

# A prospective study of patient safety incidents in gastrointestinal endoscopy



## Authors

Manmeet Matharoo<sup>1,2</sup>, Adam Haycock<sup>1,2</sup>, Nick Sevdalis<sup>3</sup>,  
Siwan Thomas-Gibson<sup>1,2</sup>

## Institutions

- 1 The Wolfson Unit for Endoscopy, St. Mark's Hospital, Harrow, UK
- 2 Department of Surgery and Cancer, Imperial College, London, UK
- 3 Centre for Implementation Science, Health Service and Population Research Department, King's College London, UK

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## Bibliography

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## Corresponding author

Manmeet Matharoo, MRCP, St. Mark's Hospital – Endoscopy,  
Watford Road Harrow HA1 3UJ, United Kingdom of Great Britain,  
Northern Ireland  
Phone: +07818412368  
Fax: +02084233588  
[m.matharoo@imperial.ac.uk](mailto:m.matharoo@imperial.ac.uk)  
[manmeet@doctors.org.uk](mailto:manmeet@doctors.org.uk)

## ABSTRACT

**Background and study aims** Medical error occurs frequently with significant morbidity and mortality. This study aims to assess the frequency and type of endoscopy patient safety incidents (PSIs).

**Patients and methods** A prospective observational study of PSIs in routine diagnostic and therapeutic endoscopy was undertaken in a secondary and tertiary care center. Observations were undertaken within the endoscopy suite across pre-procedure, intra-procedure and post-procedure phases of care. Experienced (Consultant-level) and trainee endoscopists from medical, surgical, and nursing specialities were included. PSIs were defined as any safety issue that had the potential to or directly adversely affected patient care: PSIs included near misses, complications, adverse events and “never events”. PSIs were reviewed by an expert panel and categorized for severity and nature via expert consensus.

**Results** One hundred and forty procedures (92 diagnostic, 48 therapeutic) over 37 lists (experienced operators n = 25, trainees n = 12) were analyzed. One hundred forty PSIs were identified (median 1 per procedure, range 0–7). Eighty-six PSIs (61%) occurred in 48 therapeutic procedures. Zero PSIs were detected in 13 diagnostic procedures. 21 (15%) PSIs were categorized as severe and 12 (9%) had the potential to be “never events,” including patient misidentification and wrong procedure. Forty PSIs (28%) were of intermediate severity and 78 (56%) were minor. Oxygen monitoring PSIs occurred most frequently.

**Conclusion** This is the first study documenting the range and frequency of PSIs in endoscopy. Although many errors are minor without immediate consequence, further work should identify whether prevention of such recurrent errors affects the incidence of severe errors, thus improving safety and quality.

## Introduction

A plethora of evidence supports the premise that the incidence of iatrogenic harm is significant [1, 2]. Adverse events (AEs) are defined as unintended injuries or complications caused by medical management as opposed to the disease process itself [3]. In 1999 the Institute of Medicine's report, “To err is Human” [4] stated that medical error accounts for up to 98,000 deaths, superseding mortality from breast cancer. In the UK, Vincent et al.'s retrospective record review of 1014 patients revealed that AEs occurred in 10.8% of hospital admissions, with half deemed to be preventable and one-third leading to moderate disability or death [5]. Furthermore, it was estimated that preventable AEs could save the NHS £1 billion a year in extra bed days alone, aside from the personal, social, and wider economic implications.

Retrospective analyses of cases where patients have been harmed favor a “systems approach: to safe care delivery, rather than a focus on individual physicians [6]. The systems approach

suggests that AEs often arise from multiple failures across an entire patient pathway [7], where minor errors can accumulate and lead to a major patient safety incident (e.g. performing a procedure on the wrong patient). Never events are serious preventable incidents that further highlight the importance of prevention of error. [8] Furthermore, there is growing awareness that human factors are heavily implicated in medical error. This has been well established in drug errors [9], intensive care [10] anesthetics [11] and surgery [12] but is yet to be defined in endoscopy.

AEs in endoscopy are well recognized [13] but the primary focus remains on technical procedural outcomes. Reported AEs therefore tend to be procedure-specific [14] and represent the severe (but rare) end of the spectrum as opposed to minor (but more frequent) events. The 2004 National Confidential Enquiry into Patient Outcomes and Death (NCEPOD) following gastrointestinal endoscopy sought to further understand patient safety issues in cases of fatalities within 30 days of an endoscopic examination [15]. This high-profile report recom-

mended improvements in appropriate patient selection, pre-procedural optimization of the patient and safe sedation and monitoring amongst others. In parallel, Bowles et al. [16] raised important concerns about colonoscopy in the UK. Significant quality issues were identified regarding cecal intubation rates, sedation safety and endoscopy training provision. In the United States analyses of malpractice claims also highlight suboptimal performance and diagnostic error linked with missed cancer at colonoscopy as a significant issues [17]. Optimal complication management may improve patient satisfaction and outcome and may serve to minimize litigation [18]. Taken together, these studies raise key considerations for patient safety in endoscopy.

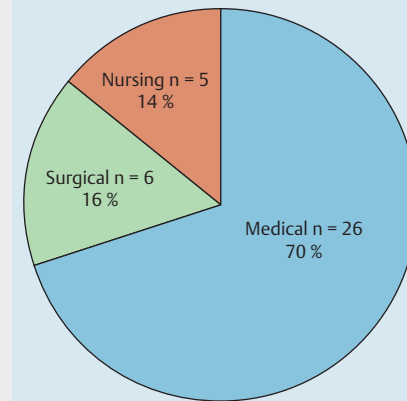
In recent years, there have been significant improvements in endoscopy [19] in the UK driven in part by the National Bowel Cancer Screening program [20] necessitating consistent high-quality practice. Additionally, the “Global Rating Scale” [21], an online assessment tool, has focused UK endoscopy to provide high-quality patient-centered care. Whilst this biannual census provides incentive to improve services, it does not capture and address day-to-day patient safety issues. There is acknowledgement from the profession that broader recognition and documentation of endoscopic AEs is important: The American Society of Gastrointestinal Endoscopy (ASGE) developed a detailed lexicon for considering AEs in endoscopy [22], although there are practical challenges to reliably using this in practice. Nevertheless, such measures represent a shift toward accurate, transparent AE data that not only clarify the scale of the problem but can also facilitate an understanding of the etiology of error in endoscopy.

It is within this context of safety and quality in healthcare that endoscopy practice should be scrutinized. Furthermore, with the expansion in bowel cancer screening programs, increasing numbers of asymptomatic individuals will undergo an endoscopic procedure. Advances in endoscopic techniques enable more complex therapy in potentially older patients with more comorbidities, with all the inherent risks. To further improve quality and safety in endoscopy, a structured analysis of current safety issues is required.

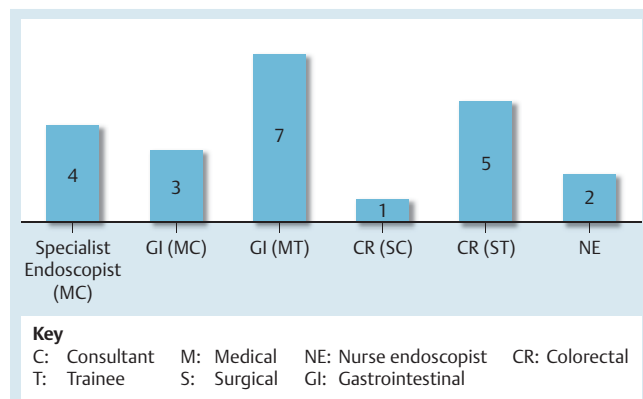
## Patients and methods

This was a prospective observational study of patient safety incidents in a single secondary/tertiary endoscopy referral center in the UK. Ethical approval for the study was obtained (NRES Committee London, Reference 08/H0719/54) and informed consent to observe each procedure was obtained from the patient and the endoscopist. Patients undergoing lower and upper gastrointestinal endoscopic examinations were included and cases were both diagnostic and therapeutic. Endoscopists performing the procedures were trainees and consultants and included medical gastroenterologists, colorectal surgeons and independent endoscopy nurse practitioners<sup>1</sup>.

<sup>1</sup> Endoscopy nurse practitioners are trained, assessed and monitor their Key Performance Indicators (KPIs) in the same manner as medical and surgical endoscopists in the UK through the Joint Advisory Group (JAG) for Endoscopy.



► Fig. 1 Endoscopy lists by specialty.



► Fig. 2 Endoscopist specialty and expertise.

Patient safety incidents (PSIs) were defined as any event during a procedure that had the potential to, or directly adversely affected patient care: PSIs with and without immediate consequences were included. Specifically, PSIs were defined [23] as near misses<sup>2</sup>, recognized procedural complications<sup>3</sup>, AEs<sup>4</sup> and “never events” according to the UK Department of Health’s classification at the time of the study [24]. “Never events” are a subset of serious incidents (e.g. patient misidentification) that are wholly preventable if established national guidance is implemented [8].

PSIs were recorded on a structured proforma by a gastroenterologist trained in skills and safety observational technique while the patient was in the endoscopy unit across pre-procedure, intra-procedure and post-procedure phases of care. Pro-

<sup>2</sup> Near Miss: Any event that could have had an adverse patient consequence but did not and was indistinguishable from a complete full-blown AE in all but outcome.

<sup>3</sup> Complication: Adapted from Clavien Dindo Classification for Surgery: Defined as any significant deviation from the normal postoperative course that may or may not require intervention.

<sup>4</sup> Adverse Event: Unintended patient injury caused by medical management (rather than the underlying disease) resulting in measurable disability, prolonged hospitalisation or both.

cedures were observed from within the endoscopy room in real time. To cross-validate the accuracy of the observational data, the medical record, nursing notes and endoscopy reports were also examined for recorded evidence of any PSIs. This methodology has been shown to enhance sensitivity of PSI detection [25] and was based on similar methods undertaken in surgery [26]. All recorded PSIs were subsequently submitted to an expert panel for review and consensus-based categorization of their nature and severity. The panel consisted of 2 expert endoscopists (STG and AH) and a patient safety expert (NS). The panel rated each PSI according to severity: minor, intermediate and severe defined by the actual or potential impact to the patient and adherence to established best practice.

## Results

One hundred forty procedures, 92 diagnostic and 48 therapeutic, were analyzed in a 4-month period in 2011 over 37 endoscopy lists by experienced (n = 25) and trainee operators (n = 12). These endoscopy lists or sessions were conducted by 22 different endoscopists of medical, surgical and nursing backgrounds (► Fig. 1 and ► Fig. 2). Therapeutic procedures consisted of polypectomy, endoscopic mucosal resection (EMR), endoscopic submucosal dissection (ESD), esophageal variceal ligation, common bile duct (CBD) stone clearance and biliary stent insertion during endoscopic retrograde cholangiography (ERCP).

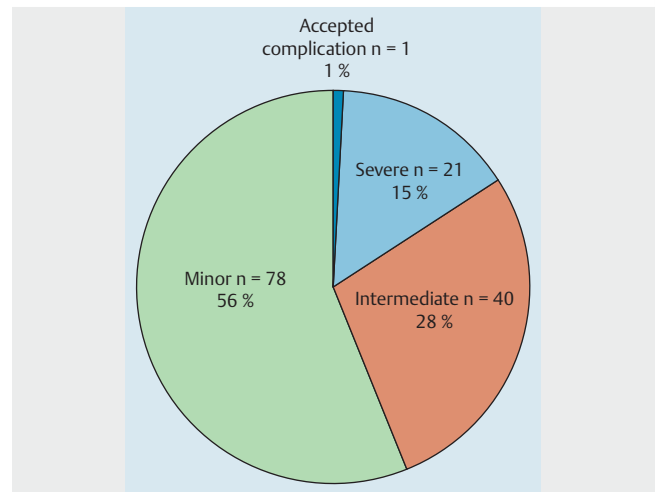
A total of 140 PSIs were identified (median 1 per procedure, range 0–7). Fifty-four (39%) PSIs were recorded within the diagnostic cases and 86 (61%) within the therapeutic cases. All therapeutic cases had at least 1 PSI. Five out of the 31 lists observed had 0 PSIs, which comprised 13 diagnostic procedures in total. Four out of 5 of these lists were performed by endoscopists who were consultants and the fifth was a senior endoscopy trainee.

Of the 140 PSIs, 21 (15%) PSIs were rated as severe and 12 (9%) had the potential to be “never events.” Forty (28%) PSIs were rated as intermediate and 78 (56%) as minor (► Fig. 3). One PSI was an anticipated procedural complication (post-polypectomy hemorrhage) requiring a repeat colonoscopy under general anesthetic with a successful clinical outcome and was not classified within this system.

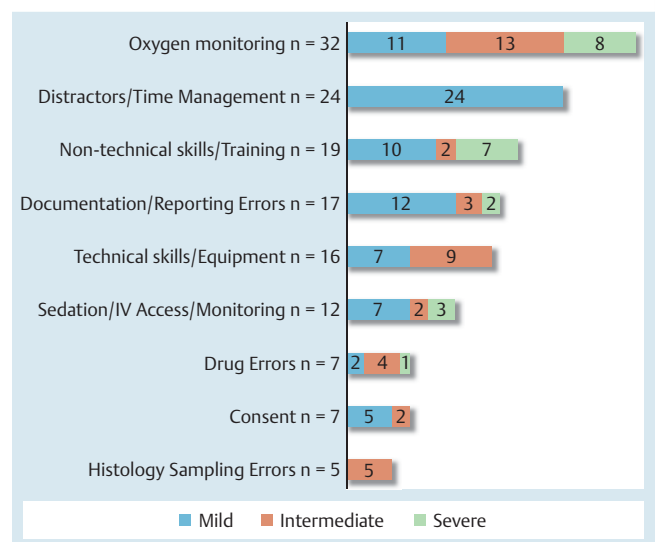
PSIs fell into 1 of 9 major categories:

1. Oxygen monitoring
2. Distractors and time management
3. Non-technical skills<sup>5</sup> [27] and training
4. Documentation and reporting errors
5. Technical skills and equipment
6. Sedation, intravenous (IV) access and monitoring
7. Drug errors
8. Consent
9. Histology and sampling errors.

<sup>5</sup> Non-Technical Skills are defined as the cognitive, social and personal resource skills that complement technical skills and contribute to safe and efficient task performance. These have been defined for endoscopy and include communication and teamwork, situation awareness, judgement and decision-making and leadership skills.



► Fig. 3 Patient safety Incidents categorized by severity.



► Fig. 4 Patient safety incident categorization by theme and severity.

The frequency and severity of PSIs within these categories is summarized in ► Fig. 4. ► Table 1 illustrates the severe PSIs observed and those that could constitute a never event. We found that severe PSIs were associated with other minor PSIs within the patient pathway, in a manner consistent with the systems view of iatrogenic errors (► Fig. 5).

Examples of intermediate PSIs included a sedated patient on a trolley with the side rails down, excess sedation<sup>6</sup> in an elderly patient with no reversal agent administered, and omission of administered IV sedatives in endoscopy report documentation.

<sup>6</sup> Defined according to BSG guidance of maintaining verbal contact with sedated patient throughout the period of conscious sedation. <http://www.bsg.org.uk/clinical-guidelines/endoscopy/guidelines-on-safety-and-sedation-during-endoscopic-procedures.html>

► **Table 1** Severe PSIs observed.

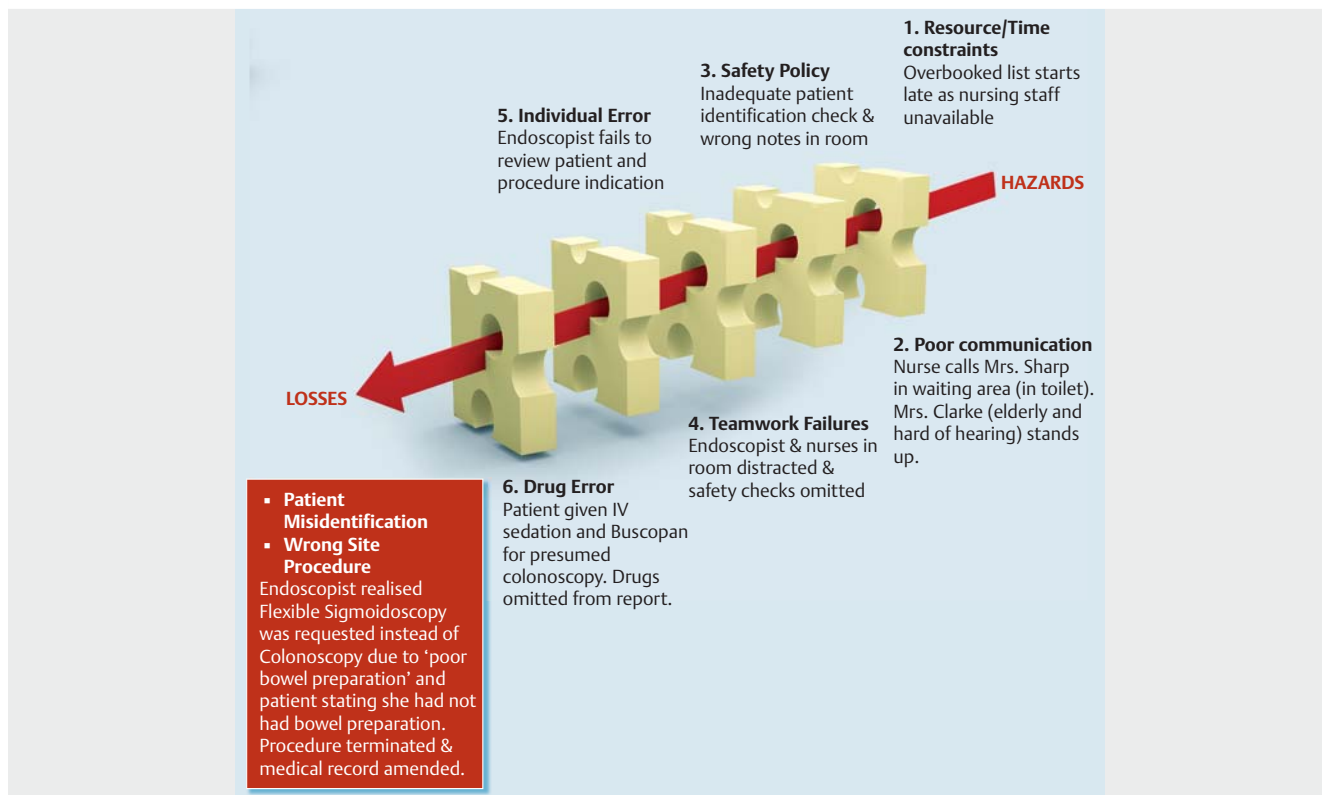
PSI Detail	Severity of PSI*	Never Event Y/N	Frequency
Patient misidentification resulting in incorrect procedure	3	Y	1
Sedation with no oxygen	3	Y	2
Sedation with no oxygen saturation monitor	3	Y	6
Sedated patient in corridor unmonitored	3	Y	2
Recovery in corridor unattended and prolonged as waiting for porter to transfer to ward. (No dedicated recovery and nurses in procedure room changing kit)	3	Y	1
Wrong drug administered – additional midazolam instead of pethidine	3	N	1
Wrong patient details on endoscopy report (similar surnames)	3	N	1
Wrong details on patient report (incorrect patient details) picked up on ward	3	N	1
Inadequate supervision of trainee (supervisor largely absent due to dual commitments, present for 1 case, distracted, trainee out of depth)	3	N	4
Procedure performed by a trainee required a Consultant	3	N	2
Post-polypectomy hemorrhage requiring re-scope under GA and an overnight admission	**	N	1

Total Procedures n = 140.

Total PSIs n = 140.

\* PSI Severity rating = Mild/Moderate/Severe based upon the actual or potential impact to the patient and adherence to established guidance.

\*\* This PSI was not categorized within this scoring system, as it was a recognized complication of the procedure with a good clinical outcome.



► **Fig. 5** Swiss cheese model illustrating the coalition of minor errors leading to significant patient safety incidents in 1 observed case.

Minor PSIs included a nurse assistant not suitably trained in polypectomy assisting in a complex high-risk case, the endoscopist asking for “usual diathermy settings” as unfamiliar with equipment and the endoscopy report stating procedure performed by consultant (absent) instead of the trainee.

## Discussion

To the best of our knowledge, this is the first study to use standardized methodology to prospectively evaluate within the gastrointestinal endoscopy suite. We found numerous instances of patient safety incidents. These constituted individual error, suboptimal team performance, and task-related problems. Our findings reinforce the need to adopt a systems approach when dissecting the causes and consequences of error. Also it should be noted that policies and protocols to prevent many of the observed PSIs were already in place but not necessarily adhered to. For example unit protocols for administering and monitoring sedation safely follow the British Society of Gastroenterology (BSG) guidance [28], but there was variation in sedation practices between endoscopists. Evidence-based protocols are a necessary first step but are likely to need reinforcement via teamwork and educational interventions.

The majority of PSIs recorded in this study were minor errors and often there were no immediate consequences. However, given that major errors frequently arise from a series of minor errors (an association we also observed here) minor problems are important to address for error prevention. These results are in keeping with studies on medical error in other specialities [26] whereby identifying latent failures in otherwise successful procedures enhances risk reduction. In addition, by preventing minor PSIs, expert teams are able to focus their time and attention on more significant issues such as technical performance, team leadership, and managing unexpected complications.

This study shows that PSIs occur across medical, surgical, and nursing specialities as well as during procedures performed by experts and trainees. Targeted training therefore needs to encompass all endoscopists to improve quality and patient safety. Considering the frequency of PSIs across themes, oxygen-monitoring errors occurred most frequently with a similar proportion of mild, intermediate and severe PSIs within this group. There were no acute hypoxic events related to these PSIs, but this category had the highest number of severe PSIs, underscoring that basic monitoring of oxygen saturations remains an under-utilized safety opportunity with further measures required to ensure adherence to established guidance on safe sedation and oxygen monitoring [29]. Sedation practices and guidance vary internationally with conscious and deep sedation options for certain patients and procedures [30], and sedation administration and monitoring by nurses, endoscopists or dedicated anesthetists. Anesthetic support would enhance sedation safety, but because it is not universally available, sedation selection, administration, titration, and monitoring are key safety issues for the endoscopist to be aware of and to consciously check. Similarly, the importance of monitoring the patient's consciousness level and vital signs even in the absence of

any sedation is prudent given the increasingly aging and comorbid population undergoing endoscopy.

PSIs related to non-technical skills were the next most prevalent group, followed by distractors and time management-related PSIs. Endoscopy non-technical skills training, although feasible [31] and considered important [32], is not yet explicitly formalized within existing training programs, accreditation processes or quality assurance measures. This is increasingly recognized as an important component of high-quality practice within screening colonoscopy, for example, [33] and would be a mechanism to address PSIs related to poor non-technical skills and teamwork.

Considering the severe errors, 12/21 met the “never events” criteria at the time. These included patient misidentification and wrong procedure (colonoscopy instead of flexible sigmoidoscopy) both occurring in a single patient. There was no significant harm to the patient and critics will state that the patient had the left side of the colon imaged as intended, therefore, it was not a “wrong procedure.” However, these errors highlight the multiple systems failures in checking essential, critical patient information as a significant problem. This PSI would be perceived to be more consequential if a percutaneous endoscopic gastrostomy (PEG) had been inserted instead of an esophago-gastro duodenoscopy (OGD), for example, yet the systemic latent failures whereby both these errors occur is the same.

It is accepted in the literature that the focus for AEs should supersede that of simply “reporting” to “understanding” the multifaceted reasons *why* an error occurred, ensuring accountability and addressing how future error may be prevented. In line with international recommendations [34], identification of error was used primarily to construct local solutions to patient safety concerns. Our study findings were fed back to the entire unit where the observations took place, and precipitated several actions to ensure that lessons were learned. Clearly optimizing patient management is key and more likely to occur when the PSI is considered to be severe or to require further corrective action. Additional measures included trainee debriefing by the clinical lead for endoscopy following a difficult list, introduction of an endoscopy safety checklist [35] to ensure essential baseline checks are re-confirmed by the team in the room undertaking the procedure, and adoption of error analysis tools such as the London Protocol [36] to educate multi-disciplinary gastroenterology teams more widely through governance meetings.

Limitations of this study include no long-term follow up data on patient outcomes. Similarly, it is difficult to demonstrate causality between PSIs and negative patient outcomes due to a number of confounding factors. This study was a single-center experience, which raises questions about the generalizability of the results. Lastly, the Hawthorne effect [37] may actually have reduced errors, as endoscopy teams may have been more careful knowing that they were being observed.

## Conclusion

This study is the first attempt, to our knowledge, to prospectively identify and analyze a broad range of patient safety incidents across gastrointestinal endoscopic procedures. While many errors were without immediate serious consequence, they represent latent failures and thus provide a golden opportunity to intervene proactively. By documenting, understanding, responding to and avoiding endoscopy error we have an opportunity to further improve endoscopy practice and believe this should be incorporated into existing quality assurance mechanisms for individual endoscopists and endoscopy units. Further work will address the question as to whether patient safety incidents in endoscopy can be reduced by implementing an endoscopy safety checklist. The long-term goal should focus on accurate, relevant and transparent endoscopy patient safety incident reporting at an individual, unit and national level.

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## Competing interests

NS is the director of London Safety and Training Solutions Ltd, which provides safety and team training and advisory services on a consultancy basis.

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