Contact Tracing	Health System Capacity	Plans
• Ability to set up safe and efficient testing sites for symptomatic individuals and trace contacts of COVID-19+ results • Ability to test syndromic/influenza-like illness-indicated persons for COVID-19 and trace contacts of COVID-19+ results • Ensure surveillance sites are screening for asymptomatic cases and contacts for COVID-19+ results are traced	• Ability to quickly and independently supply sufficient PPE and critical medical equipment for surge • Ability to surge ICU capacity	• Protect health and safety of workers in critical industries • Protect health and safety of those living and working in high-risk facilities (e.g., senior care facilities) • Protect employees and users of mass transit • Advise citizens regarding protocols for social distancing and face coverings • Monitor conditions and immediately take steps to limit and mitigate any rebounds or outbreaks by restarting a phase or returning to an earlier phase, depending on severity

TABLE 5. WHITE HOUSE/CDC – GENERAL GUIDELINES FOR ALL PHASES	
Individuals	**Employers**
Continue to practice good hygiene: • Wash hands with soap and water or use hand sanitizer, especially after touching frequently used items or surfaces • Avoid touching face • Sneeze or cough into a tissue or inside of elbow • Disinfect frequently used items and surfaces often • Strongly consider using face coverings while in public, and particularly when using mass transit	Develop/implement appropriate policies, in accordance with Federal, State, and local regulations and guidance regarding: • Social distancing • Protective equipment • Temperature checks • Sanitation • Use and disinfection of common/high-traffic areas • Business travel
People who feel sick should stay home: • Do not go to work or school • Contact and follow advice of medical provider	Monitor workforce for symptoms; do not allow symptomatic people to return to work until cleared by medical provider
	Develop/implement policies and procedures for workforce contact tracing following employee COVID-19+ test

TABLE 6. WHITE HOUSE/CDC – GUIDELINES FOR PHASE 1		
Individuals	**Employers**	**Specific Employers**
• Vulnerable individuals shelter in place • In public, all individuals maximize physical distance • Avoid socializing in groups more than 10 • Minimize non-essential travel	• Encourage telework • Return to work in phases • Close common areas • Enforce social distancing • Minimize non-essential travel • Accommodations for vulnerable personnel	• Elective surgeries can resume, as clinically appropriate, on an outpatient basis at facilities that adhere to the Centers for Medicare and Medicaid Services (CMS) guidelines • No visit to hospitals and senior living facilities • Closed: schools, organized youth activities, bars • Open: gyms and large venues (sit-down dining, movie theaters, sporting venues, places of worship), with strict physical distancing protocols

CMS Recommendations – Opening Up America Again

- The incidence of COVID-19 is variable; some areas have a low and stable incidence
- Flexibility is paramount, to permit provision of postponed but needed, non-emergent, non-COVID-19 care
- States/local areas must pass the White House/CDC Gating Criteria released on April 16, 2020, prior to proceeding to Phase 1
- Decisions regarding re-opening should be supported by public health information and state public health authorities
- CMS Recommendations (Table 7) permit healthcare facilities flexibility to provide essential non-COVID-19 care to patients without symptoms of COVID-19, in areas of low COVID-19 incidence (13)
- Coordinate with state/local officials to evaluate incidence and trends for COVID-19 in the area where re-starting care is considered
- Evaluate necessity of procedural care and prioritize care based on clinical needs
- Consider creating **Non-COVID Care (NCC) zones** to screen patients for symptoms of COVID-19, and perform temperature checks; all who enter facility require screening
- Facility should have adequate resources across phases of care, including PPE, healthy workforce, facilities, supplies, testing capacity, and post-acute care, without jeopardizing surge capacity
- All facilities should monitor whether region remains with a low incidence rate and should be ready to stop non-essential procedures if there is a surge
- By following CMS recommendations, flexibility permits safely extending in-person, non-emergent care in certain communities and facilities

TABLE 7. CMS RECOMMENDATIONS FOR REOPENING FACILITIES	
Category	**Recommendations**
Personal Protective Equipment	• Healthcare providers and staff should wear surgical face masks at all times, consistent with CDC recommendations • Procedures on mucous membranes should be done with great caution, and staff should utilize appropriate respiratory protection such as N95 masks and face shields • Patients should wear a cloth face covering that can be bought or made at home if they do not already possess surgical masks • Conserve personal protective equipment
Workforce Availability	• Staff should be routinely screened for symptoms of COVID-19 and if symptomatic, they should be tested and quarantined • Staff who will be working in these **NCC zones** should be limited to working in these areas and not rotate into "COVID-19 Care zones" (e.g., they should not have rounds in the hospital and then come to an NCC facility) • Staffing levels in the community must remain adequate to cover a potential surge in COVID-19 cases
Facility Considerations	• In a region with a low incidence rate, when a facility determines to provide in-person, non-emergent care, the facility should create NCC areas to reduce risk of COVID-19 exposure and transmission; these NCC areas should be separate from other facilities • Within the facility, facilitate social distancing, such as minimizing time in waiting areas, spacing chairs 6 feet apart, and maintaining low patient volumes • Prohibit visitors; if they are necessary for an aspect of patient care, they should also be pre-screened in the same manner as patients
Sanitation Protocols	• Ensure an established plan for thorough cleaning and disinfection prior to using spaces or facilities for patients with non-COVID-19 care needs • Ensure equipment used for COVID-19+ patients are thoroughly decontaminated, following CDC guidelines
Supplies	• Adequate supplies of equipment, medication and supplies must be ensured, and not detract from a community's ability to respond to a potential surge
Testing Capacity	• All patients and staff must be screened for potential symptoms of COVID-19 prior to entering an NCC facility • When adequate testing capability is established, patients should be screened by laboratory testing before care, and staff working in these facilities should be regularly screened by laboratory testing

State/Local Considerations

- In addition to regulatory guidance and recommendations from the White House/CDC and CMS, state/local requirements must often be met prior to re-opening
- State/local considerations may be more restrictive than federal ones, and should be identified and followed
- Check with your state government, state department of health, state medical board, state medical association, and/or state GI society for information and specific recommendations and requirements

Summary

- Professional societies have released numerous recommendations pertinent to re-opening/ramping-up an endoscopy center/unit
- The White House/CDC requirements must be met prior to re-opening or ramping-up an endoscopy center/unit for elective procedures
- CMS has released general recommendations to re-open facilities; there is flexibility in these recommendations, as not all resources are available everywhere and to everyone
- All federal recommendations serve as guidance; state and local requirements must also be met prior to re-opening/ramping-up an endoscopy center/unit

➔ A PRACTICAL OVERVIEW OF REOPENING OR RAMPING-UP

WHEN (to re-open or ramp up)?

- Location dependent, due to:
  - Local government guidance dominates
  - Local hospital capacity (not in 'crisis' care)
  - Downward trajectory x 14 days in cases, deaths
  - 'High risk' vs 'lower risk' community (defined locally)
  - Availability of testing

WHO (our patients)?

- Patient/procedure triage
  - **Immediate/urgent** procedures such as GI bleeding, removal of foreign bodies, cholangitis, dilations, cancer diagnosis or treatment, which are generally hospital-based, should continue to be done as per prior best practice
  - **Elective cases**, in which delay will be of no or minimal clinical consequence, such as screening or surveillance for colorectal cancer, Barrett's esophagus, gastric intestinal metaplasia, bariatric procedures, and most motility procedures should be deferred initially until local conditions permit
  - **For urgent cases not at the extremes above** for which there is a range of priorities, centers should develop or adopt a triage system and apply it systematically and sequentially; a number of suggested schemas have been published, for example the GI Multi-Society Guidelines of 3/31/20 (4) or the European Society of Gastrointestinal Endoscopy (ESGE) guidelines of 4/17/20 (9) that are largely concordant
  - For moderate sized or multi-site practices, consider a formal review committee to assist with adjudicating prioritization
- Pre-procedure screening
  - Telehealth ideally with intake checklist within 24-72 hours of procedure
  - The role of pre-procedure COVID-19 testing is reviewed HERE
  - Day-of procedure screening including temperature, symptom, and exposure questionnaire
- We believe the use of additional exposure consents or 'mutual statements of social responsibility' are reasonable but their use should be determined locally

WHO (our staff)?

- Assess availability of physicians, techs, RNs, CRNAs, housekeeping/facilities personnel, considering medically vulnerable staff (age, immunosuppressed)
- Avoid detracting from surge hospital needs, if locally relevant
- Minimize transfer of staff between COVID-19 zones and non-COVID-19 zones
- Minimize number of staff present (as safety allows)
- Minimize shift changes, patient handoffs, and staff changes intra-procedure to conserve PPE and minimize exposures
- Consider A/B teams to compartmentalize potential exposures
- Ensure appropriate staff retraining on PPE and infection control protocols
- Recognize that staff may be fearful of returning to work in the health care setting

WHAT (is needed to safely re-open)?

- Supplies required to re-open include medications, anesthesia supplies, PPE, cleaning supplies
- PPE training, fit testing, triage algorithm (ACG PPE Decision Tree)
- Ensure physical plant is functional including reprocessing machines, monitors, computers
- Ensure pathology service availability
- Ensure drills and inspections are up to date
- Coordination with:
  - Local regulatory authorities
  - Hospital with transfer agreement
  - Vendors
  - Facility services
- High level center cleaning and endoscope reprocessing prior to re-opening. Note: standard reprocessing algorithms are appropriate

WHERE (the physical space and how to most safely use it)?

- Intake screening area should be as externalized as feasible
  - Intake temperature, symptom, and exposure questionnaire
  - Have protocol for failed screening
- No family or escorts in center unless exceptional circumstances
- Physical distancing, six feet
- Surgical/loop masks for all staff and patients (patient self-provided cloth is acceptable)
- Modify patient flow as needed to maximize distancing
- Procedure room considerations:
  - Adequate donning and doffing areas
  - Flipping (alternating) rooms, prolonged turnover times, EGD-only rooms are reasonable considerations if environment permits
  - Enhanced cleaning reasonable in between cases
  - Standard terminal clean at end of day
  - Further discussion of room infection control HERE
- Center exit flow should be distinct from entrance if possible
- Consider post-procedure patient follow up at some predetermined interval(s)

HOW (to succeed safely)?

- PRACTICE!! Open one day early for a mock trial of operations, patient flow planning, staff retraining
- PLAN FOR CHANGE!! This is today's guidance, and will change rapidly, so we need to stay current and flexible
  - Plan for cessation of restrictions
  - Plan for possible resurgence requiring de-escalation
  - Plan for future supply needs beyond prior levels
- PROTOCOL for patient or staff exposure is required. Local public health agencies can assist with guidance
- SUPPORT your staff physically and emotionally and maintain open communications; watch for, and try to mitigate burnout

→ MAKING SENSE OF PPE AND PATIENT SAFETY

Introduction

Human to human transmission of COVID-19 may occur through respiratory droplets, aerosolization of virus, and by contact with contaminated surfaces from people with both symptomatic and asymptomatic infections (14-23). All endoscopic procedures should be considered potentially aerosol generating due to coughing and retching that can occur during upper endoscopy especially, and less likely during colonoscopy. Contaminated fluids can splatter from buttons and valves when inserting or removing devices from the endoscope and can contaminate surfaces that can be an additional source of infection exposure. While the COVID-19 virus has been identified in the stool, the infectious nature of fecal virus, if any, is not yet well characterized.

All endoscopy units must provide a safe environment for patients and staff. This should include appropriate patient selection and general distancing principles outlined above. A detailed and organized infection control plan should be in place specific to your center that is continually reviewed and updated. Designating at least one person to manage safe endoscopic practice and infection control is recommended.

General Recommendations for Safe Endoscopy Practices:

1. If N95 masks or similar protective filtering face piece respirators are available, ensure proper fit testing. Local hospitals may be able to assist with this, some private companies also offer fit testing, and instructions also can be found online.
2. Ensure familiarity with correct methods of hand hygiene.
3. Follow recommendations for proper use of PPE. This includes the proper method and sequence of donning and doffing.
4. Consider having endoscopy unit staff work at their own individual stations using designated phones and computers to avoid possible cross contamination. Frequent touch surface disinfection is also recommended.
5. Limit the number of personnel for each procedure and minimize changing personnel during procedures.
6. Consider having your anesthesia provider use a perforated procedural oxygen mask (POM) during upper endoscopy, if available. Venti masks with the creation of an opening for the endoscope is a less expensive option to the POM and may be more widely available.

Filtering Face Piece Respirator Options

1. Surgical masks
    - Routinely worn even in normal conditions during endoscopy
    - Non-N95 masks and face shields offer some protection and studies comparing N95 with regular surgical masks demonstrate mixed results (24, 25)
    - Can be combined with face shields and goggles
    - Cost < $1
    - Appropriate in low risk scenarios and situations (see algorithm below)
2. N95 and equivalent versions
    - N95 (American), KN95 (Chinese-U.S. Food and Drug Administration (FDA) approved 4-2020), FFP2 (European), P2 (Australian), DS (Japanese)
    - These masks filter at least 95% of the airborne particles 0.3 microns diameter and larger
    - Cost ≈ $1 although prices have currently risen due to limited availability
3. Powered air purifying respirator (PAPR)
    - An alternative that does not require fitting and can be used for providers with facial hair or those who fail mask fit testing
    - Uses a blower to pass contaminated air through a filter which removes contaminant and supplies purified air to a face piece
    - Expensive (≈ $1000) but performs at a level of the N95 and can be used for years
    - More comfortable than N95 masks
4. N95 masks made for industry
    - Same filtering capacity as the health care N95 masks
    - Do not protect against high velocity fluid splashes, which occur more in surgery than in endoscopy
    - As protective for airborne particle filtration as the healthcare N95 masks
    - Similar in price and can be obtained via industrial suppliers and hardware stores
    - Be aware of counterfeit products on the market; look for National Institute of Occupational Safety and Health (NIOSH) seal of approval
5. Elastomeric masks
    - Non-powered, reusable PPE that are more comfortable and easier to obtain than N95 masks
    - Cost ≈ $30-$60
    - Can be used for years and can be disinfected after each use

Reusing and Disinfecting Masks

Reuse

Given the current limited PPE availability, N95 masks are being reused as long as there is no soiling and the integrity and filtration capacity of the mask is preserved. Several reuse strategies have been proposed including rotation of the N95 daily to allow time for decreased viability of virus. Proper storage must be performed by hanging the mask or storing it in a breathable paper bag. There is no current data or formal guidance to inform a specific recommendation for mask reuse; availability should guide local best practice.

Disinfection

Several disinfection methods have been recently studied and supported:

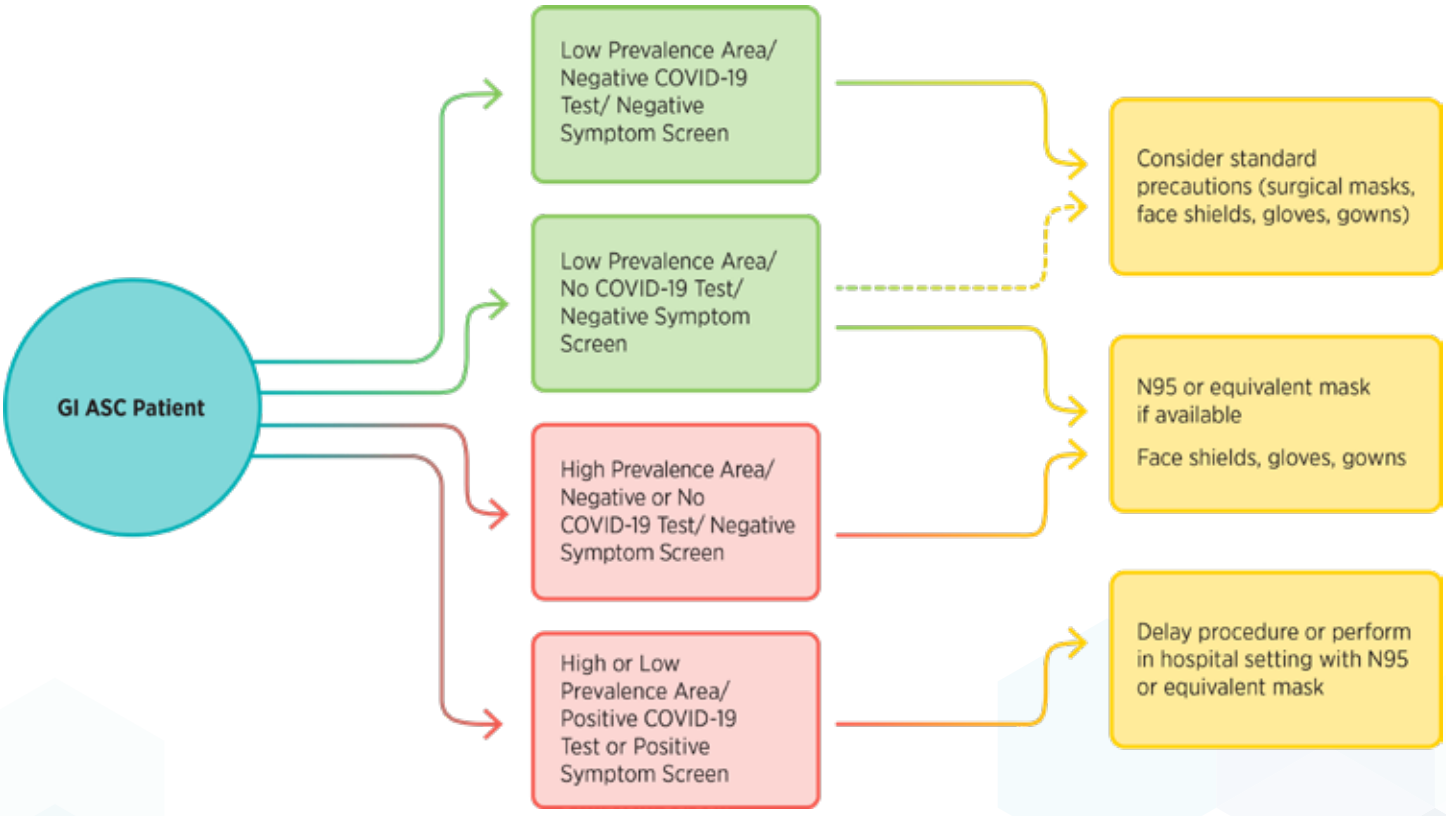
1. **Hydrogen Peroxide Vaporization** – This method is approved by the FDA and can be used multiple times (up to 20x) while still maintaining the integrity of the mask. Several companies including Battelle, Sterrad, and Steris are offering this service.
2. **Ultraviolet germicidal irradiation (UVGI)** – this method is being used by several hospital systems but is technically complex (26). Home UV light is not recommended.
3. **Moist heat** – Moist heat to 60 degrees C and 80% relative humidity have demonstrated 99.99% efficacy in viral reduction while maintaining mask integrity
4. **Steam and Liquid Hydrogen Peroxide** techniques are currently under investigation.
5. **Disinfecting wipes, soap and water, microwave ovens, alcohol or bleach are not recommended for mask disinfection.**

An Approach to Safely Performing Endoscopy During the Pandemic:

- We acknowledge a paucity of data available to support most specific recommendations; this is a fluid situation and recommendations are likely to change over time.
- A recent randomized clinical trial of over 2300 health personnel reported no significant difference between use of N95 respirators and surgical masks in the incidence of laboratory-confirmed influenza (25). Emerging data from the Italian COVID-19 Working Group, specific to GI endoscopy in patients with COVID-19, reported a very low rate of GI staff infections once safety measures, i.e., largely PPE with surgical masks, were implemented (27).
- We must attempt to balance patient and staff safety, local conditions, and availability. Clinical context is paramount and in situations of limited availability and need for supply triage, we do not believe that N95 masks are required for all endoscopy.

The **ACG PPE Decision Tree** (Figure 1) begins with an assessment and stratification of local prevalence, acknowledging that this is imprecise and evolving. Local and state health authorities can assist with this judgement. Procedures performed on patients in **low prevalence** areas with a negative COVID-19 test and negative symptom screen can reasonably be done with standard PPE. Recognizing that rapid and highly sensitive testing is not available in many community settings, procedures performed on untested patients in low prevalence areas with negative symptom screening may be done with standard surgical masks, when there is limited access to N95 or equivalent masks. Procedures performed on patients in a **high prevalence** area with no or negative test testing, and a negative symptom screen should be done with N95 or equivalent masks. Regardless of prevalence, patients with a positive test or symptom screen should have their procedures delayed for testing or performed in an appropriate hospital setting.

FIGURE 1. ACG PPE DECISION TREE



Facility Considerations

Specific strategies to minimize the environmental risk of transmission within the endoscopy suite have not been well defined. According to the CDC, an Airborne Infection Isolation Room (AIIR) is preferred for a COVID-19 positive patient (28). The room must incorporate certain specifications including direct air exhaust to the outside and a minimum of 12 air exchanges per hour and should be well-sealed with continuous monitoring and alarms for any breech (29). This is not feasible in most outpatient endoscopy centers and for this reason COVID-19 positive patient procedures should be done in a dedicated hospital setting.

We suggest that all non-dedicated and non-disposable medical equipment used for patient care should be cleaned and disinfected according to the manufacturer's instructions and facility policies. Any disposable equipment should be limited to that which is necessary. Exposed surfaces should be cleaned and disinfected with EPA-registered agents for COVID-19 with adequate contact times (30).

The amount of time that the air inside a room remains potentially infectious with COVID-19 is unknown and depends on the number of air exchanges per hour (ACH), the nature and duration of the procedure and if the patient coughed or sneezed (29,31). A CDC reference table for ACH timing can be found here. Interventions to increase the air exchange rate or to add external HEPA filtration air scrubbers can be costly, and there are no data to suggest this is effective or currently required.

Individual endoscopy centers should consider these factors in determining their local protocol. Common sense suggests that longer periods of time between procedures are safer than shorter ones, particularly in areas of endemic spread where asymptomatic but shedding patients may be more common. Alternating rooms or using longer time slots is reasonable and logical. We do not believe there is current evidence to support any specific or one-size-fits-all recommendation.

→ THE ROLE OF TESTING

1. For determining acute infection, PCR-based Nucleic Acid Amplification Tests (NAAT) are presently the most accurate test, although with variable sensitivity (Note: the Abbott IDNow test is not currently suitable as a point-of-care test for most ASCs).
2. Routine COVID-19 PCR testing for **staff and physicians** is not currently recommended. We do recommend daily symptom, exposure, and temperature screening.
3. Routine COVID-19 PCR testing for **patients** prior to endoscopy should be individualized based on disease prevalence, local availability of testing and supplies, adequate turn-around time, and sensitivity.
    - If testing is done, we recommend testing <48–72 hours prior to the procedure with patient isolating from testing to procedure time
    - If no testing is done, we recommend telehealth questionnaire screening prior to the procedure, preferably before the patient starts to prepare, and in addition, symptom, exposure, and temperature screening on arrival to the endoscopy center.
4. Serology testing currently has limited utility for patient and staff testing due to variable false positive rates and a still unclear relationship to immunity. At present, this test should not be used to diagnose active infection or determine immunity.

→ RESTORING ENDOSCOPY IN THE HOSPITAL

- Continue previously implemented hospital practices for endoscopy in patients known to be COVID-19 positive/suspected to improve patient and staff safety, minimize waste of PPE, and reduce the spread of infection
- Continue established screening/testing practices for hospitalized patients prior to endoscopy and expand to outpatients requiring endoscopy in a hospital-based facility
- Create a consensus on pre-, peri-, and post-procedure workflows that minimizes crossovers between COVID-19 positive/suspected and COVID-19 negative patients
- Consider establishing a system of staff symptom testing within an inpatient endoscopy unit if not already implemented by your hospital system (i.e. symptom check, temperature check, testing) given proximity to acute care COVID-19 patients
- Consider establishing designated, separate room/spaces for COVID-19 positive/suspected and COVID-19 negative patients requiring hospital-based endoscopy
- Consider removing supplies from endoscopy rooms, using circulators outside of procedure rooms, and/or storing in sealed bins for procedures on COVID-19 positive/suspected and COVID-19 negative patients to prevent contamination and allow for easier disinfection
- If appropriate and feasible, consider performing bedside endoscopy for COVID-19 positive/suspected hospitalized patients
- Consider storing the bedside endoscopy cart in a location separate from endoscopic care zones and designate specific supplies for bedside procedures to be done on COVID-19 positive/suspected and COVID-19 negative patients

→ THE BUSINESS OF REOPENING OR RAMPING-UP

The Prepared Team

Financial instability and uncertainty are present across every type of GI practice. The process of considering reopening endoscopy and reorganizing practice patterns has led to increased stress on practices as they scramble to find the right business processes to do so. The economic transformation of ASCs and the everchanging landscape of COVID-19 has short-term effects and will have long-term consequences (32). Practices need business fortification. Unfortunately, there is no "reset button" to mitigate the economic costs. All available resources should be mobilized to get ASCs ready to begin the process of rebuilding revenue streams safely.

First, a well-developed core team is the most important factor to developing a business plan for ASC resurgence. This team, the Reopening/Ramping-Up (RO/RU) team, is ultimately responsible for creation and implementation of goals, coordination of staffing, and assessing supplies to resume revenue generating procedures. Almost all aspects of the practice play a role. Each interacts to contribute to the overall success of the plan. Components of the team include a wide range of individuals as noted in Table 8. Without an RO/RU committee, revenue recovery is more challenging.

TABLE 8. REVISED OPERATIONS: REOPENING/RAMPING-UP TEAM

Core Members	Responsibilities
• Infection Control • Nurse Manager • Anesthesia • Medical Director • Charge Nurse • Others as needed	• WEEK 1-3: Daily assessment of supplies, patient flow, staffing levels • Track room times and utilization • Monitor all PPE usage (staff and patients) • Train and re-train staff • Procedure monitoring

What to Track and Why

A phased reopening is advised, with evolving projections regarding recovery of revenue. Setting daily, weekly, and monthly goals is appropriate, with a calculation of break-even costs. This analysis should consider volumetric data, including case mix, revenue, supply costs, and staffing inputs such as salaries. Variable costs, for example, linen services, medical waste, and others, also should be included. Each phase has a different focus for the ASC and practice and different revenue expectations (33). The ultimate goal is workforce reinforcement and training. Core business organizational skills come into play for utilization of rooms, staff retraining, and creation of templates for procedure prioritization. These initial steps begin the revenue cycle again. The RO/RU team should start to identify patients for scheduling before Phase I. Volumes will increase in later phases of ramping up when procedure indications are expanded.

To ensure continuous regeneration of revenue, endoscopy supply management is crucial (Table 9).

TABLE 9. ENDOSCOPY SUPPLY MANAGEMENT: COVID-19 RESTART/RAMP-UP

Essentials	Additional Essentials
• Gowns • Masks • Gloves • Face shields	• Germicidal wipes • POMs • Thermometers • IV fluids • Numerous other items

Questions include the following:

1. How has the supply chain been altered?
2. What needs are more likely to go unmet?
3. What is new and different in supply management (34)?

For now, most practices have experienced a slight shift in the cost and availability of essential supplies for safety. In the early months of 2020, mask, face shields, and gowns were easily procured with no need to stockpile as reordering was certain. With increased prevalence of COVID-19, the critical need to track and replace supplies has new associated costs. Prices for most items have increased modestly. The cost of additional essentials must be considered and tracked.

Four categories of expenses make up the majority of practices expenses, and these should be monitored (Table 10).

TABLE 10. EXPENSES TO MONITOR

Categories	Rationale
Staff salaries	• Largest expense of ASC
Supply utilization	• Rate-limiting factor for performance and scheduling • Track weekly, order on a schedule
Rent/mortgage/leases	• Potentially negotiable
Vendors	• Establish alternate supply chains

These can be divided into fixed or variable. Tracking is not only for inventory, but for other items such as salaries. Success of RO/RU will depend on access to adequate supplies. Until the COVID-19 pandemic subsides, enhanced PPE inventories likely will be expensive for centers to maintain. Vendors may be more reluctant to restart previous orders from fully closed ASC practices, while established customers who only partially closed are more likely to be allotted supplies. The CDC has developed a PPE Burn Rate Calculator to aid in tracking supplies (35). It simplifies the use of units of average consumption of goods, therefore allowing practices and ASCs to make projection on future needs. A link is provided in the references below.

Impact of Staff Expansion

Staffing expansion may be necessary as new duties are expected and may be a significant expense for a reopening practice. New personnel potentially may need to be hired, if available. Prior staff may need to be returned from furlough to staff the front office, intake, and billing.

Revision of block-time is a logical business and safety measure to be considered during reopening; centers should anticipate decreased revenue due to a reduction in the number of cases per room. Estimates project that enacting COVID-19 safety standards can reduce typical revenue goals during Phase I and early Phase 2. Patient flow is decreased by the need for enhanced cleaning, allowances for airflow exchange and patient distancing. Uncontrollable revenue-impacting factors include cancellations of procedures and office visits due to COVID-19 infection fears and patient employment constraints (Table 11).

TABLE 11. IMPACT OF REVISING BLOCK TIME FLOW

- Lower caseloads = less revenue
- More PPE required
- Increased patient time for each patient in unit
- Allow airflow exchange for ASCs without negative pressure rooms
- Enhanced cleaning of rooms with greater supply consumption

Multiple conversations have centered on lengthening hours of operations in order to increase revenue. Favorable outcomes include increase in patient volume, decreased patient absence from work, and use of evenings and weekends. Unfavorable consequences are possible requirements for two work shifts, increase in overtime pay, and both staff and physician fatigue.

Unrealized Revenue and Expenses

Ancillary revenue streams may generate additional income with fewer extra expenses. Infusion centers have consistently supplied income throughout the pandemic, although one must closely monitor IV supplies, which may be in shortage. For GI practices that have pharmacies, adoption of an almost complete mail-out platform can maintain a revenue stream while keeping patients distant from physical facilities. Additionally, the benefits of an effective telemedicine program are clear, and reimbursement is increasingly favorable (36).

Marketing

Marketing is an important aspect of reopening and can be inexpensive. There are multiple modes of marketing available. One frequently overlooked area is phone access; patients always should have ease in calling practices. Personal calls and letters to referring physicians to announce that a practice is once again open are appropriate. Other marketing models include public service announcements (PSAs), chamber of commerce listings, or virtual tours on practice websites, all of which can display COVID-19 safety measures to reassure patients. The important role of social media in marketing cannot be overemphasized.

Conclusions

In summary, to financially succeed in reopening and ramping up endoscopic services, a robust leadership team should be assembled as a priority. Frequency of communication and flexibility of staff and providers is essential. Scheduling the right patient at the right time is critical. Availability of supplies may be a rate-limiting step. Careful attention to the issues described can maximize the chance of success with reopening or ramping up an endoscopy unit or center.

ROAD MAP SUMMARY

- The impact of the pandemic is substantial, with only one-third of GIs performing endoscopy in their ASC and less than one quarter having adequate PPE
- There are patient consequences to delayed care, and this should inform resumption planning
- Federal guidance is extensive, but local regulations and conditions dominate
- Every aspect of ASC patient flow and operations needs thoughtful attention
- PPE recommendations are fluid and dependent on local conditions and availability; we propose a flexible algorithm
- Highly sensitive rapid PCR tests are recommended for patient screening when and where available

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→ APPENDICES

APPENDIX A: SUMMARY OF PROFESSIONAL SOCIETY GUIDANCE

Date	Society/Societies	Title
March 15	AASLD/ACG/AGA/ASGE	COVID-19 Clinical Insights for Our Community of Gastroenterologists and Gastroenterology Care Providers
March 31	AASLD/ACG/AGA/ASGE	Gastroenterology Professional Society Guidance on Endoscopic Procedures During the COVID-19 Pandemic
April 1	AGA	AGA Institute Rapid Recommendations for Gastrointestinal Procedures During the COVID-19 Pandemic
April 1	AASLD/ACG/AGA/ASGE	COVID-19 Use of Personal Protective Equipment in GI Endoscopy
April 13	ASGE/SGNA/ACG/AGA/ASCRS	Management of Endoscopes, Endoscope Reprocessing, and Storage Areas During the COVID-19 Pandemic
April 17	ACS/ASN/AORN/AHA	Joint Statement: Roadmap for Resuming Elective Surgery after COVID-19 Pandemic
April 17	ESGE/ESGENA	ESGE and ESGENA Position Statement on Gastrointestinal Endoscopy and the COVID-19 Pandemic
April 27	AGA/DHPA	Joint AGA and DHPA Guidance: Recommendations for Resumption of Elective Endoscopy During the COVID-19 Pandemic
April 28	ASGE	Guidance for Resuming GI Endoscopy and Practice Operations after the COVID-19 Pandemic

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