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SPECIAL COVID-19 REPORT

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European Society for Neurogastroenterology and Motility recommendations for conducting gastrointestinal motility and function testing in the recovery phase of the COVID-19 pandemic

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Abstract

Background: During the peak of the COronaVIrus Disease 2019 (COVID-19) pandemic, care for patients with gastrointestinal motility and functional disorders was largely suspended. In the recovery phases of the pandemic, non-urgent medical care is resumed, but there is a lack of guidance for restarting and safely conducting motility and function testing. Breath tests and insertion of manometry and pH-monitoring probes carry a risk of SARS-CoV-2 spread through droplet formation.

Methods: A panel of experts from the European Society for Neurogastroenterology and Motility (ESNM) evaluated emerging national and single-center recommendations to provide the best current evidence and a pragmatic approach to ensure the safe conduct of motility and function testing for both healthcare professionals and patients.

Results: At a general level, this involves evaluation of the urgency of the procedure, evaluation of the infectious risk associated with the patient, the investigation and the healthcare professional(s) involved, provision of the test planning and test units, education and training of staff, and use of personnel protection equipment. Additional guidance is provided for specific procedures such as esophageal manometry, pH monitoring, and breath tests.

Conclusions and Inferences: The ESNM guidelines provide pragmatic and appropriate guidance for the safe conduct of motility and function testing in the COVID-19 pandemic and early recovery phase.

KEYWORDS

breath test, COVID-19, esophageal manometry, personal protection equipment, pH monitoring

Abbreviations: COVID-19, COronaVIrus Disease 2019; ESNM, European Society for Neurogastroenterology and Motility; GI, gastrointestinal; HRM, high-resolution manometry; PPE, personal protective equipment; RT-PCR, real-time polymerase chain reaction.

*The members of Working Group are listed in Appendix 1.

1 | INTRODUCTION

Beginning at the end of 2019, a pneumonia and severe acute respiratory distress syndrome, COronaVIrus Disease 2019 (COVID-19), caused by the transmission of a novel coronavirus, named SARS-CoV-2, has rapidly spread throughout the world and was declared a pandemic on March 11, 2020, by the World Health Organization.[1,2] Healthcare systems in areas affected by the pandemic needed to focus on patients affected by this highly contagious disease, while suspending care for all but essential and urgent medical conditions. Within the specialty of gastroenterology, the focus was also redirected to urgent care, with stringent restrictions and measures for procedures such as gastrointestinal (GI) endoscopy, which aimed to protect patients and healthcare professionals from uncontrolled exposure.[3-5] Care for patients with GI motility and functional disorders, representing a significant burden of daily gastroenterology practice,[6,7] was also largely suspended. A survey of 34 gastroenterology centers in Europe showed that motility and function testing was decreased by more than 90% in the month of March 2020 and by early May, and the majority were considering to restart their services albeit at a reduced caseload over the next weeks and months.[8]

While several guidelines have been issued on how to select and safely conduct endoscopic procedures during the phase of urgent care, and early guidance exists for safe expansion of endoscopy procedures in the recovery phases of the pandemic,[9,10] there is a lack of guidance for motility and function testing procedures. Indeed, breath tests and insertion of upper GI manometry and pH-monitoring probes carry a risk of SARS-CoV-2 spread through droplet formation when probes pass the nose or mouth and pharynx, or when air is blown into breath test tubes.[11]

With this paper, the European Society for Neurogastroenterology and Motility (ESNM) aims to provide the recommendations based on the best current evidence and a pragmatic approach to ensure (a) the safe conduct of motility and function testing for both healthcare professionals and patients; (b) remodeling of the flow of scheduled motility and function testing activity; and (c) appropriate triaging of an individual patient's clinical urgency.

2 | METHODOLOGY

The recommendations herein are based on submitted manuscripts and published guidelines from several European centers and societies.[8,12-15] The authors integrated the available recommendations, and after harmonization and review for consensus generation, the current guideline document was drafted and circulated to all members for input and final approval.

The scientific understanding of the epidemiology and pathophysiology of COVID-19 is limited but is rapidly expanding and changing.[16] Hence, these guidelines reflect the current state of understanding, coupled with pragmatic recommendations, at the time of writing, and may be subject to change as our knowledge and the evidence base develop.

Key Points

- This ESNM guideline provides a pragmatic and appropriate guidance for the safe conduct of motility and function testing in the COVID-19 pandemic and early recovery phase.
- The aim of this guideline is to standardize procedures according to common recommendations throughout Europe.
- A panel of experts from the ESNM evaluated emerging national and single-center recommendations to provide the best current evidence and a pragmatic approach.
- The ESNM guidelines suggests to evaluate: a) the urgency of the procedure; b) the infectious risk associated with the patient and healthcare professional(s); c) the provision of the test planning; d) the education and training of staff; e) the use of personnel protection equipment.

3 | NEED FOR MOTILITY AND FUNCTION TESTING

3.1 | Motility and function disorders as a public health problem

In nearly half of patients presenting to gastroenterology practices, routine investigations such as imaging, endoscopy, and blood tests fail to find a clear organic cause, and disorders of GI sensorimotor function are thought to underlie the symptoms.[6,17]

These disorders are often chronic in nature, and their main impact involves symptom burden and diminution in quality of life. Potentially life-threatening complications are generally rare, although there are exceptions. Moreover, for many of these conditions, empirical treatment approaches are available, for example, proton-pump inhibitors for gastroesophageal reflux disease.[18,19]

3.2 | Short description of the tests

Investigations that objectively evaluate GI function are an indispensable tool in the assessment of patients with motility or functional disorders.[20-22] When routine diagnostic tests are negative, GI function testing is a useful additional tool to elucidate disease mechanisms in order to guide treatment and determine prognosis, taking into account the poor predictive value of the symptom pattern for the outcome of GI function tests. Function and motility tests can be invasive or non-invasive.

Tests that can be considered procedures at high risk of transmission of SARS-CoV-2 include 24-hour esophageal pH meter/pH-impedance monitoring, esophageal perfusion and/or (high-resolution)

manometry (HRM), antro-duodeno-jejunal manometry, colonic manometry and perfusion, high-resolution and/or high-definition anorectal manometry, and anorectal biofeedback evaluation and treatment. Furthermore, breath tests (C13 urea breath test, C13 octanoic acid, C14 glycocholic acid, C14 octanoic acid, H_2/methane breath test with lactose and glucose/lactulose/fructose), which are procedures to assess motility, digestive function, and bacterial colonization of the GI tract, can also carry a risk of transmission, as patients intermittently blow into tubes which may generate aerosol droplets.

3.3 | Urgent versus elective procedures

The relative urgency of the function test should always be interpreted according to the phase of the pandemic, which is likely to change over time. In case of a new surge with severe impact on healthcare functioning, it is likely that all GI function testing will be put on hold, except for the urgent procedures. Conversely, when the impact is low, functional investigation activity can resume progressively, and protective measures for patients and healthcare workers can be adapted according to the infection rate in the population and the local recommendations.

Testing for motility and functional disorders is in general not urgent and can be scheduled and well-planned. Moreover, empirical symptomatic treatment is often a suitable intervention which may allow investigations to be deferred for a period of time. Some conditions, however, are considered more urgent and need a shorter time to scheduling (Table 1).

Urgent procedures include esophageal manometry in patients with dysphagia associated with weight loss or those requiring enteral/parenteral nutrition or in those who have, or at a high risk of, aspiration. In addition, esophageal manometry should not be delayed in new cases of achalasia, especially when associated with weight loss and debilitating dysphagia, in order to confirm the diagnosis, to guide therapy choices. The same applies to re-evaluating those achalasia patients who display an insufficient symptomatic response to treatment.[20,21]

Although less common, non-cardiac chest pain may be a driver of repeated emergency department presentation and inappropriate hospitalization.[23] In these patients, after exclusion of cardiac causes, an urgent, and complete, assessment of esophageal function is justified.

In some patients undergoing surgery for rectal cancer, anorectal manometry is performed as part of the workup. As the results of this test, possibly combined with a balloon expulsion test, may influence the choice of surgical procedure (eg, coloanal anastomosis), urgent evaluation of anal sphincter function needs to be performed when requested by the surgeon.[24,25]

Breath tests are never to be considered an urgency and can easily be postponed as indicated by the infection state and recommendations in respective countries or areas.

4 | THE RISK OF TRANSMISSION OF COVID-19 ASSOCIATED WITH MOTILITY AND FUNCTION TESTING

The symptoms of COVID-19 are pleomorphic, ranging from those related to the respiratory tract (cough, fever, dyspnea, and respiratory failure), to systemic symptoms (myalgia, anosmia, asthenia), up to multi-organ failure, and death.[26] GI symptoms (eg, loss of appetite, nausea, vomiting, diarrhea, lower GI bleeding) are present in up to 30% of cases.[27-29] GI symptoms may be the initial or the unique presentation in about 10% of cases.[29]

The highest viral loads of SARS-CoV-2 are found in the nasopharynx, and the virus mainly spreads directly via droplets and aerosols, and indirectly by contact with contaminated surfaces.[26,30] Transmission by infected persons may already occur in the presymptomatic phase[26] which increases the risk when admitting outpatients for diagnostic testing. SARS-CoV-2 enters cells via the angiotensin-converting enzyme 2 (ACE2) receptor, which is expressed not only in the lungs but also in blood vessels, brain, skin, and the digestive system.[30] ACE2 is highly expressed in esophageal epithelial cells, on gastric glandular cells and on enterocytes in the small bowel and the colon, and even in peritoneal

TABLE 1 Proposed triage for GI motility and function tests

Urgent procedures	Elective procedures
HRM for functional severe dysphagia with weight loss and/or risk of aspiration	**HRM and 24-h pH-MII** for GI symptoms non-organic in origin, with incomplete response to medical therapy. (Other tests may also be considered based on the symptomatic pattern.)
HRM prior to treatment for achalasia with major impact, in order to assess the manometric pattern of the disease	**HRM and 24-h pH-MII** for atypical symptoms of GORD
HRM and 24-h pH-MII for non-cardiac chest pain with high impact in QoL (eg, repeated access to the emergency department). Also for refractory esophageal symptoms with weight loss, persistent regurgitation, risk of aspiration, and/or high impact in QoL	**HRM and 24-h pH-MII** for the preoperative assessment of GORD, when surgery is considered
Anorectal manometry + Balloon expulsion test in the pre- and postoperative assessment before colorectal surgery for cancer, and to rule out Hirschsprung disease	**Anorectal manometry + balloon expulsion test** in the pre- and postoperative assessment of benign anorectal diseases

Abbreviations: ED, emergency department; GORD, gastroesophageal reflux disease; HRM, high-resolution manometry; pH-MII, pH-multichannel intraluminal impedance; QoL, quality of life.

TABLE 2 Confirmed and suspected COVID-19 cases and high-risk state of COVID-19

Confirmed COVID-19 cases
Subjects who tested positive for COVID-19 on PCR
Subjects with a COVID-19–positive high-resolution CT scan
Suspected COVID-19 cases
Common cold symptoms (runny nose, sneezing, fatigue, cough)
A body temperature of 37.5°C or higher
Severe fatigue, migrating bodily pain, and stuffiness
Dysgeusia and anosmia without apparent cause
Digestive symptoms such as diarrhea lasting 4-5 d without apparent cause
High-risk state of COVID-19
History of close contact with COVID-19 patients within 2 wk
Travel history to an outbreak area within 2 wk

fluid, which putatively explains the GI manifestations of the infection.[27,28,31,32] Positive stool real-time polymerase chain reaction (RT-PCR) tests for SARS-CoV-2 have been reported, and fecal tests may remain positive when a respiratory test is or has become negative.[30,31] These observations support the possibility of fecal-oral transmission.

5 | EVALUATION OF THE SARS-COV-2 INFECTION STATUS IN PATIENTS

5.1 | Evaluation of infectious risk while preparing for the procedure

5.1.1 | Clinical evaluation

Throughout the COVID-19 pandemic, there is a general advise to question patients already in the planning phase, before their arrival

FIGURE 1 Flowchart for planning procedures, taking into account urgency of the procedure and the assessment of the patient's risk of infection and the allocated procedure

TABLE 3 Screening options confirming the low-risk status of the patient for COVID-19

Absence of symptoms and temperature < 37.2°C
Confirmed negative by RT-PCR test 48 h before the test
Antibody test for IgG-positive and IgM-negative
Negative thoracic high-resolution CT scan

to check for the presence of (a) fever or other symptoms, (b) occupational exposure (including healthcare professionals or laboratory staff handling COVID-19 specimens), (c) contact history with confirmed cases in the last 14 days, (d) exposure to COVID-19 clustering, and (e) in some areas of low prevalence, travel history (especially to countries with a high incidence in COVID-19 transmission within the past 14 days). In case of presence of one of these signs or risk factors, the patient is to be considered as a suspected or high-risk case (Table 2). In all suspected or high-risk cases, the test should be postponed for at least 2 weeks from the date of the risk contact (Figure 1). If the patient develops symptoms during this period, appropriate workup should be organized and function testing should be postponed until complete recovery and for at least 4 weeks from the date of symptom onset.

Specifically, for those with symptoms, it is advisable to investigate for infection, through either COVID-19 RT-PCR on a nasopharyngeal swab or a COVID-19 diagnostic multi-sliced chest computed tomography (CT) scan[33-38] (Figure 1). However, both RT-PCR and CT scanning can provide false-negative results, particularly in the early stage of the disease or in mild cases.[37,38] Where uncertainties remain regarding the infectious state of an individual patient, the safest, and most pragmatic, approach is to postpone the test. It is likely but still not definitely proven whether patients who have had COVID-19 and have been asymptomatic for 2 weeks or those who display IgG immunity (with a negative IgM) against SARS-CoV-2 are immune.[38] These patients can be considered low-risk patients and testing may proceed.

5.1.2 | Specific testing for COVID-19

The presence of active infection can be determined by a combination of the clinical presentation, RT-PCR test (nasopharyngeal swab and/or in rare cases bronchoalveolar lavage), and/or multi-sliced chest CT scan (Table 3). Detection of viral RNA by PCR has moderate-to-high sensitivity depending on timing and type of test and has become a mainstay of COVID-19 disease detection.[10,33,34] For stratification in endoscopy, it has been proposed that performing PCR tests in all patients prior to the procedure could be a suitable strategy for more efficient use of PPE when the prevalence of COVID-19 is reduced. It seems problematic that the sensitivity of RT-PCR for COVID-19–infected symptomatic patients has been estimated at only 66.7% during the first week and 54% during the second week. However, these patients are detected by the clinical screening approach, and the RT-PCR may perform better to detect potentially infected asymptomatic subjects.[39,40] This approach is widely used to stratify endoscopy risk and the level of PPE required. We, and others, advocate an identical approach for motility and function testing.[9,10,41,42] It has been recommended to consider a negative RT-PCR test valid for 48 hours.[9,10,41,42]

Antigen detection tests have a low sensitivity during the initial stages of the disease, even in symptomatic patients, but become negative before RT-PCR. Anal swabs have also been explored but seem to be inconsistent and at best are only positive in later stages of the infection.[4,31,32]

As a backup option, a thoracic high-resolution CT scan has also been advocated as a method for identifying acutely infected patients.[34-36] Antibody testing probably has the potential to play a supplementary role to RT-PCR in diagnosis, screening of contacts, and possibly in the determination of population/herd immunity.[43] However, there is a lack of standardized, reliable tests, and sensitivity varies with the stage of infection.[38] Significant questions remain with regard to the performance of individual test methods and the degree of immunity associated with the antibody response.

Taken together, given the variable reliability of possible tests and their results in combination with the possible spectrum of symptoms, there is an inherent uncertainty about the patient's COVID-19 status.[5,8,10] Therefore, systematic general protective measures and the use of different levels of PPE are recommended for all motility and function testing.[8,12-15] On the other hand, a combination of absence of risk factors, symptoms, and a negative nasopharyngeal swab seems to hold a low risk of contamination during the procedure and may justify less stringent measures to save on limited PPE resources.[8,10,41,42] In

TABLE 4 Stratification of the risk for an investigation in a patient

Healthcare professional	Patient	Procedure
Immunized = 0	Immunized = 0	Non-aerosol generation = 1
Unknown[b] = 1	Unknown[b] = 1	Aerosol generation = 2
	Suspected or high risk of infection[a] = 4	
	Confirmed infection = 5	

Note: Sum score: 0-2: low-risk procedure.

3-4: moderate-risk procedure.

>4: high-risk procedure.

[a]See Table 3: symptoms suggestive of COVID-19, or close contact with infected patients.

[b]Includes subjects not tested for COVID, as well as subjects tested with negative PCR more than 48 h before, and subjects with a previous negative IgG test.

TABLE 5 Protective measures for patients and staff

a. Before the study day

1. The number of procedures should be limited to avoid crowding on the way to and in the unit, and to provide sufficient cleaning time in between measurements.
2. Procedures should be scheduled at appropriate intervals, to help avoid crowding in the unit and to provide sufficient cleaning time.
3. The outpatient tests should be booked according to local procedures. Patients should be informed how and where to present, and with which safety measures (eg, maximum one accompanying person, facial mask/covering, etc)
4. The patients must be informed of the exact time at which they must be at the motility unit to prevent crowding in the waiting room
5. If a patient needs to be accompanied, it must be only one person, preferably younger than 60 y old, without risk comorbidities and with no signs of COVID-19 infection.
6. Before the procedure, all patients need to be called by phone to stratify the risk of COVID-19 infection (Figure 1).
7. If available, consider diagnostic testing for infection using throat and/or nasal swab and PCR, 24 h prior to the procedure (Figure 1). CT thorax is probably insufficiently sensitive in the presymptomatic phase. At present, serology is not a reliable screening test.

b. The day of the study

1. On the day of the procedure, the patient is again questioned and checked for signs or symptoms of infection, contact with potentially infected persons and clustering, prior to entry to the motility or function testing unit (Figure 1). Temperature is checked. The patient is invited to wash hands using an alcohol-based hand rub, to wear a surgical mask; gloves are an additional option. The patient is then admitted to the waiting area which is not crowded and with ample space between seats. The accompanying person, if any, is requested to wait outside the unit.
2. There must be soap, alcohol-based hand sanitizer, and a handwashing recommending poster in every patient's toilet.
3. In addition, in order to prevent droplet infection and contact infection in the examination room, the examiner should consider arranging an environment where all subjects (including attendants) can keep a safe distance. In a room with windows, if possible, open the windows on opposite or different sides simultaneously to encourage ventilation.

c. Management of motility function units

1. Individual workstations for healthcare professionals.
2. Appropriate spacing of waiting room chairs to keep appropriate social distancing of patients (at least 1.5-2 m).
3. The waiting room should be free of magazines or other objects that can act as fomites.
4. Linear patient flow through the unit (no crossing of COVID-19–positive and COVID-19–negative pathways, separate entrance, and exit)
5. Regular and frequent cleaning and disinfecting objects and surfaces in units.
6. Required masks for patients for respiratory hygiene.
7. Restricting accompanying visitors.
8. Organization of workflow patterns and job descriptions to minimize cross-contamination.
9. It is recommended to adjust the time assigned to the procedure considering the necessary measures for the prevention of COVID-19 infection. This will translate, probably, into reducing the number of procedures and increasing the time assigned to each of them.
10. Adequate time should also be assigned for air exchanges in rooms and deep cleaning between procedures, especially in unknown- or high-risk procedures.
11. Building a platform for all employees to quickly communicate and sending important messages to every staff.

TABLE 6 Staff protection equipment depends on the risk status of the patient for COVID-19

Patients classified as low risk	Gloves, surgical cap (optional), protective eyewear (goggles or face shield), gowns, and surgical masks
Patients with uncertain status	Waterproof gowns, shoe covers, surgical cap, protective eyewear (goggles or face shield), and level 2 PPE with FFP2/FFP3/N95 mask and two pairs of gloves

patients with confirmed COVID-19 infection based on RT-PCR testing, or with suspected infection based on compatible manifestations without virological confirmation, for example, CT scan, it is recommended to postpone the test until a minimum of 4 weeks has passed from the start of the symptoms, regardless of a negative result of the RT-PCR.

5.2 | Re-evaluation of change in risk at the time of presentation for the procedure

Patients should wear a surgical mask upon arrival and during their stay in the hospital. On the day of the motility test, it is recommended that patients are evaluated properly to establish that the subject (A) has not developed any novel symptoms suggestive for COVID-19, (B) that there have been no infectious/potentially infectious close contacts, and (C) that the subject's temperature is measured before entering the examination room. In case of new-onset symptoms, exposure, or a temperature rise, the healthcare professional should consider postponing the test.

A system for scoring the risk of each investigation based on 3 factors (healthcare professional immune status, patient, and procedure) is presented in Table 4. The score can be used to select the level of staff protection to be applied (see below). The healthcare professional's immune status is currently not known for most personnel but may become available in the future when antibody screening is proven reliable and more widely performed.

6 | GENERAL SAFETY CONSIDERATIONS

As there is a clear risk of transmission with many of the motility and function tests, safety procedures must be applied to reduce and prevent transmission of the virus (Figure 1). These include the following:

- Plan test timing and access to the unit to avoid crowding
- Stratify patients according to their risk of COVID-19
- Education and training of staff for dealing with the risk of COVID-19 infection
- Use of appropriate personal protective equipment (PPE) for patients and staff
- Cleaning and disinfection of the unit and decontamination of the equipment and any accessories

The exact measures are outlined in the sections below.

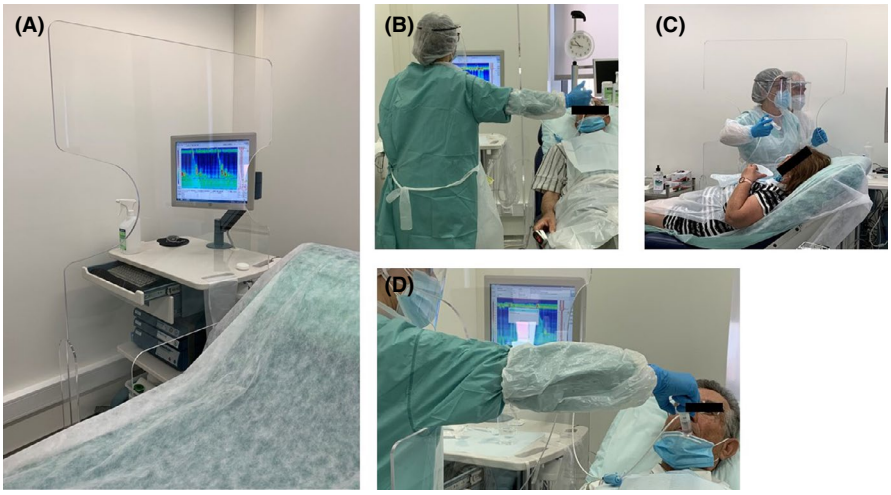

FIGURE 2 A, Acrylic barrier setup separating the bed for motility procedures from the standing and working area for the health professional during the procedure. B-D, Healthcare professional wearing personal protective equipment performing esophageal high-resolution manometry with administration of swallows, through the arm entry points

7 | PROVISION OF THE MOTILITY AND FUNCTION TESTING PLANNING AND UNITS FOR PROTECTION OF STAFF AND PATIENTS

Measures that should be taken to perform motility and function testing with sufficient protection of healthcare professionals and patients are summarized in Table 5.

8 | EDUCATION AND TRAINING OF STAFF

All healthcare professionals should receive appropriate and relevant training regarding infection control, including potential contaminated sources, measures, risk factors, and the epidemiology of COVID-19. Healthcare professionals should be screened daily with temperature check and surveyed for COVID-19 exposure and symptoms and those with symptoms or temperature rise should return home and not perform any procedures. Diligent handwashing (for at least 20 seconds) before and after each patient contact and avoiding touching the face (in particular eyes, nose, and mouth) are mandatory. Appropriate PPE should be available for each type of test for all healthcare professionals involved; see Table 6. The training of students and fellows can continue although one must observe social distancing and comply with hand hygiene and PPE measures. However, a weekly rotation should be considered in order to minimize exposure in this group.

9 | PERSONAL PROTECTION EQUIPMENT FOR HEALTHCARE PROFESSIONALS

Given the variable reliability of tests in combination with the possible spectrum of symptoms, frequently there is continued uncertainty regarding an individual patient's COVID-19 status.[4,5,8,10] Therefore, systematic general protective measures and the use of at least a general level of PPE are recommended for all motility procedures[5,8,12-15] (Figure 2).

Protective equipment directly exposed to the patient's secretions should be changed for each patient (or disinfected in case of goggles or facial shields), and the healthcare professional should thoroughly wash their hands after each test. Two possible approaches have been proposed for protection of staff, using either general or selected high-level PPE usage. The group of Dr Novais in Lisbon have used a custom-made acrylic screen to additionally generate a physical barrier between the patient and the healthcare professional, while leaving specific arm entry points to the side and the lower end, to allow manipulation of esophageal or anorectal catheters, and administration of swallows (Figure 2).

The majority of current guidelines propose high-level protection, considering each patient as potentially infected while the epidemic is ongoing, even in the absence of symptoms or risk on the clinical evaluation. In this case, for every procedure extensive PPE is worn,

TABLE 7 Donning and doffing sequences

a: The donning procedure
1. Disinfect hands with alcohol.
2. Put on long nitrile gloves (second skin).
3. Put on an impermeable gown.
4. Take a surgical hat or hairnet.
5. Put on a surgical or FFP2/FFP3/N95 mask (adjust correctly around the nose and beneath the chin).
6. Put on the goggles over the FFP2/FFP3/N95 mask.
7. Put on the face shield if required.
8. Put on a second pair of (short) nitrile gloves if required.
b: The doffing procedure
1. Remove the second pair of nitrile gloves.
2. Remove the impermeable gown.
3. Take off the face shield and put in a recycle bin for collection.
4. Take of the goggles (from behind—over the head, do not touch the front or glasses) and put them in the same recycle bin as the face shield for collection.
5. Remove the long nitrile gloves.
6. Take of the FFP2/FFP3/N95 mask (from behind—over the head, do not touch the front) into a second recycle bin for collection.
7. Removal of the surgical hat.
8. Disinfection of the hand with alcohol.

TABLE 8 Protective measures for specific procedures

a. Esophageal manometry

1. Whenever possible, a negative pressure room (not available in most places) is recommended, as the placement of a catheter may generate aerosol.
2. During transnasal positioning and advancing of the HRM catheter, the patient should continue to wear a surgical mask over the mouth. If the patient needs to drink to allow the catheter to pass the throat, the mask will need to be lowered.
3. During catheter positioning, the nurse or technician should keep a position to the side of and behind the patient, rather than in front of the patient.
4. The surgical mask is lowered to administer the swallows.
5. When administering swallows, the nurse or technician should keep a position to the side of and behind the patient.
6. The height of the bed should be adjusted in a way that the upper part of the head of the patient is under the chin of the nurse or technician.
7. When available, the use of a disposable probe cover sheath or condom is recommended to reduce the level of microbial exposure.
8. It is also recommended that all catheters and probes are cleaned and disinfected after each procedure, with a chlorine dioxide-based or comparable disinfectant. Enveloped viruses such as coronaviruses are the least resistant to inactivation by disinfection.
9. When using water-perfused systems, it is advisable to maintain the perfusion and a flow of water once the catheter has been removed from the patient, and to avoid, if possible, to open the water pump during the procedure. If the catheter is manually cleaned, it is also advised to maintain the perfusion during the phases of cleaning with soap and disinfection.
10. In order to prevent contact infection, it is necessary to thoroughly disinfect not only the catheters but also the peripherals such as the used PC, table, and bed.
11. Disposable accessories must be thrown away in the hazardous waste following local regulations.

b. pH, pH-MII, and wireless pH-capsule monitoring

1. The main risk of pH-MII measurement procedure lies in the positioning of the catheter for which the same precautionary measures, including patient selection, apply as for esophageal manometry.
2. Whenever possible, a negative pressure room is recommended (not available in most places), as the placement of a catheter may generate aerosol.
3. During transnasal positioning and advancing of the HRM catheter, the patient should continue to wear a surgical mask over the mouth. If the patient needs to drink to allow the catheter to pass the throat, the mask will need to be lowered.
4. During catheter positioning, the nurse or technician should keep a position to the side of and behind the patient, rather than in front of the patient.
5. The height of the bed should be adjusted in a way that the upper part of the head of the patient is under the chin of the nurse or technician.
6. Moreover, we recommend using single-use or washable holders and shoulder straps for the recorder.
7. The patient is sent home for the ambulatory monitoring and should return the next day with surgical mask.
8. The day after, for removing the catheter, technician should use the same PPE as for catheter insertion. It may be recommended to disconnect the probe from the registration device before extraction to facilitate immediate disposal in the waste container. Alternatively, the patient may be instructed to remove the pH or pH-MII catheter at home and bring it along with the recorder to the unit.
9. After each use, the portable registration device should be wiped with biocidal wipes. As an alternative, the portable registration device can be wrapped in transparent plastic which is sealed with tape, eliminating direct contact with body and body fluids, while allowing screen checking and use of buttons.
10. As virtually all pH-MII probes are single-use catheters, specific disinfection protocols do not apply. If reusable pH probes are applied, standard disinfection procedures should be implemented.
11. Disposable accessories must be thrown away in the hazardous waste following local regulations.
12. The catheter-free wireless pH-monitoring system can be used as an alternative, although there is no clear preference for one or the other in the current pandemic. The wireless pH capsule is positioned by the gastroenterologist, using the delivery system, usually preceded by a gastroscopy with the general safety procedures for endoscopy.

c. Anorectal manometry

1. Investigation of dyschezia or fecal incontinence is hardly ever urgent and should be restricted to low-risk patients. Although no oropharyngeal manipulations are performed, close proximity to the patient is required and therefore patients should keep wearing a mask throughout the test.
2. Prior to anorectal manometry, a water enema can be given in case of fecal loading of the rectum. As defecation is considered an aerosol-generating g process and SARS-CoV-2 particles potentially can be shed via feces, a toilet in a separate room is preferred over in-room commode seat. In all cases, toilet or commode seats should be disinfected between patients.
3. During measurement of resting pressure, but especially during measurement of squeezing pressure and simulated defecation, seepage of fecal content can occur. Therefore, staff should wear PPE throughout the entire procedure, based on the above-mentioned risk stratification.
4. Similar to esophageal manometry, reusable anorectal manometry catheters should be disinfected with standard biocidal solutions, as well as setup, computer, keyboard, bed/stretcher, and toilet/commode.
5. When using water-perfused systems, it is advisable to maintain the perfusion and a flow of water once the catheter has been removed from the patient, and to avoid, if possible, to open the water pump during the procedure. If the catheter is manually cleaned, it is also advised to maintain the perfusion during the phases of cleaning with soap and disinfection.

d. Measures for breath tests

Measures for ^{13}C and for H^2-based breath tests

(Continues)

TABLE 8 (Continued)

1. The patient should remain in the dedicated test room during the test.
2. Alternatively, conducting the breath test at the patient's home may be considered, after adequate instruction for the procedure.
3. The number of patients should be limited to 1 per 10 square meters or 1 per room.
4. Staff must maintain a distance of 1.5-2 m.
5. Patients should wash their hands before and after the test with soap or disinfectant.
6. The table must be cleaned before and after the test with disinfectant wipes.
7. Sample handling and storing should be done wearing protective gloves, and the tubes should be carried in isolation plastic bags. If required, storage for further analysis should be in dedicated shelve sections.
8. Personnel involved in the analysis should wear FFP2/FFP3/N95 masks and gloves while handling sample tubes.
9. The isotope ratio mass spectrometer used to measure $^{13}CO_2$ enrichment has a syringe with a needle that sucks the air into the system. The needle and syringe should be regularly disinfected after analysis of the suspect/positive patient samples. A filter can be positioned at the outlet section of the spectrometer and regularly changed, avoiding operator contamination.
10. H_2-based tests are usually analyzed with either a gas chromatography with thermal conductivity detection or portable instruments based on an electrochemical cell. Gas chromatographs contain a chemical-based water trap that needs periodical replacement.[44] Healthcare professionals should wear appropriate PPE when changing the filter as well as when handling sample tubes.
11. Portable H_2 analyzers in which the patient directly blows via a mouthpiece are protected by a dedicated filter that traps airborne bacteria and viruses. Similar precautions as above are needed when removing the disposable mouthpiece and when replacing this filter.

Additional measures for ^{14}C breath tests

1. With ^{14}C breath tests, the risk of aerosol generation is greater as the patient blows via a straw into a liquid-filled vial until color change occurs.[43] As the liquid consists of 70% alcohol, which is a disinfectant in its own right, the risk seems contained.
2. The same hygienic and disinfectant measures as outlined for ^{13}C and for H_2-based breath tests must be applied.

including medical scrubs, FFP2/FFP3 mask (or its equivalent in North America, the N95 mask), facial shield, a second water-impermeable apron, a second set of (long-sleeved/gauntlet) gloves, a surgical cap, apron, gloves, and shoe covers is recommended.[8-10] The advantage of this approach is that it minimizes the risk to healthcare professionals or other patients of an undetected contaminated patient undergoing a procedure. Downsides to this approach include that it consumes a large volume of PPE supplies (which may not always be available), slows the rate at which tests can be performed as well as a reduction in personal comfort of healthcare professionals performing the tests due to the multiple layers of protection being worn.

Others have proposed a lower level of PPE level, where patients with a low-risk assessment (Table 4) and a negative diagnostic test are considered to hold a low risk for contamination during the procedure[8,10] (Figure 1). In this case, and a single gown, a single pair of gloves and surgical masks rather than FFP2/N95 respirators are worn. This is encouraged by the experience of low-transmission risk when endoscopy is performed with these relatively simple protective measures.[44] In addition, a recent meta-analysis concludes that medical masks and FFP2/N95 respirators offer similar protection against viral respiratory infection including coronavirus for non-aerosolizing procedures (such as anorectal manometry).[45] For high-risk assessed procedures (Table 4), the FFP2/FFP3/N95 mask is worn as well as a second water-impermeable apron, a second set of (long-sleeved/gauntlet) gloves, in addition to goggles, a hairnet, apron, gloves, and shoe covers. The use of a disposable surgical mask with each patient, covering the FFP2/FFP3/N95, has been proposed to save on the number of FFP2/FP3/N95 masks that are needed. When an FFP3 mask with a valve is used, a surgical mask needs to be added to prevent contamination from the technician to the patient.

The sequence of dressing and undressing with these PPE is specific and should be followed in the correct order at all times to avoid patient to healthcare professional transmission. The dressing procedure is called "the donning," and the undressing procedure is called "the doffing." The donning procedure consists of 8 steps (Table 7a). The doffing procedure consists of the same 8 steps but in an altered sequence, and every step is separated from another by disinfecting your hands with alcohol (Table 7b). Steps 1-3 are inside of the room for the removal of disposable PPE, and steps 4-6 are outside of the room for collection of recyclable face shield, goggles, and mask. Due to its scarcity, specialized cleaning and sterilization programs have been implemented for these items after recollection. As contamination is most likely to happen because of errors during the "undressing/doffing" procedure, leading to accidental contact with the contaminated mask, goggles, or front of the gown, extra awareness and training for this procedure are advisable.

We recommend the possibility of taking of the face shield, goggles, and FFP2/FFP3/N95 mask after putting on a new pair of nitrile gloves outside of the room, to minimize possible transmission to the healthcare worker's skin while taking off these protection measures. An illustrative video is available on www.uzleuven.be/nl/covid-19-voor-woonzorgcentra/omkleedprocedure

10 | PROTECTIVE MEASURES FOR SPECIFIC PROCEDURES

Specific measures are summarized in Table 8a for esophageal manometry; Table 8b for pH, pH-MII, and wireless pH-capsule monitoring; Table 8c for anorectal manometry; and Table 8d for breath testing. Besides these common tests, selected centers also use EndoFLIP, SmartPill, rectal or gastric barostat, and colonic manometry. We did not include specific recommendations for these non-routine procedures.

For ^{13}C and for H_2- and CH_4-based breath tests, the patient blows a breath sample via a straw into a tube that is subsequently sealed, or directly into a hermetic bag, or directly in a portable analyzer. While one cannot exclude minor aerosol production from saliva during this repetitive sample collection where the subject has to exhale alveolar air, this is likely to be minimal. Nevertheless, for some breath tests (eg, gastric emptying test with spirulina), with adequate instructions, performance by the patient at home is feasible and avoids collection of samples in a hospital unit.

11 | CONCLUSION

With this document, the ESNM provides guidance and recommendations for safe performance of motility and function tests in the recovery phase of the SARS-CoV-2 pandemic. Nevertheless, many questions on the transmission of the virus and the risk associated with catheter-based or breath test investigations remain uncertain given the emerging nature of the pandemic. This ESNM guidance is based on the collective experiences of the authors at their own institutions and on a few early published reports in the literature.[12-16] Given the evolving nature of our scientific understanding of the SARS-CoV-2 infection, optimal protective measures, and the modes of transmission, it is likely that these guidelines will need to be updated and revised over time.

For now, we are confident they provide pragmatic and appropriate guidance for the safe conduct of motility and function testing in the COVID-19 pandemic and early recovery phase. The focus of the guideline reflects the current postpeak status, with an emphasis on limiting testing to a low-risk approach to high-necessity procedures. As the viral spread in the population lowers, the threshold to perform testing is likely to get lower, and the safety measures may become less stringent.

CONFLICT OF INTEREST

No competing interests declared.

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APPENDIX 1

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