Observational Study

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Medication safety in the perioperative setting

A comparison of methods for detecting medication errors and adverse medication events

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Abstract

The purpose of this study was to evaluate perioperative medication-related incidents (medication errors (MEs) and/or adverse medication events (AMEs)) identified by 2 different reporting methods (self-report and direct observation), and to compare the types and severity of incidents identified by each method. We compared perioperative medication-related incidents identified by direct observation in Nanji et al's 2016 study[1] to those identified by self-report via a facilitated incident reporting system at the same 1046-bed tertiary care academic medical center during the same 8-month period. Incidents, including MEs and AMEs were classified by type and severity. In 277 operations involving 3671 medication administrations, 193 MEs and/or AMEs were observed (5.3% incident rate). While none of the observed incidents were self-reported, 10 separate medication-related incidents were self-reported from different (unobserved) operations that occurred during the same time period, which involved a total of 21,576 operations and approximately 280,488 medication administrations (0.004% self-reported incident rate). The distribution of incidents (ME, AME, or both) did not differ by direct observation versus self-report methodology. The types of MEs identified by direct observation differed from those identified by self-report ($P = .005$). Specifically, the most frequent types of MEs identified by direct observation were labeling errors (N = 37; 24.2%), wrong dose errors (N = 35; 22.9%) and errors of omission (N = 27; 17.6%). The most frequent types of MEs identified by self-report were wrong dose (N = 5; 50%) and wrong medication (N = 4; 40%). The severity of incidents identified by direct observation and self-report differed, with self-reported incidents having a higher average severity ($P < .001$). The procedure types associated with medication-related incidents did not differ by direct observation versus self-report methodology. Direct observation captured many more perioperative medication-related incidents than self-report. The ME types identified and their severity differed between the 2 methods, with a higher average incident severity in the self-reported data.

Abbreviations: AME = adverse medication events, AMT = anesthesia medication template, IRB = Institutional Review Board, ME = medication errors, OR = operating room, PONV = post-operative nausea and vomiting.

Keywords: medication error, medication safety, perioperative, self-reporting

1. Introduction

Medication errors (MEs) are common inside and outside of the perioperative setting. The medication use process in the operating room (OR) differs greatly from other patient care areas such as hospital inpatient units, posing a significant challenge to identifying MEs in the perioperative setting.[1] For example, perioperative medication use frequently involves the administration of time-sensitive, high alert medications in a fast-paced, complex and stressful environment.[2–4] Furthermore, in the OR, the anesthesia clinician is typically the only clinician responsible for every step in the medication use process including: medication selection, preparation, administration, documentation and subsequent monitoring, when necessary.[1,5] This workflow often bypasses double checks by pharmacists, second clinicians, and point-of-care barcode scan safety checks that are frequently utilized in other inpatient settings.[1] While we typically rely on self-reporting of MEs in the OR, MEs are frequently

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Key points summary:

Question: How do the perioperative medication-related incidents identified by facilitated self-report differ from those identified by direct observation?

Findings: Direct observation captured many more perioperative medication-related incidents than self-report, and the type of errors identified and their average severity differed by method.

Meaning: This study demonstrates important differences in the medication-related incidents identified by self-report and direct observation, and may facilitate strategies to increase the number of incidents that are self-reported, such as improving the types of questions we ask on facilitated incident reporting systems to capture incidents that are less likely to be reported.

underreported in other patient care settings,[6–9] and it is unclear what types of perioperative MEs are underreported and why.

Common methods to detect MEs and adverse medication event (AMEs) in the perioperative setting include: self-reporting (voluntary and facilitated), mandatory incident reporting, direct observation, and chart review.[1,9] Voluntary self-reporting relies on the anesthesia provider to initiate a report of a ME or AME. Facilitated self-report systems prompt the anesthesia provider to report MEs and/or AMEs at set intervals (e.g., after each anesthetic case). Self-reporting may not reflect errors that are not recognized by the anesthesia provider.[10,11] In the U.S., mandatory incident reporting is required by law in certain states for incidents that result in serious patient harm or death.[11] Detection of MEs and/or AMEs by chart review involves the review of anesthesia records for MEs and/or AMEs via pre-defined parameters or triggers that prompt additional evaluation for error,[9,11] for example, the use of a reversal agent such as naloxone or flumazenil. Direct observation involves a trained professional observing the medication use process to flag incidents that might be MEs and/or AMEs.[9,11] Flagged incidents are typically reviewed by an adjudication committee to determine whether the flagged incident was actually a ME and/or AME. Direct observation is a more accurate, yet costly and time-consuming method of detecting MEs.[9,12] ME and AME reporting is important not only to develop robust prevention strategies, but also to enhance the culture of safe perioperative medication administration practices. An accurate understanding of perioperative MEs and AMEs is essential to determine the types of incidents that are more or less likely to be reported in order to help inform the types of questions we ask on incident reporting systems. The objective of this study was to identify the types of perioperative medication-related incidents identified by 2 different reporting methods (facilitated self-report and direct observation), and to compare the severity of incidents identified by each method.

This manuscript adheres to the Strengthening the Reporting of Observational studies in Epidemiology (STROBE) guideline.

2. Materials and Methodology

The study was approved by the Mass General Brigham Institutional Review Board (IRB). The requirement for written informed consent was waived by the IRB.

3. Definitions

3.1. Incident

An incident refers to any process (act of omission or commission) that results or may result in patent harm or risk of harm.[2] Incidents include MEs and/or AMEs.

3.2. Medication error

A medication error is a failure to complete a necessary step in the medication use process, or the use of a wrong plan to achieve a medication-related aim.[1,13,15] The medication use process has 6 distinct stages: requesting, dispensing, preparing, administering, documenting and subsequent patient monitoring, where necessary.[13–15] Examples of perioperative MEs include omitted medications, labeling errors, wrong dose, wrong medication, wrong timing, wrong route, and monitoring errors.[1,2,16–20,26,27] While MEs may not lead to patient harm in every instance, all MEs have the potential for patient harm.[1,21]

3.3. Adverse medication event

An AME is any patient harm or injury that occurs secondary to a medication, regardless of whether a ME occurred.[1,11,15,22–25] An example of a ME that results in an AME is administering a neuromuscular blocking agent, such as rocuronium to a patient with a known allergy to rocuronium, leading to an allergic response. An AME may also occur without a ME, such as the development of post-operative nausea and vomiting in a patient despite the administration of prophylactic antiemetics.[1]

3.4. Incident severity ranking

We used the following widely-accepted and validated categories of incident severity.[1,15,34,35]

Class A: Significant: Class A incidents have potential to cause symptoms that, while unpleasant or harmful, pose little or no threat to the patient's function.[13] In the medication safety literature, these are referred to as Significant. Examples include post-operative nausea and vomiting, rash, or pain.[13]

Class B: Serious: Class B incidents have the potential to cause persistent alterations to a patient's functioning that are not life-threatening.[13] In the medication safety literature, these are referred to as Serious. Examples include change in mental status, wound infection, and symptomatic hypoglycemia.[13]

Class C: Life-Threatening: Class C incidents have the potential to cause loss of life or limb, if not treated.[13] Examples include anaphylaxis, sepsis, and cardiac arrhythmia accompanied by hemodynamic instability.[13]

3.5. Study site

The study was conducted in the perioperative area of a 1046-bed, 59-OR tertiary care academic medical center. There were 237 anesthesia clinicians, including 81 (34.2%) anesthesiologists, 53 (22.4%) certified registered nurse anesthetists, and 104 (43.5%) house staff. Anesthesia clinicians had the opportunity to opt out prior to and/or during the observational data collection.[1] During the study period, available prefilled medication syringes included: phenylephrine, ephedrine, epinephrine, calcium chloride, atropine, 2% lidocaine, and sodium bicarbonate. The anesthesia information management system was MetaVision Anesthesia (iMDsoft®, Tel Aviv, Israel) and each OR had a barcode-facilitated syringe labeling system (Safe Label System®, Codonics Inc., Middleburg Heights, OH) that provided audio and visual readback of medication names at the time of label generation.[1] After each anesthetic, a facilitated incident reporting system prompted the anesthesia provider to self-report any incident that occurred during the perioperative period. The prompt included a checklist of medication- and non-medication-related incidents, as well as a box for the user to enter a free text description of the incident (see Fig. 1).

4. Study design

After obtaining IRB approval from the Mass General Brigham Human Research Committee, we conducted a retrospective data

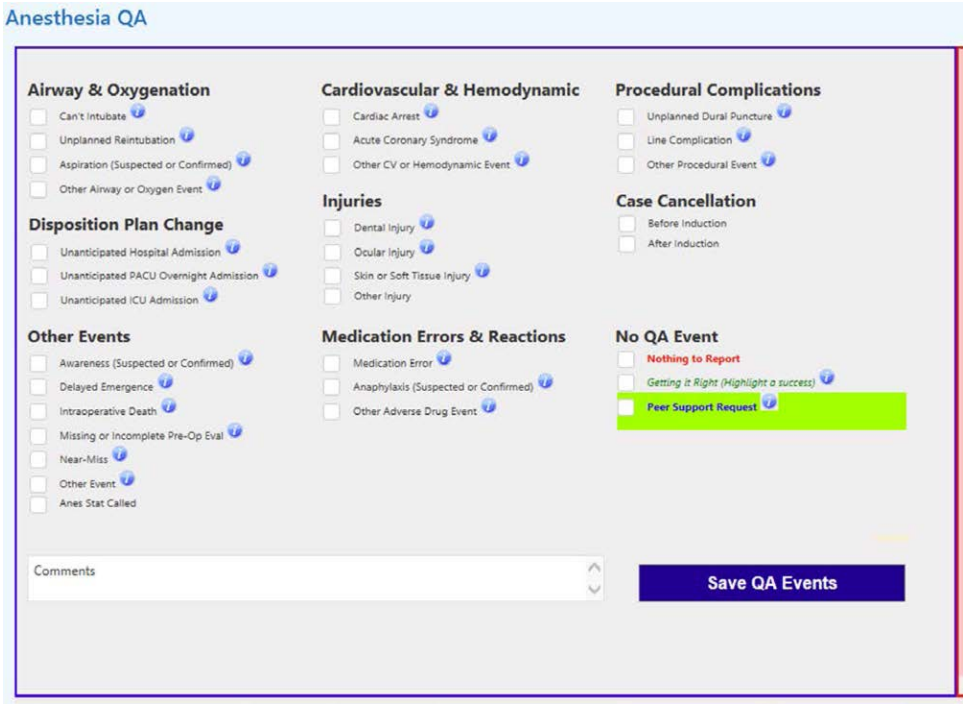

Figure 1. Incident reporting form.

analysis comparing prospective observational data from the 2016 Nanji et al study[1] with retrospective data obtained from the institution's facilitated incident reporting system during same time period.[1] The prospective observational data included the frequency, types and severity of medication-related incidents (MEs and/or AMEs) that occurred during 277 operations in the 8-month period from November 2013 to June 2014. The self-reported data included medication-related incidents that were reported by clinicians during the same time period. We excluded (from both data sets) incidents that occurred in anesthetizing locations that were outside of the main OR suites (such as interventional radiology and in vitro fertilization clinics), as well as cardiac ORs and pediatric ORs, due to unique medication considerations (such as different workflows, medications, and dosing practices) in these locations.

5. Data collection

5.1. Self-reported data

Self-reported incidents were classified by incident type (ME, AME, or both) and severity by 2 independent reviewers (authors KCN and MMS). Disagreements were resolved by discussion and consensus.

5.2. Direct observation data

The direct observation method has been previously described in detail.[1] Briefly, observers included 3 trained and practicing anesthesiologists and 1 nurse anesthetist, who all received extensive additional training on observational methodology, including review of a detailed ME detection handbook, multiple didactic sessions, and case studies of MEs. They each conducted observations with an experienced observer for at least 10 operations to ensure that they were capturing consistent information. The observers were trained to remain outside of the provider's workspace and avoid interaction with the anesthesia provider to minimize the Hawthorne effect.[1,8] The observers' task was to flag *possible* MEs and/or AMEs based on the validated error detection framework. These possible MEs and/or AMEs were each reviewed by at least 2 independent members of our adjudication committee, which consisted of anesthesiologists and ME experts. The adjudication committee's task was to exclude incidents that were not actual MEs or AMEs, and to categorize the incidents by type, preventability, potential for harm and severity of harm. To gain the necessary clinical context, they reviewed the observer notes, clarified events directly with the observers, reviewed the patient chart and consulted with experts when necessary. If a possible ME or AME passed this stage, it was included in our study. It is important to note that prior to the observations, all participants were informed that the study team would not report observed incidents to the hospital incident reporting system, to protect participant privacy per IRB policy. Participants were instructed to follow standard self-reporting protocols.

6. Statistical analysis

All analyses were performed using SAS JMP Pro version 14.2® (SAS Institute Inc., Cary, NC), and statistical significance was defined as $P < .05$. All associated patient and provider identifiers were removed. ME rates are most valid when reported as the number of MEs per medication administered (instead of per operation) because the number of medications administered varies between operations, making it difficult to determine the number of administrations with no error.[9,33,35–38] Thus, MEs were reported as the number of MEs per medication administration for both the observational and self-reported data. Pearson's Chi-Squared test ($P < .05$) was used to identify the differences in incident type and severity by reporting methods (direct observation vs self-report data) in addition to the types of errors captured by each reporting method. A Fisher's exact test was used for analyses with counts < 5. Cohen's kappa statistic was used to assess inter-rater reliability.

7. Results

Of the 237 anesthesia clinicians, 11 opted out from being observed.[1] In 277 observations involving 3671 medication

administrations, 193 MEs and/or AMEs were observed (5.3% observed incident rate). While none of the observed incidents were self-reported, 10 separate medication-related incidents were self-reported from different (unobserved) operations that occurred during the same time period, which involved a total of 21,576 operations and approximately 280,488 medication administrations (0.004% self-reported incident rate). There were 5 additional self-reported incidents that were excluded because they were from cardiac ORs (N = 4), or pediatric ORs (N = 1). The distribution of incidents (ME, AME, or both) did not differ between direct observation versus self-report methodology (see Table 1). The types of MEs identified by direct observation differed from those identified by self-report ($P = .005$, see Table 2). The most frequent types of MEs identified by direct observation were labeling errors (N = 37; 24.2%), wrong dose errors (N = 35; 22.9%) and errors of omission (N = 27; 17.6%). The most frequent types of MEs identified by self-report were wrong dose (N = 5; 50%) and wrong medication (N = 4; 40%). While 4 of the self-reported MEs led to an observable AME, none resulted in long-term patient morbidity.

The severity of incidents identified by direct observation and self-report differed ($P < .001$, see Table 3). In the observed data set, 57 (29.5%) incidents were Class A (Significant), 133 (68.9%) were Class B (Serious), and 3 (1.6%) were Class C (Life-Threatening). In the self-reported data set, none of the incidents were Class A (Significant), 7 (70.0%) were Class B (Serious), and 3 (30.0%) were Class C (Life-Threatening). The procedure types associated with medication-related incidents did not differ by observational versus self-report methodology (see Table 4). Inter-rater reliability was excellent for incident classification of the self-reported data ($\kappa > 0.99$), and very good for severity ($\kappa > 0.78$, reflects 1 disagreement that was resolved by discussion and consensus). The inter-rater reliability was previously reported for the observational data from Nanji et al's 2016 study[1] and was excellent for incident classification ($\kappa = 0.97$, 4 cases resolved by discussion and consensus) and excellent for severity ($\kappa = 0.85$, 12 cases resolved by discussion and consensus).

Table 1

Incident type*.

Classification	Observed (N = 193)[a]	Self-Reported (N = 10)[b]
ME	102 (52.8%)	6 (60%)
AME with ME	51 (26.4%)	4 (40%)
AME without ME	40 (20.7%)	0 (0%)

[a] Percentages calculated with denominator of 193 observed incidents.
[b] Percentages calculated with denominator of 10 self-reported incidents.
*$P = .245$ (Statistical significance was defined as $P < .05$).

Table 2

Error types that were observed and/or self-reported*.

Classification	Observed (N = 193)[a]	Self-Reported (N = 10)[b]
Monitoring error	37 (24.2%)	0 (0.0%)
Wrong dose	35 (22.9%)	5 (50%)
Labeling error	26 (17.0%)	0 (0.0%)
Medication omission/failure to act	10 (6.5%)	0 (0.0%)
Wrong medication	9 (5.9%)	4 (40%)
Wrong timing	5 (3.3%)	0 (0.0%)
Inadvertent bolus	2 (1.3%)	0 (0.0%)
Other	2 (1.3%)	0 (0.0%)

[a] Percentages calculated with denominator of 193 observed incidents.
[b] Percentages calculated with denominator of 10 self-reported incidents.
*$P = .005$ (Statistical significance was defined as $P < .05$).

Table 3

Severity classification*.

Classification	Observed (N = 193)[a]	Self-Reported (N = 10)[b]	ME Example	AME Example
Class A: Significant	57 (29.5%)	0 (0.0%)	No antiemetic administered to a patient with a history of PONV	PONV
Class B: Serious	133 (68.9%)	7 (70.0%)	Missed antibiotic dose	Infection
Class C: Life-threatening	3 (1.6%)	3 (30.0%)	Insulin infusion administered without dextrose in a diabetic patient with hypoglycemia	Serum glucose of 40 mg/dL

[a] Percentages calculated with denominator of 193 observed incidents.
[b] Percentages calculated with denominator of 10 self-reported incidents.
*$P < .001$ (Statistical significance was defined as $P < .05$).
PONV = post-operative nausea and vomiting.

Table 4

Procedure type*.

Classification	Observed (N = 193)[a]	Self-Reported (N = 10)[b]
General	43 (22.3%)	3 (30.0%)
Orthopedic	34 (17.6%)	2 (20.0%)
Gynecological	29 (15%)	1 (10.0%)
Urology	21 (10.9%)	0 (0.0%)
Thoracic	12 (6.2%)	0 (0.0%)
Thyroid	12 (6.2%)	0 (0.0%)
Plastic	7 (3.6%)	0 (0.0%)
Vascular	7 (3.6%)	1 (10.0%)
Neurosurgery	6 (3.1%)	1 (10.0%)
Oral and Maxillofacial surgery	5 (2.6%)	0 (0.0%)
Transplant Surgery	2 (1.0%)	1 (10.0%)

[a] Percentages calculated with denominator of 193 observed incidents.
[b] Percentages calculated with denominator of 10 self-reported incidents.
*$P = .450$ (Statistical significance was defined as $P < .05$).

8. Discussion

Perioperative medication use involves the administration of time-sensitive, high-alert medications in a fast-paced, complex and stressful environment. Furthermore, the OR is one of the only locations in the hospital where 1 clinician is solely responsible for each step in the medication use process including medication selection, preparation, administration, documentation, and subsequent monitoring. This poses a challenge to identifying the types of medication-related incidents that occur in the perioperative setting. This study highlights differences in the incidence and types of perioperative MEs and AMEs identified by self-reported versus direct observation, and may facilitate future research into strategies to increase the number of incidents captured by self-report, such as improving the types of questions we ask on incident reporting systems.

We found that none of the 193 medication-related incidents identified by direct observation in 277 operations were self-reported. Ten separate medication-related incidents were self-reported from different operations that occurred at the same institution during the same time period. While self-reported medication error rates in the literature are generally very low, facilitated self-reporting captures more errors than voluntary self-reporting.[40] Direct observational studies of MEs capture even more MEs than both prospective and retrospective self-reported studies.[40] For example, Merry et al identified a 9.1% ME rate[33] and Nanji et al identified a 5.3% ME rate using direct observation methods.[1] Our results are also consistent with prior studies comparing methods for ME detection in

non-perioperative settings. For example, in a 36-facility study assessing MEs in 2556 inpatient medication administrations, 300 MEs were identified by direct observation, 17 by retrospective chart review, and 1 by self-report.[9] In our study, we also found that the types of MEs identified differed between self-report and direct observation methodologies, and the average severity of incidents that were self-reported was higher than the severity of those that were observed.

These findings support literature from non-OR patient care areas, which shows that direct observation captures more events than self-report.[6–9] However, direct observation is more resource intensive than self-report and is typically not feasible as an ongoing method of capturing medication errors. Direct observation may be best used sporadically, as an indication of the types of events that are not being self-reported, so that self-reporting forms can be revised to capture relevant missing errors.

8.1. Contributing factors and solutions

While a number of prevention strategies exist, including the use of pharmacy pre-filled syringes and pre-mixed infusions, barcode-assisted medication administration, audio-visual feedback systems, the presence of a clinical pharmacist in the ORs, and the use of standardized medication organization, most of these recommendations are based on expert consensus and minimal evidence exists to support an associated reduction ME rates.[31] The following are 4 strategies with some evidence to support a reduction in MEs.

Pharmacy reconstituted medications: One randomized controlled trial demonstrated that pharmacy prepared pre-filled syringes and pre-mixed infusions of frequently used high alert medications reduced MEs 17-fold.[28]

Barcode-assisted medication administration: While barriers to implementation of barcode-assisted medication administration include the current anesthesia workflow of retrospective documentation of medications after their administration, inpatient care areas have seen a 27.3% reduction of MEs, and perioperative areas have seen a 63% reduction of MEs.[29,39] Future work should assess the potential benefits of barcode-assisted medication administration in the OR, which would involve scanning the syringe label immediately prior to medication administration, allowing for the introduction of intraoperative medication-related clinical decision support. For example, Merry et al found a decrease in ME rates from 11.6% to 9.1% of medication administrations after the implementation of SAFERSleep® System, a multimodal, barcode-assisted medication administration system (Safer Sleep LLC, Auckland, New Zealand).[33]

Standardized medication organization: Anesthesia medication templates (AMTs) are being evaluated to provide a tactile and systematic way of organizing medication syringes in the anesthesia workspace. AMTs are devices that facilitate drug organization in the anesthesia workspace.[30] A preliminary study showed that the implementation of AMTs reduced perioperative MEs from 10.4% to 2.4%.[30]

Incident reporting: While Wanderer et al reported a decrease in adverse events from 1.23% to 0.64% with the implementation of a mandatory incident reporting system,[32] self-reporting methods do not fully capture all perioperative MEs. For example, MEs that were under-reported in our study included errors of omission, monitoring errors, wrong timing and inadvertent boluses. Our current facilitated incident reporting template includes 3 options related to medication use: medication error, anaphylaxis, or other adverse drug event (see Fig. 1). Future work should explore expanding facilitated incident reporting templates to inquire specifically about underreported incident types including errors of omission, wrong dose, wrong timing, and inadvertent boluses, with a focus on incidents captured by direct observation and not by self-report, that had confirmed or potential Class B (Serious) or Class C (Life-threatening) patient harm.

9. Limitations

Our results have several limitations. First, the data analyzed is from the period of November 2013 to June 2014. Thus, this study does not account for safety provisions that have been implemented since the specified timeframe. At the study institution, these new implementations include the use of the Omnicell ® XT Automated Dispensing Cabinets (Omnicell Inc., Mountain View, CA) for medication dispensing in each OR, the availability of clinical pharmacists during emergent intra-operative situations, the provision of additional medications in pre-filled syringes and/or pre-mixed infusions, and the integration of Epic Anesthesia, a new anesthesia information management system (Epic Systems Corporation, Verona, WI). While there have been no formal prospective randomized controlled trials to test these safety enhancements, it is possible that they may decrease overall rates of MEs and AMEs. However, these interventions are less likely to influence the relative patterns of self-reporting of incidents compared to direct observation. Second, the self-reported data sample size was small and there may be reporter bias or lack of knowledge of the types of errors that should be disclosed, leading to the underreporting of incidents. While it is possible that some participants chose not to self-report observed incidents because they assumed the observer would report them, it is unlikely that this significantly impacted our results as all participants were informed (prior to the observations) that the study team would not report observed incidents (per IRB policy) and participants were instructed to follow standard self-reporting protocols. Finally, there is potential for Hawthorne effect in the observed data set. However, proper observer training, as was included in Nanji et al's 2016 study,[1] has been shown to minimize this effect.[8]

10. Conclusion

In summary, we found that direct observation captured many more perioperative medication-related incidents than self-report. The ME types identified, and their severity, differed between the 2 methods, with a higher average incident severity in the self-reported data. Future work should focus on strategies to increase the number of incidents captured by self-report, in particular, errors of omission, monitoring errors, wrong timing and inadvertent boluses.

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