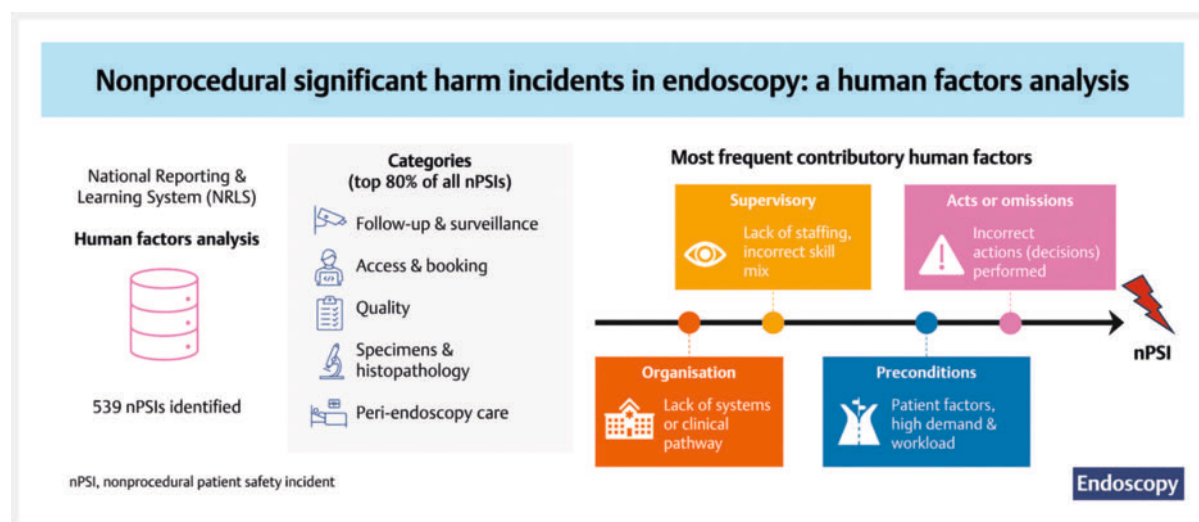# Patient safety incidents in endoscopy: a human factors analysis of nonprocedural significant harm incidents from the National Reporting and Learning System (NRLS)

GRAPHICAL ABSTRACT

Nonprocedural significant harm incidents in endoscopy: a human factors analysis

National Reporting & Learning System (NRLS)

Human factors analysis

539 nPSIs identified

Categories
(top 80% of all nPSIs)
- Follow-up & surveillance
- Access & booking
- Quality
- Specimens & histopathology
- Peri-endoscopy care

Most frequent contributory human factors

Supervisory — Lack of staffing, incorrect skill mix

Acts or omissions — Incorrect actions (decisions) performed

Organisation — Lack of systems or clinical pathway

Preconditions — Patient factors, high demand & workload

nPSI

nPSI, nonprocedural patient safety incident

Endoscopy

Authors

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ABSTRACT

Background Despite advances in understanding and reducing the risk of endoscopic procedures, there is little consideration of the safety of the wider endoscopy service. Patient safety incidents (PSIs) still occur. We sought to identify nonprocedural PSIs (nPSIs) and their causative factors from a human factors perspective and generate ideas for safety improvement.

Methods Endoscopy-specific PSI reports were extracted from the National Reporting and Learning System (NRLS). A retrospective, cross-sectional human factors analysis of data was performed. Two independent researchers coded data using a hybrid thematic analysis approach. The Human Factors Analysis and Classification System (HFACS) was used to code contributory factors. Analysis informed creation of driver diagrams and key recommendations for safety improvement in endoscopy.

Results From 2017 to 2019, 1181 endoscopy-specific PSIs of significant harm were reported across England and Wales, with 539 (45.6%) being nPSIs. Five categories accounted for over 80% of all incidents, with "follow-up and surveillance" being the largest (23.4% of all nPSIs). From the free-text incident reports, 487 human factors codes were identified. Decision-based errors were the most common act prior to PSI occurrence. Other frequent preconditions to incidents were focused on environmental factors, particularly overwhelmed resources, patient factors, and ineffective team communication. Lack of staffing, standard operating procedures, effective systems, and clinical pathways were also contributory. Seven key recommendations for improving safety have been made in response to our findings.

Conclusions This was the first national-level human factors analysis of endoscopy-specific PSIs. This work will inform safety improvement strategies and should empower individual services to review their approach to safety.

Introduction

Gastrointestinal endoscopy is generally considered safe. In recent decades, procedural safety has advanced, and measures have become embedded into quality assurance. Despite this progress, patient safety incidents (PSIs) still occur. With increasingly complex and more therapeutic procedures, safety remains paramount.

Individual services may collect and review safety data in the form of adverse events (AEs) as per auditable performance measures [1, 2]. There is a significant amount of high quality literature that highlights the breadth of AEs in endoscopy [3, 4, 5]. Given that endoscopic procedures require many factors across the patient journey to run safely, there has been surprisingly little investigation into the wider endoscopy service that delivers these procedures. Only a handful of studies have looked at this area in more detail, investigating errors and PSIs across endoscopy services [6, 7, 8]. These studies highlight the broader and deeper understanding of safety that comes with PSI analysis, but are limited by single-unit design and narrow scope.

PSIs refer to "any unintended or unexpected incident which could have, or did, lead to harm for one or more patients receiving healthcare" [9]. Incident analysis is conducted to try and understand the factors that contribute to an incident and identify learning that can be shared in order to prevent future occurrences. Human factors (the environmental, organizational, and human characteristics that influence performance) can be integrated into incident analysis to improve understanding of the whole system [10]. Indeed, a human factors approach can help us to understand the interaction of people, tools, tasks, and environment that form an endoscopy service. Frameworks, such as the Human Factors Analysis and Classification system (HFACS), have been developed and validated to identify causal human factors related to incidents [11]. This approach has been useful in other interventional specialties, such as surgery [12].

All endoscopy services will have a framework for incident analysis, but the degree to which a human factors approach is used is unknown. To our knowledge, there are no published data around PSIs at the national level. This study's goal was to use a human factors approach to learn more from national-level PSIs in endoscopy. This is an objective highlighted within the Joint Advisory Group on gastrointestinal endoscopy (JAG) safety strategy [13]. The aims of this study were threefold: (i) to characterize nonprocedural PSIs (nPSIs) in the wider endoscopy service contributing to significant harm; (ii) to identify contributory human factors; (iii) to identify goals for safety improvement.

Methods

Study design

This study followed a cross-sectional qualitative design, informed by previous studies across other healthcare areas [14, 15]. A hybrid thematic analysis approach was used alongside elements of exploratory data analysis. Methods are broken down into coding, summarizing, and mapping, with the elements of each described below.

Data source and extract

The National Reporting and Learning System (NRLS) is a database that holds records of all reported safety incidents in England and Wales. Records are generated when any healthcare professional logs an incident through an electronic incident reporting system. In the pre-pandemic era, over 1 million incidents were reported per year.

A data-sharing agreement was set up between JAG and NHS Improvement. Data extraction from the NRLS was based on ca-

tegorical and free-text searches of terms related to endoscopy (**Table 1s**, see online-only Supplementary material). Only events that were NRLS-graded "significant harm" (moderate and severe harm, and death) were included. Each incident within the data extract was reviewed to extract endoscopy-specific incidents and remove duplicates.

Coding

Data derived from the NRLS is predominantly in free-text format. These data were coded to identify primary incidents, contributory factors, and outcomes. Initially codes were developed inductively (developing codes directly from the data), guided by the "nine rules of the recursive model of incident analysis" [16]. Following this, several a priori coding frameworks were applied to initial codes to structure them more appropriately, so-called "deductive" coding. Where codes did not fit into an a priori coding framework, they were then coded inductively. This combination of inductive and deductive coding is known as "hybrid thematic analysis."

Incidents that did not fit into either the lexicon for endoscopic AEs [17] or the NHS "never events" list [18] were coded inductively as nPSIs. Contributory factors were coded using HFACS, which has a list of 219 base-level codes, known as "nanocodes," across its four levels [19]. A coding hierarchy is present where nanocodes have parent subcodes and overarching codes at each level of HFACS. These levels are: (i) acts or omissions; (ii) preconditions and local factors; (iii) supervision and local management; and (iv) organizational influences (**Fig. 1s**).

Data quality

When coding contributory factor data, it was apparent that data quality from the extract was varied. The quality of data for each incident was assessed by whether there was enough data to make assumptions about contributory factors. If an incident was categorized as "insufficient," no contributory factors were coded.

Coding reliability

Two members of the research team with backgrounds in incident analysis and experience in qualitative research methods performed coding (S.R., M.M.). The primary coder (S.R.) reviewed all data, and the second coder (M.M.) reviewed a random 10% selection to ensure reliability of the analysis. Interrater reliability was calculated using kappa statistics [20]. Any disagreements in coding were resolved by a senior clinician (S.T.G.). Notes were made alongside the coding exercise to help contextualize thoughts and ideas, and help with the subsequent summarizing and mapping processes.

Summarizing

A Pareto plot was created for primary incident categories identified in the coding process. Graphical representation of data allowed us to identify the key categories to explore.

Where multiple codes with similar concepts were identified, they were grouped under overarching themes. For each incident type, a summary of the relevant HFACS codes was created and reviewed alongside accompanying incident text and notes.

From this, broad contributory factor themes were generated relevant to each incident type. For this analysis, only contributory factors that related to the top 80% of all incidents were highlighted as it was felt that there were insufficient data within the bottom 20% to create meaningful conclusions.

Mapping

Driver diagrams were created based on the major nPSI categories to help identify areas to target with specific interventions. Contributory factor themes for each incident category were amalgamated and mapped onto driver diagrams. Information obtained from these driver diagrams was used to create exemplar interventions, which represent examples of specific interventions that could help prevent incidents occurring. Where possible, interventions were mapped to existing endoscopy quality improvement initiatives, including the JAG Global Rating Scale (GRS) [1], JAG underperformance guidance [21], the Getting It Right First Time (GIRFT) Gastroenterology report [22], and the British Society of Gastroenterology Endoscopy Quality Improvement Project (EQIP) [23]. This process was supported by regular review by senior clinicians with backgrounds in endoscopy quality assurance and training (C.H., S.T.G.).

Finally, information derived from all driver diagrams was collated to develop a set of key enablers: these can be considered as essential improvements that could be made to potentially improve safety in endoscopy.

Data analysis was supported by Microsoft Excel v16.57 (Redmond, Washington, USA) and NVIVO v12 (QSR International, Doncaster, Victoria, Australia).

Ethics statement

NRLS reports are screened to remove all identifiable data prior to dissemination to research groups. No formal ethical approval was required for this study. There was no patient involvement. The study protocol was reviewed by NHS Improvement as part of the data-sharing agreement (ref. 5215).
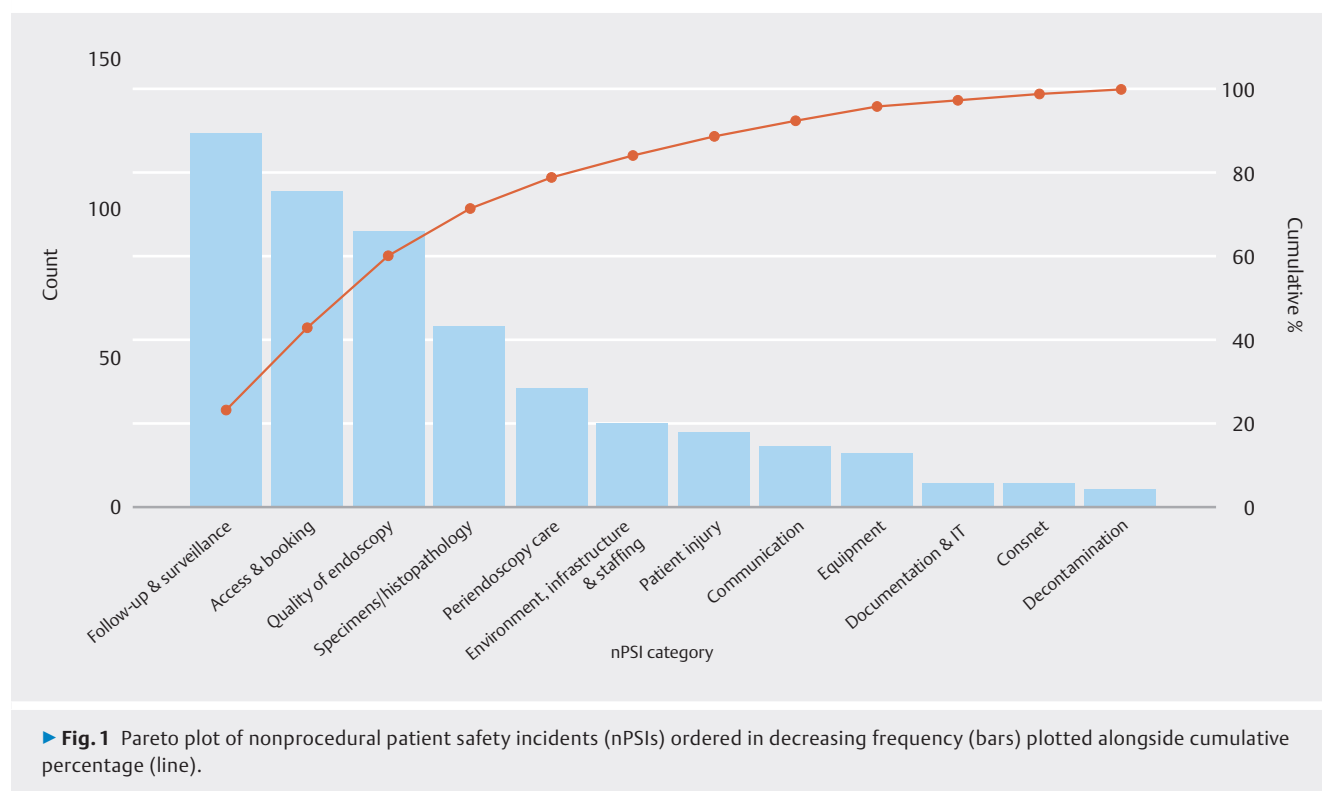
Results

Overview

A total of 2305 incidents fulfilled the search criteria. Following review and the discarding of nonendoscopy incidents and duplicates, 1181 endoscopy-related incidents were identified and analyzed. There were 627 procedure-related PSIs (53.1%), 539 nPSIs (45.6%), and 16 never events (0.01%; 1 never event was also classified within another category). In terms of reported harm for all incidents, 72.0% were classed as moderate harm, 15.6% as severe harm, and 12.4% were deaths. A breakdown of incidents by age range can be found in **Fig. 2s**. Intercoder reliability was substantial, with a kappa of 0.77.

PSI characterization
Incident categories

There were 12 overarching nPSI categories (▶ **Fig. 1**).

Review of the Pareto plot identified that the top 80% of incidents fell within the following categories: (i) follow-up and sur-

▶ **Fig. 1** Pareto plot of nonprocedural patient safety incidents (nPSIs) ordered in decreasing frequency (bars) plotted alongside cumulative percentage (line).

veillance; (ii) access and booking; (iii) quality of endoscopy; (iv) specimens and histopathology; and (v) peri-endoscopy care. Out of 539 incidents, 446 were attributed to these five incident categories. ▶ **Table 1** shows a breakdown of each category in more detail.

The majority of "follow-up and surveillance" incidents were related to failures or delays in following up a significant finding that required surveillance or delays in scheduled surveillance. "Access and booking" incidents are where patients cannot access endoscopy for any reason. The most frequent incidents were related to delayed access or no access to outpatient procedures. Most "quality of endoscopy" incidents reflected failure or delay in interpreting a significant finding. Similarly, failure or delay in acting on results was the most prevalent subcategory in the "specimens and histopathology" category. The most common "peri-endoscopy care" incidents were related to inadequate management of a pre-existing condition.

Outcomes

In terms of the reported degree of harm, 71.2% of incidents were classed as moderate harm, 24.1% as severe, and 4.5% as deaths; 13.0% of outcomes (70/539) could not be classified as there were insufficient data. ▶ **Table 2** shows the breakdown of outcomes by category and subcategory, with the percentage of contribution to the total.

Contributory factors

There were 277 incidents (51.4%) that had sufficient data to code contributory factors, from which 487 HFACS nanocodes were generated. Nanocode distribution across the levels was

as follows: level 1, 16.7%; level 2, 46.7%; level 3, 16.7%; and level 4, 20.0%.

At HFACS level 1, errors were the most commonly coded "act or omission" (71.5%), among which "decision-based errors" were most frequent (72.5% of such errors). The most common of these errors (in decreasing frequency) were "risks not acted on," "incorrect choice or task," and "risks not identified." At HFACS level 2, environmental factors (57.0%) and communication and co-ordination factors (38.2%) were the predominant preconditions and local factors. The top environmental factors were overwhelmed resources (27.1% of HFACS level 2 nanocodes) and poor patient record usability (4.5%). The major communication and co-ordination factors were ineffective information transfer within or between teams (27.1%) and ineffective patient or carer communication (4.0%). Operational planning and delivery issues (76.5.%) and organizational process issues (80.0%) were the most common categories at HFACS levels 3 and 4, respectively.

Thematic analysis, informed by HFACS nanocodes and incident notes, was performed for each category. ▶ **Table 3** shows themes from subcategories that were merged within each overarching incident category and split by HFACS level.

Broadly speaking, themes around "acts and omissions" (level 1 HFACS) focused on staff not acting on results, performing the incorrect actions, and failing to recognize risk. Preconditions (level 2) included patient factors, high demand and workload, miscommunication between team members, and inefficiencies in a variety of systems. Supervisory (level 3) themes included lack of staffing, incorrect skill mix among staff, and lack of

▶ **Table 1** Top five nonprocedural patient safety incident (nPSI) categories and their subcategories. Percentages are displayed in order of decreasing frequency for categories and subcategories.

Category	Subcategory	n (%)
Follow-up and surveillance n = 126 (23.4%)	Failure/delay to follow up significant finding requiring surveillance	48 (38.1%)
	Delay in scheduled surveillance	34 (27.0%)
	Failure/delay in booking follow-up therapeutic procedure	15 (11.9%)
	Failure/delay in arranging onward investigations or referrals from endoscopy	15 (11.9%)
	Failure/delay in removing endoscopically inserted device	14 (11.1%)
Access and booking n = 106 (19.7%)	Delayed/no access to outpatient procedure	52 (49.1%)
	Delayed/no access to emergency procedure	20 (18.9%)
	Delayed/no access to inpatient procedure	20 (18.9%)
	Delayed/no access to general anesthesia/propofol procedure	7 (6.6%)
	Inadequate/poor list management	4 (3.8%)
	Incorrect/inappropriate booking	3 (2.8%)
Quality of endoscopy n = 93 (17.3%)	Failure/delay to interpret significant finding	52 (55.9%)
	Inadequate/incomplete therapy or procedure	12 (12.9%)
	Failure to follow procedural protocols/guidelines	11 (11.8%)
	Inappropriate/unnecessary/wrong therapy or procedure	9 (9.7%)
	Failure/delay to act on significant finding	9 (9.7%)
Specimens and histopathology n = 61 (11.3%)	Failure/delay to act on	29 (47.5%)
	Missing	16 (26.2%)
	Failure/delay in testing or reporting	9 (14.8%)
	Incorrect/inappropriate handling including labelling errors	7 (11.5%)
Peri-endoscopy care n = 40 (7.4%)	Inadequate management of pre-existing condition	11 (27.5%)
	Delay/difficulty in obtaining clinical assistance	9 (22.5%)
	Delays in management/care	7 (17.5%)
	Inadequate/inappropriate preparation	6 (15.0%)
	Intravenous access/line error or complication	4 (10.0%)
	Inadequate management of emergency	3 (7.5%)

standard operating procedures (SOPs). Organizational (level 4) themes focused on lack of systems or clinical pathway.

Goals for safety improvement

Driver diagrams

Themes were extracted and mapped onto driver diagrams. The five main nPSI categories were used to develop five primary aims, which related to:

- reducing follow-up and surveillance errors
- reducing access and booking errors
- reducing histopathology and sampling errors
- delivering better quality endoscopy
- improving peri-endoscopy care.

An example of a driver diagram is shown in ▶ **Fig. 2**. Exemplar interventions are also displayed. The remaining driver diagrams can be seen as **Figs. 3s–6s**.

Key enablers

Key enablers were developed from review of drivers and interventions across all five driver diagrams. These were: SOPs, electronic systems, communication, preassessment, training, performance and teamworking, demand and capacity, and workforce planning (**Table 2s**). Enablers represent key areas to address in improving safety from a whole system perspective.

Exemplar interventions within these seven areas can also be mapped against elements of the patient journey (▶ **Fig. 3**).

▶ **Table 2** Outcomes of nonprocedural adverse events at category and subcategory levels.

Category	Subcategory	n	% of total	% per category
Impact on clinical status	Development of cancer	102	19.1%	29.7%
	Clinical deterioration	27	5.1%	
	Development of medical complication	9	1.7%	
	Infection	9	1.7%	
	Admission to hospital	8	1.5%	
	Progression of lesion / disease	5	0.9%	
Impact on delivery of care	Delay to patient care	90	16.9%	24.1%
	Increased risk of harm to patient	18	3.4%	
	Patient injury	14	2.6%	
	Suboptimal care	5	0.9%	
	Impact on subsequent surgery	3	0.6%	
Delay in diagnosis	Delay in diagnosis of cancer	101	18.9%	20.0%
	Delay in diagnosis of other condition	7	1.3%	
Delayed or cancelled procedures	Repeat procedure	30	5.6%	7.8%
	Cancelled procedures	12	2.2%	
Death	Death	24	4.5%	4.5%
Unknown	Unknown	70	13.1%	13.0%
Other	Other	5	0.9%	0.9%

Discussion

To our knowledge, this is the first overview of national-level endoscopy-specific safety data incorporating a systems approach and human factors model. While there are important caveats, we have identified that nearly half of all reported endoscopy safety incidents that result in significant patient harm are not a direct result of the procedure. There appears to be a large burden of incidents that occur across the whole endoscopy patient journey, involving people and processes beyond the core endoscopy team.

In this study, we identified 12 distinct nPSI categories in endoscopy. Of these, five categories were related to over 80% of all incidents. Notably, "follow-up and surveillance" accounted for nearly a quarter of all nPSIs combined. Delays in care, development of cancer, and delays in diagnosis of cancer accounted for over half of all nPSI outcomes. Errors, defined as "unintentional behaviors," were the most common act prior to an incident occurring. Preconditions to errors occurring reflected patient complexity, poor global communication, and inefficient processes. Supervisory and local management factors were related to insufficient or ineffective staffing, lack of guidance or SOPs, or issues around equipment. Organizational factors reflected inefficient logistics, systems, and lack of defined clinical service or pathway.

A handful of studies have categorized PSIs in endoscopy outside of procedure-related events. Minoli et al. investigated PSIs through prospective reporting across nine endoscopy units in Italy [6]. They identified incidents across preoperative, operative, and postoperative phases, classed as "mistakes (with consequences)" or "near misses." The majority of PSIs (65%) fell into the preoperative phase, highlighting booking and communication errors as being significant. This somewhat reflects our findings where there was a skew towards incidents related to administration, booking, or follow-up. Our group has previously published on periprocedural PSIs in a prospective, direct observational single-center study, identifying 140 incidents across 140 procedures [7]. While this was a prospective observational study of procedures, we also identified incidents and factors related to the wider endoscopy service, for example overbooked lists and time delays.

Although informative, these studies may be difficult to generalize owing to their limited sample size and setting. The categories we have derived are from a much larger national cohort and therefore may provide an improved understanding of PSI burden within endoscopy.

Decision-based errors were the most frequent errors identified. In their human factors analysis of surgical never events, Thiels et al. identified 45% of errors were related to decisions, with "failure to understand" a common theme [24]. Similarly, we demonstrated that risks not being identified and inaction following acknowledgement of risk were the most common decision errors. Essentially, these errors relate to deficiencies of knowledge or experience. The development of clear, user-friendly protocols, behavioral nudges, and cognitive aids may

▶ **Table 3** Major themes across each nonprocedural adverse event category, defined by the Human Factors Analysis and Classification System (HFACS) level.

HFACS	Nonprocedural patient safety incident category				
	Follow-up and surveillance	**Access and booking**	**Quality of endoscopy**	**Specimens and histopathology**	**Peri-endoscopy care**
Level 1 Acts and omissions	Did not act on report (risk not acted upon) Poor documentation of plan following procedure No action after initial therapeutic procedure – policy/protocol not followed	Referrals not checked Incorrect action by booking team Booked onto incorrect lists No agreed escalation plan between teams	Misinterpretation of findings Incorrect diagnosis/ interpretation of findings Assumption of patient background/characteristics Protocols/guidance not followed for biopsies Extent of examination not communicated in report Substandard procedure and reporting Misinterpretation of report	Not logging specimens or loss of specimens in transit SOP not followed Deviance for established pathways for checking/sending histology	Wrong advice given Poor documentation Medication inappropriately stopped/ changed Local guidance not followed Incorrect use of line Incorrect clinical decisions
Level 2 Preconditions and local factors	Complex patients Lack of capacity/ service overwhelmed Poor communication between insourcing and endoscopy teams Multiple process steps for referrals and inefficient booking processes Poor validation processes – use of paper notes ineffective	Complex patients Lack of communication between endoscopy and ward/ineffective handover Poor communication between booking and clinical team Poor communication with patient Unable to contact OOH endoscopist/ service not accessible Booking system paper-based and prone to error High demand on service/lack of capacity Overbooked lists	Insourcing teams unaware of policies Poor communication with external teams Poor communication between MDT and endoscopy Poor communication with booking teams Lack of communication between referrer and endoscopy teams	Multiple biopsies per patient Multiple personnel involved in specimen transit Lack of communication between endoscopy and lab Staff unfamiliarity of histology pathways Unfamiliarity of tests required Backlog/high workload in histology department	Lack of preassessment Lack of handover – instructions not followed Lack of communication between teams Delay in medication/ drugs being given Complex patient
Level 3 Supervision and local management	Lack of staffing	Lack of appropriate skill mix Lack of staff to undertake procedures Lack of SOP for emergency endoscopy	Guidance in draft unavailable Concerns about key performance indicators not acted upon Lack of documented SOPs		Equipment availability issues
Level 4 Organizational influences	Lack of systems to track inter-trust procedures Lack of systems to check/audit actions	Communication failure between primary and secondary care Lack of pathway for cross-site access to endoscopy Lack of emergency service		Lack of clear systems for checking results Lack of systems to log and track	Lack of clinical service Lack of clinical pathway

SOP, standard operating procedure; OOH, out of hours; MDT, multidisciplinary team.
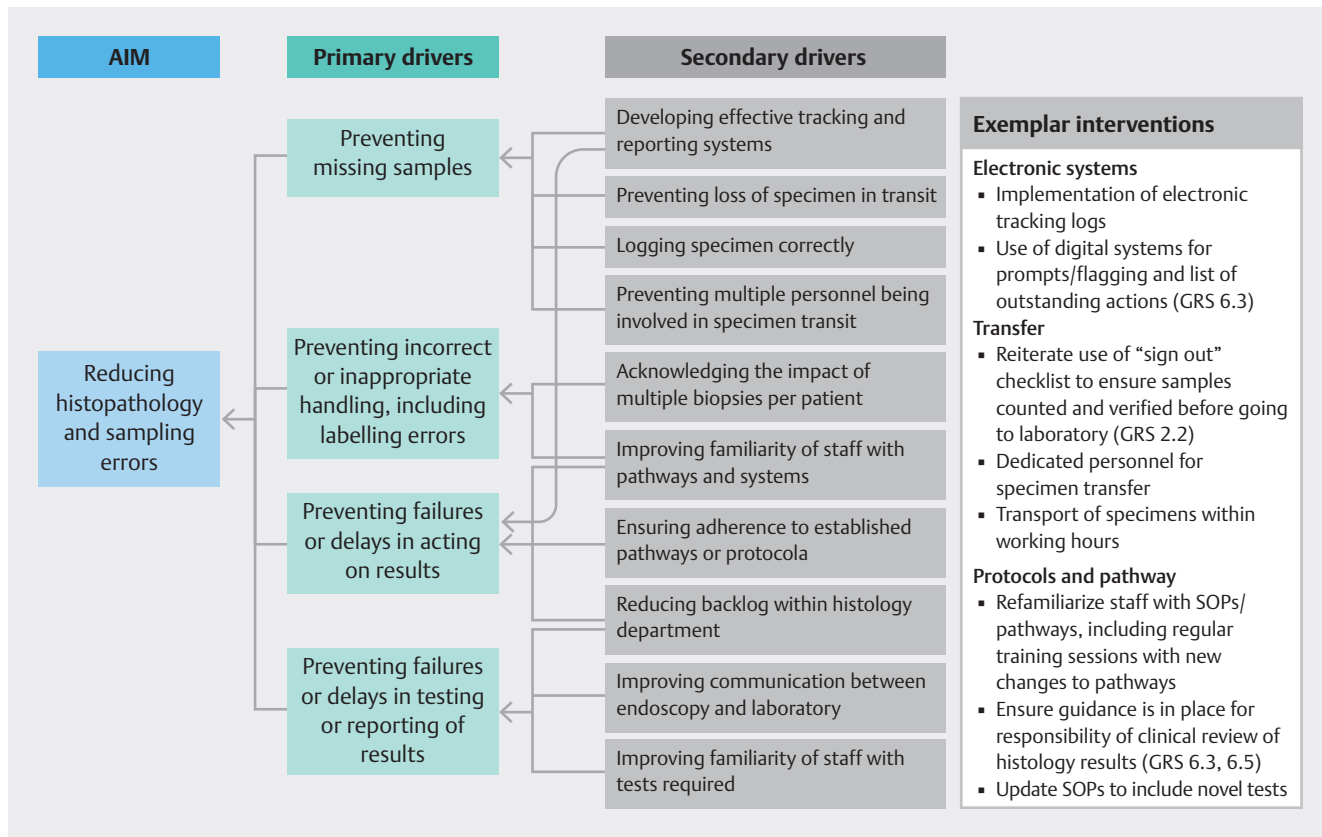
▶ **Fig. 2** Driver diagram for reducing histopathology and sampling errors. Primary and secondary drivers are derived from incident subcategories and contributory factor themes respectively. Exemplar interventions are listed on the righthand side. GRS, Global Rating Scale; SOP, standard operating procedure.
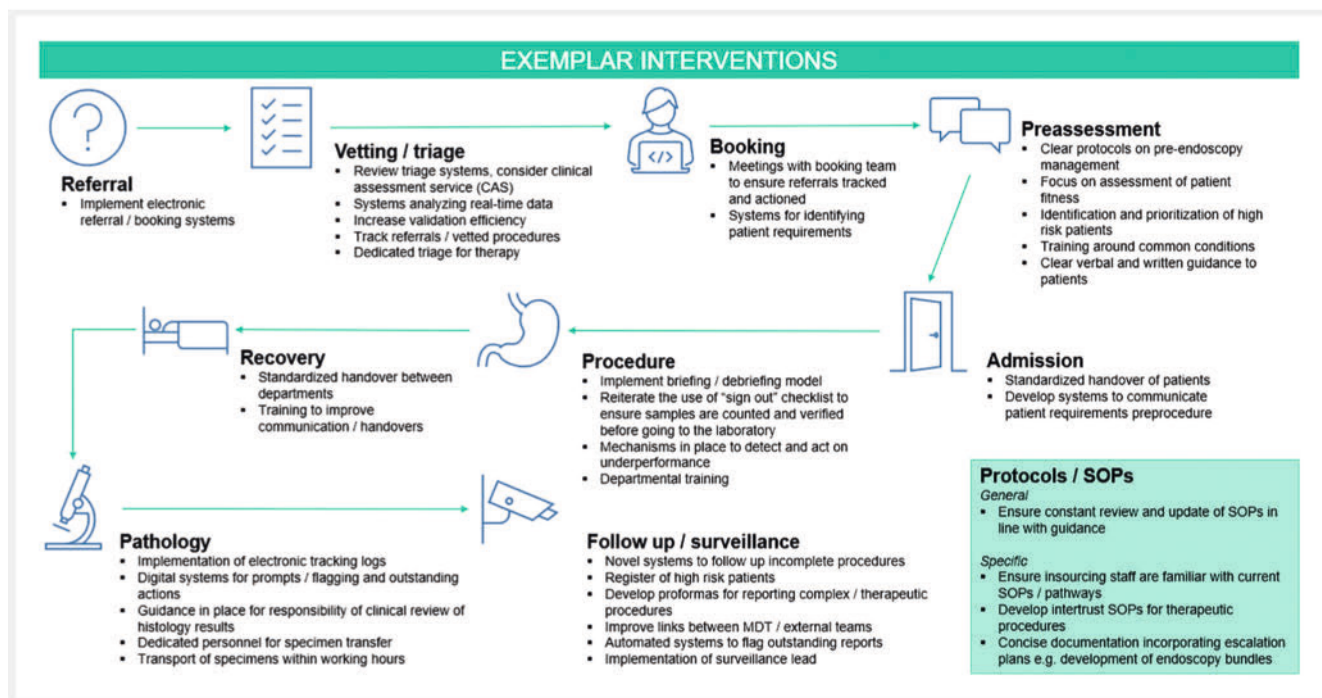
▶ **Fig. 3** Elements of the endoscopy patient journey with exemplar interventions, mapped from driver diagrams and key enablers. SOP, standard operating procedure.

help to reduce such errors [25]. Engagement with safety checklists and pre- and postprocedural debrief aids should be encouraged [26]. It is important to note that these interventions will only work when considered within the context of the wider system. Errors are a human trait and a result of system pressures.

Patient factors appear to be the most common contributory factors that are associated with hospital-level incidents across healthcare in general, with complexity, frailty, and age cited as significant factors [27]. Within endoscopy, the increasing comorbidity of our patients is something that is increasingly understood to contribute to PSIs and is often causative alongside the other factors we have identified [28]. Improving assessment and communication of risk is key to understanding and mitigating the impact of patient characteristics on safety. An example may be the use of preassessment, which forms an integral part of the patient's experience through endoscopy and manages complexity through clear management protocols and prioritization of high risk patients [29]. Counselling patients thoroughly and sometimes electing not to perform an intervention maybe the wisest decision.

There is an increasing burden on endoscopy services and we have identified how this, combined with the impact of inefficient systems and lack of organizational guidance, can impact on bookings and future follow-up or surveillance. Demand and capacity planning is an area we have highlighted to focus improvements on, backed by national guidance [22]. Our data precede the onset of the COVID-19 pandemic. In a way, the pandemic acted as a catalyst for services to review their vetting processes in order to streamline demand and improve their adherence with national guidance [30]. There should be a clear process of validating patients based on the most recent surveillance guidelines with systems in place to support this.

A key theme that arose was a lack of SOPs or clinical pathways. This appeared to be focused on newer therapeutic procedures and emergency endoscopy, with evidence of lack of up-to-date guidance. The most recent JAG GRS standards address this specifically, outlining the importance of core clinical protocols to manage pre-existing medical conditions and specific patient care [1]. A significant finding in our analysis was also the inaccessibility of existing SOPs and lack of familiarity with these among staff. Clearer communication with relevant permanent and occasional stakeholder groups around SOPs, as well as regular training, may help to familiarize all teams with a service's protocols.

Our analysis identified lack of staff and lack of appropriate skill mix as key contributory factors at the supervisory level. Workforce planning is a contentious subject and there is no single solution to recruitment and retention issues. Workplace culture may play a part in these issues. Factors such as status, certainty, autonomy, connectedness to others, and being treated fairly may contribute to improved workplace engagement and therefore retention [31]. These factors should be incorporated into any workforce planning strategies. Culture assessment tools may also be useful to gauge responses to implementation of any improvement measures. An open culture may also improve communication between endoscopy staff and management.

Team performance was a key contributory factor and an area addressed within our key enablers. Improving team dynamics and performance is a key factor in improving safety across much of the wider literature [32]. Specifically, development of nontechnical skills training may improve team performance and ultimately patient safety [33]. Briefing and debriefing models have also been developed to support processes around each endoscopy procedure or list [34]. There may be approaches to improving performance in specific team settings such as SACRED in advanced endoscopy [35].

Individual underperformance and training within teams has been clearly defined for independent endoscopists [21]; however, an area that needs further focus is the wider endoscopy team. Administrators, managers, decontamination staff, as well as endoscopy nurses and clinicians are all integral to safety across the patient pathway. Training should be extended to incorporate these team members.

A strength of our study was the use of the HFACS framework that enabled us to incorporate a systems view of incidents and highlight the main contributory factors. This approach also allowed us to define specific areas for improvement and was informed by similar studies in other healthcare domains. Coding with multiple researchers allowed a deeper interrogation of data, and inter-rater reliability was high. Our use of a national dataset allowed us to make generalizable conclusions.

It is however important to caveat our findings with acknowledgement of the limitations of our study. Analysis was based solely on incident reports, which were generated by staff entry and of variable length and quality. The content of reports may not fully reflect all the factors related to an incident, which might be apparent only with a thorough in-depth investigation. There was no ability to cross-reference reports because of their anonymized nature. We therefore had to use only those reports with enough quality data to make clear assumptions. Additionally, data were limited to significant harm events only and we might have gained a fuller understanding of system factors if nonsignificant harm events had been included. Lastly, only incidents that have been detected can be reported. A proportion of PSIs may go undetected and therefore the dataset may not be a true and full representation of all incidents.

We identified seven key enablers to create safer systems in endoscopy. These center on strengthening all parts of the endoscopy service. So how could these be used? At a local level, services could use key enablers alongside relevant driver diagrams to reflect on their own practices at individual, team, and organizational levels. There are various tools that can be used to support this, for example the PETT scan (part of the Systems Engineering Initiative for Patient Safety [SEIPS]), which involves considering the people, environment, tools, and tasks that make up a service [36]. This may involve engagement with human factors specialists and the incorporation of human factors models into incident investigation. There should be a shift from a top-down approach to understanding more of the day-to-day work of all endoscopy staff. This work-as-done concept roots any safety improvement measures in what actual

frontline staff do, rather than what is conceived by senior policymakers or managers. At a national level, our key enablers can inform ongoing communication to services, including service-wide training initiatives and safety lessons [37]. Future iterations of endoscopy service performance measures could consider embedding human factors principles as part of their safety domains.

In conclusion, in an era of increasing procedural complexity, we have identified key areas for safety improvement. Factors relate to all parts of the patient journey through endoscopy. Further work should aim to explore what endoscopy services do well to prevent safety incidents and how best to share this knowledge.

Conflict of Interest

H. Ashrafian is Chief Scientific Officer of Pre-emptive Medicine and Health Security at Flagship Pioneering. A. Darzi is Executive Chair of Pre-emptive Medicine and Health Security at Flagship Pioneering. S. Ravindran, M. Matharoo, M. Rutter, C. Healey, and S. Thomas-Gibson declare that they have no conflicts of interest.

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