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A pilot study of non-routine events in gynecological surgery: Type, impact, and effect

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HIGHLIGHTS

- Non-routine events (NREs) were observed >10 times per gynecological surgery case.
- External interruptions, teamwork, and equipment NREs were most common.
- Across surgical team members, the circulating nurse experienced NREs most frequently.
- NREs did not differ across open, laparoscopic, or robotic approaches.

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ABSTRACT

Objective. Quantifying non-routine events (NREs) assists with identify underlying sociotechnical factors that could lead to adverse events. NREs are considered any event that is unusual or atypical during surgical procedures. This study aimed to use prospective observations to characterize the occurrence of non-routine events in gynecological surgeries.

Methods. Observational data were collected prospectively within one surgical gynecology department over a five month period. Researchers captured NREs in real time using a validated tablet PC-based tool according to the NRE type, impact, whom was affected, and duration. Researchers also noted what surgical approach (i.e. open, laparoscopic, robotic) was used.

Results. Across 45 surgical cases, 554 non-routine events (M = 12.31 NREs per case, SD = 9.81) were identified. The majority of non-routine events were external interruptions (40.3%), teamwork (26.7%), or equipment (21.3%). The circulating nurse was most frequently affected by NREs (43.2%) followed by the entire surgical team (13.7%). There was no statistically significant difference in non-routine events based on surgical approach.

Conclusion. Non-routine events are prevalent in the gynecological surgical setting. Identifying the sociotechnical factors that influence non-routine events are important in determining interventions that will combat the associated risks. Interventions focusing on teamwork, managing external interruptions, and coordinating equipment may have the greatest impact to reduce or eliminate NREs in gynecological surgeries.

1. Introduction

Patient safety research methods traditionally have relied on 'hard' patient outcome variables such as adverse or sentinel events [1]. Yet at the root of most adverse events are sociotechnical factors such as issues within the organizational structure, poor communication, insufficient training, or badly designed medical equipment [1]. These factors are essentially latent errors that may only result in larger adverse events

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through very specific coincidental occurrences of related events [2]. In a recent study, Thiels and colleagues identified technology as contributing to 25% of never events—retained foreign object, wrong site/side procedure, wrong implant, wrong procedure—and supervisory and organizational factors contributing to over 10% of never events at one institution [3]. This work demonstrates the value in using alternative data collection strategies that can examine smaller non-routine events which may reveal basic latent errors that are present within the current system. Non-routine events are considered 'any event that is perceived by care providers or skilled observers to be unusual, out-of-the-ordinary, or atypical' during surgical procedures [4].

Non-routine events (NREs) allow researchers to study underlying system processes without the negative connotations surrounding medical error. NREs were initially used to retrospectively analyze work flow disruptions in anesthesia teams [4]. Since then, NREs have been used to assess surgical flow of cardiac surgery teams [5,6], trauma teams [7] and in preliminary studies of team performance in the OR [8,9]. The term NRE is also used synonymously with surgical flow disruptions [6,10,11], which have been linked to increased surgical errors [6], demonstrating their clinical significance over other objective measures.

To collect NRE data, tools have been developed and validated for the surgical domain [5,12]. More recently, Blocker [13] identified that inefficient handoffs during cardiac surgery can create NREs and potentially compromise patient safety. As part of a pilot study to develop a model for team briefings and understand how it affects teamwork and non-routine events in the OR [14], the aim of this study was to characterize the occurrence of non-routine events in gynecological surgery.

2. Methods

2.1. Setting and participants

A prospective, observation-based study was conducted in the surgical gynecology department of an academic, quaternary care center over a five month period. Surgical teams were observed during scheduled gynecological surgery. Team member roles included surgeon, resident/fellow, anesthesiologist, certified registered nurse anesthetist (CRNA), circulating nurse (RN), certified surgical assistant (CSA), and certified surgical technologist (CST). Within the department at this institution, anesthesiologists oversee multiple operating rooms (ORs) and check in with the CRNA, who are considered in the "in-room provider" for anesthesia. Observed surgical procedures included minimally invasive laparoscopic surgeries, general open surgeries, and robotic surgical procedures. Surgical gynecologic teams completed up to three cases a day. The Institutional Review Board deemed this study exempt from review.

2.2. Research protocol

Two researchers with backgrounds in human factors conducted the observations. Prior to starting data collection, both researchers conducted a training period where they observed the same surgical cases and coded NREs. Following the cases, the researchers discussed the NREs identified and addressed discrepancies. Utilizing this training method established a very good level of agreement between the two researchers, $\kappa = 0.824$, $p < 0.001$.

On observation days, researchers collected data on non-routine events (NREs) during surgical gynecology cases. Data collection started when the patient was in the room and draped. The researcher stayed outside of the sterile environment and used a validated tablet PC-based tool [12] to capture NREs. NREs were annotated and categorized in real time according to the type of disruption, impact of disruption on the surgical team, and disruption duration. Each entry was time-stamped automatically in the data collection tool. Researchers remained outside of the sterile field and performed observations discreetly as to not compromise the surgical procedures being performed.

2.3. Data collection tool

To record the occurrence of non-routine events, researchers used a tablet PC-based tool that was developed and validated for the prospective collection of non-routine events in healthcare environments [12]. The data collection tool was initially developed using the Systems Engineering Initiative for Patient Safety (SEIPS) framework [15] and allows for the real-time collection of multiple NRE data points including when the disruption occurs, how long the disruption lasts, the type of disruption (Table 1), a brief description of the disruption, how severe the disruption is to the surgical flow (Table 2), and which roles on the surgical team are impacted by the disruption. Researchers could also denote whether the 'whole team' was impacted by an NRE. While the data collection table tool was originally designed for observing cardiac surgical cases [12], it has since been generalized and found to also be a valid tool for use in other healthcare domains including emergency and trauma care [10,13,16–18].

2.4. Data analysis

The observational data was analyzed using the statistical software SPSS (Version 22; IBM, Inc., Armonk, NY) and Microsoft Excel (Microsoft Corporation, Redmond, WA). NRE duration was calculated from the time stamps. Descriptive statistics were performed to calculate means (M), medians (Mdn), and standard deviations (SD) of the observed non-routine events.

3. Results

Data were collected across 45 surgical cases (open [n = 18], laparoscopic [n = 18], robotic [n = 7], unidentified [n = 2]) which yielded 554 non-routine events (M = 12.3 NREs per case, SD = 9.8). Surgical cases ranged from 19 min to 4.3 h (M = 124.7 min, SD = 66.7). There

Table 1
Non-routine event categories with definitions and examples ([12,13,18,35]).

NRE type	Definition	Example
Teamwork	Any breach or lapse in team communication, coordination, cooperativeness, and/or familiarity negatively affecting surgical flow.	"Surgeon had to repeat his request to the RN three times."
Equipment	Equipment problems hindering the smooth progression of the surgical team's procedure.	"Monitor was malfunctioning during laparoscopic procedure."
External interruptions	Disruptions imposed on the procedure from outside, which include extraneous people, phone calls, or intercom messages that did not directly relate to the procedure at hand.	"RN receives phone call for surgeon with updates from surgery in second OR."
Environment	Disruptions affecting the auditory or visual status of the operating room and not directly relevant to the treatment of the patient.	"Anesthesiologist tripped over cord near the bed."
Technical factors	Skill-based or decision (thinking) error, including poorly executed tasks, omitted steps, or misinterpretation of relevant information.	"CSA did not know how to correctly operate the harmonic device."
Training	Training or supervision that hinders the natural progression of the surgical procedure.	"Resident had difficulty locating the ureter and needed guidance from surgeon."
Patient factors	Patient-specific issues resulting in disruptions to the natural progression of the surgical procedure.	"Patient's blood pressure (BP) spikes in Trendelenburg position and the bed must be returned to normal position until BP becomes regular."
Other	Any disruption not falling into one of the above categories.	"A specimen got on the CSA's shoe and the RN removed it."

Table 2
Non-routine event severity classification ([12,13,35]).

Severity	Definition
No Impact	No acknowledgement of the disruption.
Acknowledge/No Delay	A surgical team member is aware of the disruption, but there is no pause in the flow of the operation.
Momentary Delay	Brief pause in surgical flow of the operation for <1 min as a result of the disruption.
Moderate Delay	Significant pause in the surgical flow of the operation for >1 min as a result of the disruption.
Full Case Cessation	One or more surgical team members must pause their current task and engage in a secondary activity that impeded the progress of the original task and significantly disrupts surgical flow of the operation.

were no significant differences in non-routine events by open, laparoscopic, or robotic operative approach. Non-routine events varied in duration (Mdn = 40 s, Range: 1 s–34.4 min). Brief non-routine events usually were due to an external interruption such as answering a phone call or pager. The longest observed non-routine event lasted 34.4 min and was teamwork related. In that specific case, the team experienced a full case cessation while waiting on pathology results which were not sent to the lab at the appropriate time due to miscommunication between the surgeon and the RN.

3.1. Event type

The majority of non-routine events related to external interruptions (n = 223, 40.3%), teamwork (n = 148, 26.7%), or equipment (n = 118, 21.3%; Fig. 1). Non-routine events related to training (n = 28, 5.1%), technical skills (n = 24, 4.3%), patient factors (n = 11, 2.0%), and environment (n = 8, 1.4%) occurred less frequently.

Further analysis into the annotations for each event type revealed that non-routine events categorized as external interruptions mostly included pagers and phones (51%) and external visitors coming in to the operating room (39%). Specific teamwork related non-routine events included providing updates to the surgeon about progress in their second operating room (26%), miscommunication among team members (17%), and handoffs (36%) between team members for breaks or shift changes. Equipment related non-routine events included instances when a piece of equipment was needed and was not working (40%), was needed and was not present in the operating room (32%), or was needed and was in the room, but was not ready to be used (23%). Examples from the specific categories in which the majority of non-routines events occurred are shown in Table 3.

3.2. Roles affected

The circulating nurse (RN) was most frequently affected by NREs (43.2%) followed by the entire surgical team (13.7%). The surgeon (10.1%), resident (10.1%), and anesthesia team, including both the anesthesiologist and the CRNA (10.5%), experienced similar amounts of non-routine events. The CSA (4.2%) and CST (8.2%) were the members least frequently involved in non-routine events. Surgical roles also experienced NRE types differentially, χ^2 (48, N = 482) = 167.6, $p < 0.01$. The whole team was affected most frequently by teamwork (36.5%) and equipment (20.3%) NREs; however, the surgeon (45.8%), anesthesiologist (64.7%), and circulating nurse (53.5%) were disrupted most by external interruptions. CSAs (45.5%) and CSTs (34.8%) most frequently experienced NREs related to teamwork, and the resident was most affected by equipment NREs (31.8%). There was a significant difference in median NRE duration by surgical role, $\chi^2(6) = 55.3$, $p < 0.001$. More specifically, when the whole team was impacted by an NRE, the median duration (Mdn = 75 s) was significantly longer than when an individual role was affected.

3.3. Event severity

The impact of non-routine events observed in gynecological surgeries ranged from *No Impact* (2.1%) to *Full Case Cessation* (4.3%). The majority of non-routine events were identified as *Momentary Delay* (62.3%) or *Acknowledge/No Delay* (18.8%), with a small but significant percentage of the non-routine events deemed *Moderate Delay* (8.2%). The non-routine events identified as *Momentary Delay* were most often instances of external interruptions such as answering pagers/phones or dealing with an external visitor.

Severity levels were analyzed according to the types of non-routine events. A moderately strong association was identified between NRE severity and NRE type ($\chi^2(28) = 141.81$, $p < 0.01$, Cramer's V = 0.272). Fig. 2 illustrates the distribution of severity by the most common types of NREs, indicating that external interruptions frequently cause a momentary delay. In contrast, non-routine events related to teamwork and equipment tended to be more severe in impact than external interruptions.

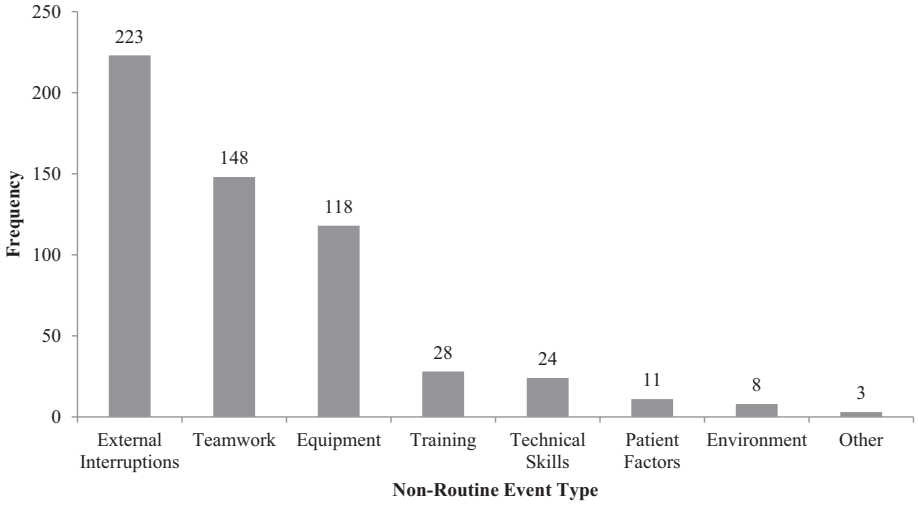

Fig. 1. Non-routine event (NRE) types.

Table 3
Examples of specific non-routine events captured by observers.

Disruption type	Specific category	Example
External Interruption	Pagers and phones	"RN had to answer the phone in the middle of the count and asked CST to wait for them to finish"
	External visitors	"Another CST comes in to talk with the CST in the room"
Teamwork	Providing updates to the surgeon	"The team is waiting for the surgeon to come back from second OR and check on port placement"
	Miscommunication	"RN asks CRNA to re-call the next case because no one did it the first time she asked"
	Handoffs	"CRNA returns from a lunch break"
Equipment	Not ready	"Cautery tools were not plugged in, pedal was not at surgeon's foot"
	Not working	"Suction canister is leaking"
	Not present/missing	"RN had to go to the core for a vag pack that should have already been out for surgeon to use"

4. Discussion

Across the 45 observed surgical cases, there were 554 NREs identified by observers, with an average of approximately 12 NREs per each surgical case. The three most frequent types of NREs, which accounted for over 80% of all NREs, were related to external interruptions, teamwork, and equipment.

Further examination of external interruptions revealed that these events most often included answering phones and pagers or dealing with external visitors coming into the OR. Schraagen and colleagues linked procedural NREs with patient outcomes, but found external interruptions had no effect on a patient's postoperative course [9]. Yet, while these types of NREs may appear to be inconsequential to the larger surgical procedure, the findings are consistent with other research which has associated latent errors to minor NREs [6,13,19]. Also, the accumulation of many smaller NREs increases the likelihood that surgical errors will occur [4,6]. Incorporating a team briefing prior to surgery to provide a clear surgical plan and identify expectations for how the surgery will proceed could alleviate the potential for minor NREs to significantly disrupt work flow—especially those related to equipment.

Teamwork–related NREs were typically categorized as handoffs, miscommunication among team members, and instances when the surgeon needed to be provided updates regarding a second OR. These types of NREs were most frequently experienced by the whole team and have been shown to be harmful to team performance and patient safety. For example, inefficient handoffs have the potential to result in NREs that compromise patient safety [13]. Further, breakdowns in communication can have significant clinical implications. Most notably, issues of miscommunication are the number one cited cause of errors in the OR [20,21] and can have severe consequences, such as wrong site surgeries [22,23]. In a study of communication during open abdominal procedures, Tschan and colleagues found the prevalence of communication irrelevant to the surgical case was independently associated with increased incidence of incisional SSIs [24]. Interventions to address teamwork-related NREs include briefings, shared documentation, and establishing a shared mental model for the team. A briefing that establishes good communication prior to the surgery and outlines a plan for how to proceed regardless of whether the surgeon is in the room or not could reduce these types of NREs. Also, documentation of the briefing could be beneficial for reducing negative consequences from these types of events. If notes or documentation of the briefing are available during a handoff, this could facilitate the transfer of knowledge between two team members and could ensure that no critical information is forgotten in the exchange [25].

Equipment-related NREs were categorized in the following three ways: equipment is needed and it is not in the room, equipment is needed and it is in the room but it is not ready to use, or equipment is needed and it is in the room, ready to use, but not working properly. These types of NREs are consistent with other findings which suggest that equipment-related disruption events have potential for serious consequences depending upon the phase of surgery in which they occur [26]. Disruptions such as equipment failures in gynecological surgery can extend surgical duration by 7–20% [27]. The same study also identified 20% of equipment failures had the potential to cause serious complications for the patient [27]. Addressing equipment needs prior to surgery should aid in alleviating this issue.

The findings revealed that the duration of NREs are typically brief (approximately 40 s on average) but can last as long as 34 min. In the latter case, poor teamwork around communication of a pathology specimen caused a half hour case cessation. This is problematic as operating room time is expensive—upwards of $20 per minute [28]. Yet patients often swallow that cost through their medical bill on top of physician and anesthesia charges [29]. Additionally, such delays cause inefficiency across the surgical schedule where subsequent cases start later or are moved to another day, suggesting NREs have the potential to become a costly expense for both the patient and the hospital. The RNs were found to be the team role that was most often impacted by the occurrence of a NRE, which is consistent with other research [5,13]. Interestingly, the whole team was the second most frequent "role" to be impacted by NREs. Previous research suggests that NREs which distract the entire surgical team can lead to errors as there is a loss of overall

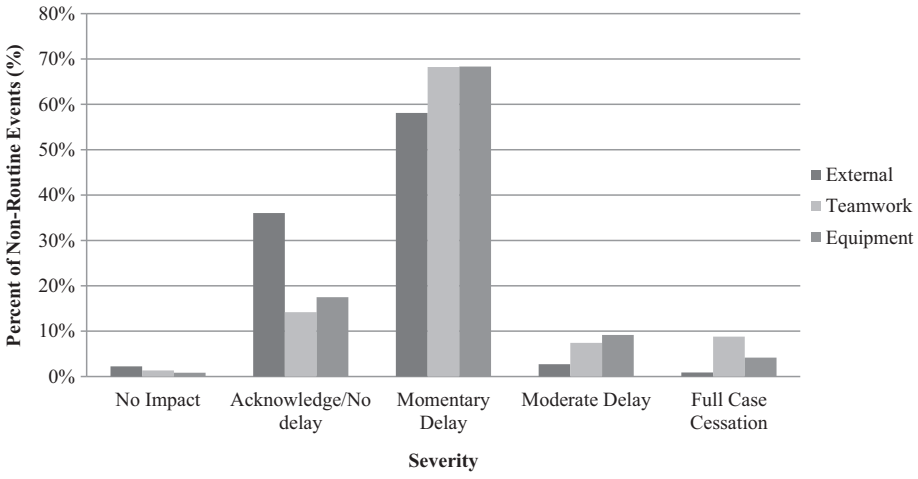

Fig. 2. Severity level for most common types of non-routine events.

concentration and focus [6]. Further analysis revealed that NREs affected the various roles differently. For example, external interruptions were most affective of the surgeon, anesthesiology, and the circulating nurse. In contrast, NREs pertaining to teamwork were more prevalent for CSAs and CSTs. Looking specifically at the surgeon and the resident who interact closely together, even the NREs they experienced differed. Nearly one half of NREs experienced by attending surgeons were external interruptions, whereas in contrast these only accounted for 10% of resident NREs. By considering the types of NREs that impact the whole team and understanding how roles are affected by NREs individually, it can identify opportunities for intervention.

Overall, the results showed that most of the NREs did not have a severe impact on the surgical work flow. Of the observed NREs, approximately 62% were categorized as *Momentary Delay* and 18% were categorized as *Acknowledge/No Delay*. Again, despite these types of NREs appearing to be non-significant since they do not seriously "delay" the work flow, they can have clinical implications. As the number of minor NREs increases, so does the probability of error [4,6]. The number of NREs that were categorized in the most severe level, *Full Case Cessation* (approximately 2%), appear to be low in comparison to the other levels. However, if the frequency of these occurrences is averaged across all briefings, it equates to one *Full Case Cessation* per surgical day observed. Further examination of the *Full Case Cessation* events revealed that these disruptions are typically due to teamwork-related NREs. Teamwork-related NREs mostly consist of breakdowns in communication, which are known to lead to errors [20,21]. Therefore, identifying interventions that support and improve team communication could provide value for overall team performance and patient safety.

Results from this study identified various characteristics in which surgical procedures deviated from the normal case and caused workflow delays, laying the groundwork for interventional opportunities. Other fields, such as automotive manufacturing, have studied how to reduce such deviations in their production workflow using lean and six sigma principles [30]. Lean focuses on quality improvement by identifying and preserving tasks or procedures that provide 'value' and eliminating sources of waste [31]. Six Sigma, on the other hand, seeks to identify and correct the causes of errors so that the probability of defects is infinitesimal. Together, these principles aim to reduce waste that is non-value added and reduce variation in processes so that they are more reliable. Limited work has been done applying these methodologies to healthcare [32], yet Cima and colleagues demonstrated how it can increase the number of on-time case starts, reduce turnover time between cases, and reduce average staff overtime [33]. While that study did not address NREs, it is important to conceptualize NREs as a form of non-value added waste that can increase the variability of surgical performance, case duration, and as a result, patient costs. Understanding the root cause of intraoperative NREs will help identify relevant interventions to support standardization and reduce variability (e.g. briefings and debriefings, use of SBAR, defining team member roles, refining equipment list).

Limitations are inherent to every study. Results from this study are grounded in a small convenience sample of surgical cases performed at one institution, limiting the generalizability of the findings. While the sampling is small over a five month period, it studied teams "in the wild" and demonstrated sociotechnical failures present in real environments [34]. Further work is needed with a larger cohort to address potential biasedness issues potentially present in the findings. As with all observational studies, participants may alter their behavior due to the Hawthorne Effect. Additionally, adverse events were not captured in this study. Future studies plan to capture NREs and adverse events in conjunction.

5. Conclusion

Non-routine events will continue to occur during surgical procedures, regardless of surgical specialty or surgical approach. Understanding the types of NREs and how they impact the surgical team members individually, and as a whole, is important for assessing where to focus risk management efforts and interventions. Finding ways to mitigate or eliminate NREs can significantly impact outcomes, whether these are operational (e.g. duration of surgery) or clinical (e.g. surgical errors leading to surgical site infections, reoperation, or retained foreign objects). Results from this study in gynecological surgery indicate interventions should address teamwork, equipment coordination issues, and managing external interruptions. Required, structured team briefings for a surgical procedure or surgical day may be one method to combat the risks and prevalence or non-routine events.

Abbreviations

CRNA	certified registered nurse anesthetist
CSA	certified surgical assistant
CST	certified surgical technologist
NRE	non-routine event
OR	operating room
RN	registered nurse
SEIPS	Systems Engineering Initiative for Patient Safety

Ethics approval and consent to participate

The Mayo Clinic IRB deemed this study to be exempt (45 CFR 46.101, item 2) from IRB review.

Consent for publication

Not applicable.

Availability of data and material

Please contact author for data requests.

Competing interests

The authors declare that they have no competing interests.

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Authors' contributions

KLF contributed to the data analysis and manuscript writing. EAH contributed to the project development, data collection, data analysis, and manuscript writing. HJH contributed to the data analysis and manuscript writing. MSH contributed to the project development and manuscript writing. RJB contributed to the project development, data analysis, and manuscript writing. SCD contributed to the project development and manuscript writing. RCB contributed to the project development, data collection, and manuscript writing. All authors read and approved the final manuscript.

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