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3 **Title Page**
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6 **Title:**

7 Recovery of Endoscopy Services in the Era of COVID-19: Recommendations from an
8 International Delphi Consensus
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3 **Recovery of Endoscopy Services in the Era of COVID-19: Recommendations from an**
4 **International Delphi Consensus**
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6
7 **Abstract**
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9 **Objective:**

10 The COVID-19 pandemic has had a profound impact on provision of endoscopy services
11 globally as staff and real estate were repurposed. As we begin to recover from the
12 pandemic, there is a need for a cohesive international approach and guidance to resume
13 endoscopy services safely to avoid unintended harm from diagnostic delays. We aimed to
14 provide consensus recommendations that clinicians can use to facilitate the swift and safe
15 resumption of endoscopy services.
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19 **Design:**

20 An evidence based literature review was carried out on the various strategies used globally
21 to manage endoscopy during the COVID-19 pandemic and infection control practice. A
22 modified Delphi process involving international endoscopy experts was used to agree on the
23 consensus statements. A threshold of 80% agreement was used to establish consensus for
24 each statement.
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28 **Results**

29 27 out of 30 statements achieved consensus after two rounds of voting by 34 experts. The
30 statements were categorised as pre-endoscopy, during endoscopy and post-endoscopy
31 addressing relevant areas of practice such as screening, personal protective equipment,
32 appropriate environments for endoscopy and infection control precautions particularly in
33 areas of high disease prevalence. Recommendations around testing of patients and
34 healthcare workers, appropriate locations of donning and doffing areas as well as social
35 distancing measures prior to endoscopy are unique and not addressed by any other
36 guidelines.
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40 **Conclusions**

41 This is the first international consensus using a modified Delphi method to produce a series
42 of best practice recommendations to aid with the safe resumption of endoscopy services
43 globally in the era of COVID-19.
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4 **Summary**
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8 1. What is already known about this subject?
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- 10 • COVID-19 has had a huge impact on elective endoscopy services worldwide
11 with drastic reduction in procedures being undertaken.
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- 13 • As the first wave of the pandemic begins to settle, there is an urgent need to
14 resume endoscopy safely and swiftly.
15
- 16 • Many major national societies have produced guidelines for endoscopy
17 during the peak of the pandemic but there is no cohesive approach to
18 guidance on resuming endoscopy.
19

20 2. What are the new findings?
21

- 22 • A comprehensive series of recommendations encompassing pre, during and
23 post endoscopy practices
24
- 25 • Recommendations tailored according to disease prevalence
26
- 27 • Recommendations around widespread testing of patients and healthcare
28 workers
29
- 30 • Personal protective equipment tailored according to disease prevalence and
31 type of procedure
32

33 3. How might it impact on clinical practice in the foreseeable future?
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- 35 • Streamline endoscopy practices to encourage confidence amongst staff and
36 patients on safe practices that will minimise disease transmission
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- 38 • Enable endoscopy units to reopen safely and gradually increase the volume
39 of procedures performed
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Introduction

The novel 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 health care professionals (HCP) 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 to only urgent and life- saving procedures. This was deemed necessary to minimise the spread of infection and divert health care resources from endoscopy to the frontline. 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. This calls for urgent resumption of endoscopy services.

While prompt resumption in a safe setting is paramount to mitigate unintended (non-viral) adverse health outcomes from the pandemic, 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, there is a need for a cohesive approach to avoid any adverse consequences to HCP and patients.

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

Methods

A modified Delphi process was used to develop the consensus statements for recovery of endoscopy services post 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 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 criterion. 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 a track record of developing International guidelines. The consensus group members were expected to meet at least three out of 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 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 reviewing

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3 public health guidance from the World Health Organisation (WHO), Centers for Disease
4 Control and Prevention (CDC). Three broad domains of Pre-Endoscopy, Endoscopy and Post-
5 endoscopy were used to categorise the statements, reflecting a typical patient journey
6 through the service. Two independent researchers who were not involved in voting verified
7 the construct validity of these statements. Statements took into account variability in global
8 disease prevalence with high prevalence areas defined as areas with estimated disease
9 prevalence rates of 2% or higher. This was chosen based on estimates from badly affected
10 countries such as the UK and USA where prevalence ranged between 1-5%.^{5,6} Inherent
11 weaknesses of prevalence estimates including testing methodology, the variance in testing
12 strategy and reporting of the real scale of infection that could adjust the benchmark for
13 high prevalence remain unfortunately unavoidable.

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18 The Delphi questionnaire was delivered using Google Forms (Google®, California, US) as part
19 of the G-Suite® package <https://www.google.co.uk/forms/about/>. All participants in the
20 consensus group received a secure link to the voting document *via* email and voted
21 anonymously. Consensus for a statement was agreed if at least 80% of the respondents
22 strongly agreed or agreed with that statement. The level of agreement was determined on a
23 five-point scale as follows:

- 24 1) Strongly Agree
- 25 2) Agree
- 26 3) Neither agree nor disagree
- 27 4) Disagree
- 28 5) Strongly Disagree

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

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

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

44 45 46 **Results**

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48 There were 34 experts from 24 countries who formed the consensus group. Voting was
49 commenced on 17th May 2020 and completed by 24th May 2020 (both rounds). A total of 30
50 statements were proposed and voted on. 17 out of 30 statements achieved consensus (at
51 least 80% agreement) in the first round. The 13 statements which did not achieve consensus
52 were modified based on feedback leading to improvement in consensus rate to 27/30
53 following the second round.

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

57 58 59 **Pre-Endoscopy**

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Screening for Infection

- 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 last 2 weeks**
- 2. The absence of clinical symptoms does not exclude SARS-CoV-2 infection as asymptomatic infections are not uncommon**
- 3. All patients undergoing endoscopy should be tested for SARS-CoV-2 infection 24-72 hours prior to endoscopy in high prevalence regions**
- 4. Patients who have tested negative for SARS-CoV-2 infection may still be infective**
- 5. Early data on the accuracy of point of care tests for detection of active infection is promising and these tests could be used to aid with risk stratification of patients prior to endoscopy in high prevalence regions**
- 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**

Multiple international society guidelines advocate the use of a screening questionnaire to risk stratify patients.^{1,2,4,7,8} Patients should be screened within 72 hours of their planned procedure and on the day of attendance. A positive screen should prompt the healthcare provider to consider deferring endoscopy if it is not urgent.

However, asymptomatic SARS-CoV-2 infections are a recognised source for transmission.^{9,10,11,12} Viral loads detected in asymptomatic patients may be similar to that of symptomatic patients indicating that infection may be transmitted from asymptomatic individuals.¹³ 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.^{14,15}

In view of the estimated proportion of asymptomatic patients (between 5-80%)¹⁶, symptom based screening alone will not be sufficient. Universal testing pre-procedure will guide risk stratification and level of precautions necessary. In a recent study from China,¹⁷ all patients completed screening questionnaires and RT-PCR tests 3 days prior to endoscopy. There were no cases of endoscopy related nosocomial COVID-19 disease transmission seen in a total of 1361 cases.

Sensitivity of conventional RT-PCR test is reported to be around 70% raising a concern about the value of these tests.¹⁸ 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 10,000 individuals when using a test with a sensitivity of 95%.¹⁹ As disease

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3 prevalence declines, the false negative rate becomes less significant.
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6 Conventional RT-PCR testing may have its drawbacks. Although it only takes 4 hours to
7 process the test, additional time is required for sample collection, transportation to the lab
8 and interpretation of results followed by communication of results to the patient or HCP.
9 This means that the tests have to be scheduled at least 48-72 hours in advance. Simple,
10 rapid (<1 hour) tests performed at the point of care (POC) are a very desirable option as it
11 can simplify the management of patients.
12

13 POC tests can fall under two broad categories: those that detect active infection (molecular
14 or antigen based) vs those detecting immune response (antibody) to a recent infection. The
15 clinical significance of antibody tests is still not clear as the host immune response to recent
16 SARS-CoV-2 varies and the relevance and duration of this response is also not well
17 understood. POC tests that detect active infection will allow rapid identification of infection.
18 The US FDA has recently approved a new test, Xpert Xpress SARS-CoV-2 (NAATs) with
19 sensitivity of 95% that can provide results in less than 45 minutes.²⁰ Clustered Regularly
20 Interspaced Short Palindromic Repeat (CRISPR) based assays can be done by using a
21 nasopharyngeal swab and can deliver results in 60 mins with reported sensitivity rate of
22 >95%.²¹ Data is limited but if results can be reproduced and tests become widely available,
23 then they could be adopted into routine practice.
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27 If universal testing is not possible, focused testing of patients undergoing prolonged
28 procedures should be considered given the link between exposure duration (> 15 minutes)
29 and increased risk of viral transmission to HCP.²² Complex prolonged procedures should only
30 be undertaken by highly experienced operators in high volume centres to minimise the risk
31 of complications. Such centres should have a standard operating procedure for
32 management of complications including the need for surgical backup. Knowledge of the
33 SARS-CoV-2 status of these patients will allow streamlined management into COVID
34 minimised pathways should emergency surgery or unplanned hospital admission be
35 required.
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40 **Protecting the Workforce**

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42 **7. All HCPs should be self reporting any new symptoms to a responsible health**
43 **professional who is able to advise on further appropriate action**
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46 **8. All HCPs working in endoscopy should be tested once for SARS-CoV-2 infection, undergo**
47 **daily symptom and temperature checks and in high prevalence regions consider retesting**
48 **on a regular basis**
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51 **9. All patients attending for endoscopic procedures should wear simple surgical masks at**
52 **all times apart from the time when an endoscope has to be inserted into the oral cavity**
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55 **10. All healthcare professionals should be wearing surgical masks at all times in clinical**
56 **areas within the endoscopy department**
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59 **11. Elective endoscopy for suspected or confirmed COVID-19 patients should be deferred**
60 **until they are asymptomatic and have tested negative**

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3 **12. Patients should observe adequate social distancing for 1 week prior to endoscopy in**
4 **high prevalence regions to minimise the risk of viral exposure to health care professionals**
5 **in endoscopy departments**
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8 **13. Health care professionals should receive appropriate training in infection control**
9 **practices and handling of personal protective equipment (PPE)**
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11 As we emerge from the pandemic, the areas where the virus is likely to linger will be in care
12 homes and health care facilities. Given the heterogeneity of the symptom profile in COVID-
13 19,¹⁰ it may not be immediately obvious that certain symptoms (ageusia, anosmia) could
14 represent infection. Therefore, strict guidance is required for all HCP to report any new
15 symptoms. In the context of asymptomatic transmission,²³ clinical history alone is
16 insufficient. The value of antibody-based tests is not yet clear, so it is advisable to test HCP
17 for the presence of active infection using molecular tests until the reliability and relevance
18 of antibody testing becomes apparent. In areas of high infection prevalence, regular testing
19 may be useful until such time that a definitive, reliable vaccine becomes available or the
20 significance of antibodies and level of immunity conferred is clear. There are no large scale
21 robust studies on cyclical testing of healthcare workers. However, retesting on a fortnightly
22 basis will enable detection of infection, allowing for the incubation period of 5-12 days.³²
23 Testing intervals will need to take into consideration testing resources and willingness of
24 healthcare workers to comply with the recommendation.
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30 Surgical masks are an effective physical intervention to reduce the spread of respiratory
31 viruses.²⁴ They may not be very effective in preventing the wearer contracting infection but
32 can reduce the spread of infection from the wearer particularly when social distancing may
33 be difficult to implement in endoscopy departments.²⁵
34

35 The use of facemasks by patients is recommended in several endoscopy guidelines.^{26,2,1}
36 For endoscopies involving the oral route, the surgical mask will need to be removed just
37 before the endoscope is inserted and replaced as soon as the patient has recovered enough
38 to maintain oxygen saturation above 90% on room air.²⁷
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41 Endoscopy can result in aerosolization of secretions containing virus. These contaminants
42 can spread in the immediate environment²⁸ and stay on hard surfaces for up to 3 days.²⁹
43 Therefore, it is vital that HCP should wear surgical masks in the endoscopy department at all
44 times to protect themselves and patients. In addition to surgical masks or physical barriers
45 (eye protection), strict adherence to hand hygiene including handwashing or use of alcohol
46 gels are required and should form a crucial part of infection control practice on the
47 endoscopy unit.
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51 Emergency procedures for potentially life threatening conditions should not be deferred
52 and the risks of COVID-19 transmission should be mitigated by effective measures. All
53 international society guidance were consistent in recommending postponement of elective
54 endoscopy in COVID-19 patients.³⁰ Viral shedding can occur even after the patient has
55 stopped displaying symptoms.³¹ The link between PCR positivity for viral RNA, viable viral
56 shedding, viral load and risk of viral transmission is not clear and therefore the safest
57 strategy seems to be postponing the procedure.
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3 Social distancing for 1 week prior to endoscopy may protect against exposure to the virus
4 particularly in areas of high prevalence. The median incubation period for SARS-CoV-2 is
5 approximately 5 days³² which justifies a 7 day period of social distancing. In regions where
6 prompt testing cannot be carried out then a combination of symptom based screening and
7 social distancing for a week prior to endoscopy is the next best approach.
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10 HCP working in endoscopy are at a higher risk of contracting the virus.³³ These risks should
11 be mitigated by ensuring adequate supply of PPE and the correct technique of wearing
12 (donning) and removing (doffing) PPE to avoid inadvertent contact with the face. A buddy
13 system may also be useful where another colleague assists in “donning” and “doffing” to
14 ensure compliance.³⁴ HCP should also be trained in correct hand hygiene practices.
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18 During Endoscopy

19 **Personal Protective Equipment (PPE)**

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22 **14. Gastroscopy is an aerosol generating procedure (AGP) and health care professionals**
23 **should wear enhanced PPE (N95/FFP3 respirators) in high prevalence regions**

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

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

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35 **17. In the absence of active testing all patients undergoing endoscopic procedures should**
36 **be presumed to be potentially infective and health care professionals should wear**
37 **enhanced PPE (N95/FFP3 respirators)**
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40 Standard PPE encompasses a single pair of gloves, hairnet, protective eyewear (goggles or
41 face shield), long sleeved fluid resistant gowns, shoe covers, and a simple surgical mask.
42 Enhanced PPE includes all the above except the single gloves, which get replaced by double
43 gloves and the surgical mask which gets replaced by an FFP-3 (N-95) respirator. Surgical
44 masks are designed to block large particles but are less effective in blocking smaller particle
45 aerosols (<5 µm). However, N-95 respirator masks filter at least 95% of aerosols (<5 µm).³⁵
46 Several studies have shown surgical masks to be non-inferior to N-95 respirators in the
47 prevention of viral infections like influenza. ^{36,37} Notably, none of these trials were
48 performed with SARS-CoV-2 virus or in the context of AGP.
49

50 On the other hand, a systematic review and a meta-analysis involving AGP, showed a
51 benefit in using N95 respirators over standard masks in protecting HCP from SARS although
52 the data was imprecise with wide confidence intervals.³⁸ There is limited evidence that air
53 powered respirator hoods may provide greater protection than N95/FFP3 respirators which
54 depend on the mask being adequately fitted to the face for maximum protection.^{39,40}
55 However, there are no comparative trials. Users do not need to be fit tested for loose fitting
56 respirator hoods and these may be more useful for high aerosol generating procedures.
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Currently, 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 from COVID-19 patients demonstrated the inability to isolate infective virions from their stool despite an abundance of viral RNA in the stools.⁴¹ However, the risk of gut colonisation and faeco-oral transmission does exist given the presence of key ACE2 and transmembrane serine protease 2 receptors required for SARS-CoV-2 entry that are present in the oesophagus, ileum and colon.⁴² 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 significant issue 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 tested negative for infection in low prevalence areas, it would be reasonable to wear standard PPE for upper GI endoscopy.

Environment

18. The “Donning” area should be located outside of the endoscopy room and away from the “doffing” area

Viral respiratory infections can be spread by touching an infected person or the surfaces and fomites that the person has either touched, or on which virus-containing droplets expired by the person have landed. Therefore, frequent hand-washing and maintaining a distance of at least 1m are considered the main precautions against contracting the infection.⁴³ Another notable transmission route is via aerosol. Immediately after droplets are expired, the liquid content starts to evaporate, and some droplets become so small that transport by air current affects them more than gravitation. They can carry their viral content meters away from where they originated. The sequence and place of donning is important to avoid self infection and PPE contamination.

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 HCP where cloth contamination may occur. Chin et al., showed that SARS-CoV-2 virus remains stable on fabric for up to 2 days.⁴⁴ Contaminated clothes can become potential sources of spreading infection in the community.

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

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3 transmission.⁴⁵ However, providing a negative pressure room may not always be possible.
4 Therefore, a specific room should be allocated for high risk patients so as to minimise the
5 risk to uninfected patients. If this is not practical, then a specific slot should be allocated
6 ideally at the end of a morning or afternoon session to allow for terminal cleaning. Spacing
7 of procedures in the absence of a negative pressure environment was not agreed in this
8 consensus as explored in the discussion.
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11 12 13 **POST-ENDOSCOPY**

14 15 **Statement 21**

16 **The “Doffing” area for removal of PPE could be appropriately positioned in one corner of**
17 **the room**
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20 Accidental contamination during the act of removal of PPE is possible. Due to the distance
21 that large droplets can travel, a 2 metre distance between the doffing station and potential
22 source of infection is recommended.⁴⁶ The biggest risk of inadequate doffing will be to
23 nullify the protection conferred by PPE to HCP. The sequence and technique of doffing are
24 as important as the distance from the procedure spot.
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27 28 29 **Statement 22**

30 **The endoscopy procedure room should be deep cleaned after every procedure in a**
31 **suspected or confirmed case of COVID-19**
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34 CDC guidance⁴⁷ on disinfection of medical equipment advises the use of bleach containing
35 solutions in a ratio of 1:100 as these agents are effective viricidal. ASGE guidelines advise
36 terminal cleaning after known cases of transmissible infection by organisms as determined
37 by the local institution.⁴⁸ The terminal cleaning process should involve cleaning the room
38 and all surfaces to remove soil and biofilm followed by appropriate disinfection.
39
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41 42 **Statement 23**

43 **Patients with suspected or confirmed COVID-19 infection should be recovered in a**
44 **designated area away from all the other non-COVID-19 patients**
45

46 WHO guidance for rational use of PPE states that patients with COVID-19 should be
47 cohorted to streamline workflow.⁴³ BSG guidance recommends linear flow through the
48 endoscopy unit with separate entrances and exits for patients with suspected or confirmed
49 COVID-19 infection.¹ There should be a designated recovery area for patients suspected of
50 COVID-19 with separate staff in appropriate PPE. If there are space constraints, then known
51 COVID-19 patients should be scheduled at the end of the day when all other patients from
52 recovery have been discharged to minimise contact with non-infected patients.
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55 56 **Statement 24**

57 **In high prevalence regions, health care professionals in the endoscopy recovery areas (for**
58 **non COVID-19 patients) should wear standard PPE with surgical masks**
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3 Close contact with the patient may be unavoidable due to the need to monitor vital signs or
4 conduct clinical examination as required if the patient is symptomatic. Passage of
5 gastrointestinal contents is not uncommon following endoscopy and this can result in
6 spread of infection. Direct clinical care should therefore be provided to patients in the
7 recovery area using standard PPE (surgical mask, gown, gloves, eye protection).
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10 **Statement 25**

11 **Strict adherence to endoscope disinfection policies are mandatory**

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14 The SARS-CoV-2 virus is sensitive to the standard endoscope cleansing measures and no
15 new measures are required.⁷ The standards applied should be consistent with the
16 recommendations set out by international endoscopy guidelines.^{48,49} If current guidelines
17 are followed, the risk of viral transmission secondary to endoscope disinfection practice is
18 extremely unlikely.
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21 **Statement 26**

22 **Adequate social distancing should be maintained throughout all areas of the endoscopy** 23 **unit in high prevalence regions**

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26 Social distancing is an important means of minimising nosocomial spread.⁵⁰ Endoscopy is a
27 team based activity where multiple HCP come into contact with patients and relatives.
28 Adequate social distancing should be practiced with a 1-2m distance between staff and
29 patients whenever possible. Reception, waiting areas, recovery space may all need to be
30 redesigned to limit the number of people in a confined zone. The use of protective screens
31 in reception and separate recovery area for suspected or confirmed COVID-19 patients
32 should be considered. A no visiting policy (except if deemed absolutely necessary) should be
33 enforced.²⁷ Accompanying persons should drop the patient off at the entrance to the
34 endoscopy unit and wait off premises until the patient is ready to be collected. They too
35 should adhere to social distancing measures and wear face coverings at all times.
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40 **Statement 27**

41 **All patients should be followed up by phone in 10-14 days to identify any symptoms** 42 **suggestive of COVID-19 in high prevalence regions**

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45 There remains a risk that patients may be exposed to SARS-CoV-2 when attending for their
46 endoscopic procedures. The median incubation period of the virus is 5 days and the vast
47 majority who do develop symptoms will do so within 11.5 days.³²
48 Most National Guidance on endoscopy currently advocates contacting patients within 14
49 days³⁴ to enquire about symptoms suggestive of COVID-19.
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52 **Discussion**

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54 A recent study looked at the impact of a hypothetical suspension of elective endoscopy for 6
55 months in USA, and predicted a delayed diagnosis of over 2,800 colorectal cancers and
56 22,000 high-grade adenomatous polyps with malignant potential.⁵¹ The 6 month mortality
57 rate for those eventually diagnosed with colorectal cancer would increase by 6.5%.⁵² This
58 emphasises the need for a rapid yet safe resumption of endoscopy services and our
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3 consensus guidance aims to facilitate that.
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6 This is the first international consensus document produced using a modified Delphi process
7 to enable a cohesive approach to resuming endoscopy services globally. Although various
8 national societies have produced separate guidelines for endoscopy practice during this
9 pandemic, we are now in a post-pandemic phase where infection prevalence is rapidly
10 declining. We have therefore accounted for prevalence in our statements and have
11 comprehensively mapped the entire patient journey through endoscopy and risks
12 associated with it for patients and HCP.
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16 Table 2 summarises our recommendations and draws comparison with other published
17 major guidance. Importantly, we identify key recommendations below that have evolved
18 through this Delphi consensus that set it apart from other guidelines.
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21 The value of testing during the post-pandemic phase should not be underestimated and this
22 was demonstrated by strong consensus around pre-procedure testing of all patients in high
23 prevalence regions. This will allow services and patients to be risk stratified with increased
24 confidence in ramping up the volume of endoscopy with reasonable use of PPE. We also
25 highlight high sensitivity point of care testing as a way of minimising risks of false negative
26 tests. Concerns related to false negative rates of current molecular tests have been
27 eloquently highlighted in a recent publication predicting that in an endoscopy unit that
28 serves 10,000 patients annually in the United States (prevalence: 0.26%), a POC test with
29 95% sensitivity would result in only 1 false negative result. Comparatively, in a higher-
30 prevalence population of 2%, there would be 10 false negative results per 10,000 patients.¹⁹
31 This is no higher than a fatal automobile crash in the USA (mortality of 10.3 per 100,000
32 according to CDC figures).
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37 The is the first document recommending testing of all patients having an endoscopy longer
38 than an hour, highlighting the increased risk of infection with prolonged aerosol generation.
39 Testing of HCP has also emerged as another important recommendation given that HCP are
40 increasingly recognised as a nidus for future clusters of outbreaks in hospital.
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43 The practice of social distancing for a week pre-endoscopy prompted much debate prior to
44 achieving consensus. In the current climate, without the realistic prospect of a vaccine or
45 treatment, social distancing will remain an integral part of reducing transmission risk. We
46 recognise that isolating from household members is not required at present but distancing
47 from external contacts is essential. This approach will strike a balance between protecting
48 patients and staff from infection without negatively affecting uptake of endoscopy. Indeed,
49 there is strong data from a recent meta-analysis demonstrating the effect of non-
50 pharmacological interventions such as physical distancing, face masks and eye protection on
51 preventing transmission of SARS-CoV-2 in healthcare and community settings.⁵³
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55 We have also produced a set of unique recommendations providing practical advice around
56 the location of “donning” and “doffing” areas not covered by other endoscopy guidelines.
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59 We failed to achieve consensus around the use of general anaesthesia with endotracheal
60 intubation for upper endoscopic procedures longer than 30 minutes. Long procedures are

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3 less likely to be well tolerated thereby increasing the risk of coughing and aerosol
4 generation. General anaesthesia may reduce this risk by eliminating coughing. However,
5 endotracheal intubation is in itself an AGP and there was concern that this would simply be
6 transferring the risk from the endoscopist to the anaesthesiologist. We believe that the
7 decision regarding the use of anaesthesia will be based on the complexity and duration of
8 procedures and availability of anaesthesia rather than on the risk of infection.
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10 The other statement that lacked sufficient agreement was on the use of single use
11 accessories in areas of high disease prevalence. The fact that the virus can easily be killed
12 during routine disinfection procedures with ethanol, glutaraldehyde and sodium
13 hypochlorite⁵⁴ swayed opinions. We believe that single use accessories will become a
14 universal standard once readily affordable and available.
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18 Another recommendation that failed to achieve consensus was on implementing downtime
19 of 20 to 30 minutes after each procedure. SARS-CoV-2 infection is transmitted by droplets
20 and these droplets can remain suspended for variable length of time depending on size and
21 air exchange rates, before settling.⁵⁵ These issues have led to recommendations on a 30-60
22 mins delay between procedures if the procedure was carried out in the absence of a
23 negative pressure setting.²⁷ However, the uncertainties around the air exchange rates and
24 differences in aerosols related to gastroscopy and colonoscopy did not allow for a
25 consensus to be reached on exact length of time and type of procedure.
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29 In the absence of high quality data, we have produced a series of best practice
30 recommendations around the patient's journey through endoscopy. These practical
31 recommendations can empower units around the world to ensure a safe and rapid
32 resumption of endoscopy services.
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Table 1: International Consensus Recommendations to Guide Endoscopy Recovery in the post pandemic phase of COVID-19

Statement Number	Statements	Consensus after Round 1	Statement modification	Final Consensus
PRE-ENDOSCOPY				
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 last 2 weeks	97.1%	None	97.1%
2	The absence of clinical symptoms does not exclude SARS-CoV-2 infection as asymptomatic infections are not uncommon	94.1%	None	94.1%
3	All patients undergoing endoscopy should be tested for SARS-CoV-2 infection 24-72 hours prior to endoscopy	65.5%	All patients undergoing endoscopic procedures should be tested for SARS-CoV-2 infection 24-72 hours prior to endoscopy in high prevalence regions	82.4%
4	Patients who have tested negative for SARS-CoV-2 infection may still be infective	80.6%	None	80.6%
5	The data on the accuracy of point of care tests to detect active infection is limited but promising. They should be used in a research or audit setting until more	69%	Early data on the accuracy of point of care tests for detection of active infection is promising and these tests could be used to aid with risk stratification of patients prior to endoscopy in high prevalence regions	91.1%

	data becomes available			
6	All patients having endoscopic procedures lasting longer than 1 hour should be tested for SARS-CoV-2 infection	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	85.3%
7	All health care professionals should be self reporting any new symptoms to a responsible health professional who is able to advise on further appropriate action	100%	None	100%
8	All healthcare professionals working in endoscopy should be tested for SARS-CoV-2 infection on a cyclical basis	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 retesting on a regular basis	88.2%
9	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	97.1%	None	97.1%
10	All health care professionals should be wearing surgical	94.1%	None	94.1%

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	masks at all times in clinical areas within the endoscopy department			
11	Elective endoscopy for suspected or confirmed COVID-19 patients should be deferred until they are asymptomatic and have tested negative	94.1%	None	94.1%
12	Self isolation of patients for 1 week prior to endoscopy is not necessary if they are undergoing testing for SARS-CoV-2 infection prior to endoscopy	44.8%	Patients should observe adequate social distancing for 1 week prior to endoscopy in high prevalence regions to minimise the risk of viral exposure to health care professionals in endoscopy departments	80.6%
13	Health care professionals should receive appropriate training in infection control practices and handling of personal protective equipment (PPE)	100%	None	100%
DURING ENDOSCOPY				
14	Gastroscopy is an aerosol generating procedure (AGP) and health care professionals should wear enhanced personal protective equipment (N95/FFP3 respirators) in high prevalence regions	82.3%	None	82.3%

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15	We recommend the use of enhanced personal protective equipment (N95/FFP3) respirators for all endoscopic procedures in the upper and lower gastrointestinal tract	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	88.2%
16	Standard PPE with a surgical mask is sufficient for low aerosol generating procedures such as colonoscopy	37.9%	In low prevalence regions, standard PPE (surgical mask) is sufficient for low aerosol generating procedures such as colonoscopy	82.4%
17	In the absence of active testing all patients undergoing endoscopic procedures should be presumed to be potentially infective and health care professionals should wear enhanced PPE (N95/FFP3 respirators)	85.3%	None	85.3%
18	The “Donning” area (where PPE is worn) should be located outside of the endoscopy room and away from the “doffing” area (where PPE is removed)	94.0%	None	94.0%
19	All patients in high prevalence regions should change into hospital gowns before entering the endoscopy suites	85.3%	None	85.3%

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	100%	None	100%
POST-ENDOSCOPY				
21	The “Doffing” area for removal of PPE could be appropriately positioned in one corner of the room	85.2%	None	85.2%
22	The endoscopy procedure room should be deep cleaned after every procedure	69%	The endoscopy procedure room should be deep cleaned after every procedure in a suspected or confirmed case of COVID-19	97.1%
23	Patients with suspected or confirmed COVID-19 infection should be recovered in a designated area away from all the other non-COVID-19 patients	97.1%	None	97.1%
24	Staff in the recovery area (for non-COVID-19 patients) should wear standard PPE with surgical masks	72.4%	In high prevalence regions, health care professionals in the endoscopy recovery areas (for non COVID-19	85.3%

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			patients) should wear standard PPE with surgical masks	
25	Strict adherence to endoscope disinfection policies are mandatory	100%	None	100%
26	Adequate social distancing should be maintained throughout all areas of the endoscopy unit in high prevalence regions	100%	None	100%
27	All patients should be followed up by phone in 14 days to identify any symptoms suggestive of COVID-19	62%	All patients should be followed up by phone in 10-14 days to identify any symptoms suggestive of COVID-19 in high prevalence regions	82.3%
REJECTED STATEMENTS				
1	All units should aim to move towards single use (disposable) accessories	75.9%	All units in high prevalence regions should aim to move towards single use (disposable) accessories such as biopsy forceps, snares, needles, biopsy valves etc.	73.5%
2	Use of general anaesthesia with endotracheal intubation should be considered for all upper GI procedures taking longer than 30 mins	37.9%	Use of general anaesthesia with endotracheal intubation should be considered for all upper GI procedures in high prevalence regions taking longer than 30 mins	50%
3	The endoscopy procedure room should be left empty	51.7%	The endoscopy procedure room in high prevalence regions	67.7%

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	for 20 to 30 minutes after the patient leaves the room to allow for all droplets to settle down before deep cleaning is performed		should be left empty for 20 to 30 minutes after the patient leaves the room to allow for all droplets to settle down before deep cleaning is performed	
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7	Self surveillance and reporting of new symptoms amongst all HCP in endoscopy	Not specified	Yes	Not specified	Not specified	Not specified	Not specified
8	All health care professionals working in endoscopy should be tested once for SARS-CoV-2 infection and have daily temperature/ symptom screening & retesting in high prevalence	Not specified	Not specified	Not specified	Not specified	Daily staff screening (symptom s/temperature) recommended	Daily staff screening (symptoms /temperature) recommended
9	Use of surgical masks for all patients attending endoscopy	Yes- face masks	Yes – face masks	Face masks for patients who are shielding	Not specified	Yes (surgical face masks)	Yes
10	Use of surgical masks for all health care professional working in clinical areas of the endoscopy department	“All members of the endoscopy team should wear a full set of PPE, predicated on resource availabilities ”	Yes (surgical face masks)	Not specified	Not specified	Yes (surgical face masks)	Yes
11	Deferment of elective endoscopy for suspected or confirmed COVID-19 patients	Yes	Yes	Yes	Yes	Yes	Yes

12	Patients should observe adequate social distancing for 1 week prior to endoscopy (in high prevalence regions)	Not specified	Not specified	Not specified	Not specified	Not specified	Not specified
13	Training of health care professionals in using PPE	Yes	Yes	Not specified	Yes	Yes	Not specified
14	Health care professionals to wear N95/FFP3 respirators for all gastroscopies in high prevalence regions	Yes (for patients with COVID-19 and those at high risk of exposure)	Yes	Yes	PPE according to risk stratification (Enhanced PPE for suspected or confirmed COVID-19)	Yes	If test is negative, standard surgical mask for all procedures
15	In high prevalence regions, the use of enhanced PPE (N95/FFP3 respirators) for both upper and lower gastrointestinal endoscopic procedures	Yes (see above)	Yes (see above) PPE choice based on likelihood of COVID-19 infection	As per Public Health England guidance (constantly changing)	As above	Yes	If test is negative, standard surgical mask for all procedures
16	In low prevalence regions, standard PPE	Enhanced PPE for all GI procedures	PPE choice based on likelihood of COVID-	Standard PPE for lower GI procedur	PPE according to risk stratificati	N95 respirator s for all endoscopi	If test is negative, standard surgical

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	(surgical mask) is sufficient for colonoscopy		19 infection	es if patient has tested negative for COVID-19	on/likelihood of COVID-19	c procedures	mask for all procedures (no distinction between OGD or colonoscopy)
17	In the absence of active testing all patients should be presumed to be infective and health care professionals should wear enhanced PPE	Yes	Yes	Yes	Yes	Yes	Yes
18	The “Donning” area should be located outside of the endoscopy room and away from the “doffing” area	Not specified	Not specified	Not specified	Not specified	Not specified	Not specified
19	All patients in high prevalence regions should change into hospital gowns before entering the endoscopy suites	Not specified	Not specified	Not specified	Not specified	Not specified	Not specified
20	Use of negative pressure rooms (or	Yes (for suspected or confirmed COVID-19)	Yes (for suspected or	Negative pressure not specified	Yes (for suspected or	Not specified (“Rooms lacking	Not specified

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	designated rooms/specific procedure slots) for COVID-19 patients		confirmed COVID-19)		confirmed COVID-19)	negative pressure benefit from additional aeration time")	
21	Location of "Doffing" area	Not specified	Not specified	Not specified	Not specified	Not specified	Not specified
22	Deep cleaning of procedure room after every procedure	Yes	Yes	Yes	Yes	Yes	Yes
23	Separate recovery area required for COVID-19 patients	Not specified	Yes	Not specified	Not specified	Not specified	Not specified
24	Health care professionals in non-COVID-19 recovery areas should wear standard PPE with surgical masks	Not specified	Not specified	Not specified	Yes	Surgical mask, gloves required in post operative areas (N-95 depending on availability)	Yes
25	Strict adherence to endoscope disinfection policies	Yes	Yes	Yes	Yes	Yes	Yes
26	Adequate social distancing measures in endoscopy	Yes	Yes	Yes ("linear patient flow")	Not specified	Yes	Yes
27	Follow up of patients 10-14 days post procedure	Not specified	At 7 and 14 days after endoscopy	Not specified	Not specified	Yes (1-2 weeks post procedure)	Not specified

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			for all patients				
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ESGE: European Society of Gastrointestinal Endoscopy; BSG: British Society of Gastroenterology; APDSE: Asia Pacific Society for Digestive Endoscopy; ASGE: American Society of Gastrointestinal Endoscopy; AGA: American Gastroenterological Association; DHPA: Digestive Health Physicians Association; PPE: Personal Protective Equipment

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