REGISTER NOW...
ACG’s IBD School & Eastern Regional!
Are now VIRTUAL events, with
On-Demand Presentations and LIVE Webcast Q&A sessions!

Visit meetings.gi.org to register for both today!

NEW!!
ACG 2020 ABSTRACT SUBMISSION DEADLINE
EXTENDED 2 WEEKS!

NEW!! DEADLINE: JUNE 15, 2020
11:59pm Eastern
How to Receive CME and MOC Points

LIVE VIRTUAL GRAND ROUNDS WEBINAR
ACG will send a link to a CME & MOC evaluation to all attendees on the live webinar.

ABIM Board Certified physicians need to complete their MOC activities by December 31, 2020 in order for the MOC points to count toward any MOC requirements that are due by the end of the year. No MOC credit may be awarded after March 1, 2021 for this activity.

ACG will submit MOC points on the first of each month. Please allow 3-5 business days for your MOC credit to appear on your ABIM account.

MOC QUESTION
If you plan to claim MOC Points for this activity, you will be asked to: Please list specific changes you will make in your practice as a result of the information you received from this activity.

Include specific strategies or changes that you plan to implement.

THESE ANSWERS WILL BE REVIEWED.
According to ACCME guidance, because there are no current preventive or specific treatments for coronavirus infection, there are no relevant conflicts of interest for any speakers or moderators.
COVID-19: Resuming Endoscopy: Unanswered Questions and Ongoing Controversies

Current guidance and best practices for the difficult issues of reopening, including personal and environmental safety

Hosted by:

Costas H. Kefalas, MD, MMM, FACG
Trustee, ACG Board of Trustees

Neil H. Stollman, MD, FACG
Chair, ACG Board of Governors

And
The ACG Endoscopy Resumption Task Force

THE ACG ENDOSCOPY RESUMPTION TASK FORCE

Co-Chairs:

Costas H. Kefalas, MD, MMM, FACG
Neil H. Stollman, MD, FACG

Members:

Sapna V. Thomas, MD, FACG
Vonda G. Reeves, MD, MBA, FACG
Harish K. Gagneja, MD, FACG
Michael S. Morelli, MD, CPE, FACG
Louis J. Wilson, MD, FACG
Melissa Latore, MD, MS
Whitfield Knapple, MD, FACG
Jeffry L. Nestler, MD, FACG
COVID-19: Resuming Endoscopy: Unanswered Questions and Ongoing Controversies

PRESENTERS

Neil H. Stollman, MD, FACG
Chair, ACG Board of Governors

Costas H. Kefalas, MD, MMM, FACG
Trustee, ACG Board of Trustees

Whitfield Knapple, MD, FACG
Chair, ACG Legislative and Public Policy Council

Melissa Latorre, MD, MS
ACG Endoscopy Resumption Task Force

Sapna V. Thomas, MD, FACG
ACG Governor for No. OH

Jeffry L. Nestler, MD, FACG
ACG Governor for CT

Introduction

Neil H. Stollman, MD, FACG
Oakland, CA
Chair, ACG Board of Governors
Co-Chair, ACG Endoscopy Resumption Task Force
Why are we here again today?

- Resuming endoscopy Webinar #1: 4/27/20
- Roadmap published online: 5/12/20
- Since then, unanswered questions and confusion remains
- Role for “COVID-19 specific” consent?
- New legislative updates from CDC
- Evolving roles of and controversies over:
  - PPE
  - Environmental safety
  - Pre-procedure COVID testing

We’re ready to get working but are our patients ready to come back?

- No specific data, but providers anticipate concerns
- Survey 123 practices, 4/24-5/8
- “What are barriers to ramping up once cleared….”
  - Limited COVID testing: 69%
  - Patient safety concerns: 66%
  - Inadequate PPE: 54%
  - Staff safety concerns: 37%

Kushnir VM et al. pre-proof 5/22/20. Clinical Gastroenterology and Hepatology
Are patients avoiding care?

- ER visits in CA

Peds ER visits in Italy early March

How to best reassure them?

- All large HC systems now have pages on ‘How we’ll keep you safe’ including social distancing, masks, screenings, no visitors, decontamination, patient flow (as do retailers, equally motivated to get people back…)

- Modalities include press coverage, social media, local public health officials and direct-to-patient communications

- A number have videos, including ….
Accentuate the positives!

- Can start with the pre-consult / telehealth visit; we routinely and proactively address potential concerns; don’t wait to be asked!
- Re-emphasize during pre-procedure screening telehealth calls
- HCWs are viewed favorably and patients generally have trust and gratitude…we can leverage that trust and strive to actually make it one of the few places they CAN feel safe and provide a positive experience during what may be their first ‘re-entry’ into the seemingly scary outside world.
COVID-19: Resuming Endoscopy: Unanswered Questions and Ongoing Controversies

“How Human Centered Design” (HCD)

Costas H. Kefalas, MD, MMM, FACG
Trustee, ACG Board of Trustees
Akron Digestive Disease Consultants, Inc.
Akron, Ohio
ACG Roadmap for Safely Resuming or Ramping-Up Endoscopy in the COVID-19 Pandemic

ACG Endoscopy Resumption Task Force

“We believe the use of additional exposure consents or ‘mutual statements of social responsibility’ are reasonable but their use should be determined locally”

Procedural COVID-19 Consent: Beneficial?

- **YES**
  - May be needed to fully inform patient of potential procedure risks and benefits
  - Formalizes additional risk and memorializes it in the medical record

- **NO**
  - General infection risk listed in any standard procedure consent form is enough
  - Unclear if additional consent decreases (or increases) liability
  - May unnecessarily frighten patients away from a needed procedure
Procedural COVID-19 Consent: Required?

- Depends: Varies across the country

- Some states, regions, and/or institutions **REQUIRE** advising patients regarding COVID-19 risks associated with performing a procedure during the pandemic

Example of State Requirement: **Ohio**

“Hospital and ambulatory surgery facility providers should now inform patients of the risk of contracting COVID-19 and how that could impact the postoperative recovery process. Provide all information necessary for patients to make informed decisions.”

*Ohio Department of Health COVID-19 Information on Non-Essential Procedures, April 22, 2020*
Procedural COVID-19 Consent: The Process

- May be included in *existing* procedural consent document or as a *separate* consent document; either option may be acceptable depending on your state, region and/or institution

- Endoscopist should discuss the COVID-19 procedural risk and patient should sign consent document *before* procedure is performed

Example of Procedural COVID-19 Consent: Digestive Health Center, Akron, Ohio*

“I understand that I am undergoing this procedure during the COVID-19 pandemic. I understand the COVID-19 virus has a long incubation period during which carriers of the virus may not show symptoms and still be highly contagious. I have been informed of the possible risks associated with undergoing this procedure during the COVID-19 pandemic and possible post-procedure complications. I understand that the COVID-19 pandemic is ongoing and traveling to healthcare facilities will increase my possible exposure to COVID-19. I will follow all safety precautions required by my physician and the State of Ohio when traveling for any treatment. I authorize my physician to follow standard precautions to protect myself, staff, and other patients including taking my temperature upon arrival and asking me questions to assess my health. If I am experiencing any of the following symptoms I may be asked to reschedule my appointment: fever, shortness of breath, loss of sense of taste or smell, dry cough, runny nose, or sore throat.”

*Used with permission. Consent wording is provided for educational purposes only and does not constitute a recommendation or legal advice.*
Take Home Points

- There are pros and cons to adding COVID-19 procedural consent
- There is no federal guidance regarding this additional consent
- One should adhere to pertinent state, regional, and/or institutional recommendations, which may vary by location

Update in Federal Regulations

Whitfield Knapple, MD, FACG
Chair, ACG Legislative and Public Policy Council
Little Rock, Arkansas
Opening Up America Again – The White House & CDC:

Refresher from April 27 Webinar

- Three-phased approach based on public health experts
- Guide to assist state/local officials when reopening economies

These Guidelines include:
- State or Regional Gating Criteria
- Core State Preparedness Responsibilities
- General Guidelines for All Phases
- Guidelines for Specific Phases
NS12 i think i asked earlier, but is this the best way to show prevalence, if its simply total case numbers, rather than rate / 100,000 or such?
Neil Stollman, 5/30/2020
### COVID-19: Resuming Endoscopy: Unanswered Questions and Ongoing Controversies

<table>
<thead>
<tr>
<th>Opening Up America Again: Phase 1</th>
<th>Opening Up America Again: Phase 2</th>
<th>Opening Up America Again: Phase 3</th>
</tr>
</thead>
<tbody>
<tr>
<td>States and regions must meet the gating criteria</td>
<td>States and regions with no evidence of rebound and satisfy gating criteria a second time</td>
<td>States and regions with no evidence of rebound and satisfy gating criteria for a third time</td>
</tr>
<tr>
<td>Encourage Telework</td>
<td>Continue to encourage Telework</td>
<td>Resume unrestricted staffing of worksites</td>
</tr>
<tr>
<td>Close common areas</td>
<td>Close common areas/ moderate social distancing</td>
<td>Visits to hospitals and senior care facilities can resume (continued diligent hygiene)</td>
</tr>
<tr>
<td>Schools remain closed</td>
<td>Non-essential travel can resume</td>
<td>Large venues can operate under limited physical distancing protocols</td>
</tr>
<tr>
<td>ELECTIVE SURGERIES- can resume, as clinically appropriate, on an outpatient basis at facilities that adhere to CMS guidelines</td>
<td>ELECTIVE SURGERIES- can resume as clinically appropriate, on an outpatient basis at facilities that adhere to CMS guidelines</td>
<td></td>
</tr>
</tbody>
</table>

---

### Opening Up America Again – CMS

- Coordinate with state/local officials to evaluate incidence and trends for COVID-19 in area where re-starting care is considered
- **Prioritize surgical/procedural care**, high-complexity chronic disease management, and select preventive services
- **Consider establishing Non-COVID Care (NCC) zones** to screen all patients and staff for symptoms of COVID-19, including temperature
- Staff who will be working in these NCC zones should be limited to working in these areas and not rotate into COVID Care zones
- **Facility should have sufficient resources available** across phases of care without jeopardizing surge capacity
Opening Up America Again – CMS

- CMS recommends healthcare providers and staff wear surgical facemasks at all times, consistent with CDC
- Procedures on mucous membranes should be done with great caution, and staff should utilize appropriate respiratory protection such as N95 masks and face shields
- Within facility, facilitate social distancing, such as minimizing time in waiting areas, spacing chairs 6 feet apart, and maintaining low volumes
- Prohibit visitors; if they are necessary, should also be pre-screened
- 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 tests

Opening up America Again - CDC Surveillance Objectives

To identify both symptomatic and asymptomatic / presymptomatic cases and track contacts to slow transmission of COVID-19 in the U.S.
To monitor spread and intensity of COVID-19 in the US
To identify disease clusters requiring special intervention
To understand disease severity, spectrum of the illness, and risk factors for severe disease and transmission
To monitor for virus changes, and produce data for forecasting the spread and impact of COVID-19
To identify methods of preventing infection
To identify when thresholds have been met and adjust community mitigation measures
Opening up America Again - CDC Testing Objectives

**Extensive, rapid, and widely available COVID-19 testing is essential**

CDC is working within the "all of government and all of America approach" to increase testing capacity and availability to improve case detection and contact tracing through all phases of Opening Up America Again

**Testing for diagnosis, clinical management, surveillance, and outbreak control**

CDC is working with state/local partners to define circumstances where testing of asymptomatic persons is likely to be helpful in controlling the pandemic, as well as the best application of surveillance testing

Asymptomatic infections play an important role in the epidemiology of COVID-19 infections and testing should focus on persons with increased likelihood of infections and in settings with particularly vulnerable populations

Opening up America Again - CDC Serology Objectives

**CDC is working to identify indications for serologic testing**

- Serologic prevalence of populations
- Serologic testing of individuals to determine if they had prior infection

**Current CDC COVID-19 serologic testing is not currently designed for individual use**

- Serology has the potential to provide important insights into the transmission dynamics of the disease as well as a more complete picture of the total burden of COVID-19 infections in the community, and among first responders and healthcare providers

More information is needed to determine how results of serologic testing correlate with possible immunity
<table>
<thead>
<tr>
<th>Gating Criteria</th>
<th>Threshold for entering Phase 1</th>
<th>Threshold for entering Phase 2</th>
<th>Threshold for entering Phase 3</th>
</tr>
</thead>
<tbody>
<tr>
<td>Decreases in ED and/or outpatient visits for influenza-like illness (ILI) Decreases in ED and/or outpatient visits for COVID-like illness (CLI)</td>
<td>Downward trajectory of ILI/CLI (or minimal ILI activity or near pre-pandemic level of CLI ED visits) reported over a 14-day period • Uses a 3-day average in a cubic smoothing spline • 14 consecutive days of decline required but can use a 2–3 day grace period if data are inconsistent • Look at both total visits for ILI/CLI and percentage of visits for ILI/CLI • 14th day must be lower than 1st day • If near pre-pandemic level of CLI ED visits has been reached, can meet if pre-pandemic level is maintained over 14 consecutive days (2–3 day grace period)</td>
<td>Downward trajectory of ILI/CLI (or minimal ILI activity or near pre-pandemic level of CLI ED visits) reported for at least 14 days after entering Phase 1 without experiencing a rebound • Same criteria but for a second 14-day period • Rebound is determined if the trajectory increases in a 5-day period</td>
<td>Downward trajectory of ILI/CLI (or minimal ILI activity or near pre-pandemic level of CLI ED visits) reported for at least an additional 14 days after entering Phase 2 without experiencing a rebound • Same criteria but for a second 14-day period • Rebound is determined if the trajectory increases in a 5-day period</td>
</tr>
<tr>
<td>Decreases in newly identified COVID-19 cases</td>
<td>Downward trajectory (or near-zero incidence) of documented cases over a 14-day period • Uses a 3-day average in a cubic smoothing spline • 14 consecutive days of decline required but can use up to a 5-day grace period if data are inconsistent • 14th day must be lower than 1st day • To be near-zero incidence, must have fewer than 10 cases per 100k population over 14 days and must have previously had elevated cases</td>
<td>Downward trajectory (or near-zero incidence) of documented cases for at least 14 days after entering Phase 1 • Same criteria as Phase 1 for another 14 days • Rebound is defined as having 5 consecutive days of increase</td>
<td>Downward trajectory (or near-zero incidence) of documented cases for at least 14 days after entering Phase 2 • Same criteria as Phase 2 for another 14 days • Rebound is defined as having 5 consecutive days of increase</td>
</tr>
</tbody>
</table>
### COVID-19: Resuming Endoscopy: Unanswered Questions and Ongoing Controversies

<table>
<thead>
<tr>
<th>Gating Criteria</th>
<th>Threshold for entering Phase 1</th>
<th>Threshold for entering Phase 2</th>
<th>Threshold for entering Phase 3</th>
</tr>
</thead>
</table>
| **Decreases in percentage of COVID-19 tests positive** | Downward trajectory (or near-zero percent positive) of positive tests as a percent of total tests over a 14-day period (flat or increasing volume of tests)  
- Divide total positive results by total positive + negative  
- Remove incomplete and inconclusive results  
- 14 consecutive days of downward trend with up to 2–3 consecutive days of a grace period due to data inconsistency  
- 14th day must be lower than 1st day  
- If a near-zero plateau has been reached, can meet if plateau is maintained over 14 consecutive days (2–3 day grace period)  
- Test volume must remain the same or be increasing to use this criterion  
- Should include all test results from all labs | Downward trajectory (or near-zero percent positive) of positive tests as a percent of total tests for 14 days after entering Phase 1 (flat or increasing volume of tests)  
- Same criteria as Phase 1 for another 14 days  
- Rebound is defined as having multi-day increases in percent positivity with stable or increasing testing volume  
- Look at positive results and cases when assessing for rebound | Downward trajectory (or near-zero percent positive) of positive tests as a percent of total tests for at least 14 days after entering Phase 2 (flat or increasing volume of tests)  
- Same criteria as Phase 1 for another 14 days  
- Rebound is defined as having multi-day increases in percent positivity with stable or increasing testing volume  
- Look at positive results and cases when assessing for rebound |

<p>| <strong>Treat all patients without crisis care/hospital indicators</strong> | Inpatient and ICU beds &lt;80% full for 7 consecutive days AND no staff shortages for 7 consecutive days AND PPE supplies adequate and available for &gt;4 days | Inpatient and ICU beds &lt;75% full for 7 consecutive days AND no staff shortages for 7 consecutive days AND PPE supplies adequate and available for &gt;4 days | Inpatient and ICU beds &lt;70% full for 7 consecutive days AND no staff shortages for 7 consecutive days AND PPE supplies adequate and available for &gt;15 days |</p>
<table>
<thead>
<tr>
<th>Gating Criteria</th>
<th>Threshold for entering Phase 1</th>
<th>Threshold for entering Phase 2</th>
<th>Threshold for entering Phase 3</th>
</tr>
</thead>
<tbody>
<tr>
<td>Robust testing program</td>
<td>Test availability such that % positive tests ≤20% for 14 days</td>
<td>Test availability such that % positive tests ≤15% for 14 days</td>
<td>Test availability such that % positive tests ≤10% for 14 days</td>
</tr>
<tr>
<td></td>
<td>Median time from test order to result &lt;4 days</td>
<td>Median time from test order to result &lt;3 days</td>
<td>Median time from test order to result &lt;2 days</td>
</tr>
</tbody>
</table>

**Reopening: State Level Resources/Updates**

- Your State Governor's website (COVID-19 page)
- The Council of State Governments “state executive orders” website
- Your ACG Governor

**COVID-19: Resuming Endoscopy: Unanswered Questions and Ongoing Controversies**

**Gating Criteria Threshold for entering**

<table>
<thead>
<tr>
<th>Phase 1</th>
<th>Phase 2</th>
<th>Phase 3</th>
</tr>
</thead>
<tbody>
<tr>
<td>Test availability such that % positive tests ≤20% for 14 days</td>
<td>Test availability such that % positive tests ≤15% for 14 days</td>
<td>Test availability such that % positive tests ≤10% for 14 days</td>
</tr>
<tr>
<td>Median time from test order to result &lt;4 days</td>
<td>Median time from test order to result &lt;3 days</td>
<td>Median time from test order to result &lt;2 days</td>
</tr>
</tbody>
</table>

**Test availability such that**

<table>
<thead>
<tr>
<th>% positive tests</th>
<th>14 days</th>
<th>% positive tests</th>
<th>14 days</th>
<th>% positive tests</th>
<th>14 days</th>
</tr>
</thead>
<tbody>
<tr>
<td>≤20%</td>
<td></td>
<td>≤15%</td>
<td></td>
<td>≤10%</td>
<td></td>
</tr>
<tr>
<td>≤15%</td>
<td></td>
<td>≤10%</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>≤10%</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
Example: Arkansas’ Timeline

April 27 - Elective Outpatient Procedures (Hospital & ASC) - negative COVID test within 48 hours of procedure (asymptomatic patients) (patients with symptoms do not require COVID testing)

May 11 - Elective Outpatient Procedures with hospital stay up to 48 hours - negative COVID test within 48 hours of procedure

May 18 - Negative COVID test within 72 hours of procedure (instead of 48 hours)

May 25 - Elective Procedures with no restrictions on expected length of stay - negative COVID test within 72 hours of procedure

May 27 - Screening colonoscopy does not require COVID-19 testing

“Federal guidance is extensive, but local regulations and conditions dominate”

The ACG Guidance on Safely Reopening Your Endoscopy Center recognizes that not all areas of the country are the same, and each region/state is dealing with various levels of COVID-19 prevalence, ability to test patients/staff, as well as the ability to access personal protective equipment.
Controversies in Personal Protective Equipment Use

Melissa Latorre, MD, MS
Director, Inpatient GI Services at Tisch/Kimmel
Assistant Professor of Medicine
NYU Langone Health
New York, NY

ACG: PPE Decision Tree

- Low Prevalence Area/ Negative COVID-19 Test/Negative Symptom Screen
  - Consider standard precautions (surgical masks, face shields, gowns)
- Low Prevalence Area/ No COVID-19 Test/Negative Symptom Screen
- High Prevalence Area/ Negative or No COVID-19 Test/Negative Symptom Screen
- High or Low Prevalence Area/Positive COVID-19 Test/Positive Symptom Screen
  - Face shields, gowns
  - Delay procedure or perform in hospital setting with N95 or equivalent mask

GI ASC Patient

FIGURE 1. ACG PPE DECISION TREE
# PPE Recommendations by Society

<table>
<thead>
<tr>
<th>SOCIETY</th>
<th>RECOMMENDATION HIGHLIGHTS</th>
</tr>
</thead>
</table>
| ACG        | • Practical approach to PPE balancing patient/staff safety, local conditions, and availability  
              • Uses prevalence/screening to help stratify PPE use  
              • Permits supply triage                                                                                                                 |
| AGA/DHPA   | • Test based strategies for PPE masks: N95 v. surgical  
              • No test + No N95 = No procedure  
              • If test is negative, standard surgical masks are acceptable for use by all endoscopy personnel                                           |
| ASGE       | • All pre/post admission staff with surgical mask/gloves and N95 considered for direct patient care  
              • Procedural Staff: N95 or equivalent  
              • Testing should not alter PPE                                                                                                           |

## Initial Guidance on PPE

- **High-Risk**: Suggested PPE: 1. N95 or FFP2-3 respirator 2. Hairnet 3. Goggles (or face shield) 4. Long-sleeved water-resistant gown 5. Two pairs of gloves

---

Repici A et al. Gastrointest Endosc. Mar 2020

Gastrointestinal Endoscopy doi: [10.1016/j.gie.2020.03.019](https://doi.org/10.1016/j.gie.2020.03.019)
Unanswered Questions

- Should testing change PPE use?
- Should local prevalence change PPE use?
- Does everyone in the procedure room need PPE?
- When do/can we de-escalate PPE use?
- Should the type of procedure change PPE use?

What Can We Learn from Italy?

- Survey of 41 endoscopy units
- Northern Italy at the pandemic peak (March 16-21, 2020)
- 968 endoscopy personnel: 323 endoscopists, 496 nurses and 149 healthcare assistants.

Outcomes

- 14 units performed COVID + procedures and 20 units performed COVID suspected procedures
- PPE availability was variable for COVID positive procedures
- 12 units confirmed staff infection, 42 (4.3%) staff tested positive and 6 (0.6%) required hospitalization (felt to be community acquired and before widespread PPE measures)
- No cases of health care personnel infection/transmission directly related to endoscopic procedures – highlighting success of double masks (patient/HCW)

So, what about the United States?

- Web-based survey
- April 24 - May 8, 2020
- 123 North American practices: 55% ASC and 45% hospital-based
- Representing 32 states and 4 Canadian provinces
- Urban (48.8%), suburban (37.7%) and rural (13.8%)

Kushnir VM et al. Clinical Gastroenterology and Hepatology, 2020

Top Considerations to Reopening

1. Community prevalence (79.5%)

2. PPE Availability (74.6%)

3. Availability of COVID-19 testing (68.9%)
Top Perceived Barriers to Ramping Up

1. Limited Testing Capacity (69%)

2. Patient Safety Concerns (65.9%)

3. Inadequate PPE Availability (54%)

So What’s the Plan?

- In *asymptomatic* COVID-19 test negative patients, 45.5% are (or anticipate) recommending the use of surgical masks by healthcare workers and 52.9% will continue the use of N95 respirators after negative testing.

- In *asymptomatic* COVID-19 patients where pre-procedure testing is NOT being performed, 71.5% are recommending use of N95 masks and 20.3% surgical masks.

- There was no significant difference in planned PPE use between hospital-based and ASC-based centers.
COVID-19: Resuming Endoscopy: Unanswered Questions and Ongoing Controversies

How Do We Safely Ramp Up?

Atul Gawande: Amid the Coronavirus Crisis, a Regimen for Reëntry
(The New Yorker, May 13, 2020)

1. Hygiene
2. Screening
3. Distancing
4. Masks

5. Culture
Back to Our Questions:

- Should testing change PPE use?
- Should local prevalence change PPE use?
- Does everyone in the procedure room need PPE?
- When do/can we de-escalate PPE use?

Going forward, PPE decision making should be tailored to prevalence and testing/screening. There is NO one-size-fits-all solution!

When ramping up and transitioning back to “normalcy,” continue to re-evaluate the 5 pillars and focus closely on creating a culture of safety within your practice.
Environmental Safety and the Role of Room Air Exchange

Sapna V. Thomas, MD, FACG
Medical Director, West Region – Digestive Health Institute
University Hospitals of Cleveland
ACG Governor – Northern Ohio
President - Ohio Gastroenterology Society

Current data suggests that SARS-CoV-2 is transmitted by close-range aerosolized large droplets that may be inhaled or in contact with eyes, nose, mouth of persons nearby.
Air changes/hour

• The minimum number of air changes per hour in an endoscopy room is 6 ACH/hour
• This is generally determined when the HVAC system is installed and evaluated annually
• Depending on the age of the building and installed system – it may be feasible to increase the ACH
  • this may affect the humidity and temperature of the room
• “Air scrubbers” are external units with HEPA filters that can be added to a room to increase the ACH

Asymptomatic Patient, Negative screening questions, w/wo COVID negative test

CONSIDER
• Standard Room
• Standard Precautions
• Standard air changes/hour may be adequate
Are Endoscopic Procedures Aerosol Generating Procedures?

- aerosol generating procedures - generate higher concentration of infectious respiratory aerosols than cough, sneeze, talk, or breathing (https://www.cdc.gov/coronavirus/2019-ncov/hcp/infection-control-faq.html)
- Endoscopy
  - initial insertion of the endoscope inducing cough, flatus
  - insertion and removal of instruments through the endoscope channel

**YES:** Endoscopy tests are AGP’s
- ASGE, AGA
- American Society of Anesthesiologists
- Canadian Association of Gastroenterology
- British Society of Gastroenterology
- Massachusetts General Hospital
- Infection Control Guidelines for AGP

**NO:** Endoscopy should not be considered AGP’s:
- IDSA guidelines on the Infection Prevention for Health Care Personnel Caring for Patient with Suspected or Known COVID-19
- CDC
- WHO

What measures should be taken for source control?

- Ensure all HCW, patients, accompanying attendants wear a face covering
  - Face mask/surgical mask if available for both source control and protection against exposure to splashes and sprays of infectious material from others
  - Cloth face mask to preserve PPE if needed
- Consider POM mask for EGD
- Covering of orifices
- Exposure time matters-
  - <15 minutes spent in the company of an infected person makes spread unlikely

Ensure all HCW, patients, accompanying attendants wear a face covering
- Face mask/surgical mask if available for both source control and protection against exposure to splashes and sprays of infectious material from others
- Cloth face mask to preserve PPE if needed
- Consider POM mask for EGD
- Covering of orifices
- Exposure time matters-
  - <15 minutes spent in the company of an infected person makes spread unlikely
Should we use additional disinfection?

- Surface cleaning and disinfection – high touch surface
  - EPA List N: disinfectants for use against SARS-CoV-2
    - Registration Number
    - Active Ingredient
    - Use Site
    - Contact time – amount of time the surface should be visibly wet
- Alternative Disinfection Methods
  - Ultraviolet lights
    - UV-C – wavelength in the spectrum 200-280 nm – optimal 265 nm
    - Efficacy against SARS-CoV2 is not known
    - Not recommended by EPA, CDC

Summary

- At this time, the primary mode of transmission appears to be large droplet
  - Although the virus has been detected in smaller aerosols – the risk of aerosol based transmission has yet to be determined
- Source Control measures should be taken to contain large droplets
- There is no data to suggest increasing air changes/hour or obligate ‘room settling time’ is effective or currently required
- Endoscopy as an AGP is debatable
Pre-Procedure Covid-19 Testing

Jeffry Nestler, MD, FACG
ACG Governor – Connecticut
President, Connecticut GI PC
Director, Division of Gastroenterology Hartford Hospital
Associate Clinical Professor, University of Connecticut

Pre-Procedure Covid-19 testing

“To test or not to test, that is the question”

Questions?
- What types of Covid-19 tests are available?
- Who to test? Staff? Patients?
- What is the current sensitivity and specificity of testing?
- What is the optimal timing of testing?
- Are there federal, state or other society guidelines?
- What are the barriers to testing?
- Is there any data available?
Types of Testing

- Nucleic Acid Amplification Testing (NAAT)
  - Polymerase Chain Reaction (RT-PCR)
  - Isothermal Nucleic Acid Amplification - Abbott ID Now, Cepheid
  *None are “true” point of care tests applicable to ASC*
- Covid-19 antibody testing
  - IgM
  - IgG
- Covid-19 antigen testing – Quidel - Sofia 2 (80% sensitivity)

Who to test?

- Staff testing
  - Current NAAT testing not useful; How often? Every day? Once a week?
  - Antibody testing helpful for prevalence only
  - Antibody testing has an unclear relationship to immunity
  - Reliable POC antigen testing may change testing strategy
- Patient testing
  - Resource intensive (reagent, media, PPE)
  - Time sensitive (<72 hours)
  - Patient perception – safety vs inconvenience & expense
  - Staff perception – less angst but potential false sense of security
Sensitivity and Specificity

- Varies among RT-PCR tests
- Specificity – close to 100%
- Sensitivity – from 71-98% sensitive
- PPV and NPV depends on prevalence

Effects of Prevalence on Testing

FDA Calculator

<table>
<thead>
<tr>
<th>Prevalence</th>
<th>Test 1</th>
<th>Test 1</th>
<th>Test 2</th>
<th>Test 2</th>
</tr>
</thead>
<tbody>
<tr>
<td>10.0%</td>
<td>%Pos1</td>
<td>%Neg1</td>
<td>%Pos2</td>
<td>%Neg2</td>
</tr>
<tr>
<td>%Sp1</td>
<td>%Sp2</td>
<td>%Sp2</td>
<td>%Sp2</td>
<td>%Sp2</td>
</tr>
<tr>
<td>71.0% 99.0%</td>
<td>8.0% 88.8%</td>
<td>92.0% 96.8%</td>
<td>90.0% 99.0%</td>
<td>9.9% 90.9%</td>
</tr>
<tr>
<td>71.0% 99.0%</td>
<td>1.7% 41.8%</td>
<td>98.3% 99.7%</td>
<td>90.0% 99.0%</td>
<td>1.9% 47.6%</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Prevalence</th>
<th>Test 1</th>
<th>Test 1</th>
<th>Test 2</th>
<th>Test 2</th>
</tr>
</thead>
<tbody>
<tr>
<td>1.0%</td>
<td>%Pos1</td>
<td>%Neg1</td>
<td>%Pos2</td>
<td>%Neg2</td>
</tr>
<tr>
<td>%Sp1</td>
<td>%Sp2</td>
<td>%Sp2</td>
<td>%Sp2</td>
<td>%Sp2</td>
</tr>
<tr>
<td>71.0% 99.0%</td>
<td>8.0% 88.8%</td>
<td>92.0% 96.8%</td>
<td>90.0% 99.0%</td>
<td>9.9% 90.9%</td>
</tr>
<tr>
<td>71.0% 99.0%</td>
<td>1.7% 41.8%</td>
<td>98.3% 99.7%</td>
<td>90.0% 99.0%</td>
<td>1.9% 47.6%</td>
</tr>
</tbody>
</table>
Symptom Screening

- Not a “molecular test” but extremely important
- Symptom screening mandatory regardless of PCR testing
- Appropriate timing of symptom screening – (For example - procedure day minus 4 and minus 1, day zero “at the door”, and day 7 (? 14) post-procedure
- Staff & provider symptom screening daily

AMA Symptom Screen
(Physician Practice Guide to Reopening Updated 5/01/20)
Pre-Procedure COVID Testing Recommendations

- Federal – none
- State/County – varies
- Hospital system – varies
- Joint venture partner – varies
- Professional Societies

AGA/DHPA Joint Guidance

All patients should receive **PCR-based testing** for active COVID-19 infection *wherever possible*. Ideally, this testing should be performed within **48 hours** of the procedure……If pre-procedure COVID-19 testing **cannot be performed**, clinicians should consider having patients keep a daily temperature log for 10 days prior to the procedure. A **symptom questionnaire and temperature check** should be administered to **all patients on the day of procedure**.

Infectious Disease Society of America

- The IDSA panel suggests against SARS-CoV-2 RNA testing in asymptomatic individuals without a known exposure to COVID-19 who are undergoing a time-sensitive aerosol generating procedure (e.g., bronchoscopy) when PPE is available (conditional recommendation, very low certainty of evidence).
- The IDSA panel suggests SARS-CoV-2 RNA testing in asymptomatic individuals without a known exposure to COVID-19 who are undergoing a time-sensitive aerosol generating procedure (e.g., bronchoscopy) when PPE is limited, and testing is available (conditional recommendation, very low certainty of evidence).
- "Logistically, individual institutions will need to decide whether a strategy of test and triage PPE or just use PPE matches available resources."

https://www.idsoc.org/COVID19guidelines/dx published 5/6/2020

ASGE Guidance for Resuming Endoscopy

"Ideally......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."

Barriers to Testing

- Local availability of testing (reagents, swabs, viral transport media)
- Timing of testing (<72 hours)
- Obtaining results in time to prep
- Insurance coverage of testing
- Reliability of local lab for adequate turnaround
- Patient acceptance
- Physician acceptance
- Last minute procedure cancellations because of testing delays

Pre-Procedure Covid-19 Testing Data

- Multi-site CT GI practice
  - Week 1 – 4/258 (1.6%) - CT prevalence – 9.8%
  - Week 2 – 1/374 (0.27%) - CT prevalence – 7.9%
  - Week 3 – 0/380 (0%) - CT prevalence - 6.7%
- Wichita, TX hospital outpatients: 1/1300 (0.08%)
- Austin, TX hospital testing: 3/1792 (0.17%) (Austin prev: 1%)
- Miami, FL outpatient procedures: 1/396 (0.25%) (Miami-Dade prev: 12.7%)

Forde J et al. Gastroenterology pre-print 5/21/20
**Take Aways**

“To test or not to test, that is the question”

- PCR testing still suboptimal and no “true” point of care test available yet
- If you are going test, test patients not staff
- Optimal time for testing is <72 hours or shorter
- Significant barriers to testing including availability and patient acceptance
- Low pre-procedure COVID testing prevalence in asymptomatic patients undergoing elective procedures
- Pre-procedure COVID patient testing may not be necessary in low prevalence areas (especially if it does not change PPE usage)
- If low prevalence area, consider altering PPE (i.e. surgical masks vs N95)
- Symptom screening remains essential and mandatory

---

**ACG Endoscopy Resumption Roadmap**

“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.”
COVID-19: Resuming Endoscopy: Unanswered Questions and Ongoing Controversies

Questions?

Neil H. Stollman, MD, FACP
Chair, ACG Board of Governors

Costas H. Kefalas, MD, MMM, FACP
Trustee, ACG Board of Trustees

Whitfield Knapple, MD, FACP
Chair, ACG Legislative and Public Policy Council

Melissa Latorre, MD, MS
ACG Endoscopy Resumption Task Force

Sapna V. Thomas, MD, FACP
ACG Governor for No. OH

Jeffry L. Nestler, MD, FACP
ACG Governor for CT

Visit ACG's COVID-19 Resource Page
www.gi.org/COVID19