



Digestive Endoscopy

International Delphi Consensus Study on disposable single-use endoscopy: A path to clinical adoption[☆]

Alessandro Repici^{a,b,1}, Kareem Khalaf^{a,f,1,*}, Edoardo Troncone^e, Sharmila Subramaniam^c, Cesare Hassan^{a,b}, Pradeep Bhandari^{c,d}, DISPOSE Group²

^a Department of Biomedical Sciences, Pieve Emanuele, Humanitas University, Rozzano, Italy

^b Humanitas Clinical and Research Centre -IRCCS-, Endoscopy Unit, Rozzano, Italy

^c Department of Gastroenterology, Portsmouth Hospitals University NHS Trust, Portsmouth, UK

^d School of Pharmacy and Biomedical Sciences, University of Portsmouth, Portsmouth, UK

^e Department of Systems Medicine, Gastroenterology Unit, University of Rome "Tor Vergata", Rome, Italy

^f Division of Gastroenterology, Department of Medicine, St. Michael's Hospital, University of Toronto, Toronto, Ontario, Canada

ARTICLE INFO

Article history:

Received 8 February 2023

Accepted 26 July 2023

Available online xxx

Keywords:

Single use endoscopy

Multi drug resistant organism

Sustainability

Delphi

ABSTRACT

Background/objective: Increasing infectious rate estimates and low microbiological surveillance affect safety of gastrointestinal endoscopy globally. Single use endoscopes and accessories have been claimed to improve safety, but there is lack of data on their indication and sustainability. We aimed to identify a series of best practice recommendations for the use of single use endoscopes and accessories using a modified Delphi.

Methods/design: Consensus statements for the use of single use endoscopy and accessories were developed using a modified Delphi process, utilizing an international endoscopist expert panel of 62 experts from 33 nations. The main steps in the process were selecting the consensus group, conducting systematic literature reviews, developing statements, and anonymous voting on the statements until consensus was reached. High-risk patients were defined as those with multi-drug-resistant infections, immunosuppressive medication or chemotherapy, post-transplantation, or with severe neutropenia.

Results: Of the 26 statements that were voted upon through two rounds, 17 statements reached consensus. Category 1: single use accessories (8 statements), related to defining recommendations for the use of single use accessories in all patient populations or high-risk patients. Category 2: clinical indication for single use endoscopes (9 statements), including indications to high-risk patients, protecting the endoscope apparatus and contamination measures in endoscopy units. Category 3: technical factors (4 statements), related to superior performance and technical specifications with the new innovation. Category 4: environmental issues (2 statements), concerning mechanisms that reduce the detrimental burden to the environment. Category 5: financial implications (3 statements), related to healthcare policies, cost neutrality and other financial associations of single use endoscopy.

Conclusions: This is the first international initiative in determining clinical indications for single use endoscopy and accessories. The study's findings should serve as a framework for future physicians to guide future research and aid the proper evidence-based indications for the implementation of single use endoscopes in clinical practice.

© 2023 Editrice Gastroenterologica Italiana S.r.l. Published by Elsevier Ltd. All rights reserved.

1. Introduction

The estimated incidence of endoscope associated infections (EAI) in 1993 was 1 in 1.8 million, equating to a risk of 0.00006% [1]. In 2013, an increase in reports showed 1 in 300,000 incidents of EAI, equating to a risk of 0.0003% [2]. The actual number of incidents was severely under-reported, as the number of infectious ERCP complications was reported between 2 and 4%, including endogenous infections [3]. Endoscopy-related infections

[☆] Experts: DISPOSE Group (DISPOSable Single-use Endoscopy)

* Corresponding author at: Humanitas Research Hospital and University, Via Manzoni 56, 20089 Rozzano, Milano, Italy.

E-mail address: kareem.khalaf@mail.utoronto.ca (K. Khalaf).

¹ Shared First Authorship position: Alessandro Repici and Kareem Khalaf

² "DISPOSE Group": full names and affiliations of each member of this study group are listed in APPENDIX 4.

can be endogenous infections from the patient's own microbial flora after an endoscopic procedure; exogenous infections caused by drawbacks in peri-endoscopic patient care (e.g., insufficient hand hygiene in patient care resulting in cross-contamination); or a consequence of inadequately reprocessed equipment (ie, endoscopes, endoscope components, and reusable endoscopic accessories) [4]. In a recent systematic review, the calculated minimum estimated duodenoscope-associated infection risk was 0.01% and the minimum estimated duodenoscope-associated colonisation was 0.023%–0.029% [5].

A potential risk of infection is inherent with all endoscopies [6]. Many centres do not have a set protocol to follow when a unit outbreak occurs. The financial implication ultimately drives the incentive and cost estimates of endoscope reprocessing. Associated infections bear scrutiny to endoscope reprocessing, that are inevitably error prone. While all efforts were done to resolve this problem, no solution could be found [7].

Single use endoscopes have been pioneered as a consequence of the increasing infectious rate. There is some knowledge on its technical performance that makes the innovation a desirable option but in reality, single use accessories have been widely used but with scarce data [8–10]. Evaluating the sustainability of such an innovation must be stratified according to the clinical need for its use. From a clinical standpoint, this advancement would eliminate the possibility of endoscope-related infection transmission [11]. However, there may be several drawbacks related with their costs and recycling.

Uncertainty also affects the benefit/risk ratio for single-use accessories, such as biopsy forceps or snares. Despite their wide availability, there is lack of evidence as well as of recommendations on the actual superiority and clinical application of these single-use devices over those reusables. Initially, single use accessories were perceived as more expensive than reusable ones. However, when reprocessing costs, material wear after repeated use and possible biomaterial contamination are taken into account, cost-efficacy balance has been reported to favor disposable devices, even though solid evidence is still lacking [12–14].

This international consensus study used a modified Delphi method to produce a series of best practice recommendations that aid the proper evidence-based indications for the use of single use endoscopes and accessories in gastroenterology.

2. Methods

2.1. Study design

A Delphi process is an established method for determining consensus opinion. The aim of this study was to identify expert recommendations for the use of single use endoscopes encompassing their clinical utility, technical features, financial and environmental impact. This study's consensus statements for the use of single use endoscopy and accessories were developed using a modified Delphi process. Delphi methodology differs from the process used to create consensus statements as it predefines a threshold of average agreement among the voters.

The modified Delphi method used in our study utilised the core group to develop the domains of research and statements and conduct a targeted literature review. Unlike the traditional Delphi method where there may be no limit on the number of voting rounds required to achieve consensus, the modified Delphi process involved the core group collating and presenting feedback in a 'digestible' summary to the expert panel in order to provide context to the experts, thereby resulting in just two rounds of individualised voting in order to achieve consensus. Following the first round of voting and qualitative analysis of the results, the core group conducted a virtual meeting with the expert panel to dis-

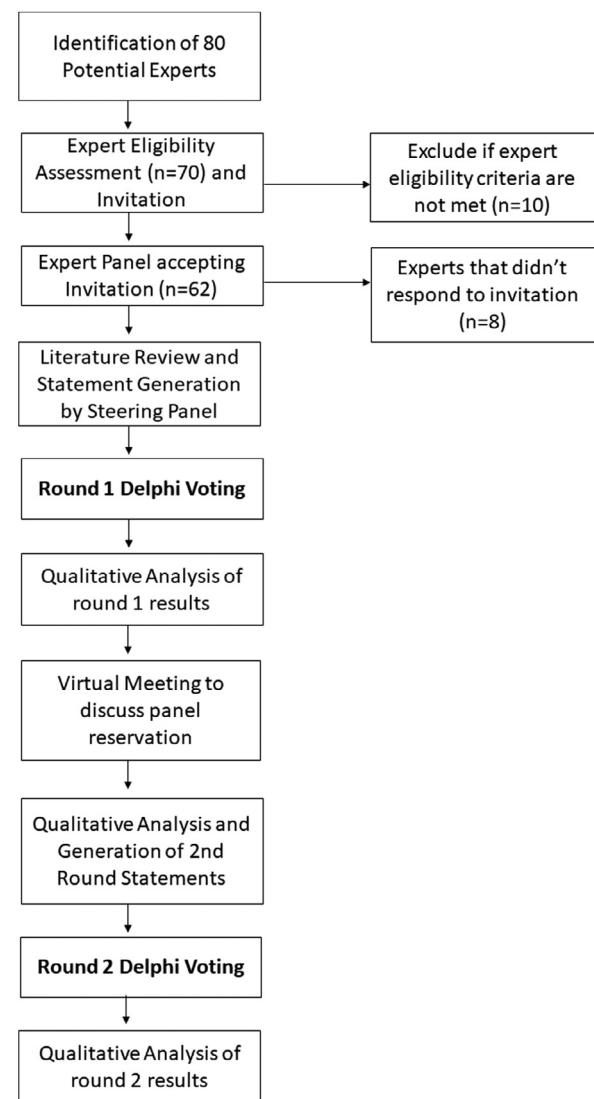


Fig. 1. Study flowchart.

cuss the relevant statements and address any uncertainties raised by panel members in a focused fashion. This method of direct discussion and debate allowed the group to reformulate the statements appropriately and efficiently to achieve consensus in the final round of voting.

A literature review using the search strings 'single use endoscopy'; 'single use duodenoscopes'; 'disposable endoscope' in the Medline, Scopus and Google Scholar databases yielded evidence to develop the statements. This study was conducted over an 8-month period between September 2021 until May 2022 encompassing two rounds of voting. For a visual representation of the study design flowchart, please consult Fig. 1.

2.2. Recruitment of international panel of experts

A purposive sampling system was employed to recruit an international panel of experts in advanced endoscopy with specialized knowledge in single use endoscopes and accessories. The following approach was used:

1. Literature Search: A comprehensive literature search was conducted to identify individuals who had published relevant articles within the last 10 years. The search encompassed promi-

uent academic databases, including but not limited to PubMed, Scopus, and Google Scholar.

2. Publication Record Review: Experts identified through the literature search were evaluated based on their publication record in the field. Those with a significant number of publications on the topic were considered eligible for inclusion in the panel.
3. Key Opinion Leaders: Additionally, internationally recognized experts in the field of endoscopy, acknowledged as key opinion leaders within relevant endoscopic societies, were invited to join the panel. These experts were identified through established networks and recommendations from peers.
4. Geographical Representation: To ensure a diverse representation of expertise and geographical distribution, efforts were made to include experts from various regions with significant contributions to GI endoscopy research. This geographical distribution aimed to encompass a broad range of perspectives and experiences.

The recruitment process involved contacting identified experts via email or other appropriate communication channels. Potential panel members were provided with a detailed description of the study's objectives, the Delphi methodology, and the expected time commitment for participation. Confidentiality was assured, and interested experts were requested to provide their consent to join the panel. The final composition of the international panel of experts was determined based on the willingness of experts to participate and their relevance to the study's focus.

2.3. Expert participants

The voting committee named the DISPOSE group was formed as the key advisory group of 62 experts in the field of gastrointestinal endoscopy. Certain spheres of experience were explored, such as the procedures performed, number of years practicing and in which professional setting. The inclusion criteria 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 and have a track record of developing international guidelines. The consensus group members were expected to meet at least three of the four criteria. The panel was selected from the continents of Asia, Europe, Africa, Oceania, and the Americas to achieve a wide global representation. Eighty expert participants that met the inclusion criteria were invited, 62 accepted the invitation in both rounds of the study. Data on providing identification (name) was optional, to keep track of responses from invited expert panellists. Data was later de-identified by KK to maintain anonymity for the expert panel. All rounds of voting had the possibility for the voter to decline and recuse themselves from the study, there was no obligatory requirement for participation. In comparison to the first round, the second round received 58 responses, owing to experts who did not respond or informed us that they would not participate in the second round.

2.4. Statement preparation

There were two groups in the study: a core group and a consensus group. The consensus group included 62 expert panellists, whereas the core group included the five authors. The primary research team in charge of carrying out the study was the core group. To formulate the opening statements, the core group convened through multiple meetings prior to any rounding. The core group also modified the revised statements after the virtual meeting in the first round. To categorize the statements, six broad domains were used: single use accessories, clinical indications for single use endoscopes, clinical indications for single use duodenoscopes, technical factors, environmental issues, and financial implications. Google Forms was used to deliver the Delphi survey through the online platform found on; <https://www.google.com/forms/>. Following the first round, the consensus group communicated qualitative comments, suggestions, and views to the core group via a virtual meeting and email communication. The statements chosen for the second round of voting were modified based on the comments received in the virtual meeting. The core team received all votes and compiled the data for final analysis. We defined high-risk patients as those who have multi-drug-resistant infections, are on immunosuppressive medication, are undergoing chemotherapy, have had a transplant, or have severe neutropenia [4,15].

scopes, technical factors, environmental issues, and financial implications. Google Forms was used to deliver the Delphi survey through the online platform found on; <https://www.google.com/forms/>. Following the first round, the consensus group communicated qualitative comments, suggestions, and views to the core group via a virtual meeting and email communication. The statements chosen for the second round of voting were modified based on the comments received in the virtual meeting. The core team received all votes and compiled the data for final analysis. We defined high-risk patients as those who have multi-drug-resistant infections, are on immunosuppressive medication, are undergoing chemotherapy, have had a transplant, or have severe neutropenia [4,15].

2.5. Feedback

Following the first round of statements, experts relayed their reservations and feedback through a virtual meeting. The meeting took place on the 12th of April 2022 scheduled a month prior, each approved statement was presented and then each rejected statement and its possible revision were discussed and drafted. In the second round, experts provided comments and feedback to each statement on the online survey. The panel commented at the virtual meeting on the objections they had regarding statements that failed to achieve consensus in the first round and were regarded to be dissented and ambiguous. If a statement was unclear, we provided an explanation in elaborating the statement further both in the virtual meeting and in the revised statement. If further explanation was warranted, the addition of a pretext to the categorical section was made to better explain the reasoning behind the statements.

2.6. Data analysis

The statement responses were predetermined on a five-point system, the level of agreement was determined by a range of strongly agree, agree, neutral, disagree and strongly disagree. Agreement levels were determined by the number of experts who agreed or strongly agreed and vice versa, while neutral responses were not accounted for as a separate category in our analysis. Simple calculation through Microsoft Office Applications; Excel software, was done for conducting the summation for our analyses. A statement was deemed to have reached consensus when at least 80% of respondents strongly agreed or agreed with it. Descriptive statistics were used to present the data as a summative percentage of agreement for each statement.

3. Results

Sixty-two experts representing 33 countries formed the consensus group. A total of 26 statements were proposed and voted on (Table 1). Eleven of the 24 statements proposed achieved consensus in the first round, following the addition of 2 statements in the second round, to make the total of 26. Statements which did not achieve consensus, were modified based on feedback through a virtual meeting, leading to improvement in the consensus rate to (17/26) following the second round (Table 2). Relevant statements within the category of 'clinical indication for single use duodenoscopes' were integrated into the broader category of 'clinical indication for single use endoscopes' following the first round leaving 5 categories remaining. Here, we summarize the statements that achieved consensus during the Delphi process.

Category 1: single use accessories (8 statements, 6 reached consensus), related to defining recommendations for the use of single use accessories in all patient populations or high-risk patients. Accepted statements:

Table 1

Delphi consensus recommendations to guide disposable single use endoscopy and accessories in clinical practice.

Statement Number	Statements	Consensus after round 1	Statement modification	Final Consensus
Single Use Accessories				
1	Single use scope channel valves for endoscope biopsy channels should be used in all patients	57.60%	We recommend the use of single use endoscope channel valves for endoscope biopsy channels in high-risk patients	81.10%
2	Single use suction buttons should be used in all patients	42.20%	We recommend the use of single use suction buttons in high-risk patients	74.20%
3	Single use air-water buttons should be used in all patients	39.70%	We recommend the use of Single use air-water buttons in high-risk patients	69.00%
4	Single use biopsy forceps should be used in all patients	93.20%	–	93.20%
5	Single use cold polypectomy and cold EMR snares should be used in all patients	89.80%	–	89.80%
6	Single use hot polypectomy and hot EMR snares should be used in all patients	84.70%	–	84.70%
7	Single use sphincterotomes should be used in all patients	86.00%	–	86.00%
8	Single use endoscopic clips should be used in all patients	82.70%	–	82.70%
Clinical Indications for Single Use Endoscopes				
9	Single use endoscopes should be used for endoscopic procedures performed outside the endoscopy unit (e.g., in the intensive care unit/by the bedside/emergency setting)	39.70%	We recommend the use of single use endoscopes for procedures performed outside the endoscopy unit to improve accessibility in areas where reusable endoscopes are not readily available (e.g., in the intensive care unit/by the bedside/emergency setting)	55.1%
10	Single use endoscopes should be used for endoscopic procedures performed out of hours when reprocessing equipment or staff may not be available	56.90%	Single use endoscopes may be preferred over reusable endoscopes for endoscopic procedures performed out of hours when reprocessing facilities are not immediately available	63.80%
11	Single use endoscopes could be used for endoscopies carried out in non-hospital settings (e.g., office-based community practice)	50.00%	Single use endoscopes may provide a more cost-effective and safe approach over reusable endoscopes for procedures carried out in non-hospital settings (e.g., office-based community practice) when effective reprocessing systems or specialized staff dedicated to reprocessing are not available or the investment in reprocessing facilities are too expensive.	62.00%
12	Single use endoscopes should be used in scenarios when the performance and safety of the scope could be compromised by the type of procedure	60.40%	Single use endoscopes may be preferred over reusable endoscopes when performing procedures that carry a high risk of damaging the endoscope (Example: Injection of Glue)	56.90%
13	–	–	Endoscopes with a single use tip and/or elevator mechanism may reduce the risk of infection when used in high-risk patients at significant risk of acquiring or transmitting infection	87.90%
14	–	–	In order to protect the re-usable endoscope armamentarium from contamination with a MDRO, it is a viable option to use single use endoscopes in patients with a known MDRO infection or in known MDRO carriers.	94.80%
15	Single use duodenoscopes should only be used in high-risk patients	75.90%	Single use endoscopes (including duodenoscopes) may offer a safer option when used in high-risk patients at significant risk of acquiring or transmitting infection	89.60%
16	Single use duodenoscopes should be used in all patients when a MDRO outbreak is reported in the endoscopy unit	79.70%	Single use duodenoscopes may be considered in all patients when MDRO are cultured from reusable duodenoscopes whilst appropriate measures are taken to isolate and manage the source of the infection	86.20%
Technical Factors				
17	The performance and technical specification of single use endoscopes should be similar to that of conventional reusable/multi-use endoscopes	96.50%	–	96.50%
18	The performance and technical specifications of single use endoscopes should be assessed via well designed clinical research studies prior to widespread adoption	96.60%	–	96.60%

(continued on next page)

Table 1 (continued)

Statement Number	Statements	Consensus after round 1	Statement modification	Final Consensus
19	Single use endoscopes should be customizable according to the user's preference	71.20%	Single use endoscopes carry the advantage of being customizable according to the user's preference (left handedness, small hands, musculoskeletal issues-) to maximize maneuverability, make it user friendly and to facilitate more efficient endoscopy	53.50%
20	Single use endoscopes should have an artificial intelligence integrated system/be AI compatible	45.80%	Given the current trend of AI integration in all endoscopy platforms; it is advisable for future single use endoscopy platforms to have integrated AI systems.	72.40%
Environmental Issues				
21	Single use endoscopes should be distributed with an effective recycling mechanism in place.	94.90%	–	94.90%
22	The patients' perspective about safety, environmental impact, sustainability, and acceptability of single use endoscopes should be explored prior to their adoption	81.40%	–	81.40%
Financial Implications				
23	An adequate reimbursement policy should be discussed with healthcare providers to integrate single use endoscopes in daily practice in a financially sustainable manner	91.50%	–	91.50%
24	Single use endoscopes should be cost neutral with similar technical performance to conventional multi-use/reusable endoscopes	80.30%	–	80.30%
25	The volume of procedures in each center should be used to determine the cost of single use endoscopes	62.70%	The economic burden of single use endoscopes will be dependent on the volume and set up of individual centres.	81.00%
Abandoned Statements				
26	Single use duodenoscopes should be used in all patients	–	–	10.00%

Table 2

Delphi consensus recommendations.

Single Use Accessories	
1	<i>We recommend the use of single use endoscope channel valves for endoscope biopsy channels in high-risk patients</i>
2	<i>Single use biopsy forceps should be used in all patients</i>
3	<i>Single use cold polypectomy and cold EMR snares should be used in all patients</i>
4	<i>Single use hot polypectomy and hot EMR snares should be used in all patients</i>
5	<i>Single use sphincterotomes should be used in all patients</i>
6	<i>Single use endoscopic clips should be used in all patients</i>
Clinical Indications for Single Use Endoscopes	
7	<i>Endoscopes with a single use tip and/or elevator mechanism may reduce the risk of infection when used in high-risk patients at significant risk of acquiring or transmitting infection</i>
8	<i>In order to protect the re-usable endoscope armamentarium from contamination with a Multidrug Resistant Organism (MDRO), it is a viable option to use single use endoscopes in patients with a known MDRO infection or in known MDRO carriers.</i>
9	<i>Single use endoscopes (including duodenoscopes) may offer a safer option when used in high-risk patients at significant risk of acquiring or transmitting infection</i>
10	<i>Single use duodenoscopes may be considered in all patients when multi-drug related organisms (MDRO) are cultured from reusable duodenoscopes whilst appropriate measures are taken to isolate and manage the source of the infection</i>
Technical Factors	
11	<i>The performance and technical specification of single use endoscopes should be similar to that of conventional reusable/multi-use endoscopes</i>
12	<i>The performance and technical specifications of single use endoscopes should be assessed via well designed clinical research studies prior to widespread adoption</i>
Environmental Issues	
13	<i>Single use endoscopes should be distributed with an effective recycling mechanism in place.</i>
14	<i>The patients' perspective about safety, environmental impact, sustainability, and acceptability of single use endoscopes should be explored prior to their adoption</i>
Financial Implications	
15	<i>An adequate reimbursement policy should be discussed with healthcare providers to integrate single use endoscopes in daily practice in a financially sustainable manner</i>
16	<i>Single use endoscopes should be cost neutral with similar technical performance to conventional multi-use/reusable endoscopes</i>
17	<i>The economic burden of single use endoscopes will be dependent on the volume and set up of individual centres.</i>

- We recommend the use of single use endoscope channel valves for endoscope biopsy channels in high-risk patients (final consensus: 81.10%).
- Single use biopsy forceps should be used in all patients (final consensus: 93.20%).
- Single use cold polypectomy and cold EMR snares should be used in all patients (final consensus: 89.80%).
- Single use hot polypectomy and hot EMR snares should be used in all patients (final consensus: 84.70%).

Category 2: clinical indication for single use endoscopes (9 statements, 4 reached consensuses, 1 was abandoned in the first round), including indications to high-risk patients, protecting the endoscope apparatus and contamination measures in endoscopy units. Accepted statements:

- Endoscopes with a single use tip and/or elevator mechanism may reduce the risk of infection when used in high-risk patients at significant risk of acquiring or transmitting infection (final consensus: 87.9%).
- In order to protect the re-usable endoscope armamentarium from contamination with a MDRO, it is a viable option to use single use endoscopes in patients with a known MDRO infection or in known MDRO carriers (final consensus: 94.8%).
- Single use endoscopes (including duodenoscopes) may offer a safer option when used in high-risk patients at significant risk of acquiring or transmitting infection (final consensus: 89.6%).
- Single use duodenoscopes may be considered in all patients when MDRO are cultured from reusable duodenoscopes whilst appropriate measures are taken to isolate and manage the source of the infection (final consensus: 86.2%)

Category 3: technical factors (4 statements, 2 reached consensus), related to superior performance and technical specifications with the new innovation. Accepted statements:

- The performance and technical specification of single use endoscopes should be similar to that of conventional reusable/multi-use endoscopes (final consensus: 96.5%).
- The performance and technical specifications of single use endoscopes should be assessed via well designed clinical research studies prior to widespread adoption (final consensus: 96.6%).

Category 4: environmental issues (2 statements that reached consensus), concerning mechanisms that reduce the detrimental burden to the environment. Accepted statements:

- Single use endoscopes should be distributed with an effective recycling mechanism in place (final consensus: 94.6%).
- The patients' perspective about safety, environmental impact, sustainability, and acceptability of single use endoscopes should be explored prior to their adoption (final consensus: 81.4%).

Category 5: financial implications (3 statements that reached consensus), related to healthcare policies, cost neutrality and other financial associations of single use endoscopy. Accepted statements:

- An adequate reimbursement policy should be discussed with healthcare providers to integrate single use endoscopes in daily practice in a financially sustainable manner (final consensus: 91.5%).
- Single use endoscopes should be cost neutral with similar technical performance to conventional multi-use/reusable endoscopes (final consensus: 80.3%).
- The economic burden of single use endoscopes will be dependent on the volume and set up of individual centres (final consensus: 81%).

4. Discussion

According to our Delphi consensus, the only accepted indication for the use of the new single use duodenoscopes is infection control in patients with multi-drug-resistant infections or those at risk for immunosuppressive medication or comorbidities. However, similar goals may be achieved by single use tip and/or elevator mechanism, according to our Delphi, somewhat limiting the application of single-use scopes. Alternative indications related to the chance of avoiding the reprocessing process, i.e., 'out-of-hours' emergencies or facilities without reprocessing machines, or damage to the re-usable scope, i.e., glue injection, failed to reach agreement. Similarly, the option of customizing the single-use scope according to the operator or the procedure, as well as integration with artificial intelligence did not achieve consensus.

The lack of expanded indications for single-use scopes underscored the need for additional data before incorporating these devices into the market. This research should not be limited to technical aspects. There was wide agreement that a multi-dimensional research approach is required, also addressing the cost-neutrality, reimbursement policy, sustainability, and acceptability of these single-use scopes. The environmental impact of single use endoscopes does need to be further studied. Effective recycling mechanisms for single use endoscopes would need to involve recycling all electronic, metal and plastic parts of the endoscope. Companies producing these scopes would need to look at a system of having used scopes returned to them for remanufacturing to avoid an escalating amount of waste generation. Single use scopes may achieve cost neutrality by selective use and increased competition by manufacturers to drive down prices. There also needs to be increased oversight on the indications for endoscopy in order to avoid unnecessary procedures.

The fact that infection control appeared to be the only accepted indication for the use of single-use scopes is in line with current evidence for single-use bronchoscopy devices. COVID-19 has been the main driver for single-use bronchoscopes, and current recommendations in pneumology are similarly limited to immunosuppressed patients or other contagious diseases, such as tuberculosis, multi-drug resistant microorganism, or prion disease [16,17].

According to our panel, technical equivalence between single-use and re-usable scopes must be proven in well-designed trials. Thus, retrospective comparisons are unlikely to match these criteria, while randomized or prospective studies are required. With this regard, Bang et al. conducted a randomised controlled trial comparing ERCP performed with single-use ($n = 48$) or reusable ($n = 50$) duodenoscopes, exploring as primary outcome the number of attempts to achieve successful cannulation [18]. Interestingly, the median number of attempts to achieve successful cannulation was significantly lower in the single-use group (2 vs 5, $p = 0.013$), while reusable duodenoscope performed significantly better in several technical aspects, such as ease of passage into stomach, image quality, image stability and air-water button functionality. No significant differences in adverse events rate were reported. Notably, most procedures were graded as low-complexity ERCP. This study concluded that single use duodenoscope has similar safety and technical performance when used in low-complexity ERCP by expert endoscopists, even though several secondary technical aspects needed to be improved. Such good results have been confirmed by other observational studies, which also included different types of single use duodenoscope and subjective evaluations by the endoscopists [19–22]. Importantly, good technical performances of single use duodenoscope were also confirmed in less experienced endoscopists and in more difficult procedures [23]. Furthermore, the risk of post-ERCP adverse events, i.e., post-ERCP pancreatitis, are not increased by the use of single use duodenoscopes [21,22,24]. The results discussed above are promising about the

high level of technical performance of single use duodenoscopes, even though such performance should be further investigated in procedures performed by non-expert endoscopists or during ERCP training, and probably the use of these endoscopes should be integrated early during ERCP training. Our Delphi showed that the performance and technical specifications of single use endoscopes must encompass aspects relating to stability, positioning in front of the papilla, elevator functionality, operative channel compatibility, load ability and overall push ability. These features should be further assessed via well designed clinical research studies prior to widespread adoption. This is relevant to maintain a baseline standard for all diagnostic and therapeutic interventions done with these new devices.

According to our Delphi, there was agreement on the use of single use biopsy forceps, cold/hot polypectomy and EMR snares, sphincterotomes and endoscopic clips in all patients. Of note, this is unlikely to be related to previous well-designed research, but possibly on a long-lasting availability at a reasonable cost of these devices. Paradoxically, the only accessory that failed to achieve consensus for indiscriminate use was single-use valves, despite evidence on contamination risk. Thus, long-lasting habits rather than evidence-based choices may have been a driver for such recommendations even among experts. As stated above, despite a perceived higher cost of disposable devices, when reprocessing costs and progressive material wear of reusable accessories are considered in the global evaluation, disposable devices may outperform reusable ones in terms of technical performance and cost-efficacy [12–14]. These observations, together with the hypothesis of an increased risk of contamination/cross-infection risk with reusable devices, helped to further the use of single use accessories, and lead international societies to recommend such uses in clinical practice, despite the paucity of high-quality studies [4]. The results of our Delphi on single use accessories may also be interpreted in light of these recommendations.

The recommendations on the environment issues related to single use endoscopes/devices proposed in this Consensus achieved agreement during the first round, indicating that the awareness on this topic has considerably grown among endoscopists. Accordingly, a recent position statement from European Society of Gastrointestinal Endoscopy (ESGE) and European Society of Gastroenterology Nurses and Associates (ESGENA) proposed some recommendations aimed at reducing the environmental impact of gastrointestinal endoscopy and finding a path towards a sustainable activity [4]. In particular, ESGE-ESGENA suggest that single-use endoscopes should be used only in highly selected patients, on a case-by case basis, therefore recommending against routine use. This is in agreement with what is reported in this Consensus. On the other hand, the ESGE-ESGENA position statement warns about the need to reevaluate the economic and environmental impact of single use accessories, as sustainability was not taken into consideration in previous position statements [4]. An additional open question is the possibility to reprocess and reuse accessories that have been manufactured as single use, in order to minimize material waste and environmental impact. Despite some evidence suggesting this solid evidence is still lacking, and current legislation is not uniform [25–28]. Moreover, investigating the feasibility and safety of such an approach was beyond the aim of our Delphi. Considering the ongoing climate change emergency and the increasing attention given to this issue globally, including in gastrointestinal endoscopy, it is conceivable that future recommendations will be influenced by all the above-discussed issues.

This study has several limitations. The goals of each round of voting and what was accomplished between each round was not predefined. Experts were instructed to limit their inherent bias regarding their disclosures, ultimately accounting for such a bias would be unfeasible. Additional limitations exist regarding the fi-

nal and intended group of experts. Unequal gender representation with few female endoscopists may have resulted in a different perspective. There was also unbalanced representation from each continent as some experts declined to participate despite the invitation. The outcome from this Delphi process has provided a series of statements by experts that can be used to guide the adoption of single use endoscopes and accessories in clinical practice. Given that there is still a paucity of data on head-to-head comparisons between reusable and single use endoscopes the statements provide a foundation for further research that can shape evidence-based guidelines in the future.

5. Conclusion

In conclusion, this is the first global collaborative effort to comprehensively define the single use endoscopic priorities with a special emphasis on clinical implementation. Key aspects with respect to infection control, endoscope protection and limiting MDROs and other infectious agents in endoscopy units were important statements that gained approval. Further research is needed for expanding possible indications of single-use scopes.

Author contributions

AR, PB: Conception and design of study, critical revision of the manuscript. KK: Literature review, reviewed statement construct. KK, SS, ET: wrote manuscript. KK, SS, ET, CH: constructed statements. KK: Designed voting platform, analysed and compiled voting data. All other (excluding KK, SS, ET, PB, AR) co-authors were voting members of the consensus group.

Conflict of interest

Cesare Hassan: Consulting fees for Fuji, and Medtronic. Alessandro Repici: Consulting fees for Fuji, Olympus, and Medtronic and receiving research grant and speaker fees from Boston Scientific, ERBE, Alfasigma, Norgine. Pradeep Bhandari: Research support from Fujifilm Europe, Boston Scientific, Pentax and Olympus Medical. Other authors declare no competing interests.

Acknowledgements

We thank the DISPOSE group for their assistance as voting members of the consensus group and contributing to this work.

Funding or grant support

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

Patient and public involvement

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

Patient consent for publication

Not required.

Data availability statement

All data relevant to the study are included in the article.

Supplementary materials

Supplementary material associated with this article can be found, in the online version, at doi:[10.1016/j.dld.2023.07.026](https://doi.org/10.1016/j.dld.2023.07.026).

References

- [1] Kimmery MB, Burnett DA, Carr-Locke DL, DiMarino AJ, Jensen DM, Katon R, et al. Transmission of infection by gastrointestinal endoscopy. *Gastrointest Endosc* 1993;39:885–8. doi:[10.1016/S0016-5107\(93\)70316-8](https://doi.org/10.1016/S0016-5107(93)70316-8).
- [2] Ofstead CL, Dirlam Langley AM, Mueller NJ, Tosh PK, Wetzler HP. Re-evaluating endoscopy-associated infection risk estimates and their implications. *Am J Infect Control* 2013;41:734–6. doi:[10.1016/j.ajic.2012.10.008](https://doi.org/10.1016/j.ajic.2012.10.008).
- [3] Kovaleva J, Peters FTM, Van Der Mei HC, Degener JE. Transmission of infection by flexible gastrointestinal endoscopy and bronchoscopy. *Clin Microbiol Rev* 2013;26:231–54. doi:[10.1128/CMR.00085-12](https://doi.org/10.1128/CMR.00085-12).
- [4] Beilenhoff U, Biering H, Blum R, Brljak J, Cimbro M, Dumonceau JM, et al. Re-processing of flexible endoscopes and endoscopic accessories used in gastrointestinal endoscopy: position statement of the European Society of Gastrointestinal Endoscopy (ESGE) and European Society of Gastroenterology Nurses and Associates (ESGENA) – Update 2018. *Endoscopy* 2018;50:1205–34. doi:[10.1055/a-0759-1629](https://doi.org/10.1055/a-0759-1629).
- [5] Kwakman JA, Erler NS, Vos MC, Bruno MJ. Risk evaluation of duodenoscope-associated infections in the Netherlands calls for a heightened awareness of device-related infections: a systematic review. *Endoscopy* 2022;54:148–55. doi:[10.1055/a-1467-6294](https://doi.org/10.1055/a-1467-6294).
- [6] Muscarella LF. Risk of transmission of carbapenem-resistant *Enterobacteriaceae* and related “superbugs” during gastrointestinal endoscopy. *WJGE* 2014;6:457. doi:[10.4253/wjge.v6.i10.457](https://doi.org/10.4253/wjge.v6.i10.457).
- [7] Rauwers AW, Voor In 't Holt AF, Buijs JG, De Groot W, Hansen BE, Bruno MJ, et al. High prevalence rate of digestive tract bacteria in duodenoscopes: a nationwide study. *Gut* 2018;67:1637–45. doi:[10.1136/gutjnl-2017-315082](https://doi.org/10.1136/gutjnl-2017-315082).
- [8] Petersen BT. Advantages of disposable endoscopic accessories. *Gastrointest Endosc Clin N Am* 2000;10:341–8.
- [9] Croffie J, Carpenter S, Chuttani R, DiSario J, Hussain N, Liu J, et al. ASGE technology status evaluation report: disposable endoscopic accessories. *Gastrointest Endosc* 2005;62:477–9. doi:[10.1016/j.gie.2005.07.005](https://doi.org/10.1016/j.gie.2005.07.005).
- [10] Jager E, Hausemann A, Hofmann H, Otto U, Heudorf U. Struktur- und Prozessqualität bei der Aufbereitung flexibler Endoskope in Klinik und Praxis in Frankfurt am Main –2013 im Vergleich zu 2003. *Z Gastroenterol* 2014;52:1402–7. doi:[10.1055/s-0034-1366776](https://doi.org/10.1055/s-0034-1366776).
- [11] Gromski MA, Sherman S. Technological review: developments in innovative duodenoscopes. *Gastrointest Endosc* 2022;95:42–50. doi:[10.1016/j.gie.2021.08.019](https://doi.org/10.1016/j.gie.2021.08.019).
- [12] Lim C-H, Choi M-G, Kim WC, Kim JS, Cho YK, Park JM, et al. Performance and cost of disposable biopsy forceps in upper gastrointestinal endoscopy: comparison with reusable biopsy forceps. *Clin Endosc* 2012;45:62. doi:[10.5946/ce.2012.45.1.62](https://doi.org/10.5946/ce.2012.45.1.62).
- [13] Yang R, Ng S, Nichol M, Laine L. A cost and performance evaluation of disposable and reusable biopsy forceps in GI. *Endoscopy* 2000;51.
- [14] Rizzo J, Bernstein D, Gress F. A performance, safety and cost comparison of reusable and disposable endoscopic biopsy forceps: a prospective, randomized trial. *Gastrointest Endosc* 2000;51:257–61. doi:[10.1016/S0016-5107\(00\)70351-8](https://doi.org/10.1016/S0016-5107(00)70351-8).
- [15] Kim S, Mohamadnejad M, Russell D, Makkar J, Sedarat A, Watson RR, et al. Risk factors for transmission of carbapenem resistant enterobacteriaceae (CRE) infection during endoscopic retrograde cholangiopancreatography (ERCP): 52. *Off J Am Coll Gastroenterol | ACG* 2015;110.
- [16] Commissioner O of the. FDA recommends health care facilities and manufacturers begin transitioning to duodenoscopes with disposable components to reduce risk of patient infection. FDA 2020. <https://www.fda.gov/news-events/press-announcements/fda-recommends-health-care-facilities-and-manufacturers-begin-transitioning-duodenoscopes-disposable> (accessed July 2, 2023).
- [17] Lenz RJ, Colt H. Summarizing societal guidelines regarding bronchoscopy during the COVID -19 pandemic. *Respirology* 2020;25:574–7. doi:[10.1111/resp.13824](https://doi.org/10.1111/resp.13824).
- [18] Bang JY, Hawes R, Varadarajulu S. Equivalent performance of single-use and reusable duodenoscopes in a randomised trial. *Gut* 2021;70:838–44. doi:[10.1136/gutjnl-2020-321836](https://doi.org/10.1136/gutjnl-2020-321836).
- [19] Shahid HM, Bareket R, Tyberg A, Sarkar A, Simon A, Gurram K, et al. Comparing the safety and efficacy of two commercially available single-use duodenoscopes: a multicenter study. *J Clin Gastroenterol* 2022. doi:[10.1097/MCG.0000000000001752](https://doi.org/10.1097/MCG.0000000000001752).
- [20] Napoléon B, Gonzalez J, Grandval P, Lisotti A, Laquière AE, Boustière C, et al. Evaluation of the performances of a single-use duodenoscope: prospective multi-center national study. *Dig Endosc* 2022;34:215–21. doi:[10.1111/den.13965](https://doi.org/10.1111/den.13965).
- [21] Rama D, Smit E, Kani HT, Papaefthymiou A, Warner L, Chandan S, et al. Cannulation rates and technical performance evaluation of commercially available single-use duodenoscopes for endoscopic retrograde cholangiopancreatography: a systematic review and meta-analysis. *Dig Liver Dis* 2023 S1590865823005133. doi:[10.1016/j.dld.2023.02.022](https://doi.org/10.1016/j.dld.2023.02.022).
- [22] Lisotti A, Zagari RM, Fusaroli P, Napoléon B. Optimal safety and pooled technical success rate for ERCP performed with single-use duodenoscopes. *Dig Liver Dis* 2022;54:291–2. doi:[10.1016/j.dld.2021.11.003](https://doi.org/10.1016/j.dld.2021.11.003).
- [23] Slivka A, Ross AS, Sejpal DV, Petersen BT, Bruno MJ, Pleskow DK, et al. Single-use duodenoscope for ERCP performed by endoscopists with a range of experience in procedures of variable complexity. *Gastrointest Endosc* 2021;94:1046–55. doi:[10.1016/j.gie.2021.06.017](https://doi.org/10.1016/j.gie.2021.06.017).
- [24] Muthusamy VR, Bruno MJ, Kozarek RA, Petersen BT, Pleskow DK, Sejpal DV, et al. Clinical evaluation of a single-use duodenoscope for endoscopic retrograde cholangiopancreatography. *Clin Gastroenterol Hepatol* 2020;18:2108–17.e3. doi:[10.1016/j.cgh.2019.10.052](https://doi.org/10.1016/j.cgh.2019.10.052).
- [25] Kozarek RA, Sumida SE, Raltz SL, Merriam LD, Irizarry DC. In vitro evaluation of wire integrity and ability to reprocess single-use sphincterotomes. *Gastrointest Endosc* 1997;45:117–21. doi:[10.1016/S0016-5107\(97\)70232-3](https://doi.org/10.1016/S0016-5107(97)70232-3).
- [26] Kozarek RA, Raltz SL, Ball TJ, Patterson DJ, Brandabur JJ. Reuse of disposable sphincterotomes for diagnostic and therapeutic ERCP: a one-year prospective study. *Gastrointest Endosc* 1999;49:39–42. doi:[10.1016/S0016-5107\(99\)70443-8](https://doi.org/10.1016/S0016-5107(99)70443-8).
- [27] Prat F, Spieler J-F, Paci S, Pallier C, Fritsch J, Choury AD, et al. Reliability, cost-effectiveness, and safety of reuse of ancillary devices for ERCP. *Gastrointest Endosc* 2004;60:246–52. doi:[10.1016/S0016-5107\(04\)01685-2](https://doi.org/10.1016/S0016-5107(04)01685-2).
- [28] Rodríguez De Santiago E, Dinis-Ribeiro M, Pohl H, Agrawal D, Arvanitakis M, Baddeley R, et al. Reducing the environmental footprint of gastrointestinal endoscopy: European Society of Gastrointestinal Endoscopy (ESGE) and European Society of Gastroenterology and Endoscopy Nurses and Associates (ESGENA) position statement. *Endoscopy* 2022;54:797–826. doi:[10.1055/a-1859-3726](https://doi.org/10.1055/a-1859-3726).