

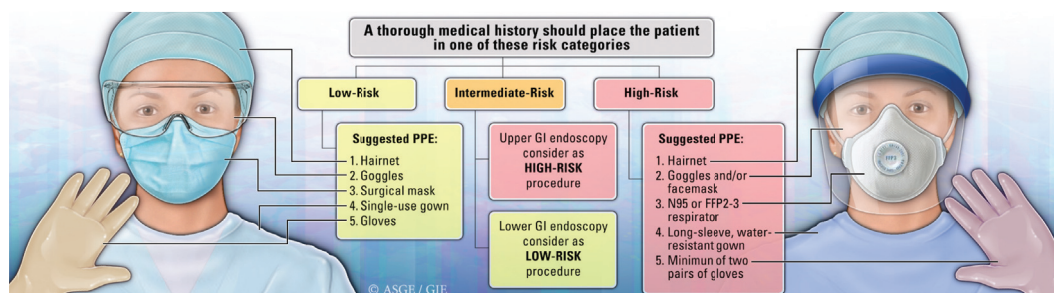


Coronavirus (COVID-19) outbreak: what the department of endoscopy should know

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GRAPHICAL ABSTRACT



Italy recorded its first case of confirmed acute respiratory illness because of coronavirus on February 18, 2020, soon after the initial reports in China. Since that time, Italy and nations throughout the world have adopted very stringent and severe measures to protect populations from spread of infection. Despite these measures, the number of infected people is growing exponentially, with a significant number of patients developing acute respiratory insufficiency. Endoscopy departments face significant risk for diffusion of respiratory diseases that can be spread via an airborne route, including aspiration of oral and fecal material via endoscopes. The purpose of this article is to discuss the measures, with specific focus on personal protection equipment and dress code modalities, implemented in our hospital to prevent further dissemination of COVID-19 infection. (*Gastrointest Endosc* 2020;92:192-7.)

Abbreviations: ASGE, American Society for Gastrointestinal Endoscopy; PPE, personal protective equipment; SARS-CoV, severe acute respiratory syndrome coronavirus.

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Coronaviruses are nonsegmented, enveloped, positive-sense, single-strand RNA viruses.¹ Six coronavirus species are known to cause human disease. Most of them generally cause mild respiratory disease; however, fatal coronaviruses have emerged periodically in the last decades, such as severe acute respiratory syndrome coronavirus (SARS-CoV) in 2002 and the Middle East respiratory syndrome coronavirus in 2012. In December 2019 the World Health Organization China office was informed of cases of pneumonia of unknown etiology detected in Wuhan,² and a new coronavirus, called SARS-CoV-2, was extracted from lower respiratory tract samples of several patients.

Since then, as of March 10, 2020 more than 100,000 cases have been confirmed worldwide,³ with the infection spreading to many countries all over the world. Italy has one

of the highest rates with more than 10,000 confirmed infections.³ As of March 11, 2020, the World Health Organization has declared the infection a pandemic, indicating significant worldwide involvement of the disease (see <https://www.who.int/dg/speeches/detail/who-director-general-s-opening-remarks-at-the-media-briefing-on-covid-19—11-march-2020>).

The most common symptoms of SARS-CoV-2–related disease, called COVID-19, are fever, weakness, cough, and diarrhea.^{4,5} More than half of patients report shortness of breath, with few developing acute respiratory distress syndrome. After septic shock, refractory metabolic acidosis and coagulation dysfunction can lead to death with a case fatality rate reported to be 3.5%.⁶

Human-to-human transmission occurs primarily through direct contact or air droplets.^{7,8} The higher risk of transmission is within approximately 1 meter (about 3 feet) from the infected person; however, the maximum distance is still undetermined.⁹

Although healthcare personnel working in endoscopy units are not directly involved in the diagnostic and therapeutic evaluation of COVID-19–positive patients, endoscopy should still be regarded as a risky procedure. This risk of exposure and subsequent infection of endoscopy personnel is, in fact, substantial in cases of patients with respiratory disease that can be spread via an airborne route.¹⁰ A recent study by Johnston et al¹¹ confirmed the significant and unrecognized exposure of the endoscopist's face to potentially infectious biologic samples during endoscopy. Endoscopy procedures demand short physical distance from patients to personnel, and according to studies performed during the global SARS outbreak of 2003, droplets from infected patients could reach persons located 6 feet (approximately 1.83 meters) or more from the source.¹²

Finally, we do believe the risk of exposure of endoscopy personnel is not limited to upper endoscopy procedures considering the recent detection of SARS-CoV in biopsy specimens and stools, suggesting a possible fecal–oral transmission.¹³ This could be even more relevant given that virus transmission can occur during the incubation period in asymptomatic patients.

In general, establishing infection prevention measures and guidelines within an endoscopy department is essential for creating a high-quality and extremely safe environment to protect both patients and personnel. In this new era of the COVID-19 outbreak, it is imperative that these measures be implemented and maintained to avoid further unrecognized spread of the disease.

SARS-CoV-2 INFECTION DEFINITION

The median estimated incubation period of the virus is about of 5.5 days, with a range from 0 to 14 days. Robust evidence coming from China and Italy confirms that about



Figure 1. Risk assessment by country.

80% of patients have asymptomatic or mild disease and that the median patient age is less than 60 years.^{4,5,7} These data clearly show that a significant number of patients undergoing endoscopy procedure may fall in the category of asymptomatic carriers and preventive measures are necessary to avoid massive endoscopy-related diffusion of the virus.

A tricky issue in this epidemic context is patient risk stratification and definition of subgroups of patients. We believe it is important to adopt a common definition of potential COVID-19 patients. According to several recently issued guidance, COVID-19 should be considered in anybody who has been in contact with confirmed SARS-CoV-2 infection or has returned from a high-risk country in the 14 days before the onset of following symptoms: fever (even without respiratory symptoms), cough, acute respiratory infection of any degree and severity (with or without fever), severe acute respiratory infection requiring hospital admission, and clinical/radiologic evidence of pneumonia. Contacts are defined as those living in the same household as a patient with a confirmed infection, those with direct or face-to-face contact (for any length of time) with an infected person or with his or her biologic fluids without wearing appropriate protective dress code, or those who have come within 2 meters (about 6½ feet) from a person with a confirmed infection.

The classification of high-risk countries will be in constant evolution, but as of March 2, 2020 several countries have been categorized as highest-risk (category 1) and high-risk (category 2) as seen in Figure 1. Given the rapidly evolving epidemiology, hospitals should stay up to date through their national disease control centers. For U.S. hospitals the Centers for Disease Control and Prevention (<https://www.cdc.gov/coronavirus/2019-ncov/travelers/index.html>) provides up-to-date information. The World Health Organization provides similar information (<https://www.who.int/health-topics/coronavirus>).

TABLE 1. Potential SARS-CoV-2 infection risk in endoscopy patients

Classification of potential SARS-CoV-2 infection risk in patients undergoing endoscopic examination	
Low risk	■ No symptoms (eg, cough, fever, breathlessness, diarrhea) ■ No contact with SARS-CoV-2-positive person ■ Nonstay in high-risk area during the previous 14 days
Intermediate risk	■ Presence of symptoms with ○ No medical history for contact with SARS-CoV-2-positive person ○ Nonstay in high-risk area during the previous 14 days ■ No symptoms but ○ Contact with SARS-CoV-2-positive person ○ Stay in high-risk area during the previous 14 days
High risk*	■ At least 1 symptom + 1 of the following: ○ Contact with SARS-CoV-2-positive person ○ Stay in high-risk area during the previous 14 days

SARS-CoV, Severe acute respiratory syndrome coronavirus.

*In an emergency setting, all procedures must be considered high risk if adequate patient history cannot be assessed.

PATIENT MANAGEMENT AND RISK ASSESSMENT

Once a patient is scheduled for an endoscopic procedure, the risk of COVID-19 infection should be checked and stratified individually. The day before the procedure, all patients should be called and surveyed about symptoms of a respiratory infection and potentially rescheduled according to the specific patient's disease and condition. When the patient reaches the hospital, a nurse-directed triage protocol should be to stratify the risk of COVID-19 (Table 1), using the following questions¹⁴:

- In the last 14 days have you had fever ($>37.5^{\circ}\text{C}$ or 99.5°F), cough, sore throat, or respiratory problems?
- Have you had family or close contact with a suspicious or confirmed case of COVID-19?
- Do you come from areas at higher risk of COVID-19?

If a patient is referred by a different healthcare facility, the same triage protocol is delivered by phone the same day of the procedure before the patient leaves the facility. This is instrumental to allow endoscopy personnel to prepare for the patient.

We also suggest checking the patient's body temperature before entering in endoscopy and to reclassify those patients with a temperature above 37.5°C (99.5°F). Based on this preliminary screening, patients can be classified as low, intermediate, and high risk, which translates to different modalities of infection control precautions.

Caregivers and relatives of patients are strictly prohibited from entering the endoscopy department unless the patient requires specific assistance and translation service. We recommend regular phone follow-up with a dedicated triage at 7 and 14 days after endoscopy procedure for

all patients until this infectious outbreak is completely resolved.

PERSONAL PROTECTIVE EQUIPMENT DESCRIPTION AND RECOMMENDATIONS

Personal protective equipment (PPE) is worn to reduce exposure to hazards that cause workplace injuries and illnesses. PPE may include gloves, goggles, face shields, gowns, and respiratory protective equipment.¹⁵

One of the most important pieces of protective equipment is the facemask, whose primary function is to keep respiratory particles from the source such as splashes, saliva, or mucus from contaminating the work environment. Medical or surgical facial masks are defined as loose-fitting, disposable devices that create a physical barrier between the mouth and nose of the wearer and potential contaminants in the immediate environment. The standard facial mask may be effective in blocking splashes and large-particle droplets but by design does not filter or block very small particles in the air that may be transmitted by coughs, sneezes, or certain medical procedures and does not provide complete protection from germs and other contaminants.

On the other hand, respirators protect the wearer against potentially hazardous particles created by the work environment. More specifically the N95, filtering facepiece (FFP) 2, or FFP3 respirator is a protective device designed to achieve a very close facial fit and extremely efficient filtration of airborne particles (up to $.3\ \mu\text{m}$) that can be inhaled through the nose or mouth. The edges of the respirator are designed to form a seal around the nose and mouth.

As a general measure, as of March 4, 2020 the World Health Organization recommends respiratory protection for providers with use of the standard medical mask. This means that all personnel not directly in close contact with patients (those in charge of endoscope disinfection, etc) need to constantly wear the medical mask for the time they stay in the hospital.

Patient dress code

All patients entering the endoscopy unit should be invited to wear a surgical mask. In addition, those classified as intermediate risk or high risk should wear a surgical mask and gloves. The surgical mask has to be removed just before commencing the procedure. Because most endoscopic procedures are performed with the patient under conscious or deep sedation, we adopted the policy to replace the mask again once the patient has recovered from sedation sufficiently to maintain oxygen saturation above 90% on room air.

Endoscopy personnel precautions and dress code

All staff involved in the endoscopy department are invited to follow standardized precautions as a measure

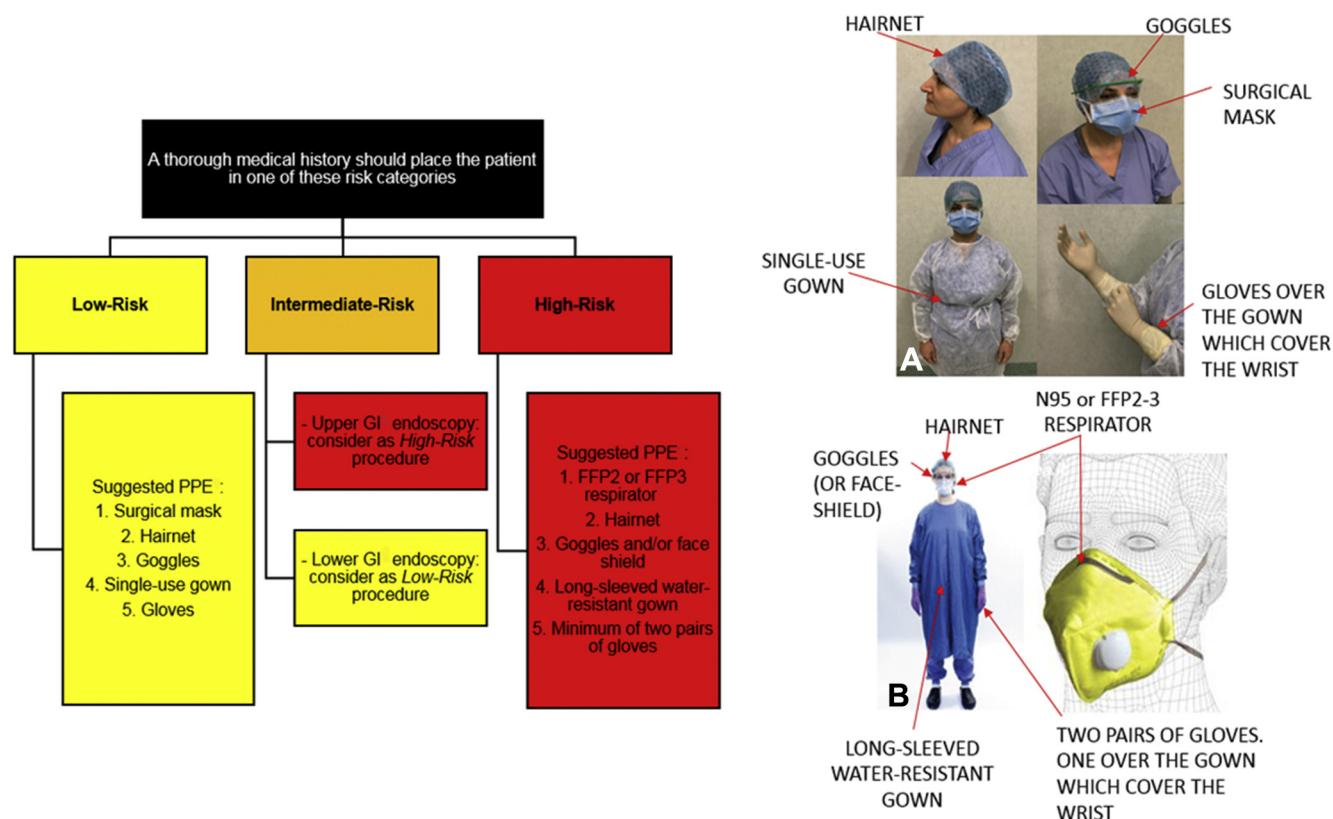


Figure 2. **A**, Low-risk dressing equipment. **B**, High-risk dressing equipment. PPE, Personal protective equipment; FFP, filtering face-piece (FFP2/3 are equivalent to N95 mask).

for optimal infection control among employers. We recommend that personnel keep a reasonable distance from every patient during all steps taken before beginning endoscopic procedures (informed consent signature, vital signs recording, patient instructions for the procedure, etc). It is mandatory to wash hands with soap and water or alcohol-based hand rub before and after all patient interaction, contact with potentially infectious sources, and before putting on and on removal of PPE, including gloves. The minimal composition of a set of PPE for personnel in endoscopy should be modified on the basis of risk stratification, as shown in [Figure 2](#).

In a time when shortage of devices may happen, we strongly discourage the reuse of any disposable device. In case of shortages, alternatives to respirators should be considered, including other classes of FFP respirators, elastomeric half-mask, and full face-piece air-purifying respirators.

How to wear PPE

The U.S. Centers for Disease Control and Prevention provide detailed, graphic instructions on proper use of PPE in the setting of COVID-19 (see <https://www.cdc.gov/hai/pdfs/ppe/ppe-sequence.pdf>). The first PPE to be donned is the hairnet. Always check that the equipment has not expired because this will compromise their integ-

rity. Then, proper hand hygiene should be performed using an alcohol-based solution. The second PPE to be worn is the gown; in case of a gown with back closure, a second operator should assist in closing up the back. After the gown, donning a filtering face-piece (N95, FFP2, or FFP3) respirator is recommended; it is crucial to perform a fitting test after the equipment has been put on the face. In case of shortage of filtering face-piece respirators, the use of a surgical mask as substitution is recommended. Once the respirator has been correctly positioned, the next step is goggles for eye protection. Gloves are next: Users should consider 2 pairs of gloves, 1 inner pair of gloves covering the skin up to the wrist (eg, surgical gloves) and 1 outer pair of gloves, the real “working gloves.”

How to remove PPE

At the end of the examination, the removal of the PPE is an essential and crucial part of the entire procedure that needs to be carefully carried out to prevent ourselves from contamination, because the PPE could by now be contaminated. The gloves are removed first because they are now considered to be heavily contaminated. Use of alcohol-based hand disinfectant should be considered before removing the gloves. Once the gloves are removed, hand hygiene should be performed again; next, a new pair of gloves should be worn to prevent self-contamination

and to continue the procedure safely. Once the new pair of gloves are on, the gown should be removed, using a second operator to assist for gowns with back closures. Eye protection should be removed next. When removing goggles or face shields, touching the front part, which can be contaminated by droplets or particles, should be avoided. Removal of respiratory protection comes next; it is important not to touch the respirator during its removal. After that, the hairnet should be taken off. The last PPE to be removed are the latest pair of gloves worn, which may now be contaminated. After glove removal, hand hygiene should be repeated.

ROLE OF THE NEGATIVE-PRESSURE ROOM IN THE COVID-19 OUTBREAK

Despite American Society for Gastrointestinal Endoscopy (ASGE) suggestions to perform endoscopic procedures in a negative-pressure room,¹⁶ in most endoscopy facilities around the world this is not available. Therefore, it is advisable to urgently equip at least 1 endoscopic room with a negative-pressure system to be used for all patients with respiratory symptoms. When this is not feasible, we recommend performing endoscopy on patients who are high risk or positive for SARS-CoV-2 in negative-pressure rooms located outside the endoscopy department as long as this space is properly equipped to perform any endoscopy procedure safely and properly.

REPROCESSING OF FLEXIBLE ENDOSCOPES AND ENDOSCOPIC ACCESSORIES

The ASGE guidelines for infection control in the endoscopy unit can be found and are available in open access at https://www.asge.org/docs/default-source/default-document-library/51e78060-cd85-4281-b100-6abebcb04c49.pdf?sfvrsn=4c109450_0. Similarly, the 2018 European Society of Gastrointestinal Endoscopy guidelines¹⁷ recommend that all endoscopes and reusable accessories should be reprocessed with a uniform, standardized reprocessing procedure. Disinfectants used for this purpose should be tested according to the European Standard EN 14885. The product used must be as follows: bactericidal, mycobactericidal, fungicidal, and virucidal against enveloped and nonenveloped viruses. Cases of hepatitis B and C virus transmission have been reported in the medical literature but have been related to inappropriate cleaning and disinfection. When all currently reprocessing guidelines are strictly followed, the risk of transmission of any kind of viruses is extremely rare to nonexistent. This is why we have reinforced training sessions and personnel meetings on the importance of strictly following endoscope reprocessing policy as a safe and efficient method to prevent the spread of viral infection.

DECONTAMINATION POLICY FOR ENDOSCOPY ROOMS

Each endoscopy department should have a detailed plan to address the cleaning of rooms, including methods and chemical agents for cleaning and disinfecting the procedure space at the end of daily procedures. The cleaning process should include cleaning of all surfaces in the procedure room to remove all soil and biofilm, followed by proper disinfection,¹⁶ as clearly reported in the ASGE guideline. Data on the virucidal efficacy of chemical agents against SARS-CoV-2 are not available; therefore, our recommendations are based on studies done for other coronaviruses.

SARS-CoV is known to be stable in feces and urine for at least 1 to 2 days; thus, surfaces might be a possible source of contamination and lead to infection. Until more precise recommendations are available, noncritical environmental surfaces frequently touched by hands (eg, bedside tables, bed rails) and endoscopy furniture and floor should be considered heavily contaminated in patients with intermediate or high risk of COVID-19 and should be thoroughly disinfected at the end of each procedure. Standard room disinfection policy should be kept in rooms where non-COVID-19 or low-risk patients undergo endoscopy. For surface and noncritical patient-care equipment disinfection, we are currently using 1:100 dilution of household bleach and water.¹⁸ In negative-pressure rooms, a delay of about 30 minutes is suggested before allowing a new patient to enter the room. Because small particles remain airborne for some period of time, in the absence of negative-pressure rooms alternative measures such as diluting the air with cleaner air from the outdoors should be considered and the room kept empty for at least 1 hour.

CONCLUSIONS

It is a challenging time for the world, and we as endoscopists and physicians have additional responsibility of protecting our patients and ourselves. It is of paramount importance in the next months to enforce and strictly maintain these infection control measures using written protocols and dedicated meetings. The level of commitment and the amount of individual effort that everyone will contribute for preventing infection dissemination is like little grains of sand that together will help in creating a solid and durable barrier against this deadly virus.

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