# Defining standards for fluoroscopy in gastrointestinal endoscopy using Delphi methodology

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## ABSTRACT

**Background and study aims** Use of fluoroscopy in gastrointestinal endoscopy is an essential aid in advanced endoscopic interventions. However, it also raises concerns about radiation exposure. This study aimed to develop consensus-based statements for safe and effective use of fluoroscopy in gastrointestinal endoscopy, prioritizing the safety and well-being of healthcare workers and patients.

**Methods** A modified Delphi approach was employed to achieve consensus over three rounds of surveys. Proposed statements were generated in Round 1. In the second round, panelists rated potential statements on a 5-point scale, with consensus defined as ≥80% agreement. Statements were subsequently prioritized in Round 3, using a 1 (lowest priority) to 10 (highest priority) scale.

**Results** Forty-six experts participated, consisting of 34 therapeutic endoscopists and 12 endoscopy nurses from six continents, with an overall 45.6% female representation (n = 21). Forty-three item statements were generated in the first round. Of these, 31 statements achieved consensus after the second round. These statements were categorized into General Considerations (n = 6), Education (n = 10), Pregnancy (n = 4), Family Planning (n = 2), Patient Safety (n = 4), and Staff Safety (n = 5). In the third round, accepted statements received mean priority scores ranging from 7.28 to 9.36, with 87.2% of statements rated as very high priority (mean score ≥ 9).

**Conclusions** This study presents consensus-based statements for safe and effective use of fluoroscopy in gastrointestinal endoscopy, addressing the well-being of healthcare workers and patients. These consensus-based statements aim to mitigate risks associated with radiation exposure while maintaining benefits of fluoroscopy, ultimately promoting a culture of safety in healthcare settings.

## Introduction

Use of fluoroscopy in gastrointestinal endoscopy is routine practice for certain procedures, such as endoscopic retrograde cholangiopancreatography (ERCP), offering diagnostic and therapeutic guidance. Healthcare professionals (HCPs) minimize radiation exposure by employing techniques including pulsed fluoroscopy and image enhancement [1]. Moreover, shielding and protective equipment, such as lead aprons, thyroid shields, and leaded glasses, play a pivotal role in safeguarding vulnerable areas of the body [1, 2]. However, radiation exposure during fluoroscopy-guided procedures can be highly variable and not easily predicted. Studies have shown important heterogeneity in radiation safety practices [3]. Furthermore, while guidance from the Centers for Disease Control suggests that radiation doses should be "as low as reasonably achievable" (ALARA) [4], adherence to this principle is also variable. There are also limited data regarding radiation exposure in gastrointestinal endoscopy and specific regulations are lacking, particularly for individuals of childbearing age [5].

Therefore, it is imperative that fluoroscopy use in gastrointestinal endoscopy be thoughtfully evaluated, particularly in relation to weighing the perceived benefits and potential risks. The challenges and complexities associated with fluoroscopy safety encompass considerations for physicians, nurses, technicians, trainees, and the patient [1]. Presence of pregnant staff in the room adds additional considerations, because radiation exposure may have implications on the career choices of a pregnant HCP, and the developing fetus.

While the ALARA principle is a fundamental concept for minimizing radiation exposure, a more thorough exploration is needed to address the multifaceted dimensions of fluoroscopy safety [4]. This study sought to establish a comprehensive, consensus-based framework for enhancing the safety of all individuals participating in fluoroscopy-guided endoscopic procedures. These statements aimed to prioritize the safety of both HCPs and patients, while addressing the challenges posed by repeated exposure. In doing so, we also strove to safeguard well-being, enhance education, and foster the professional prospects of HCPs.

# Methods

## Study design

This study employed modified Delphi methodology with three rounds of surveys to develop expert-guided statements for use of fluoroscopy in gastrointestinal endoscopy. The Delphi method is a research technique that harnesses the collective expertise of a diverse group of individuals to reach agreement on a particular subject. This is achieved through iterative rounds of questionnaires with controlled feedback. The limited existing literature and a lack of widely accepted practice standards specifically addressing multifaceted challenges stemming from repeated fluoroscopy exposure make this topic particularly suited to using Delphi methodology. Considerations extended beyond safety, prompting the need for a comprehensive approach. This study was deemed exempt from ethical approval.

## Delphi panel recruitment and selection process

A purposive sampling approach was used to recruit experts in fluoroscopy-guided endoscopy. This approach aimed to be inclusive of all (HCPs) in the room, including therapeutic endoscopists and endoscopy nurses. Recruitment criteria were developed to assist in the creation of the expert panel.

### Therapeutic endoscopist eligibility

Internationally recognized expertise – Participants with internationally recognized expertise in advanced therapeutic endoscopy, specifically in fluoroscopic-dependent endoscopic procedures.

Publication record – Individuals with a track record (of more than 15) endoscopy-related publications within the past 10 years.

Key opinion leaders – Experts who are considered key opinion leaders in the field of endoscopy and hold national or international recognition.

Exceptional achievements – Individuals who have demonstrated exceptional achievements within their respective endoscopy departments, such as enhancing awareness about fluoroscopy radiation and advocating for safer practices at the institutional level.

Department heads and established researchers – Heads of endoscopy departments, established researchers, and clinicians in the field of endoscopy (including hepatobiliary or any fluoroscopic endoscopy) were invited to ensure a diverse range of expertise.

Therapeutic endoscopists must have met at least one of the aforementioned criteria to be included as a Delphi panelist. The decision to prioritize a robust publication record and established researchers is based on the understanding that individuals with extensive scholarly contributions in endoscopy bring a wealth of theoretical and practical insights. Their collective experiences, coupled with their formal endoscopy training, uniquely positions them to reflect on the broader implications of fluoroscopy use and advocate for quality statements.

### Endoscopy nurse and technician eligibility

Nursing staff from tertiary centers – Nurses working in tertiary centers known for their excellence in endoscopic research and training worldwide were identified and invited to participate.

Unit leaders – In addition to nursing staff, unit leaders or individuals with a demonstrated role in leading endoscopy units were considered eligible. This includes nurses who have shown expertise and leadership in the development and implementation of advanced therapeutic endoscopy procedures.

Society involvement – Nurses who are actively involved in endoscopic societies were identified through online databases, society publications, professional conferences and meetings, and collaboration networks. Their contributions and engagement within these societies were considered as an additional criterion for eligibility.

Research experience – Nurses who have conducted independent research or have actively contributed to endoscopy-related research studies were included in the recruitment process. Their research experience encompasses areas such as patient outcomes, procedural techniques, safety measures, or innovations in endoscopy.

Fluoroscopy technicians – Nurses who are specifically trained as fluoroscopy technicians and have experience in performing fluoroscopic-dependent endoscopic procedures.

Endoscopy nurses must have met at least one of the above criteria to be included as a Delphi panelist. We sought to assemble a diverse and qualified panel of endoscopy nurses and technicians. We approached nursing professionals globally who had championed radiation safety and/or possess formal training in nurse endoscopy.

### General eligibility

International representation – To achieve a well-balanced international consensus, a proportionate number of endoscopists from low-resource settings were recruited, with less rigorous requirements compared to established experts.

Proportional representation – To ensure diversity and representation, efforts were made to include endoscopy nurses from different regions and healthcare settings, including both developed and developing/low-resource nations.

It is imperative to acknowledge that our recruitment strategy extended beyond professional qualifications alone, demonstrating a commitment to inclusivity and diversity within our expert panel. Deliberate efforts were made to ensure gender balance among our expert panelists and achieve geographic representation.

Proactive measures were also taken to include female therapeutic endoscopists, to achieve more balanced representation and foster a broader spectrum of insights. Additionally, our approach aimed to incorporate geographic diversity, recognizing that practices and experiences in fluoroscopy-dependent endoscopic procedures may vary across different regions.

In consideration of the special topics involving children, we ensured the inclusion of a pediatric gastroenterology expert (CW) on our panel. This deliberate choice aimed to bring specialized knowledge regarding the unique considerations related to pediatric patients within the scope of our study.

## Delphi process

### Statement generation

To facilitate establishment of statements for use of fluoroscopy, a systematic and data-driven approach was adopted. Twenty-seven objective prompts were provided to expert panelists during Delphi Round 1 (**Supplementary Data)**. These prompts were crafted by the steering committee based on a comprehensive literature review [1, 6, 7, 8, 9, 10, 11, 12, 13, 14, 15, 16, 17] which yielded five domains of focus: General Considerations, Patient and Staff Safety, Education, Pregnancy, and Family Planning. This literature review was conducted on Medline, searching for articles related to fluoroscopy and radiation safety within gastrointestinal endoscopy from conception to May 13, 2023. After reviewing all relevant articles and identifying common themes, the 27 prompts were generated after extensive discussion among the steering committee, which considered the study objectives, target population and findings of the literature review. The steering committee consisted of members of the primary research team with extensive ERCP expertise.

During Round 1, expert panelists including physicians and nurses were asked to propose an unlimited number of statements in response to the provided prompts. Verbatim statements were then compiled to create an anonymous list of items for evaluation by the steering committee. Similar issues expressed in multiple responses were consolidated into a single statement through discussions within the steering committee, with independent mediation used to resolve conflicts, when required. Following the initial generation of potential statements, related statements were grouped into the aforementioned five categories based on their subject matter.

### Special considerations

Upon reviewing the potential statements that were generated, we developed a category focused on special considerations (**Supplementary Data**), that was crucial to address nuanced aspects related to specific patient groups. Indeed, the objective was to outline these considerations, within specific contexts to ensure recommendations cover not only general fluoroscopy safety principles but also specific challenges associated with a diverse patient population. We refer to the following patient groups as ‘patients requiring special considerations.

### Delphi process: Consensus and prioritization

In the second Delphi round, participants were asked to rate each proposed statement on a 1 (low agreement) to 5 (high agreement) point scale. Panelists were provided the opportunity to offer feedback on the phrasing of potential statements, provide rationales for their preferences, and/or propose additional statements. The mean rating of each statement (1 to 5) was calculated. Consensus was defined a priori as at least 80% of respondents assigning a statement a score of 4 or higher on the 5-point Likert scale. The term "consensus" was predetermined in our study as the agreement criterion for item inclusion into the final statements. We acknowledge that consensus can be measured by various methods; however, our study operationalized consensus based on a specified Likert scale threshold. This predetermined criterion served as a foundation for identifying statements that would be prioritized during the third and final Delphi round. Steering committee members, blinded to the identity of the respondent, met to review, and discuss the qualitative comments. When required, the wording of statements was modified based on comments from the expert panel.

In the third Delphi round, panelists were asked to rate statements that reached consensus during the second round on a 1 (lowest priority) to 10 (highest priority) scale to prioritize the statements. Round 3 also provided an opportunity for panelists to offer feedback on the statements presented.

Surveys were created using the online platform Google Forms. Participants received the surveys via email and were given 4 weeks to complete each round. A minimum response rate threshold was established a priori. This threshold stipulated that a minimum of 85% participation from the expert panel was required to move forward to the next Delphi round. When the response rate surpassed the predetermined threshold at the 4-week mark, the research team proceeded to the next study round. If the response rate fell below the specified threshold, additional efforts were made to encourage participation from the remaining panel members. These efforts included general reminder emails, personal messages, and/or extensions of the response deadline, aiming to increase the response rate and obtain more comprehensive and generalizable results.

# Results

A total of 118 potential experts were identified, of whom 72 were excluded either because they did not respond or did not meet the eligibility criteria (▶ **Fig. 1**). Forty-Six experts (34 therapeutic endoscopists and 12 endoscopy nurses) from 11 countries spanning six continents (Oceania, North America, South America, Europe, Africa, and Asia) participated in the Delphi study, with female representation accounting for 45.6% of the experts (n = 21). In the initial round, all participants responded, achieving a 100% response rate. The second round yielded a response rate of 97.83%, while the third round saw a response rate of 95.65%.

After the first round, 43 item statements were generated and re-sent to the panel for voting in the second round, categorized into the following domains: General Considerations (n = 9), Education (n = 14), Pregnancy (n = 4), Family Planning (n = 4), Patient Safety (n = 6), and Staff Safety (n = 6). Of the 43 initial statements, 31 (71%) achieved consensuses after the second round and met the criteria for inclusion in the third round of voting. The categories with accepted statements included General Considerations (n = 6), Education (n = 10), Pregnancy (n = 4), Family Planning (n = 2), Patient Safety (n = 4), and Staff Safety (n = 5). All statements and their consensus ratings from Round 2 are outlined in **Supplementary Data – Table 1**.

In Round 3 of the Delphi study, the mean prioritization scores for the 31 consensuses-based statements, which were scored on a 10-point scale, ranged from 7.28 to 9.36, with 87.2% of statements rated as very high priority (mean score of ≥ 9) (▶ **Table 1**). Consensus-based statement 17 ("The benefits of fluoroscopy-guided procedures must outweigh the potential risks to the fetus. When possible, non-urgent procedures should be deferred until after the first trimester of pregnancy") received the highest mean prioritization score of 9.36 ± 1.14 with 61.5% of the respondents rating this statement as very high priority.
Consensus-based statement 1 ("Patient's medical history and physical limitations should be carefully reviewed to determine the suitability of fluoroscopy-guided procedures", mean score = 8.51±1.68 priority ranking = 13) received the highest number of responses in the 9 to 10 range, with 87.18% of panelists rating this statement as very high priority. Consensus-based statement 9 ("Case-based learning should be implemented in trainee curricula to educate trainees on fluoroscopy use in real-world scenarios") received the lowest mean prioritization score of 7.28 ± 1.86 with only 51.3% of panelists considering this statement to be very high priority.

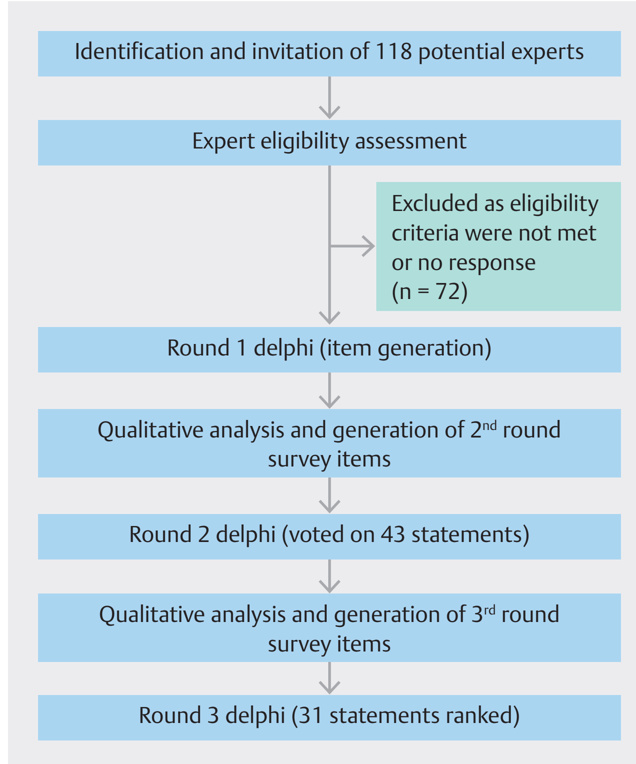
The following consensus-based statements from each domain that had the highest mean prioritization ratings in round 3 include:

General considerations: Consensus-based statement 3 – "Procedures involving the use of fluoroscopy should only be performed by interventionists who are formally trained and experienced in fluoroscopy-guided endoscopic procedures" (mean = 9.15±1.14

Education: Consensus-based statement 23 – "Trainees should have formal education on medical imaging, including cholangiogram interpretation." (mean = 8.44 ± 1.39

Pregnancy: Consensus-based statement 17 – "The benefits of fluoroscopy-guided procedures must outweigh the potential risks to the fetus. When possible, non-urgent procedures should be deferred until after the first trimester of pregnancy" (mean = 9.36 ± 1.14

Family Planning: Consensus-based statement 28 – "Foster supportive environments that respect trainees' family planning decisions and priorities by encouraging dialogue between trainees and program directors" (mean = 8.51 ± 1.47




▶ **Fig. 1** Study flow diagram.

Patient Safety: Consensus -based statement 26 – "The distance between the flat-panel detectors and patients should be minimal to reduce scattered radiation exposure" (mean = 8.79 ± 1.17

Staff Safety: Consensus-based statement 27 – "Ensure staff compliance with safety guidelines and provide well-maintained protective equipment, including lead aprons, shields, glasses, and headwear to minimize fluoroscopy exposure risks and long-term complications such as malignancy, cataracts, retinopathy and thyroid disease to foster a culture of safety among healthcare professionals." (mean = 9.26 ± 1.07)

## Discussion

This first-of-its-kind, international, multidisciplinary Delphi study has yielded a series of consensus-based statements, organized in key domains, for safe and effective fluoroscopy use in gastrointestinal endoscopy. In the domain of General Considerations, there was unanimous agreement that a patient's medical history and physical limitations must be meticulously reviewed, and procedures involving fluoroscopy should only be performed by formally trained and experienced interventionists or trainees under their direct supervision. Education emerged as a critical domain, with consensus on mandates for formal radiation safety training, education using a variety of teaching modalities, and ongoing education for both trainees and staff

▶ **Table 1** Priority ratings for statements reaching consensus (Round 3).

| # | Standard | Mean rating (± SD) | Priority ranking | Responses scoring 9 or 10 (%) |
|---|---|---|---|---|
| 1 | Patient's medical history and physical limitations should be carefully reviewed to determine the suitability of fluoroscopy-guided procedures. | 8.51 ± 1.68 | 13 | 87.18 |
| 2 | Fluoroscopy (*) should always be used to prevent complications, minimize repetitions, reduce hospitalizations and optimize resource utilization. | 8.44 ± 1.82 | 18 | 33.33 |
| 3 | Procedures involving the use of fluoroscopy should only be performed by interventionists who are formally trained and experienced in fluoroscopy-guided endoscopic procedures. | 9.15 ± 1.14 | 3 | 41.03 |
| 4 | Ergonomic adjustments (i. e., adjustable tables, supportive seating, positioning aids) and proper patient positioning should be used to minimize patients' physical strain based on agility, stature, and procedure requirements, especially for patients requiring special considerations. | 8.51 ± 1.55 | 14 | 71.79 |
| 5 | Fluoroscopy techniques should be regularly modernized by integrating new tools, software, and low-dose equipment in accordance with the latest technology. | 8.77 ± 1.31 | 10 | 46.15 |
| 6 | Fluoroscopy in use signage at clearly visible locations should be implemented to ensure that only staff wearing proper protective equipment may enter. | 9.08 ± 1.09 | 4 | 53.85 |
| 7 | Formal radiation safety training with a focus on GI procedures should be mandated for trainees with annual recertification | 7.85 ± 2.05 | 27 | 66.67 |
| 8 | Teaching units should allow trainees to observe procedures and interact with staff to understand fluoroscopy use/interpretation while simultaneously avoiding exposure (i. e., observation room) | 7.56 ± 1.73 | 30 | 51.28 |
| 9 | Case-based learning should be implemented in trainee curricula to educate trainees on fluoroscopy use in real-world scenarios. | 7.28 ± 1.86 | 31 | 51.28 |
| 10 | Fluoroscopy education should be incorporated into the core curriculum for endoscopists, integrating exposure components into assessment tools, training modules and quizzes, and implementing feedback mechanisms to assess trainee comprehension of fluoroscopy principles. | 7.77 ± 1.74 | 28 | 58.97 |
| 11 | Ongoing education should be provided to staff regarding fluoroscopy safety, effective dose minimization, equipment uses and maintenance protocols. | 8.31 ± 1.47 | 21 | 43.59 |
| 12 | Comprehensive educational videos, online courses, webinars, and electronic learning modules focusing on radiation safety during fluoroscopy-guided procedures should be provided. | 7.74 ± 1.74 | 29 | 76.92 |
| 13 | Didactic lectures and explicit instruction on fluoroscopy imaging techniques, radiation safety and interpretation of fluoroscopic images should be provided. | 7.90 ± 1.41 | 26 | 69.23 |
| 14 | Supervising endoscopists should be present during the entire procedure to guide trainees on fluoroscopy use best practices. | 8.10 ± 1.68 | 24 | 23.08 |
| 15 | Pediatric-specific educational modules should be developed to address the specific considerations needed for pediatric patients undergoing fluoroscopy-guided procedures. | 8.05 ± 2.13 | 25 | 41.03 |
| 16 | Trainees should have formal education on medical imaging, including cholangiogram interpretation. | 8.44 ± 1.39 | 19 | 46.15 |
| 17 | The benefits of fluoroscopy-guided procedures must outweigh the potential risks to the fetus. When possible, non-urgent procedures should be deferred until after the first trimester of pregnancy. | 9.36 ± 1.14 | 1 | 61.54 |

**Table 1** (Continuation)

| # | Standard | Mean rating (± SD) | Priority ranking | Responses scoring 9 or 10 (%) |
|---|---|---|---|---|
| 18 | Procedures involving fluoroscopy during pregnancy should ensure the procedure's efficacy using the lowest possible radiation dose. Exposure should be continuously monitored, with regular follow-ups for patients. | 9.05 ± 1.30 | 5 | 58.97 |
| 19 | A multidisciplinary approach between gastroenterologists, radiologists, and obstetricians is crucial when fluoroscopy is necessary for pregnant persons. | 9.05 ± 1.34 | 6 | 76.92 |
| 20 | Considerations, including but not limited to reduced fluoroscopy room time, evaluations of physical strain, supportive seating, fetal dosimeters, comfort and well-being support should be considered for all pregnant persons or those planning pregnancy. | 8.90 ± 1.10 | 8 | 53.85 |
| 21 | Foster supportive environments that respect trainees' family planning decisions and priorities by encouraging dialogue between trainees and program directors. | 8.51 ± 1.52 | 15 | 76.92 |
| 22 | Ensure healthcare workers are protected and accommodated schedule-wise to make their family planning choices freely and safely. | 8.49 ± 1.30 | 16 | 51.28 |
| 23 | Alternative imaging modalities that do not involve ionizing radiation should be explored and utilized whenever possible. | 8.49 ± 1.43 | 17 | 48.72 |
| 24 | Fluoroscopy time should be regularly monitored and included in the endoscopy report to foster awareness and encourage responsible use. | 8.21 ± 1.84 | 22 | 35.90 |
| 25 | To minimize unnecessary fluoroscopy exposure, restrict the frequency of hard fluoroscopy images per procedure, use low frame rates and limit fluoroscopy time, optimize imaging parameters like collimation and beam adjustments. | 8.67 ± 1.38 | 11 | 56.41 |
| 26 | The distance between the flat-panel detectors and patients should be minimal to reduce scattered radiation exposure. | 8.79 ± 1.17 | 9 | 53.85 |
| 27 | Ensure staff compliance with safety guidelines and provide well-maintained protective equipment, including lead aprons, shields, glasses, and headwear to minimize fluoroscopy exposure risks and long-term complications such as malignancy, cataracts, retinopathy and thyroid disease to foster a culture of safety among healthcare professionals. | 9.26 ± 1.07 | 2 | 64.10 |
| 28 | Reduce cumulative exposure to staff by placing limits on fluoroscopy room time and implementing staff rotations/breaks to minimize prolonged exposure. | 8.41 ± 1.62 | 20 | 35.90 |
| 29 | Comprehensively document fluoroscopy doses with real time observations, dosimeter levels, and post-procedural monitoring for radiation related complications. | 8.13 ± 1.47 | 23 | 25.64 |
| 30 | Thorough maintenance of fluoroscopy units should be conducted via regular inspections, and performance testing following repairs or new equipment. | 8.95 ± 1.02 | 7 | 64.10 |
| 31 | Promote collaboration between healthcare professionals and within teams to improve safety measures and enhance two-way communication to limit unnecessary fluoroscopy exposure. | 8.64 ± 1.72 | 12 | 61.54 |

*Procedures involving pancreaticobiliary endoscopy (including ERCP and interventional EUS), interventions requiring hypaque studies, dilations, and luminal stenting may necessitate mandatory use of fluoroscopy.
ERCP, endoscopic retrograde cholangiopancreatography.

to ensure maintenance of competence. The Pregnancy domain highlights the importance of carefully balancing the benefits and risks for pregnant persons undergoing fluoroscopy-guided procedures, emphasizing a multidisciplinary approach and considerations for physical well-being. Patient Safety recommendations underscore the need for fostering supportive environments, monitoring fluoroscopy time, and exploring alternative imaging modalities for pregnant patients. HCP safety recommendations emphasize the provision of well-maintained protective equipment, limits on fluoroscopy room time, and comprehensive documentation of fluoroscopy doses.

Previous guidelines have focused on general considerations regarding fluoroscopy use in gastrointestinal endoscopy with the aim to minimize exposure; however, they do not comprehensively address the complexities associated with repeated exposure [16, 17]. Indeed, the focus of this study was to achieve expert consensus on key aspects of fluoroscopy practice in gastrointestinal endoscopy to minimize risks and prioritize the well-being of HCPs and patients. The Delphi panel emphasized the importance of education, including imaging interpretation, and maintenance of safety standards. Furthermore, the results underscored special considerations for groups for whom exposure to fluoroscopy may be associated with an additional risk, such as pregnant persons or those planning a pregnancy [18]. This concerted effort aims to minimize risks of fluoroscopy exposure and its derived potential long-term complications, such as malignancy, cataracts, retinopathy, and thyroid disease [16, 17]. Some technical considerations outlined by the expert panel emphasize the need for minimizing distance between flat-panel detectors and patients to reduce scattered radiation exposure. Furthermore, there was unanimous agreement on regular modernization of fluoroscopy techniques through integration of new tools, software, and low-dose equipment. Regular inspections and performance testing of fluoroscopy units following repairs or new installations are also highlighted, emphasizing the importance of maintaining equipment standards for optimal safety.

Ergonomic adjustments, such as use of adjustable tables, supportive seating, and positioning aids, are identified as crucial elements to minimize patients' physical strain, tailored to factors like agility, stature, and specific procedural requirements. This focus on patient well-being aligns with the broader objective of enhancing the overall safety and effectiveness of endoscopy. In addition, it is imperative to extend the discussion of ergonomics beyond patient considerations and incorporate measures that address the well-being of endoscopists and nurses. The ergonomics of the procedural setup, including positioning of the endoscopist and design of equipment interfaces (e. g. two-piece lead aprons), should be meticulously addressed to minimize physical strain and fatigue among HCPs and mitigate risk of injury [19, 20, 21, 22]. Research to further assess the role of ergonomics for HCPs during endoscopy and fluoroscopy, including use of simulation (e. g. Simbionix, EndoSim or ERCP Mechanical Simulator) to inform optimal design and educate providers, is warranted.

Education emerged as a central theme in this study, with statements emphasizing its critical role in ensuring safe fluoroscopy use. It is suggested that only interventionists formally trained and experienced in fluoroscopy-guided endoscopic procedures should perform such procedures. The absence of a formal curriculum or guide on how therapeutic endoscopy training programs should provide education in safe and effective use of fluoroscopy is acknowledged [16]. Our expert panel advocates for integration of fluoroscopy education into the core curriculum for endoscopists, incorporating exposure components into assessment tools, training modules, quizzes, and feedback mechanisms. Fluoroscopy education should incorporate a variety of teaching methods such as case-based learning, videos, online courses and webinars, and didactic sessions. Current models of training used internationally take a structured competency-based approach which incorporates the aforementioned methods of educational integration into pre-procedural knowledge acquisition and teaching, procedural skills development in simulated or clinical settings, and assessment phases where trainees are formally evaluated on procedural benchmarks [23, 24, 25]. Formal education on medical imaging, including cholangiogram interpretation, was also viewed as being important. A survey-based study of 58 ERCP trainees from the United Kingdom revealed that fewer than 40% of trainees were aware of existing safety standards or average procedural radiation doses and up to one-quarter of trainees did not routinely wear thyroid protection or radiation protection goggles [26]. Studies from Korea and Japan have demonstrated similar findings, with more than one-quarter of respondents in each respective study stating that they did not routinely wear thyroid protection or radiation protection goggles [8, 27]. These findings highlight the need to enhance training in this area, as was underscored by the Delphi panel in this study. In addition, presence of a supervising endoscopist throughout procedure, to offer guidance to trainees on fluoroscopy use and best practices, was viewed as a crucial element of training. Moreover, experts acknowledged the complexity of education in radiation use, which should cover skill development at various levels. Finally, education regarding fluoroscopy safety, effective dose minimization, equipment-use, and maintenance protocols should extend beyond endoscopy training. These elements should be incorporated into continuing professional development education for staff.

Pregnancy and family planning considerations were prioritized highly by the Delphi panel. Rigorous assessment of a patient's medical history and physical limitations, particularly for pregnant individuals, is underscored. A multidisciplinary approach involving gastroenterologists, radiologists, and obstetricians is recommended when fluoroscopy is deemed necessary during pregnancy. The consensus aligns with existing literature [16, 28, 29, 30, 31], emphasizing the need to weigh the benefits against potential risks and defer non-urgent procedures until after the first trimester. However, it should be noted that shielding of pregnant patients was not discussed in the consensus-based statements.

Concerns about radiation exposure may contribute to gender disparity in therapeutic endoscopy. A US program directors' survey revealed that these concerns dissuade women from pursuing advanced therapeutic endoscopy careers, emphasizing the need for targeted education on safe fluoroscopy practices during reproductive years [32]. Encouragingly, the study also suggests that addressing barriers and introducing education initiatives regarding radiation exposure could serve as a facilitator. Similar findings have been reported in medical specialties in which fluoroscopy is used heavily, such as interventional cardiology and radiology [33, 34]. In this study, the panel highlighted that HCPs should have full autonomy to decide if they want to participate in fluoroscopy studies. Pregnant HCPs should be able to decline to participate in such procedures if they do not feel safe or comfortable doing so. In addressing family planning among endoscopy staff, this study advocates for fostering supportive environments and open dialogue, as evidenced by endoscopy-focused studies that have revealed stigma surrounding discussions about pregnancy and family planning [23]. Practical measures, including reduced fluoroscopy room time, evaluation of physical strain, supportive seating, and provision of fetal dosimeters and more frequent readings, are recommended to accommodate pregnant healthcare workers. Future studies estimating the amount of exposure to radiation adjusted to case complexity could facilitate planning schedules for pregnant staff and trainees accordingly, if desired and needed.

The importance of delineating clear pathways for implementation of the generated consensus-based statements into actionable changes in clinical practice should be acknowledged. It is evident that the statements provided, while highlighting essential principles, lack specificity regarding the responsible parties and practical steps for execution. To address this, we propose a pragmatic approach to enhance applicability of these recommendations. First, the responsibility for fostering a supportive environment and open dialogue between trainees and program directors should be shared among key stakeholders within the healthcare institution, including department heads, trainees, human resources, and program directors. Initiating conversations regarding family planning and accommodating HCPs should be a collaborative effort, with clear guidelines provided by the institution on how these discussions can be conducted. Practical measures, such as provision of fetal dosimeters and evaluation of physical strain, should be overseen by occupational health and safety committees, involving input from endoscopy unit managers and relevant HCPs.

Implementation of consensus-based statements related to fluoroscopy education and ongoing professional development should involve endoscopy training program directors, continuing medical education coordinators, and accrediting bodies. These entities should work collectively to integrate radiation safety education into the core curriculum, develop assessment tools, and establish mechanisms for ongoing training and assessment. Clear communication channels and standardized protocols should be established to ensure that the responsibility for education and adherence to safety statements is distributed effectively among endoscopy unit leaders, training program directors, and individual HCPs.

Although this study contributes valuable insights, it has several limitations. The modified Delphi procedure has an inherent potential for selection and response biases [35]. Selection bias may be present in this study due to selective participant recruitment from tertiary expert centers, recruitment of multiple nurse participants from the same departments, and exclusion of certain categories of HCPs who may perform endoscopy, such as technicians in countries such as the United States and radiologists from centers where ERCP is performed with dedicated radiologists. The exclusion of certain categories of HCPs may have led to omission of important topics in the prompts and final consensus statements. In particular, the topic of diagnostic reference levels (DRLs) was not included in the verbatim responses, and posed a challenge given the lack of globally established thresholds within interventional endoscopy from major societies and guidelines. However, previous studies have described DRLs in specific populations, such as the large multicenter study based in Japan by Hayashi et al., which described median/third quartile threshold values in ERCP of 69/145 mGy, 16/32 Gy $cm^2$, and 11/20 minutes for air kerma at the patient entrance reference point, air kerma area product, and fluoroscopy time, respectively [15]. Dedicated practice guidelines incorporating DRLs from recent studies are urgently needed in order to make uniform and evidence-based recommendations.

Last, this study does not delve deeply into the implementation process for the consensus-based statements or their impact on clinical practice and patient outcomes, which should be considered in future research and practice guidelines. It has, however, highlighted priority domains in fluoroscopy-assisted endoscopy practice that are shared globally, and has identified strategies to implement changes, particularly in the education domain.

## Conclusions

In conclusion, this global collaborative effort represents a milestone in defining standards for gastrointestinal endoscopy-related fluoroscopy. The consensus-based statements established in this study underscore the critical importance of education, technical considerations, and a multidisciplinary approach to ensure safe and effective use of fluoroscopy in therapeutic endoscopy procedures with special considerations in subpopulations of patients and HCPs. Ongoing efforts are essential to create and implement evidence-based guidelines into daily practice with a focus on enhancing patient and healthcare worker safety in the evolving landscape of gastrointestinal endoscopy.

## Conflict of Interest

Tyler Berzin - Consultant for: Medtronic, Boston Scientific, Wision AI, Microtech. Alan N. Barkun - Consultant for Olympus Inc and Medtronic Inc. Cecilia Binda – Lecturer for Steris, Fujifilm, Boston Scientific, Q3 Medical. Alessandro Fugazza – Consultant for Boston Scientific. Rogier P. Voermans - Consultancy and research grant for Boston Scientific, Research grant Prion Medical; Consultancy fee form from Cook Medical. Lecturer Viatris and Zambon. Nauzer Forbes – Speaker for Boston Scientific, Pentax Medical. Consultant for Boston Scientific, Pentax Medical and AstraZeneca. Mariano Villarroel – Consultant for Boston Scientific. Yen-I Chen – Consultant for Boston Scientific. President of Chess Medical. Robert Bechara – Consultant for Olympus, Pentax, Vantage, Medtronic, Pendopharm. Payal Saxena – Consultant for Boston Scientific, Ambu, Erbe. Amrita Sethi – Consultant for Boston Scientific, Interscope, Medtronic, Olympus; Research Support for Boston Scientific, Fujifilm and ERBE. Cesare Hassan: Fujifilm Co. (consultancy); Medtronic Co. (consultancy). Alessandro Repici: Fujifilm Co. (consultancy); Olympus Corp (consultancy); Medtronic Co. (consultancy). Bret Peterson – Consultant for Olympus, Pentax. Investigator for Boston Scientific and Ambu. Silvia Carrara – Consultant for Olympus and Aboca. Jeffrey D. Mosko – Speaker for Boston Scientific, Pendopharm, SCOPE rounds, Vantage, Medtronic. Medical Advisory Board for Pendopharm, Boston Scientific, Janssen, Pentax, Fuji. Grants and Research support from CAG. Christopher W. Teshima – Speaker for Medtronic and Boston Scientific, Consultant for Boston Scientific. Gary R. May – Consultant for Olympus. Speaker for Pentax, Fuji and Medtronic. Samir C Grover –Research grants and personal fees from AbbVie and Ferring Pharmaceuticals, personal fees from Takeda, Sanofi, and BioJAMP, education grants from Janssen, and has equity in Volo Healthcare. All the authors have no relevant financial disclosures or conflicts of interest to declare.

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