An Observational Study of the Frequency, Severity, and Etiology of Failures in Postoperative Care After Major Elective General Surgery

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Objective: To investigate the nature of process failures in postoperative care, to assess their frequency and preventability, and to explore their relationship to adverse events.

Background: Adverse events are common and are frequently caused by failures in the process of care. These processes are often evaluated independently using clinical audit. There is little understanding of process failures in terms of their overall frequency, relative risk, and cumulative effect on the surgical patient.

Methods: Patients were observed daily from the first postoperative day until discharge by an independent surgeon. Field notes on the circumstances surrounding any nonroutine or atypical event were recorded. Field notes were assessed by 2 surgeons to identify failures in the process of care. Preventability, the degree of harm caused to the patient, and the underlying etiology of process failures were evaluated by 2 independent surgeons.

Results: Fifty patients undergoing major elective general surgery were observed for a total of 659 days of postoperative care. A total of 256 process failures were identified, of which 85% were preventable and 51% directly led to patient harm. Process failures occurred in all aspects of care, the most frequent being medication prescribing and administration, management of lines, tubes, and drains, and pain control interventions. Process failures accounted for 57% of all preventable adverse events. Communication failures and delays were the main etiologies, leading to 54% of process failures.

Conclusions: Process failures are common in postoperative care, are highly preventable, and frequently cause harm to patients. Interventions to prevent process failures will improve the reliability of surgical postoperative care and have the potential to reduce hospital stay.

Keywords: adverse event, observation, postoperative care, process assessment, process failure, surgery

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Surgeons are familiar with errors, omissions, and failures of various steps in the postoperative care pathway, despite the best efforts of the health care professionals involved.[1] These failures in the process of care frequently become part of the background against which surgeons work, particularly as there is often no direct harm to the patient.[2] Process failures do however occasionally cause serious harm, increased length of hospital stay, wasted resources, and worse outcomes for patients.[3–5] Such failures are more likely in complex environments where there are multiple processes carried out by large dispersed teams. For instance, direct observation of care has shown that more than 175 activities per day are performed on patients in intensive care and there are 1.7 errors per patient per day.[2] In addition to the large number of activities (or processes) performed, the number of people involved in this care has risen. The development of the surgical multidisciplinary team has greatly increased the amount of communication and synchronization required to avoid care failures and adverse events.[6,7]

Adverse events have a significant impact on health care systems, costing an estimated $17 billion per year in the United States alone.[8] Surgical inpatients are particularly at risk and at least 14% suffer an adverse event during their hospital stay.[4,5,9] Analysis of these events has demonstrated numerous etiologies, often as a result of systemic issues in the provision of care.[10] Efforts to reduce the frequency of adverse events have often focused on the events themselves but rarely on the failures in the process of care that underlie them.[11,12] This is important because a single adverse event may have multiple causes and because process failures do not always lead to adverse events. An optimal strategy to reduce harm would therefore be to minimize adverse events by focusing upon the process failures that act as key contributors. Individual care processes are often assessed using clinical audit, but there is little understanding of process failures in terms of their overall frequency, relative risk, and cumulative effect on the surgical patient. The purpose of this study was to investigate the frequency and nature of failures in the process of postoperative care for elective surgical patients. Secondary endpoints were the preventability and harm caused by process failures and their relationship to adverse events.

METHODS

Study Design

A prospective observational study of postoperative care was performed at a large, urban teaching hospital between November 2008 and August 2010. The study included any adult patient undergoing either open or laparoscopic major elective gastrointestinal surgery under the care of 1 of 4 surgeons. Two of these surgeons perform primarily upper gastrointestinal surgery and 2 specialize in colorectal surgery. The surgical unit has separate teams of doctors for upper and lower gastrointestinal patients, though there is some cross cover at junior levels and numerous common policies. Each team consists of 3 to 4 consultants (attendings), 3 to 4 registrars (senior residents), 2 to 3 senior house officers (junior residents), and 3 house officers (interns). The hospital has cancer specialist nurses for both upper and lower gastrointestinal cancer patients and specialist stoma nurses, an acute pain team, occupational therapy, and physiotherapy. All hospital facilities are shared equally and an enhanced recovery protocol is in place for all gastrointestinal surgical patients. Every patient

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in this study was discharged to their own home. All patients were nursed in the same gastrointestinal surgical ward and adjacent 4-bed high-dependency bay. Patients admitted directly to the intensive care unit after their surgery were excluded from the study. Those patients who returned to the ward or high-dependency area postoperatively and had a subsequent unplanned intensive care admission were followed throughout this time and until discharge. Planned intensive care admissions were excluded because the type and intensity of care available and the staff-to-patient ratios are inherently different from those available in a general surgical ward. For this exploratory study, patient recruitment was discontinued once preliminary analysis indicated that minimal new process failures were being uncovered. The study was approved as a service evaluation by the local research ethics committee (08/H0715/112).

Definitions

Several terms are used in the literature to describe untoward incidents in medical care. A "nonroutine event" is the broadest term used (Box 1). Nonroutine events include episodes in which medical management has been optimal, for example, deep vein thrombosis despite the use of appropriate thromboprophylaxis. The concept of nonroutine events has been adapted from the nuclear industry for use in the assessment of patient safety.[13,14] "Process failures" are a subset of nonroutine events and consist of those events in which an aspect of medical care was omitted, performed incorrectly, or was incomplete (Table 1). An "adverse event" (Box 1) is a more specific term and, according to a strict definition,[15] it is only present when a patient's length of stay in hospital is prolonged or he/she has an ongoing disability upon discharge. In this study, we wished to capture as wide a range of problematic events as possible. We therefore began by observing and collating all nonroutine events, before assessing whether or not a process failure had occurred and what impact this had on the patient.

Box 1. Definitions

Nonroutine event
Any event that is perceived by care providers or skilled observers to be unusual, out-of-the-ordinary, or atypical.[13,14]

Clinical processes
The activities that constitute health care—including diagnosis, treatment, rehabilitation, prevention, and patient education.[26]

Adverse event
An injury caused by medical management (rather than the disease process) that results in either a prolonged hospital stay or disability at discharge.[4]

TABLE 1. Examples of Coding Classification

Non-routine event without process failure
After a first dose of cyclizine antiemetic, a patient became confused and agitated. There was no previous history of cyclizine use and the patient recovered spontaneously.

Process failure with no harm but considered preventable
A patient's epidural was removed at 5 PM and thromboprophylaxis prescription (normally given at 6 PM) was delayed until 11 PM. Because of the unusual timing, this prescription was overlooked and the patient missed their thromboprophylaxis. No DVT or PE occurred.

Process failure with minor harm, not preventable
A patient's nasogastric tube was withdrawn 5 cm based on x-ray appearances, leading to profound retching and vomiting. The tube had to be removed and a new one placed.

Process failure and adverse event, preventable
A postoperative CT scan in an unwell patient was reported as normal. This report was subsequently amended as the CT showed an anastomotic leak; however, this information was not communicated to the surgical team, leading to a delay in treatment and increased length of stay.

DVT indicates deep vein thrombosis; PE, pulmonary embolism; CT, computerized tomography.

Phase 1—Observation

From the first postoperative day until discharge, the research team conducted daily observation of the patient's care that consisted of attending morning ward rounds, examining patient casenotes, medication charts, and vital sign observation charts, and conducting unstructured interviews with clinical staff. Observation was undertaken by 1 of 2 independent general surgical residents with research experience in patient safety (K.N., N.R.A.S.). Both the observers had worked in the surgical unit before the commencement of the study and so were familiar with the local policies and protocols. Observers were known to the surgical team but they had not worked with the unit's junior surgeons. Ethnographic field notes were used to collect data on any nonroutine event, whether leading to patient harm or not. The majority of these field notes related to events that had occurred in the preceding 24 hours. For these incidents, field notes reflected the content of the casenotes, charts, and discussion with the surgical team. A minority of nonroutine events were directly observed during the ward rounds attended. In these cases, the field notes reflected the researcher's own observations in addition to other sources. Field notes recorded the circumstances surrounding each nonroutine event, any precipitating factors, and the outcome for the patient. At this stage, the presence or absence of process failures and adverse events was not considered.

Phase 2—Data Analysis

Once data collection was complete, nonroutine event field notes were analyzed independently by 2 surgical residents. One coder had participated in the data collection (N.R.A.S.) and one was blinded to patient outcomes to minimize hindsight bias (A.M.A). Both coders had experience in surgical postoperative care and patient safety research. Nonroutine events were assessed for the presence of a process failure to exclude those events that were not a result of medical management (Table 1).

Process failures were then coded according to the degree of harm suffered by the patient and the incident's preventability. This coding was based on the methods employed by case-record review studies for similar incidents and events,[3–5] specifically the Quality in Australian Health Care Study[4] (Table 2). Coding for harm was adapted to differentiate adverse events, minor harm that did not meet

TABLE 2. Coding of Nonroutine Events and Interrater Reliability

Coding Category	Coding Variables	Interrater Reliability (Intraclass Correlation Coefficient)
Process failure	Present/absent	0.777, $P < 0.001$
Patient harm	No harm/minor harm/adverse event	0.654, $P < 0.001$
Preventability	1–6 Likert scale, ≥4 considered preventable	0.755, $P > 0.001$
Communication failure	Present/absent	0.557, $P < 0.001$
Delay	Present/absent	0.566, $P < 0.001$

the threshold for adverse events, and no harm. This differentiation was not included in case-record review studies as these studies had a lower sensitivity and a higher threshold for reporting harm. Process failures scoring 4 or more on a 6-point Likert scale for preventability were considered preventable (Table 2).[4] Finally, field notes were assessed for any communication failures or delays that led, directly or indirectly, to the process failure in question.

Interrater reliability for all domains was assessed using the intraclass correlation coefficient and a 2-way mixed, single measures model with absolute agreement[16] (Table 2). Discrepancies in coding were then resolved by consensus discussion between the raters. Statistical analyses were performed using IBM SPSS Statistics v19 (IBM Corporation, Armonk, NY).

RESULTS

We studied 50 patients undergoing elective major general surgery, which corresponded to the observation of 659 days of inpatient care (Table 3). This cohort represented a range of elective upper and lower gastrointestinal operations and is representative of the caseload in our unit. The median age of the cohort was 60 years (range: 24–87) and 66% of the patients were male. The majority of the cases were performed for cancer and the median American Society of Anesthesiologists (ASA) score was 2 (range: 1–3; Table 3). No postoperative deaths occurred within 90 days of operation. One patient had an unplanned admission to intensive care after relaparotomy for an organ space collection.

Nonroutine and Process Failures

We recorded 352 nonroutine events, a median of 6 per patient with a range of 0 to 20. A total of 256 out of 352 nonroutine events (73%) were classified as process failures, a median of 4.5 per patient (range: 0–16; Fig. 1). A wide range of incidents were documented from minor process failures, with no patient harm or consequences, to those resulting in serious postoperative complications (Table 1). The majority of the remaining 96 nonroutine events consisted of recognized postoperative complications for which no precipitating process failure was evident.

Failures were classified into 1 of 4 categories by the raters: medication provision, care management and delivery, assessment and diagnosis, and postoperative investigations (Table 4). These categories were then subdivided into logical groups according to the process of care affected. Medication administration and prescribing subcategories had the highest incidence of process failures. Processes to do with lines, tubes, and drains (eg, central venous catheters, nasogastric tubes, and surgical drains) and pain control modalities such as epidurals and patient-controlled analgesia (Table 4) were the next most frequent. There was no statistically significant difference in the number of nonroutine events per day or the number of process failures per day dependent on the age of the patient, either for upper versus lower gastrointestinal surgery or for benign versus malignant operative indications. The number of process failures and nonroutine events was independent of the surgeon, the postoperative day, and the day of the week.

TABLE 3. Demographics of Study Population

Sex (male:female)	33:17
Age (years): median (range)	60 (24–87)
ASA score (%)	
1	9 (18%)
2	30 (60%)
3	11 (22%)
Procedure (%)	
Gastrectomy	22 (44%)
Segmental colectomy	14 (28%)
Rectal resection	11 (22%)
Small bowel resection	2 (4%)
Reversal of end stoma	1 (2%)
Laparoscopic-assisted procedures (%)	10 (20%)
Surgery for malignancy (%)	37 (74%)
Length of stay (days): median (range)	11 (4–45)
Unplanned admission to ICU (%)	1 (2%)
Deaths within 90 days (%)	0 (0%)

ASA indicates American Society of Anaesthesiologists; ICU, intensive care unit.

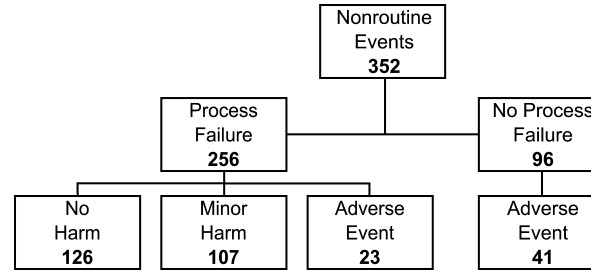

FIGURE 1. Flowchart of incident coding.

Further, 216 out of 256 process failures (85%) were deemed to be preventable. This included more than 90% of medication delivery and postoperative investigation failures. Although no patient in this study suffered permanent disability or died, 130 process failures (51%) led to patient harm or prolonged hospital stay (Table 4). Care management/delivery failures had a significantly greater probability of leading to harm than other groups ($\chi^2 = 80.251$, $P < 0.001$). The lines, tubes, and drains (93%) and epidural and other pain control modalities subgroups (91%) had the highest rates of harm. Of the 130 process failures that led to harm, 96 (74%) were considered preventable. Process failures that led to harm were significantly less preventable than those that did not ($\chi^2 = 26.729$, $P < 0.001$). This was because the care management/delivery processes, which had a high rate of harm, had a lower preventability than other categories.

Adverse Events

We identified 64 adverse events in 34 patients (68% of the patients, range: 0–5), but only 23 of these were associated with a process failure (Fig. 1). The remaining 41 adverse events related to recognized postoperative complications for which no precipitating failure in the process of postoperative care could be identified. The 23 adverse events associated with process failures occurred in 19 patients (38%) and all were due to delayed discharge, rather than ongoing disability. Postoperative investigations had the highest rate of adverse events (Table 4). A number of these were, however, due to delayed investigations, and therefore delayed discharge, with no harm to the patient. Conversely, a number of line, tube, and drain process failures caused significant patient harm but did not delay discharge, nor result in ongoing disability, and therefore did not qualify as adverse events. All but 2 adverse events (21/23, 91%) associated with process failures were considered preventable. Adverse events associated with process failures had significantly greater preventability than those not associated with process failures (16/41, 39%; $\chi^2 = 16.512$, $P < 0.001$). The overall preventability of adverse events was 58% (37/64), which is comparable with other similar studies.[4,5,9]

Etiology of Process Failures and Adverse Events

Communication failures and delays were the main causes of process failure and adverse events (Table 5). Communication failures

TABLE 4. Process Failure Frequency, Preventability, and Harm Caused

Process Failure	Frequency (% of Total)	Preventability (% of Frequency)	Harm Caused by Process Failures (% of Frequency)		
			No Harm	Minor Harm	Adverse Event
Medication	*112 (44%)*	*110 (98%)**	*86 (77%)†*	*20 (18%)†*	*6 (5%)†*
Prescribing	47	45 (96%)	29 (62%)	13 (28%)	5 (11%)
Distribution/supply	7	7 (100%)	3 (43%)	4 (57%)	—
Administration	58	58 (100%)	54 (93%)	3 (5%)	1 (2%)
Care management/delivery	*101 (39%)*	*72 (71%)**	*18 (18%)†*	*71 (70%)†*	*12 (12%)†*
Lines/tubes/drains	42	27 (64%)	3 (7%)	35 (83%)	4 (10%)
Epidural/pain control	35	25 (71%)	3 (9%)	30 (86%)	2 (6%)
Blood products	8	6 (75%)	3 (38%)	4 (50%)	1 (13%)
Therapies	7	5 (71%)	3 (43%)	1 (14%)	3 (43%)
Other	9	9 (100%)	6 (67%)	1 (11%)	2 (22%)
Assessment	*22 (9%)*	*16 (73%)**	*10 (46%)†*	*11 (50%)†*	*1 (5%)†*
Delay	13	12 (92%)	8 (62%)	4 (31%)	1 (8%)
Other	9	4 (44%)	2 (22%)	7 (78%)	—
Investigations	*21 (8%)*	*20 (95%)**	*12 (57%)†*	*5 (24%)†*	*4 (19%)†*
Blood investigations	11	10 (91%)	7 (64%)	3 (27%)	1 (9%)
Imaging	8	8 (100%)	4 (50%)	2 (25%)	2 (25%)
Microbiology	2	2 (100%)	1 (50%)	—	1 (50%)
Total	*256*	*216 (85%)*	*126 (49%)*	*107 (42%)*	*23 (9%)*

*$\chi^2 = 34.855$, $P < 0.001$; †$\chi^2 = 80.251$, $P < 0.001$.

TABLE 5. Proportion of Process Failures Caused by Communication Failures or Delays

Process Failure Category	Communication Failure (%)	Delay (%)
Medication	45/112 (40%)*	31/112 (28%)†
Care management/delivery	35/101 (35%)*	33/101 (33%)†
Assessment	8/22 (36%)*	13/22 (59%)†
Investigations	17/21 (81%)*	14/21 (67%)†
	105/256 (41%)	91/256 (36%)

*$\chi^2 = 15.764$, $P < 0.001$; †$\chi^2 = 17.590$, $P < 0.001$.

and delays contributed to over half of all process failures (138/256, 54%) and almost three quarters of adverse events (17/23, 74%). Fifty-eight process failures exhibited both communication failure and delay and these factors were significantly correlated with one another (Spearman $\rho = 0.358$, $P < 0.001$). Ordering, undertaking, and reporting of investigations had a significantly greater proportion of communication failures ($\chi^2 = 15.764$, $P < 0.001$) and delays ($\chi^2 = 17.590$, $P < 0.001$) than other groups (Table 5). Other common causes of process failure were lapses in care,[17] for example, failure to administer a prescribed medication, and patient-related factors such as displaced lines, tubes, and drains.

DISCUSSION

This study identified a median of 4.5 postoperative care process failures per patient, over half of which caused harm or prolonged hospital stay. Failures in medication prescribing and administration were most prevalent and failures related to lines, tubes, and drains and pain control modalities had the highest rates of harm. About 85% of process failures were preventable and more than half were caused by either communication failure or delays.

Stevenson et al[18] assessed adherence to a number of selected processes during the admission of emergency surgical patients and found a mean of 4.8 process failures per admission before intervention. This is similar to the median of 4.5 process failures per patient found in this study. Kreckler et al[19] identified "safety events" in 26% of emergency admissions when assessed by a surgical observer and also noted a high rate of process failure in 7 audited processes but did not match harm with failed processes or account for processes other than the ones audited. Andrews et al[20] conducted a large observational study in surgical and intensive care units. They documented adverse events (albeit using a different definition) in 46% of elective and emergency patients, many more than those found in case-record review studies but still short of the 68% of patients identified in this study. Andrews and colleagues used nonsurgical observers who recorded adverse events identified by clinical staff on ward rounds, morbidity and mortality meetings, and patients' medical records but lacked direct observation by independent clinicians, which may have reduced the sensitivity of their study.

We identified harm as a result of 51% of all process failures. It is likely that this is an underestimate for 2 reasons. Firstly, there may be a delay between failure of a process and harm occurring, for example, missed chest physiotherapy leading to pneumonia, and this makes harm difficult to detect. Secondly, it is frequently not possible to determine the effect of a process failure; for instance, a missed antibiotic dose may impair the patient's recovery from an infection but it is not possible to quantify any delay that occurs or establish causality. Nearly 85% of all failures and three quarters of failures leading to harm were preventable. Processes with clear, unambiguous documentation, such as prescribing and administration of medication and requesting and reporting of investigations, had high rates of preventability. This suggests that the majority of these incidents were of failures of routine procedures, rather than due to sudden, unexpected (and therefore unpreventable) events.

Process failures accounted for over half of all preventable adverse events in this study and so are excellent targets for quality improvement efforts. The failures identified in this study were diverse but the data suggest 2 potential avenues for intervention. Firstly, it is possible to identify those processes with the greatest frequency and severity (ie, lines, tubes, and drains and epidurals and pain control) and prioritize their improvement.[21] Secondly, it is possible to address the common etiologies of process failures. Two such underlying causes identified by this study are communication failures and delays and, by addressing these factors, it may be possible to reduce the frequency of many types of process failure simultaneously. Simple

interventions, such as documented daily goals for each patient, have shown promise in improving multidisciplinary team communication in intensive care[22] and this may translate to the surgical ward environment. Nagpal et al[6] have shown that daily plans for intravenous fluids, physiotherapy, and surgical drains are absent in about 40% of cases. Team training, based on the aviation industry's crew resource management, has been shown to reduce surgical mortality when applied to operating theater teams[23] and a similar program for ward staff may address the common issues underlying process failures.

Observational studies such as the one described here require significant resources to perform, but they have the ability to identify the underlying causes of process failures and adverse events. This is often impossible using retrospective methodologies such as case-record review. This deeper understanding of the etiology of failure allows this methodology to guide quality improvement strategies and uncover changes in process failure patterns before and after interventions.

Limitations

Observational studies can be distorted by the Hawthorne effect, in which observed health care workers improve their performance in response to being watched. In this study, the majority of field notes related to incidents that had occurred in the previous 24 hours and only a minority were directly observed. In addition, the Hawthorne effect would tend to reduce, not increase, the number of process failures identified. It is possible that a small number of process failures would not have been identified because they were not documented, not discussed, and did not lead to patient harm. These limitations mean that the frequency of process failures may be underestimated by this study. Patients require a large number of care processes after major surgery to optimize recovery, and this number will vary according to the patients' health, the disease being treated, and the patients' postoperative course. For this reason, the total number of processes performed is unknown and therefore the overall rate of process failure cannot be calculated. Although the implicit methodology used for identifying process failures in this study relies on expert opinion, it enabled the researchers to identify any nonroutine event that they considered a failure in care, rather than just those from an explicit predetermined list. This allowed a greater number and variety of failures to be detected.[12,24] This was a single center study, and therefore, the results may not be representative of other units. The facilities and staff available to elective general surgical patients in the hospital studied are, however, typical of large gastrointestinal cancer centers in the United Kingdom National Health Service. In addition, the types of process failure identified here will be familiar to all surgeons. The outcomes of patients in the study were good, especially considering the complexity of the surgery. The hospital trust studied has a standardized mortality rate significantly below the mean and a lower than average rate of deaths after surgery based on Hospital Episode Statistics data for England from April 2009 to March 2010.[25] It is possible that hospitals with less good elective surgical outcomes would have a greater number of process failures to explain their results and this is a potential area for future research.

CONCLUSIONS

Despite good patient outcomes, we identified a large number of process failures in the postoperative care of patients undergoing major elective general surgery. These process failures are highly preventable and many of them cause harm. This study has developed a methodology that can be used to investigate ward-based surgical care and provides a baseline measurement of process failures in postoperative care, against which further similar studies can be compared. Improving high-risk processes and mitigating the underlying causes of process failures will avoid harm to patients, decrease wastage of resources, and has the potential to reduce hospital stay.

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