Recovery of endoscopy services in the era of COVID-19: recommendations from an international Delphi consensus


ABSTRACT
The COVID-19 pandemic has had a profound impact on provision of endoscopy services globally as staff and real estate were repurposed. As we begin to recover from the pandemic, a cohesive international approach is needed, and guidance on how to resume endoscopy services safely to avoid unintended harm from diagnostic delays. The aim of these guidelines is to provide consensus recommendations that clinicians can use to facilitate the swift and safe resumption of endoscopy services. An evidence-based literature review was carried out on the various strategies used globally to manage endoscopy during the COVID-19 pandemic and control infection. A modified Delphi process involving international endoscopy experts was used to agree on the consensus statements. A threshold of 80% agreement was used to establish consensus for each statement. 27 of 30 statements achieved consensus after two rounds of voting by 34 experts. The statements were categorised as pre-endoscopy, during endoscopy and postendoscopy addressing relevant areas of practice, such as screening, personal protective equipment, appropriate environments for endoscopy and infection control precautions, particularly in areas of high disease prevalence. Recommendations for testing of patients and for healthcare workers, appropriate locations of donning and doffing areas and social distancing measures before endoscopy are unique and not dealt with by any other guidelines. This international consensus using a modified Delphi method to produce a series of best practice recommendations to aid the safe resumption of endoscopy services globally in the era of COVID-19.

INTRODUCTION
The new coronavirus SARS-CoV-2 is highly infectious and predominantly spread by droplets emitted from the upper respiratory tract. Endoscopy is an aerosol-generating procedure (AGP) with the potential to spread infection, thereby placing both healthcare professionals (HCPs) and patients at risk. This led most national societies to produce guidance on how to improve safety in endoscopy during the pandemic. 1–4 One of the key recommendations common to all these guidelines was a drastic reduction in procedure volume, restricting it to urgent and life-saving procedures. This was deemed necessary to minimise the spread of infection and divert healthcare resources from endoscopy to the front line. Consequently, elective endoscopy ceased on a global scale. The unintended consequence of this is a resultant delay in diagnosis and treatment of various benign and malignant gastrointestinal diseases, which calls for urgent resumption of endoscopy services.

Prompt resumption in a safe setting is paramount to mitigate unintended (non-viral) adverse health outcomes from the pandemic, but informed scientific guidance on how to fully restart endoscopy services is lacking. The guidance that exists is ad hoc and heavily influenced by local and personal perspectives, resulting in confusion and lack of compliance. Thus, a cohesive approach is needed to avoid any adverse consequences to HCPs and patients.

The aim of this project was to gather opinions from endoscopy leaders around the world in order to develop universally accepted consensus statements to guide the recovery of endoscopy services in the postpandemic era.

METHODS
A modified Delphi process was used to develop the consensus statements for recovery of endoscopy services after the COVID-19 pandemic. The main steps in the process were the selection of the consensus group, systematic literature reviews to collate supporting evidence, development of
Guidelines

statements and anonymous voting on the statements until consensus was achieved.

Selection of Delphi voting group
The outcome of the Delphi process is dependent on the voting group. We therefore developed inclusion criteria. These included, individuals who have demonstrated leadership in endoscopy at an international level, managed large endoscopy departments, produced high impact publications in the field of endoscopy or COVID-19 and have a track record of developing international guidelines. The consensus group members were expected to meet at least three of the four criteria. We selected prospective members from Asia, Europe, the Middle East, USA, Russia, Australia and Latin America to achieve global representation.

Development of statements
Two endoscopy experts, working in Italy (AR) and the United Kingdom (PB), reviewed the literature and developed the statements. Evidence was obtained by searching Medline databases using the keywords 'COVID-19', 'SARS-CoV-2' and 'Endoscopy' and by reviewing public health guidance from WHO and Centres for Disease Control and Prevention (CDC). Three broad domains of pre-endoscopy, endoscopy and postendoscopy were used to categorise the statements, reflecting the passage of a typical patient through the service. Two independent researchers who were not involved in voting verified the construct validity of these statements. Statements took into account variability in global disease prevalence with high-prevalence areas defined as areas with estimated disease prevalence rates of 2% or higher. This was chosen based on estimates from badly affected countries, such as the UK and USA, where prevalence ranged between 1% and 5%. Inherent weaknesses of prevalence estimates, including testing methodology, variance in testing strategy and reporting of the real scale of infection that could adjust the benchmark for high prevalence, remain unfortunately unavoidable.

The Delphi questionnaire was delivered using Google Forms (Google, California, USA) as part of the G-suite package https://www.google.co.uk/forms/about/. All participants in the consensus group received a secure link to the voting document by email and voted anonymously. Consensus for a statement was agreed if at least 80% of the respondents strongly agreed or agreed with that statement. The level of agreement was determined on a five-point scale as follows:
1. Strongly agree
2. Agree
3. Neither agree nor disagree
4. Disagree
5. Strongly disagree.

At the end of the first round, qualitative comments, suggestions and views were communicated by email from the consensus group to the core group (AR, PB) only. Based on the comments received, the statements selected for the second round of voting were modified before this round of voting.

All votes were received by an independent researcher who had no connection with any of the participants and collated the data for final analysis.

Patient and public involvement was not sought for the development of this consensus statement document.

RESULTS
Thirty-four experts from 24 countries formed the consensus group. Voting started on 17 May 2020 and was completed by 24 May 2020 (both rounds). A total of 30 statements were proposed and voted on. Seventeen of 30 statements achieved consensus (at least 80% agreement) in the first round. The 13 statements which did not achieve consensus were modified based on feedback, leading to improvement in the consensus rate to 27/30 following the second round.

The statements included in the final consensus are as follows (table 1):

Pre-endoscopy
Screening for infections
Statement 1. All patients coming for endoscopy should have a clinical history taken to diagnose active COVID-19 disease or contact with any infected person in the past 2 weeks.
Statement 2. The absence of clinical symptoms does not exclude SARS-CoV-2 infection as asymptomatic infections are not uncommon.
Statement 3. All patients undergoing endoscopy should be tested for SARS-CoV-2 infection 24–72 hours before endoscopy in high-prevalence regions.
Statement 4. Patients who have tested negative for SARS-CoV-2 infection may still be infective.
Statement 5. Early data on the accuracy of point-of-care tests for detection of active infection are promising and these tests could be used to aid with risk stratification of patients before endoscopy in high-prevalence regions.
Statement 6. In the absence of universal testing, all patients having therapeutic endoscopic procedures lasting longer than 1 hour should be tested for SARS-CoV-2 infection in high-prevalence regions.

Many international society guidelines advocate the use of a screening questionnaire to risk stratify patients. Viral loads detected in asymptomatic patients may be similar to those of symptomatic patients, indicating that infection may be transmitted from asymptomatic individuals. Studies on the temporal dynamics of viral shedding and transmissibility of COVID-19 noted that the highest viral load was present at the time of symptom onset, which may indicate that the peak of infectiousness could be on, or just before, symptom onset.

In view of the estimated proportion of asymptomatic patients (between 5% and 80%), symptom-based screening alone will not be sufficient. Preprocedure universal testing will guide risk stratification and the level of precautions necessary. In a recent study from China, all patients completed screening questionnaires and reverse transcriptase polymerase chain reaction (RT-PCR) tests 3 days before endoscopy. No cases of endoscopy-related nosocomial COVID-19 disease transmission were seen in a total of 1361 cases.

Sensitivity of the conventional RT-PCR test is reported to be around 70%, raising a concern about the value of these tests. False negatives are related to improper sampling techniques, low viral load, mutation of the viral genome and local prevalence. A modelling exercise reported that even in a higher-prevalence population (2%) there would only be 10 false negative results per 10000 individuals when using a test with a sensitivity of 95%. As disease prevalence declines, the false negative rate becomes less significant.
Patients with suspected or confirmed COVID-19 infection should be isolated for 1 week before endoscopy and any associated procedures. If these patients are undergoing testing for SARS-CoV-2 infection before endoscopy, they should be tested for SARS-CoV-2 infection 24–72 hours before endoscopy.

In the absence of universal testing, all patients having therapeutic endoscopic procedures lasting longer than 1 hour should be tested for SARS-CoV-2 infection in high-prevalence regions. Early data on the accuracy of point-of-care tests for detection of active infection are promising and these tests could be used to aid risk stratification of patients before endoscopy in high-prevalence regions.

Patients should observe adequate social distancing for 1 week before endoscopy in high-prevalence regions to minimise the risk of viral exposure to healthcare professionals in endoscopy departments. All patients attending for endoscopic procedures should wear simple surgical masks at all times apart from the time when an endoscope has to be inserted into the oral cavity.

Table 1 International consensus recommendations to guide endoscopy recovery in the postpandemic phase of COVID-19

<table>
<thead>
<tr>
<th>Statement number</th>
<th>Statements</th>
<th>Consensus after round 1</th>
<th>Statement modification</th>
<th>Final consensus</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>All patients coming for endoscopy should have a clinical history taken to diagnose active COVID-19 disease or contact with any infected person in the past 2 weeks</td>
<td>97.1% None</td>
<td>None</td>
<td>97.1%</td>
</tr>
<tr>
<td>2</td>
<td>The absence of clinical symptoms does not exclude SARS-CoV-2 infection as asymptomatic infections are not uncommon</td>
<td>94.1% None</td>
<td>None</td>
<td>94.1%</td>
</tr>
<tr>
<td>3</td>
<td>All patients undergoing endoscopy should be tested for SARS-CoV-2 infection 24–72 hours before endoscopy</td>
<td>65.5% All patients undergoing endoscopic procedures should be tested for SARS-CoV-2 infection 24–72 hours before endoscopy in high-prevalence regions</td>
<td>82.4%</td>
<td></td>
</tr>
<tr>
<td>4</td>
<td>Patients who have tested negative for SARS-CoV-2 infection may still be infective</td>
<td>80.6% None</td>
<td>None</td>
<td>80.6%</td>
</tr>
<tr>
<td>5</td>
<td>Data on the accuracy of point-of-care tests to detect active infection are limited but promising. They should be used in a research or audit setting until more data become available</td>
<td>69% Early data on the accuracy of point-of-care tests for detection of active infection are promising and these tests could be used to aid risk stratification of patients before endoscopy in high-prevalence regions</td>
<td>91.1%</td>
<td></td>
</tr>
<tr>
<td>6</td>
<td>All patients having endoscopic procedures lasting longer than 1 hour should be tested for SARS-CoV-2 infection</td>
<td>51.7% In the absence of universal testing, all patients having therapeutic endoscopic procedures lasting longer than 1 hour should be tested for SARS-CoV-2 infection in high-prevalence regions</td>
<td>85.3%</td>
<td></td>
</tr>
<tr>
<td>7</td>
<td>All healthcare professionals should be self-reporting any new symptoms to a responsible health professional who is able to advise on further appropriate action</td>
<td>100% None</td>
<td>None</td>
<td>100%</td>
</tr>
<tr>
<td>8</td>
<td>All healthcare professionals working in endoscopy should be tested for SARS-CoV-2 infection on a cyclical basis</td>
<td>58.6% All healthcare professionals working in endoscopy should be tested once for SARS-CoV-2 infection, undergo daily symptom and temperature checks and, in high-prevalence regions, consider regular retesting</td>
<td>88.2%</td>
<td></td>
</tr>
<tr>
<td>9</td>
<td>All patients attending for endoscopic procedures should wear simple surgical masks at all times apart from the time when an endoscope has to be inserted into the oral cavity</td>
<td>97.1% None</td>
<td>None</td>
<td>97.1%</td>
</tr>
<tr>
<td>10</td>
<td>All healthcare professionals should be wearing surgical masks at all times in clinical areas within the endoscopy department</td>
<td>94.1% None</td>
<td>None</td>
<td>94.1%</td>
</tr>
<tr>
<td>11</td>
<td>Elective endoscopy for patients with suspected or confirmed COVID-19 infection should be deferred until they are asymptomatic and have tested negative</td>
<td>94.1% None</td>
<td>None</td>
<td>94.1%</td>
</tr>
<tr>
<td>12</td>
<td>Self-isolation of patients for 1 week before endoscopy is not necessary if they are undergoing testing for SARS-CoV-2 infection before endoscopy</td>
<td>44.8% Patients should observe adequate social distancing for 1 week before endoscopy in high-prevalence regions to minimise the risk of viral exposure to healthcare professionals in endoscopy departments</td>
<td>80.6%</td>
<td></td>
</tr>
<tr>
<td>13</td>
<td>Healthcare professionals should receive appropriate training in infection control practices and handling of personal protective equipment (PPE)</td>
<td>100% None</td>
<td>None</td>
<td>100%</td>
</tr>
</tbody>
</table>

During endoscopy

<table>
<thead>
<tr>
<th>Statement number</th>
<th>Statements</th>
<th>Consensus after round 1</th>
<th>Statement modification</th>
<th>Final consensus</th>
</tr>
</thead>
<tbody>
<tr>
<td>14</td>
<td>Gastroscopy is an aerosol-generating procedure and healthcare professionals should wear enhanced personal protective equipment (N95/FFP3 respirators) in high-prevalence regions</td>
<td>82.3% None</td>
<td>None</td>
<td>82.3%</td>
</tr>
<tr>
<td>15</td>
<td>The use of enhanced personal protective equipment (N95/FFP3) respirators is recommended for all endoscopic procedures in the upper and lower gastrointestinal tract</td>
<td>69% In high-prevalence regions, the use of enhanced PPE (N95/FFP3 respirators) for both upper and lower gastrointestinal endoscopic procedures is recommended due to uncertainty surrounding the risk of infection during colonoscopy</td>
<td>88.2%</td>
<td></td>
</tr>
<tr>
<td>16</td>
<td>Standard PPE with a surgical mask is sufficient for low aerosol-generating procedures, such as colonoscopy</td>
<td>37.9% In low-prevalence regions, standard PPE (surgical mask) is sufficient for low aerosol-generating procedures such as colonoscopy</td>
<td>82.4%</td>
<td></td>
</tr>
<tr>
<td>17</td>
<td>In the absence of active testing all patients undergoing endoscopic procedures should be presumed to be potentially infective and healthcare professionals should wear enhanced PPE (N95/FFP3 respirators)</td>
<td>85.3% None</td>
<td>None</td>
<td>85.3%</td>
</tr>
<tr>
<td>18</td>
<td>The ‘doffing’ area (where PPE is worn) should be located outside the endoscopy room and away from the ‘doffing’ area (where PPE is removed)</td>
<td>94.0% None</td>
<td>None</td>
<td>94.0%</td>
</tr>
<tr>
<td>19</td>
<td>All patients in high-prevalence regions should change into hospital gowns before entering the endoscopy suites</td>
<td>85.3% None</td>
<td>None</td>
<td>85.3%</td>
</tr>
<tr>
<td>20</td>
<td>All patients with suspected or confirmed COVID-19 infection should be endoscoped in negative pressure rooms. In the absence of a negative pressure room, endoscopy departments should have a designated room and /or specific slots for these patients</td>
<td>100% None</td>
<td>None</td>
<td>100%</td>
</tr>
</tbody>
</table>

Postendoscopy

<table>
<thead>
<tr>
<th>Statement number</th>
<th>Statements</th>
<th>Consensus after round 1</th>
<th>Statement modification</th>
<th>Final consensus</th>
</tr>
</thead>
<tbody>
<tr>
<td>21</td>
<td>The ‘doffing’ area for removal of PPE could be appropriately positioned in one corner of the room</td>
<td>85.2% None</td>
<td>None</td>
<td>85.2%</td>
</tr>
<tr>
<td>22</td>
<td>The endoscopy procedure room should be deep cleaned after every procedure</td>
<td>69% The endoscopy procedure room should be deep cleaned after every procedure in a suspected or confirmed case of COVID-19</td>
<td>97.1%</td>
<td></td>
</tr>
<tr>
<td>23</td>
<td>Patients with suspected or confirmed COVID-19 infection should be allowed to recover in a designated area away from all the other non-COVID-19 patients</td>
<td>97.1% None</td>
<td>None</td>
<td>97.1%</td>
</tr>
</tbody>
</table>
Conventional RT-PCR testing may have its drawbacks. Although it takes only 4 hours to process the test, additional time is required for sample collection, transportation to the laboratory and interpretation of results, followed by communication of results to the patient or HCP. This means that the tests have to be scheduled at least 48–72 hours in advance. A simple, rapid (<1 hour) test performed at the point-of-care (POC) is a desirable option as it can simplify the management of patients.

POC tests fall into two broad categories: those that detect active infection (molecular or antigen based) and those detecting immune response (antibody) to a recent infection. The clinical significance of antibody tests is still not clear as the host immune response to recent SARS-CoV-2 varies and the relevance and duration of this response is also not well understood. POC tests that detect active infection will allow rapid identification of infection. The US FDA has recently approved a new test, Xpert Xpress SARS-CoV-2 (nucleic acid amplification tests) with sensitivity of 95%, which can provide results in less than 45 min. 20 Clustered regularly interspaced short palindromic repeat (CRISPR)-based assays can be done using a nasopharyngeal swab and can deliver results in 60 min, with reported sensitivity rate of >95%. 21 Data are limited, but if results can be reproduced and tests become widely available, then they could be adopted into routine practice.

If universal testing is not possible, focused testing of patients undergoing prolonged procedures should be considered, given the link between exposure duration (>15 min) and increased risk of viral transmission to HCPs. 22 Complex prolonged procedures should be undertaken only by highly experienced operators in high-volume centres to minimise the risk of complications. Such centres should have a standard operating procedure for management of complications, including the need for surgical backup. Knowledge of the SARS-CoV-2 status of these patients will allow streamlined management into COVID-19 minimised pathways should emergency surgery or unplanned hospital admission be required.

Protecting the workforce

Statement 7. All HCPs should be self-reporting any new symptoms to a responsible health professional who is able to advise on further appropriate action.

Statement 8. All HCPs working in endoscopy should be tested once for SARS-CoV-2 infection, undergo daily symptom and temperature checks and in high-prevalence regions consider regular retesting.

Statement 9. All patients attending for endoscopic procedures should wear single-use surgical masks at all times apart from the time when an endoscope has to be inserted into the oral cavity.

Statement 10. All healthcare professionals should be wearing single-use surgical masks at all times in clinical areas within the endoscopy department.

Statement 11. Elective endoscopy for patients with suspected or confirmed COVID-19 should be deferred until they are asymptomatic and have tested negative.

Statement 12. Patients should observe adequate social distancing for 1 week before endoscopy in high-prevalence regions to minimise the risk of viral exposure to healthcare professionals in endoscopy departments.

Statement 13. Healthcare professionals should receive appropriate training in infection control practices and handling of personal protective equipment (PPE).

As we emerge from the pandemic, the areas where the virus is likely to linger will be in care homes and healthcare facilities. Given the heterogeneity of the symptom profile in COVID-19, 19 it may not be immediately obvious that certain symptoms (ageusia, anosmia) could represent infection. Therefore, strict guidance is required for all HCPs to report any new symptoms. In the context of asymptomatic transmission, 21 clinical history alone is insufficient. The value of antibody-based tests is not yet clear, so it is advisable to test HCPs for the presence of active infection using molecular tests until the reliability and relevance of antibody testing becomes apparent. In areas of high infection prevalence, regular testing may be useful until such time that a definitive, reliable vaccine becomes available or the significance of antibodies and level of immunity conferred is clear. There are no large-scale robust studies on cyclical testing of healthcare workers. However, retesting fortnightly will enable detection of infection, allowing for the incubation period of 5–12 days. 24 Testing intervals will need to take into consideration testing resources and willingness of healthcare workers to comply with the recommendation.
Surgical masks are an effective physical intervention to reduce the spread of respiratory viruses. They may not be very effective in preventing the wearer from contracting infection but can reduce the spread of infection from the wearer, particularly when social distancing may be difficult to implement in endoscopy departments.

The use of face masks by patients is recommended in several endoscopy guidelines. For endoscopies involving the oral route, the surgical mask will need to be removed just before the endoscope is inserted and replaced as soon as the patient has recovered enough to maintain oxygen saturation above 90% on room air. Endoscopy can result in aerosolization of secretions containing virus. These contaminants can spread in the immediate environment and stay on hard surfaces for up to 3 days. Therefore, it is vital that HCPs should wear surgical masks in the endoscopy department at all times to protect themselves and patients. In addition to surgical masks or physical barriers (eye protection), strict adherence to hand hygiene, including hand washing or use of alcohol gels, is required and should form a crucial part of infection control practice on the endoscopy unit.

Emergency procedures for potentially life-threatening conditions should not be deferred and the risks of COVID-19 transmission should be mitigated by effective measures. All international society guidance was consistent in recommending postponement of elective endoscopy in patients with COVID-19. Viral shedding can occur even after the patient has stopped displaying symptoms. The link between PCR positivity for viral RNA, viable viral shedding, viral load and risk of viral transmission is not clear and therefore the safest strategy seems to be postponing the procedure.

Social distancing for 1 week before endoscopy may protect against exposure to the virus, particularly in areas of high prevalence. The median incubation period for SARS-CoV-2 is approximately 5 days, which justifies a 7-day period of social distancing. In regions where prompt testing cannot be carried out, a combination of symptom-based screening and social distancing for a week before endoscopy is the next best approach.

HCPs working in endoscopy are at a higher risk of contracting the virus. These risks should be mitigated by ensuring an adequate supply of PPE and the correct technique of wearing (donning) and removing (doffing) PPE to avoid inadvertent contact with the face. A buddy system may also be useful where another colleague assists in donning and doffing to ensure compliance. HCPs should also be trained in correct hand hygiene practices.

During endoscopy

**Personal protective equipment (PPE)**

**Statement 14.** Gastroscopy is an aerosol-generating procedure (AGP) and healthcare professionals should wear enhanced PPE (N95/FFP3 respirators) in high-prevalence regions

**Statement 15.** In high-prevalence regions, the use of enhanced PPE (N95/FFP3 respirators) for both upper and lower gastrointestinal endoscopic procedures is recommended due to uncertainty surrounding the risk of infection during colonoscopy.

**Statement 16.** In low-prevalence regions, standard PPE (surgical mask) is sufficient for low aerosol-generating procedures such as colonoscopy.

**Statement 17.** In the absence of active testing all patients undergoing endoscopic procedures should be presumed to be potentially infective and healthcare professionals should wear enhanced PPE (N95/FFP3 respirators).

Standard PPE encompasses a single pair of gloves, hairnet, protective eye wear (goggles or face shield), long-sleeved fluid resistant gowns, shoe covers, and a simple surgical mask. Enhanced PPE includes all the above, except the single gloves, which get replaced by double gloves, and the surgical mask which gets replaced by an FFP-3 (N95) respirator. Surgical masks are designed to block large particles but are less effective in blocking smaller particle aerosols (<5 µm). However, N95 respirator masks filter at least 95% of aerosols (<5 µm). Several studies have shown surgical masks to be non-inferior to N95 respirators in the prevention of viral infections like influenza. Notably, none of these trials were performed with SARS-CoV-2 virus or in the context of AGP.

On the other hand, a systematic review and a meta-analysis involving AGP showed a benefit in using N95 respirators over standard masks in protecting HCPs from SARS, although the data were imprecise with wide confidence intervals. There is limited evidence that air-powered respirator hoods may provide greater protection than N95/FFP3 respirators, which depend on the mask being adequately fitted to the face for maximum protection. However, there are no comparative trials. Users do not need to be fit tested for loose fitting respirator hoods and these may be more useful for high AGPs.

Colonoscopy is not universally classified as an AGP but the risk of aerosolisation increases with overdistension of the colon and exchange of devices through the accessory channel of the colonoscope. A recent study of patients with COVID-19 demonstrated the inability to isolate infective virions from their stool despite an abundance of viral RNA in the stools. However, the risk of gut colonisation and faeco-oral transmission does exist given the presence of key angiotensin converting enzyme 2 and transmembrane serine protease two receptors required for SARS-CoV-2 entry that are present in the oesophagus, ileum and colon. These uncertainties related to the risk associated with colonoscopy resulted in differing recommendations between high- and low-prevalence regions.

The availability of testing, cost and time taken to obtain results can be a considerable problem in some parts of the world. Given the risk of asymptomatic infection, the safest approach in the absence of testing would be to wear enhanced PPE during AGP. If patients are screened and test negative for infection in low-prevalence areas, it would be reasonable to wear standard PPE for upper GI endoscopy.
### Table 2 A comparison of this international consensus document and major national endoscopy guidance in the era of COVID-19

<table>
<thead>
<tr>
<th>This guidance</th>
<th>Joint GI society (USA) message on COVID-19</th>
<th>ESGE</th>
<th>BSG</th>
<th>APDSE</th>
<th>ASGE</th>
<th>AGA/DHPA</th>
</tr>
</thead>
<tbody>
<tr>
<td>1 Clinical screening for all patients pre-endoscopy</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
</tr>
<tr>
<td>2 Recognition that patients with COVID-19 can be asymptomatic</td>
<td>Yes</td>
<td>Not specified</td>
<td>Yes</td>
<td>Not specified</td>
<td>Yes</td>
<td>Not specified</td>
</tr>
<tr>
<td>3 Testing of all patients before endoscopy (in high-prevalence regions)</td>
<td>Not specified</td>
<td>Not specified</td>
<td>Not specified</td>
<td>Can be considered</td>
<td>Testing advised depending on availability</td>
<td>Yes</td>
</tr>
<tr>
<td>4 Patients who have tested negative for SARS-CoV-2 infection may still be infective</td>
<td>Not specified</td>
<td>Not specified</td>
<td>Not specified</td>
<td>Not specified</td>
<td>Yes</td>
<td>Not specified</td>
</tr>
<tr>
<td>5 Point-of-care tests for detection of infection may be useful</td>
<td>Not specified</td>
<td>Not specified</td>
<td>Not specified</td>
<td>Not specified</td>
<td>Not specified</td>
<td>Not specified</td>
</tr>
<tr>
<td>6 Testing before therapeutic endoscopy lasting &gt;1 hour (in high-prevalence regions)</td>
<td>Not specified</td>
<td>Not specified</td>
<td>Not specified</td>
<td>Not specified</td>
<td>Not specified</td>
<td>Not specified</td>
</tr>
<tr>
<td>7 Self-surveillance and reporting of new symptoms among all healthcare professionals in endoscopy</td>
<td>Not specified</td>
<td>Yes</td>
<td>Not specified</td>
<td>Not specified</td>
<td>Not specified</td>
<td>Not specified</td>
</tr>
<tr>
<td>8 All healthcare professionals working in endoscopy should be tested once for SARS-CoV-2 infection and have daily temperature/symptom screening and retesting in high-prevalence regions</td>
<td>Not specified</td>
<td>Not specified</td>
<td>Not specified</td>
<td>Not specified</td>
<td>Daily staff screening (symptoms/temperature) recommended</td>
<td>Daily staff screening (symptoms/temperature) recommended</td>
</tr>
<tr>
<td>9 Use of surgical masks for all patients attending endoscopy</td>
<td>Yes—face masks</td>
<td>Yes—face masks</td>
<td>Face masks for patients who are shielding</td>
<td>Not specified</td>
<td>Yes (surgical face masks)</td>
<td>Yes</td>
</tr>
<tr>
<td>10 Use of surgical masks for all healthcare professionals working in clinical areas of the endoscopy department</td>
<td>All members of the endoscopy team should wear a full set of PPE, predicated on resource availabilities</td>
<td>Yes (surgical face masks)</td>
<td>Not specified</td>
<td>Not specified</td>
<td>Yes (surgical face masks)</td>
<td>Yes</td>
</tr>
<tr>
<td>11 Deferral of elective endoscopy for patients with suspected or confirmed COVID-19</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
</tr>
<tr>
<td>12 Patients should observe adequate social distancing for 1 week before endoscopy (in high-prevalence regions)</td>
<td>Not specified</td>
<td>Not specified</td>
<td>Not specified</td>
<td>Not specified</td>
<td>Not specified</td>
<td>Not specified</td>
</tr>
<tr>
<td>13 Training of healthcare professionals in using PPE</td>
<td>Yes</td>
<td>Yes</td>
<td>Not specified</td>
<td>Yes</td>
<td>Yes</td>
<td>Not specified</td>
</tr>
<tr>
<td>14 Healthcare professionals to wear N95/FFP3 respirators for all gastroscopies in high-prevalence regions</td>
<td>Yes (for patients with COVID-19 and those at high risk of exposure)</td>
<td>Yes</td>
<td>Yes</td>
<td>PPE according to risk stratification (enhanced PPE for suspected or confirmed COVID-19)</td>
<td>Yes</td>
<td>If test is negative, standard surgical mask for all procedures</td>
</tr>
<tr>
<td>15 In high-prevalence regions, the use of enhanced PPE (N95/FFP3 respirators) for both upper and lower gastrointestinal endoscopic procedures</td>
<td>Yes (see above)</td>
<td>Yes (see above)</td>
<td>PPE choice based on likelihood of COVID-19 infection</td>
<td>As per Public Health England guidance (constantly under review)</td>
<td>As above</td>
<td>Yes</td>
</tr>
<tr>
<td>16 In low-prevalence regions, standard PPE (surgical mask) is sufficient for colonoscopy</td>
<td>Enhanced PPE for all GI procedures</td>
<td>PPE choice based on likelihood of COVID-19 infection</td>
<td>Standard PPE for lower GI procedures if patient has tested negative for COVID-19</td>
<td>PPE according to risk stratification/likelihood of COVID-19</td>
<td>N95 respirators for all endoscopic procedures</td>
<td>If test is negative, standard surgical mask for all procedures (no distinction between OGD or colonoscopy)</td>
</tr>
<tr>
<td>17 In the absence of active testing all patients should be presumed to be infective and healthcare professionals should wear enhanced PPE</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
</tr>
<tr>
<td>18 The 'donning' area should be located outside of the endoscopy room and away from the 'doffing' area</td>
<td>Not specified</td>
<td>Not specified</td>
<td>Not specified</td>
<td>Not specified</td>
<td>Not specified</td>
<td>Not specified</td>
</tr>
<tr>
<td>19 All patients in high-prevalence regions should change into hospital gowns before entering the endoscopy suites</td>
<td>Not specified</td>
<td>Not specified</td>
<td>Not specified</td>
<td>Not specified</td>
<td>Not specified</td>
<td>Not specified</td>
</tr>
</tbody>
</table>
Statement 19. All patients in high-prevalence regions should change into hospital gowns before entering the endoscopy suites.

During endoscopy, there is a risk of exposure to aerosols, splashes of body fluids and inadvertent contact with patients and HCPs where cloth contamination may occur. Chin et al, showed that SARS-CoV-2 virus remains stable on fabric for up to 2 days. Contaminated clothes can become potential sources of spreading infection in the community.

Statement 20. All patients with suspected or confirmed COVID-19 infection should be endoscoped in negative pressure rooms. In the absence of a negative pressure room, endoscopy departments should have a designated room and /or specific slots for these patients.

The one-way flow of air with no leakage of infected aerosol into the environment is a key advantage of a negative pressure room, which could reduce the risk of infection transmission. However, providing a negative pressure room may not always be possible. Therefore, a specific room should be allocated for high-risk patients to minimise the risk to uninfected patients. If this is not practical, then a specific slot should be allocated, ideally at the end of a morning or afternoon session, to allow for terminal cleaning. Spacing of procedures in the absence of a negative pressure environment was not agreed in this consensus as explored in the discussion.

Post-endoscopy

Statement 21. The ‘doffing’ area for removal of PPE could be appropriately positioned in one corner of the room.

Accidental contamination during removal of PPE is possible. Owing to the distance that large droplets can travel, a 2m distance between the doffing station and potential source of infection is recommended. The biggest risk of inadequate doffing will be to nullify the protection conferred by PPE to HCPs. The sequence and technique of doffing are as important as the distance from the procedure spot.

Statement 22. The endoscopy procedure room should be deep cleaned after every procedure in a suspected or confirmed case of COVID-19.

CDC guidance on disinfection of medical equipment advises the use of bleach-containing solutions in a ratio of 1:100 as these agents are effective viricidal agents. American Society of Gastrointestinal Endoscopy (ASGE) guidelines advise terminal cleaning after known cases of transmissible infection by organisms as determined by the local institution. The terminal cleaning process should involve cleaning the room and all surfaces to remove soil and biofilm, followed by appropriate disinfection.

Statement 23. Patients with suspected or confirmed COVID-19 infection should be allowed to recover in a designated area away from all the other non-COVID-19 patients.

WHO guidance for rational use of PPE states that patients with COVID-19 should be seen as a cohort to streamline workflow. British Society of Gastroenterology (BSG) guidance recommends linear flow through the endoscopy unit with separate entrances and exits for patients with suspected or confirmed COVID-19 infection. There should be a designated recovery area for patients suspected of having COVID-19 with separate staff in appropriate PPE. If there are space constraints, then patients with known COVID-19 should be scheduled at the end of the day when all other patients from recovery have been discharged to minimise contact with non-infected patients.

Statement 24. In high-prevalence regions, healthcare professionals in the endoscopy recovery areas (for non COVID-19 patients) should wear standard PPE with surgical masks.

Close contact with the patient may be unavoidable due to the need to monitor vital signs or conduct clinical examination, as required, if the patient is symptomatic. Passage of gastrointestinal contents is not uncommon following endoscopy and can result in the spread of infection. Direct clinical care should therefore be provided to patients in the recovery area using standard PPE (surgical mask, gown, gloves, eye protection).

Statement 25. Strict adherence to endoscopy disinfection policies is mandatory.

Statement 26. achieves 10.1136/gutjnl-2020-322329 on 14 August 2020. Downloaded from http://gut.bmj.com on February 18, 2021 by guest. Protected by copyright.

Table 2 Continued

<table>
<thead>
<tr>
<th>This guidance</th>
<th>Joint GI society (USA) message on COVID-19</th>
<th>ESGE</th>
<th>BSG</th>
<th>APDSE</th>
<th>ASGE</th>
<th>AGA/DHPA</th>
</tr>
</thead>
<tbody>
<tr>
<td>20 Use of negative pressure rooms (or designated rooms/specific procedure slots) for patients with COVID-19</td>
<td>Yes (for suspected or confirmed COVID-19)</td>
<td>Yes (for suspected or confirmed COVID-19)</td>
<td>Negative pressure not specified</td>
<td>Yes (for suspected or confirmed COVID-19)</td>
<td>Not specified</td>
<td>Rooms lacking negative pressure benefit from additional aeration time</td>
</tr>
<tr>
<td>21 Location of doffing area</td>
<td>Not specified</td>
<td>Not specified</td>
<td>Not specified</td>
<td>Not specified</td>
<td>Not specified</td>
<td>Not specified</td>
</tr>
<tr>
<td>22 Deep cleaning of procedure room after every procedure</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
</tr>
<tr>
<td>23 Separate recovery area required for patients with COVID-19</td>
<td>Not specified</td>
<td>Yes</td>
<td>Not specified</td>
<td>Not specified</td>
<td>Not specified</td>
<td>Not specified</td>
</tr>
<tr>
<td>24 Healthcare professionals in non-COVID-19 recovery areas should wear standard PPE with surgical masks</td>
<td>Not specified</td>
<td>Not specified</td>
<td>Not specified</td>
<td>Yes</td>
<td>Surgical mask, gloves required in postoperative areas (N95 depending on availability)</td>
<td>Yes</td>
</tr>
<tr>
<td>25 Strict adherence to endoscope disinfection policies</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
</tr>
<tr>
<td>26 Adequate social distancing measures in endoscopy</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
</tr>
<tr>
<td>27 Follow-up of patients 10–14 days postprocedure</td>
<td>Not specified</td>
<td>At 7 and 14 days after endoscopy for all patients</td>
<td>Not specified</td>
<td>Not specified</td>
<td>Yes</td>
<td>(1–2 weeks postprocedure)</td>
</tr>
</tbody>
</table>

AGA, American Gastroenterological Association; APDSE, Asia Pacific Society for Digestive Endoscopy; ASGE, American Society of Gastrointestinal Endoscopy; BSG, British Society of Gastroenterology; DHPA, Digestive Health Physicians Association; ESGE, European Society of Gastrointestinal Endoscopy; OGE, oesophagogastroduodenoscopy; PPE, personal protective equipment.
The SARS-CoV-2 virus is sensitive to the standard endoscope cleansing measures, and no new measures are required. The standards applied should be consistent with the recommendations set out by international endoscopy guidelines. If current guidelines are followed, the risk of viral transmission secondary to endoscope disinfection practice is extremely unlikely.

Statement 26. Adequate social distancing should be maintained throughout all areas of the endoscopy unit in high-prevalence regions.

Social distancing is an important means of minimising nosocomial spread. Endoscopy is a team-based activity where many HCPs come into contact with patients and relatives. Adequate social distancing should be practised with a 1–2 m distance between staff and patients whenever possible. Reception, waiting areas and recovery space may all need to be redesigned to limit the number of people in a confined zone. The use of protective screens in reception and a separate recovery area for patients with suspected or confirmed COVID-19 should be considered. A no-visiting policy (except if deemed absolutely necessary) should be enforced. Accompanying people should drop the patient off at the entrance to the endoscopy unit and wait off the premises until the patient is ready to be collected. They too should adhere to social distancing measures and wear face coverings at all times.

Statement 27. All patients should be followed up by phone in 10–14 days to identify any symptoms suggestive of COVID-19 in high-prevalence regions.

There remains a risk that patients may be exposed to SARS-CoV-2 when attending for their endoscopic procedures. The median incubation period of the virus is 5 days and the vast majority who do develop symptoms will do so within 11.5 days.

Most national guidance on endoscopy advocates contacting patients within 14 days to enquire about symptoms suggestive of COVID-19.

DISCUSSION

A recent study looked at the impact of a hypothetical suspension of elective endoscopy for 6 months in the USA, and predicted a delayed diagnosis of over 2800 colorectal cancers and 22 000 high-grade adenomatous polyps with malignant potential. The 6-month mortality rate for those eventually diagnosed with colorectal cancer would increase by 6.5%. This emphasises the need for a rapid, yet safe, resumption of endoscopy services, which our consensus guidance aims to facilitate.

This is the first international consensus document produced using a modified Delphi process to enable a cohesive approach to resuming endoscopy services globally. Although various national societies have produced separate guidelines for endoscopy practice during this pandemic, we are now in a postpandemic phase where infection prevalence is rapidly declining. We have therefore accounted for prevalence in our statements and have comprehensively mapped the entire route of the patient through endoscopy, and the associated risks for patients and HCPs.

Table 2 summarises our recommendations and compares them with other published major guidance. Importantly, we identify key recommendations below that have evolved through this Delphi consensus that set it apart from other guidelines.

The value of testing during the postpandemic phase should not be underestimated and this was demonstrated by strong consensus for preprocedure testing of all patients in high-prevalence regions. This will allow services and patients to be risk stratified, with increased confidence in ramping up the volume of endoscopy with reasonable use of PPE. We also highlight high-sensitivity POC testing as a way of minimising risks of false negative tests. Concerns about false negative rates of current molecular tests have been eloquently highlighted in a recent publication predicting that in an endoscopy unit that serves 10 000 patients annually in the USA (prevalence 0.26%), a POC test with 95% sensitivity would result in only one false negative result. Comparatively, in a higher-prevalence population of 2%, there would be 10 false negative results per 10 000 patients. This is no higher than a fatal automobile crash in the USA (mortality of 10.3 per 100 000 according to CDC figures).

This document recommends testing all patients having an endoscopy of longer than an hour, highlighting the increased risk of infection with prolonged aerosol generation. Testing of HCPs has also emerged as another important recommendation given that they are increasingly recognised as a nidus for future clusters of outbreaks in hospital.

The practice of social distancing for a week before endoscopy prompted much debate before achieving consensus. In the current climate, without the realistic prospect of a vaccine or treatment, social distancing will remain an integral part of reducing transmission risk. We recognise that isolating from household members is not required at present but distancing from external contacts is essential. This approach will strike a balance between protecting patients and staff from infection without negatively affecting uptake of endoscopy. Indeed, there are strong data from a recent meta-analysis demonstrating the effect of non-pharmacological interventions, such as physical distancing, face masks and eye protection, on preventing transmission of SARS-CoV-2 in healthcare and community settings.

We have also produced a set of unique recommendations providing practical advice for the location of donning and doffing areas not covered by other endoscopy guidelines.

We failed to achieve consensus about the use of general anaesthesia with endotracheal intubation for upper endoscopic procedures longer than 30 min. Long procedures are less likely to be well tolerated, thereby increasing the risk of coughing and aerosol generation. General anaesthesia may reduce this risk by eliminating coughing. However, endotracheal intubation is itself an AGP and there was concern that this would simply be transferring the risk from the endoscopist to the anaesthesiologist. We believe that a decision for the use of anaesthesia will be based on the complexity and duration of procedures and availability of anaesthesia rather than on the risk of infection.

The other statement that lacked sufficient agreement related to single-use accessories in areas of high-disease prevalence. The fact that the virus can easily be killed during routine disinfection procedures with ethanol, glutaraldehyde and sodium hypochlorite swayed opinions. We believe that single-use accessories will become a universal standard once readily affordable and available.

Another recommendation that failed to achieve consensus was on implementing downtime of 20–30 min after each procedure. SARS-CoV-2 infection is transmitted by droplets and these droplets can remain suspended for variable lengths of time depending on size and air exchange rates, before settling. These issues have led to recommendations on a 30–60 min delay between procedures if the procedure is carried out in the absence of a negative pressure setting. However, uncertainties about air exchange rates and differences in aerosols related to gastroscopy and colonoscopy did not allow a consensus to be reached on the exact length of time and type of procedure.

In the absence of high-quality data, we have produced a series of best practice recommendations for the patient’s journey
through endoscopy. These practical recommendations can empower units around the world to ensure a safe and rapid resumption of endoscopy services.

Author affiliations
1Department of Gastroenterology, Portsmouth Hospitals University NHS Trust, Portsmouth, UK
2School of Pharmacy and Biomedical Sciences, University of Portsmouth, Portsmouth, UK
3Department of Gastroenterology and Hepatology, Westmead Hospital, Westmead, New South Wales, Australia
4Department of Gastroenterology, Al Jahra Hospital, Kuwait City, Al Jahra, Kuwait
5Department of Surgery, The Chinese University of Hong Kong, Hong Kong, Hong Kong
6Department of Gastroenterology and Hepatology, Northwestern University, Chicago, Illinois, USA
7Department of Gastroenterology, University Hospital Gasthuisberg, Leuven, Vlaams Brabant, Belgium
8Gastroenterology Unit, Nuovo Regina Margherita Hospital, Rome, Italy
9Department of Gastroenterology, Hepatology and Nutrition, Universidad of Texas MD Anderson Cancer Center, Houston, Texas, USA
10Division of Digestive Diseases, Department of Medicine, David Geffen School of Medicine at University of California, Los Angeles, California, USA
11Division of Digestive and Liver Diseases, Columbia University Medical Center, New York, New York, USA
12Department of Medicine, St. Michael’s Hospital, University of Toronto, Toronto, Ontario, Canada
13Gastroenterology Department, Complejo Hospitalario de Navarra, Pamplona, Spain
14Department of Gastroenterology and Hepatology, Erasmus Medical Centre, Rotterdam, The Netherlands
15Department of Gastroenterology, Hepatology and Oncology, Centre for Postgraduate Medical Education, Warsaw, Poland
16Department of Gastroenterology, Oncology, The Maria Skłodowska-Curie Memorial Cancer Centre, Institute of Oncology, Warsaw, Poland
17Department of Gastroenterology, Obaidulla Hospital, Ras Al Khaimah, United Arab Emirates
18Department of Gastroenterology, King Khalid University Hospital, King Saud University, Riyadh, Saudi Arabia, Riyadh, Saudi Arabia
19Department of Gastroenterology and Hepatology, Theodor Bilharz Research Institute, Cairo, Giza, Egypt
20Gastroenterology Division, Universidad de La Sabana, Chia, Colombia
21Department of Advanced GI Endoscopy, EmuraCenter LatinoAmerica, Bogota, Colombia
22Department of Gastroenterology, University of Sao Paulo Medical School, Sao Paulo, Sao Paulo, Brazil
23Department of Surgery, Clínica Santa Maria, Santiago, Chile
24Department of Gastroenterology, Hospital de Emergencias Dr Clemente Alvarez, Rosario, Rosario, Argentina
25Department of Gastroenterology and Hepatology, Singapore General Hospital, Singapore
26Department of Gastroenterology, Prince Court Medical Centre, Kuala Lumpur, Malaysia
27Digestive Disease Center, Showa University, Northern Yokohama Hospital, Yokohama, Japan
28Endoscopy Division, National Cancer Center Hospital, Tokyo, Japan
29Department of Gastroenterology, Toranomon Hospital, Tokyo, Japan
30Cancer Center, Keio University, Tokyo, Japan
31Department of Endoscopy, Yaroslavl Regional Cancer Hospital, Yaroslavl, Russian Federation
32Department of Gastroenterology, Pirogov Russian National Research Medical University, Moscow, Russian Federation
33Department of Gastroenterology, Renmin Hospital of Wuhan University, Wuhan, Hubei, China
34Department of Surgery, Baldota Institute of Digestive Sciences, Global Hospitals, Mumbai, India
35Asian Healthcare Foundation, Asian Institute of Gastroenterology, Hyderabad, Andhra Pradesh, India
36Division of Gastroenterology, Mayo Clinic, Jacksonville, Florida, USA
37Division of Gastroenterology, NYU Langone Medical Center, New York, New York, USA
38Department of Interdisciplinary Endoscopy, University Hospital Hamburg-Eppendorf, Hamburg, Germany
39Endoscopy Unit, Veteran Affairs Medical Center and University of Kansas, Kansas City, Kansas, USA
40Gastroenterology and Endoscopy Unit, Istituto Clinico Humanitas, Milan, Italy

Preparing the manuscript for subsequent publication

Contributors PB - Concept and design of study, construction of study, critical revision of the manuscript. SS - Literature review, reviewed statement construct, wrote manuscript. MIB, AA - Consensus participation, critical revision of the manuscript. JFB - Designed voting platform, analysed and compiled voting data. AR - Study design, constructed statements, critical revision of the manuscript. All other coauthors were voting members of the consensus group and contributed to the final revision of the manuscript. *Both PB and SS contributed equally to the manuscript.

Funding The authors have not declared a specific grant for this research from any funding agency in the public, commercial or not-for-profit sectors.

Competing interests PB - Research support from Fujifilm Europe, Boston Scientific, Pentax and Olympus Medical VRM - consultant and research support for Boston Scientific, Medtronic; consultand. Medivators, Interspace Diagnostics; honoraria/speakers bureau: Torax Medical/Ethicon; equity interest/stockholder: Capsovision.

Patient and public involvement Patients and/or the public were not involved in the design, conduct, or reporting, or dissemination plans of this research.

Patient consent for publication Not required.

Provenance and peer review Not commissioned; externally peer reviewed.

Data availability statement All data relevant to the study are included in the article.

This article is made freely available for use in accordance with BMJ's website terms and conditions for the duration of the covid-19 pandemic or until otherwise determined by BMJ. You may use, download and print the article for any lawful, non-commercial purpose (including text and data mining) provided that all copyright notices and trade marks are retained.

ORCID iDs
Sharmila Subramaniam http://orcid.org/0000-0002-3104-7616
Philip Wai Yan Chiu http://orcid.org/0000-0001-9292-112X
Cesare Hassan http://orcid.org/0000-0001-7167-1459
Honggang Yu http://orcid.org/0000-0001-5986-1294
Thomas Rösch http://orcid.org/0000-0003-2270-2495

REFERENCES

Twitter Eduardo Albéniz @edalbeniz and Mostafa Ibrahim @mostafaliprivate

Gut: first published as 10.1136/gutjnl-2020-322329 on 14 August 2020. Downloaded from http://gut.bmj.com/ on February 18, 2021 by guest. Protected by copyright.