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The Nature and Severity of Adverse Events in Select Outpatient Surgeries in the Veterans Health Administration

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Abstract

Background: Research on adverse events (AEs) in outpatient surgery has been limited. As part of a Veterans Health Administration (VA) project on AE surveillance, we chart-reviewed selected outpatient surgical cases to characterize the nature and severity of AEs.

Methods: We abstracted FY2012–15 VA outpatient surgery cases selected with high (n=1,185) and low (n=1,072) likelihood of an AE based on post-operative healthcare utilization. The abstraction tool included established AE definitions and validated harm and severity scales.

Results: We found AEs in 608 high-likelihood (51%) and 126 low-likelihood outpatient surgeries (12%). Among 1,010 unique AEs, the most common were wound issues (n=261, 26%) urinary retention (23%) and urinary tract infections (12%). While 63% of all AEs involved minimal harm, 28% required hospitalization, and 9% were severely harmful including 8 AEs requiring intervention to sustain life and 2 deaths. Overall, 102 AEs (10%) required, at minimum, a repeat surgery to treat.

Conclusions: Among VA outpatient surgeries selected based on likelihood of an AE, nearly 40% of identified events carried more than minimal patient harm, undermining the claim that outpatient surgery is relatively safe. Prevalent and preventable AEs such as wound dehiscence and urinary retention may be useful targets for quality improvement.

Keywords

Veterans Health Administration; Ambulatory Surgery; Adverse Event Surveillance; Patient Safety

Introduction

Outpatient surgeries are frequently performed and considered relatively safe; however, research on adverse events (AEs) in this setting has been limited. Some of the most reliable data on outpatient surgical AEs have been generated by the VA Surgical Quality Improvement Program (VASQIP; the private sector's version of this program is the National Surgical Quality Improvement Program, or NSQIP).^{1,2} VASQIP/NSQIP provides surgical staff with detailed information about specific types of AEs;¹ however, because it was developed primarily for inpatient care, the sampling methodology excludes many outpatient surgeries from review. Furthermore, the list of specific AEs may therefore not include commonly occurring events in outpatient surgery.³ As more high-complexity surgeries move to the outpatient setting, clinicians, quality managers, and policy makers may not have complete information about AEs to direct quality improvement (QI) efforts.

There is evidence that AEs occur after outpatient surgery, particularly from the VASQIP/NSQIP literature;^{4,5} yet many studies focus only on one explicit event, such as postoperative nausea/vomiting⁶ or surgical site infections,⁷ instead of examining the range of AEs that may occur. Research on this setting of care has focused primarily on patient-reported postoperative symptoms. These symptoms may or may not meet established AE definitions set by the gold standard of AE detection, "chart review." A literature review of post-discharge symptoms related to outpatient surgery found patients experienced high rates of pain (45%), drowsiness (42%) and nausea (17%) among other symptoms.⁸ Two survey-based studies assessing postoperative symptoms found that 86% of patients experienced relatively minor complications, including pain and nausea, in the first days after surgery, with 25% reporting undesirable symptoms as late as one week after their operation.^{9,10} Studies of postoperative emergency department visits and admissions have typically used diagnosis codes to determine the reason for further treatment and found patients returned because of pain, infection or medical conditions (e.g., heart disease).^{11,12} One of the most methodologically sound studies of the range of AEs associated with outpatient surgery was based on more than 1,000 chart review cases and used standardized criteria to assess AEs; however, the data were from a single facility and the list of AEs examined was narrow and had little overlap with VASQIP/NSQIP.¹³

Consequently, there remains a significant gap in the literature with respect to the frequency and nature of standardized AEs identified through chart review in a large sample of outpatient surgical cases. Furthermore, there is little reliable data on the associated harm and severity of these events. This study addresses this gap. As part of a larger effort to develop

and validate a surveillance model to detect AEs, we 1) developed a chart review tool that included standard AE criteria and validated harm and severity scales, and 2) used this tool to review medical charts of outpatient surgical cases selected with high or low likelihood of AEs from four years of outpatient surgeries done in the Veterans Health Administration (VA). The likelihood of an AE was determined based on certain types of postoperative healthcare utilization identified in prior research.¹⁴ Our findings can inform clinical care, quality improvement and healthcare policy.

Methods

Data Sources

This study uses data obtained in a larger study to develop and validate a surveillance model for AEs in outpatient surgery. Data on VA outpatient surgeries and postoperative healthcare utilization were identified in the VA Corporate Data Warehouse. Chart review data on AEs were derived from patients' VA electronic health records (EHR) available through the research-approved national VistAWeb system. Our local Institutional Review Board approved this study.

Sample Selection

The study population for the surveillance model study was all VA outpatient surgeries performed between FY2012 and FY2015 (Oct. 1, 2011 – Sept. 30, 2015) across 111 VA inpatient facilities and 20 freestanding ambulatory surgery centers (ASCs). We used Current Procedure Terminology (CPT) codes and Centers for Medicare and Medicaid Services (CMS)'s Relative Value Units (RVUs) to determine the principal CPT code for unique VA outpatient encounters. Then, we applied the Agency for Healthcare Research and Quality (AHRQ)'s Healthcare Cost and Utilization Program (HCUP)'s 2014 Surgery Flag Software to the principal CPT to retain only cases that matched the "narrow" definition of outpatient surgery: "involving incision, excision, manipulation, or suturing of tissue that penetrates or breaks the skin." Lastly, we excluded VA encounters that were likely miscoded inpatient surgeries by removing cases in our sample with a CPT code on the CMS "Inpatient Only" list or as indicated by the VA National Surgery Office. The surveillance model study excluded eye procedures because a VA surveillance mechanism is already in place for this specialty.¹⁵

The larger study used chart review to develop and then validate the surveillance model. Cases for the development stage of the surveillance model were selected based on certain types of postoperative healthcare utilization (admission, emergency room visit, multiple visits to any surgical clinic, or multiple visits to the urology clinic) as an indicator of a possible AE.¹⁴ FY12–14 outpatient surgeries with postoperative utilization were randomly sampled for chart review; the development sample also included randomly sampled outpatient surgeries assumed to have a low likelihood of an AE based on the absence of postoperative utilization.

The validation sample in the surveillance model study used FY15 outpatient surgeries. The model itself was developed to assign a predicted probability of an AE given postoperative

utilization, as well as patient, procedure and facility factors. Cases were chart reviewed if the predicted probability of an AE was greater than 0.8; a random sample of cases with a predicted probability between 0.3–0.4 also underwent chart review to validate the surveillance model's predictive validity.

Therefore, the FY12–15 chart-reviewed cases used in our study were purposively sampled to have a higher likelihood of an AE than a random assessment of outpatient surgeries.

Chart Review Tool

We built our chart review tool from an outpatient surgical AE detection tool developed and tested in previous work.¹⁴ The original tool included the AE definitions used by VASQIP/NSQIP. We adapted our tool to also include 1) AEs from the literature and expert input and 2) AEs identified by the nurse chart abstractor based on her clinical expertise. To accomplish the first adaptation, we reviewed the literature to identify commonly occurring AEs related to outpatient surgery and two surgeon members of the research team [KI, MH] reviewed the list to determine which of these events could be reliably defined for the purposes of chart review. For the second adaptation, we included a text box for the abstractor to write in “other” events.

We further expanded the review tool to include spaces to record the date of the AE, patient harm using the Institute for Healthcare Improvement (IHI)'s harm scale, and AE severity using Clavien-Dindo classifications of surgical complications (see Table 1).¹⁶ The chart review tool was developed electronically using Microsoft InfoPath and hosted on a secure VA SharePoint site.

Chart Review Process

Our chart review process built upon established practices.¹⁷ A trained VA nurse abstractor [SM] reviewed VA EHRs to identify potential AEs present in the review tool. Prior to chart review, the nurse abstractor and a research nurse were trained to use the chart review tool; inter-rater reliability was established using the research nurse's results as the gold standard and iteratively testing five abstractor-reviewed cases at a time until agreement exceeded 90%. Thereafter, consistent with previous work, chart review was conducted solely by the nurse abstractor and questions regarding specific chart-reviewed cases were resolved by the two surgeons on the research team [KI, MH].¹⁴ We followed the Institute for Healthcare Improvement (IHI) chart review process by limiting reviews to 20 minutes and reviewing various sections of the VA medical record in succession beginning with the operative note.¹⁸ Chart reviewed cases from the reliability tests were included in our study.

Analysis

We downloaded chart review results from the larger surveillance model study's SharePoint site into Microsoft Excel and assessed the median and range of days to event, harm ratings and severity scores by AE type, as well as the review time for each case. We used SAS version 9.2 to compare demographic differences between cases with and without an AE in our chart review sample.

Results

Chart Review Sample

In the larger surveillance model study there were 1,001,938 outpatient surgeries in the VA between FY12 and FY15 and 15% of these were considered to have a higher likelihood of an AE based on postoperative healthcare utilization. The chart review sample used in our study had 1,185 high-likelihood cases and 1,073 low-likelihood cases. There was at least one AE in 734 outpatient surgeries; 608 in high-likelihood (51%) and 126 in low-likelihood cases (12%). In total, chart review identified 1,010 unique AEs. Of the cases with more than one AE, there were 160 cases with 2 AEs, 38 cases with 3 AEs, seven cases with 4 AEs and 3 cases with 5 AEs. The median number of days to event was 5, with 18% of AEs occurring the day of the outpatient surgery (see Appendix 1 for the median and range of days to event by AE type) and 75% of AEs occurred outside the VA facility after the outpatient surgery occurred. On average, chart review took 18 minutes per case. Our review sample was 93% male and 75% white; the most prevalent surgery procedures were genitourinary (20%), general surgery (18%) and skin/soft tissue (15%, see Table 2). Compared to chart-reviewed cases without an AE, cases with at least one AE were significantly older (64 years versus 62 years, $p<0.0002$).

Chart Review Tool

We initially identified 12 new types of outpatient surgical AEs with standardized definitions from the literature to add to our review tool (see Table 3). These included hematoma, urinary retention, and postoperative nausea and vomiting, among others. Although we excluded eye surgeries and therefore AEs commonly reported in these cases, a surgeon expert on our team recommended we include corneal abrasions from taping during anesthesia. Postoperative pain was considered an important and adverse surgical outcome in the literature; however, there were several definitions of pain and thus it was hard to find a definition that would work for chart review. Midway through the review process, the nurse abstractor identified the first case of postoperative bleeding. The research team agreed *any* postoperative bleeding after outpatient surgery was adverse and replaced the VASQIP/NSQIP definition of a transfusion requiring more than 4 units of blood¹ with a new standardized definition that was more appropriate for outpatient surgery: “Bleeding Requiring Any Units Packed Red Blood Cells or Transfusions <72 hours after Surgery.” The complete tool with AE definitions used for chart review is available in Appendix 2.

We examined where the AE was documented in the VA EHR to better understand the type of provider who identified AEs in outpatient surgery and how we might review the medical record more efficiently in future work. Table 4 presents the *a priori* list of EHR fields as well as our *post hoc* classification of “other” fields in the VA EHR. Surgery and consult notes made up 23% and 10% of EHR fields, respectively, but 38% of AEs were documented in an “other” field of the EHR. These were primarily ED visit notes. We found no evidence of AEs in laboratory or pharmacy/medication notes.

Adverse Events

The most common AEs were urinary problems (n=371, 37%), including urinary tract infections (12%) and urinary retention (23%); and wound issues (n=313, 31%), including dehiscence (8%) and hematoma (8%; see Table 5). Approximately 30% of the AEs fit a VASQIP/NSQIP definition, 50% were based on new AEs resulting from our literature review, and the remaining 20% were classified as “Other” AEs – of these, 12% were not assigned to wound, cardiac, respiratory, urinary or central nervous system (CNS) organ systems. There were two CNS occurrences defined by VASQIP/NSQIP that were not identified in our sample: coma and peripheral nerve injury. Similarly, we did not find two of the newly defined AEs: burns and corneal abrasions.

Compared with the other AE definitions, VASQIP/NSQIP-defined AEs were more frequently associated with increased patient harm and higher Clavien-Dindo scores. The majority of the new, literature-based AEs (75%) had a Clavien-Dindo score of 1 and the lowest level of patient harm; however, hematoma cases were the second most frequent new AE and 30% required initial or prolonged hospitalization. The “Other” AEs were associated with somewhat higher patient harm ratings and Clavien-Dindo scores - half required a hospitalization and more than 50% had a Clavien-Dindo score greater than 1.

We examined the “textbox” descriptions of AEs particularly to understand severely harmful and complicated events as well as “Other” AEs. We found two deaths associated with outpatient surgery: a cardiac arrest in a terminally-ill patient whose family requested comfort care and a spouse report of death in a non-VA hospital. Many “Other” events could be attributed to specific organ systems and were similar to, but did not meet, other AE definitions. An example was a patient with concerning symptoms of infection, such as fever and pain, but a negative laboratory result a day later. For the “Other” AEs that did not fit a specific organ system category, postoperative pain was the most frequent AE. While, as noted, we could not find a standardized definition of pain to include in the chart review tool, the nurse reviewer did determine that pain was the best description for several AEs based on EHR documentation. The “Other” category of harmful events also included changes in mental health status.

Harm and Severity Results

With respect to overall harm, more than 50% of all AEs resulted in temporary harm to the patient that required some intervention, 28% entailed temporary harm requiring hospitalization and 9% were severely harmful. In addition to the 2 deaths, there were 8 AEs requiring intervention to sustain life. Overall, 22% of AEs detected required at minimum a repeat surgery (Clavien-Dindo Grades IIIa or higher) and the majority of these were hematomas and iatrogenic injuries. In addition to the patients who died, there were 10 cases requiring substantial medical intervention (Clavien-Dindo Grades IVa or higher): unplanned intubation for cardiac arrest, extended ventilator use, pneumonia, organ space surgical infection, myocardial infarction, sepsis, clostridium difficile colitis and bleeding requiring transfusion.

Discussion

The purpose of our study was to better understand the nature and severity of outpatient surgical AEs by taking advantage of chart review results generated in a larger AE surveillance study. In our chart review sample, where a majority of cases had a high likelihood of an AE, we identified more than 1,000 events and determined that 63% incurred mild harm and 50% required limited medical effort to treat; however, we also identified patients who required a hospitalization to undergo a more intense reparative procedure for their AE. Notably, had we limited our review to VASQIP/NSQIP-defined AEs, we would have identified only 1/3 of all the AEs that occurred. Despite the value of adding more defined AEs to our review tool, 20% of the AEs we identified did not fit any of the AE definitions in our list.

Our results show that many AEs associated with outpatient surgery result in patient harm and require medical intervention. AEs may precipitate a number of other negative surgical outcomes, including prolonged postoperative stay, unanticipated hospital admission, return visit, poor postoperative function and low patient satisfaction.¹⁹ Research using chart review to assess overall rates of AEs, found that approximately 1.5% of patients were hospitalized for a complication related to outpatient surgery^{11,12} and 0.7% returned to the emergency department (ED). Although the literature shows that the risk of AEs due to outpatient surgery is lower than that for inpatient surgery,²⁰ the events that occur represent a substantial impact on healthcare resources due to the high volume of outpatient surgeries performed annually. Additionally, as outpatient surgeries become more complex and involve greater numbers of older, frail patients, the risk of AEs will likely increase. We found older age was significantly associated with AEs in our findings and future work should explore whether age is a risk factor for outpatient surgical AEs, controlling for other factors.

Many of the VASQIP/NSQIP AEs detected in our sample have been noted in the literature, including SSIs. In total, there were more than 200 cases of infection in our chart review sample, ranging from *clostridium difficile* colitis to urinary tract infections, and these cases often required a hospitalization for treatment. Considerable resources have been focused on hospital infection control to prevent AEs and readmissions after surgery,²¹ however, the movement to increase adoption of infection prevention practices in outpatient surgery has been slower than in inpatient settings.²² A recent CMS study found 67% of ASCs in 3 states failed to fully comply with infection control standards.²³ Prevention and early treatment of postoperative infection may reduce the number of AEs in outpatient surgery.

As has been observed with VASQIP/NSQIP,^{24,25} changes to clinical care and targeted quality improvement efforts in outpatient surgery may be spurred by better information about AEs. Policy makers may also improve the safety of outpatient surgical care with policies to measure postoperative outcomes as a proxy for AEs. The Centers for Medicare and Medicaid Services (CMS) have an ongoing, voluntary pay-for-reporting program for ASCs to report specific AEs. More recently, CMS issued a policy to track all postoperative ED visits and admissions following surgery in an ASC. These postoperative outcomes may be due to outpatient surgical AEs and some of these AEs may be preventable. Therefore, improvements in outpatient postoperative patient outcomes depend on studying the types of

AEs occurring in this setting and addressing problems with clinical care and overall patient safety.

Our study is not without limitations. We did not perform follow-up inter-rater reliability testing during our chart review, potentially introducing some subjective bias into our findings; however, we did establish reliability at the outset of chart review and followed a previously established method of surgeon re-review when the nurse abstractor had concerns about a possible AE.¹⁴ As with all VA studies, results based on VA outpatient surgeries may not necessarily be generalizable to non-VA outpatient surgery cases, particularly considering the high prevalence of genitourinary procedures in our sample. We used a stringent definition of outpatient surgery that excluded many dermatological procedures and all eye surgeries; this definition of outpatient surgery may explain why we did not find burns or corneal abrasions, even though these are reported in the literature. Lastly, we were unable to reliably define 20% of the AEs we identified (the “other” category). This creates an opportunity for future work to explore and standardize more types of outpatient surgical AEs, particularly those related to postoperative pain.²⁶

This research also has many strengths. We used literature review and expert opinion to broaden the list of potential AEs associated with outpatient surgery in order to expand a previously developed and tested chart review tool. We also confirmed the use of a 20-minute chart review process that reliably identified outpatient surgical AEs, captured detailed notes on the context of the event, and rated the AE’s harm and severity using validated scales. Although chart review is widely considered the gold standard for AE detection, studies using small sample sizes do not often produce useful findings. We used a chart review dataset with more than 2,000 charts and identified more than 1,000 AEs, which was sufficiently large to identify meaningful information about the types of AEs occurring in outpatient surgery and the level of harm and severity attributable to these events. This information should be useful to clinicians, quality managers and policy makers as they design interventions to improve patient outcomes in outpatient surgery.

Conclusions

Within select VA outpatient surgeries with a high or low likelihood of an AE, nearly 40% of identified events carried more than minimal patient harm, undermining the claim that outpatient surgery is relatively safe. As many AEs identified did not meet standardized definitions, further work is needed to standardize AE definitions in outpatient surgical cases. Tracking outpatient surgical AEs can provide valuable information to clinicians, quality managers and policy makers as they strive to improve patient safety. Prevalent and preventable AEs such as urinary retention and hematoma may be important to include in future QI work.

Supplementary Material

Refer to Web version on PubMed Central for supplementary material.

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Table 1.

Descriptions of the Harm and Complication Scales Used to Describe Outpatient Surgical Adverse Events

Institute for Healthcare Improvement Harm Scale¹⁸	
Considering the patient 30 days after the AE, please select first applicable category. Only rate harms associated with the AE:	
E	Temporary harm to the patient and required intervention
F	Temporary harm to the patient and required initial or prolonged hospitalization
G	Permanent patient harm
H	Intervention required to sustain life
I	Patient death
Clavien-Dindo Classification Scale¹⁶	
Considering the patient 30 days after the AE, please select first applicable category. Only rate surgical or medical care associated with the AE:	
Grade I	Any deviation from the normal postoperative course without the need for pharmacological treatment or surgical, endoscopic, and radiological interventions; Allowed therapeutic regimens are: drugs as antiemetics, antipyretics, analgesics, diuretics, electrolytes, and physiotherapy. This grade also includes wound infections opened at bedside
Grade II	Requiring pharmacological treatment with drugs other than such allowed for grade I complications; Blood transfusions and total parenteral nutrition (TPN) are also included
Grade III	Requiring surgical, endoscopic, or radiological intervention
III a	Intervention NOT under general anesthesia
III b	Intervention under general anesthesia
Grade IV	Life-threatening complication (including CNS complications) requiring IC/ICU management
IV A	Single organ dysfunction, including brain hemorrhage, ischemic stroke, subarachnoid bleeding, but excluding transient ischemic attacks
IV b	Multi-organ dysfunction; requires ICU-level of care
Grade V	Death of a patient

NOTE: CNS=central nervous system; IC=intermediate care; ICU=intensive care unit.

Table 2.

Demographic and Procedure Characteristics of Chart Review Sample of FY12–15 VA Outpatient Surgeries

Characteristics	Total n=2,257	No Adverse Event n=1,523 (67%)	Any Adverse Event n=734 (33%)	Statistical Test
Postoperative Healthcare Utilization	1,185 (53%)	577 (37%)	608 (83%)	Chi-Square p<0.0001
Race, n (%)				
White	1,700 (75%)	1,114 (73%)	556 (75%)	Chi-Square p=0.61
African American	360 (16%)	238 (16%)	122 (17%)	
Asian/Pacific Islander	18 (1%)	15 (<1%)	3 (<1%)	
Native American	15 (1%)	11 (<1%)	4 (<1%)	
Mixed Race	54 (2%)	36 (2%)	18 (2%)	
Unknown/Declined answer	110 (5%)	79 (5%)	31 (4%)	
Male Sex, n (%)	2,091 (93%)	1,408 (92%)	683 (93%)	Chi-Square p=0.61
Age, mean (std dev)	62.8	62 (13.8)	64 (14.0)	T-test p=0.0002
Surgical Procedure Type, n (%)				
Genitourinary	454 (20.1%)	258 (16.9%)	196 (26.7%)	Chi-Square p<0.0001
General Surgery	413 (18.3%)	181 (11.9%)	232 (31.6%)	
Skin/Soft Tissue	346 (15.3%)	304 (20%)	42 (5.7%)	
Orthopedics	261 (11.6%)	226 (14.8%)	35 (4.8%)	
Ear/Nose/Throat	162 (7.2%)	125 (8.2%)	37 (5%)	
Hand	146 (6.5%)	118 (7.8%)	28 (3.8%)	
Foot	101 (4.5%)	73 (4.8%)	28 (3.8%)	
Cardiac	80 (3.5%)	55 (3.6%)	25 (3.4%)	
Proctology	73 (3.2%)	40 (2.6%)	33 (4.5%)	
Vascular Access	66 (2.9%)	37 (2.4%)	29 (4%)	
Facial	32 (1.4%)	27 (1.8%)	5 (0.7%)	
Vascular	30 (1.3%)	21 (1.4%)	9 (1.2%)	
Gynecology	27 (1.2%)	16 (1.1%)	11 (1.5%)	
Neurosurgery	24 (1.1%)	18 (1.2%)	6 (0.8%)	
Spine	19 (0.8%)	6 (0.4%)	13 (1.8%)	
Plastic/Reconstructive	10 (0.4%)	8 (0.5%)	2 (0.3%)	
Breast	8 (0.4%)	5 (0.3%)	3 (0.4%)	
Unclassified	5 (0.2%)	5 (0.3%)	0	

NOTE: Data are from development and validation samples for a larger study on an AE surveillance model for outpatient surgery. Chart review cases were not sampled to represent surgical specialties. Std dev= standard deviation.

Table 3.

Outpatient Surgical Adverse Events in Chart Review Tool

Category	Specific Adverse Events
Wound Occurrences	<ul style="list-style-type: none"> - Superficial Incisional Surgical Site Infection (SSI) - Deep Incisional SSI - Organ/Space SSI - Wound <i>Dehiscence</i>/Disruption - <i>Hematoma</i>
Respiratory Occurrences	<ul style="list-style-type: none"> - Pneumonia - Unplanned Intubation for Respiratory/Cardiac Arrest - <i>Unplanned Intubation - other</i> - Pulmonary Embolism - On Ventilator > 48 hours
Urinary Tract Occurrences	<ul style="list-style-type: none"> - Progressive Renal Insufficiency - Acute Renal Failure - Urinary Tract Infection - <i>Urinary Retention</i>
Central Nervous System Occurrences	<ul style="list-style-type: none"> - Cerebral Vascular Accident/Stroke - Coma > 24 hours - Peripheral Nerve Injury
Cardiac Occurrences	<ul style="list-style-type: none"> - Cardiac Arrest req. CPR - Myocardial Infarction
Other Occurrences	<ul style="list-style-type: none"> - Graft/Prosthesis/Flap Failure - Deep Vein Thrombosis/ Thrombophlebitis - Sepsis - Septic Shock - Clostridium difficile Colitis - Postoperative Ileus - Iatrogenic Pneumothorax - Death - <i>Bleeding Requiring Any Units Packed Red Blood Cells or Transfusions <72 hours after Surgery</i> - <i>Intraoperative Iatrogenic Injuries</i> - <i>Persistent Nausea/Vomiting</i> - <i>Dental Occurrences</i> - <i>Burn</i> - <i>Allergic Reaction</i> - <i>Adverse Drug Event</i> - <i>Corneal Abrasion</i>

NOTE: Plain text definitions come from the National Surgical Quality Improvement Program (NSQIP) list of postoperative complications. Italics indicate a new adverse event definition derived from the literature or revised from NSQIP to better fit outpatient surgical care.

Table 4.

Adverse Event Documentation in the VA Electronic Health Record (EHR)

Section of the VA EHR	Frequency	% of Total
Included in the Chart Review Tool		
Surgery Notes	230	23%
Consult Notes (e.g., surgery, infectious disease)	106	10%
Nurse Reassessment Note	90	9%
Provider H&P Note	48	5%
Discharge Summary	46	5%
Provider Admission Note	39	4%
Surgery Reports	22	2%
Progress Notes	16	2%
Nurse Admission Note	10	1%
Laboratory Reports	8	1%
Missing	8	1%
Radiology Reports	4	0%
Procedures Reports	3	0%
Visits/Admissions Reports	1	0%
Labs	0	
Medications	0	
Nurse Skin Note	0	
Orders	0	
Order Summary Reports	0	
Pharmacy Reports	0	
Medication Administration Log Reports	0	
Medication Administration History (BCMA)	0	
Imaging Reports	0	
Other, Classified After Chart Review	379	38%
Emergency Department Clinic Note	126	12%
Other Miscellaneous Records	93	9%
Specialty-level Notes (e.g., urology clinic)	78	8%
Emergency Department Attending Note	23	2%
Surgical Attending Note	12	1%
Telephone Note	10	1%
Primary Care Note	9	1%
Physician Attending Note	7	1%
Physician Assistant Note	6	1%
Medical Resident/Student Note	6	1%
Hospitalist Note	5	0%
Surgery Resident Note	4	0%

Section of the VA EHR	Frequency	% of Total
TOTAL	1,010	

Table 5.
Harm Ratings and Clavien-Dindo Classifications for Outpatient Surgical Adverse Events (AEs)

Adverse Event	Total AEs (n=1,010 in 734 surgeries)	IHI Harm Rating				Clavien-Dindo Classification					
		E	F	G	H	Grade I	Grade II	Grade IIIa	Grade IIIb	Grade IVa	Grade IVb
National Surgical Quality Improvement Program-defined AEs											
Urinary Tract Infection	120 (12%)	94	26	0	0	8	112	0	0	0	0
Superficial Incisional Surgical Site Infection (SSI)	31 (3%)	28	3	0	0	2	28	1	0	0	0
Postoperative Ileus	28 (3%)	1	27	0	0	11	15	0	2	0	0
Sepsis	22 (2%)	0	21	0	1	0	19	1	0	1	1
Deep Incisional SSI	20 (2%)	3	16	1	0	0	14	1	5	0	0
Organ/Space SSI	13 (1%)	2	10	0	1	0	5	4	3	1	0
Pneumonia	13 (1%)	3	10	0	0	0	13	0	0	0	0
Deep Vein Thrombosis/ Thrombophlebitis	12 (1%)	7	5	0	0	1	10	1	0	0	0
Progressive Renal Insufficiency	11 (1%)	1	10	0	0	7	3	0	1	0	0
Graft/Prosthesis/Flap Failure	6 (1%)	4	2	0	0	3	0	1	2	0	0
Myocardial Infarction	5 (<1%)	0	3	0	2	0	1	2	0	1	1
Pulmonary Embolism	5 (<1%)	0	5	0	0	0	5	0	0	0	0
Acute Renal Failure	3 (<1%)	0	3	0	0	0	2	0	1	0	0
Clostridium difficile Colitis	3 (<1%)	0	2	1	0	0	2	0	0	1	0
CVA/Stroke	3 (<1%)	1	2	0	0	0	3	0	0	0	0
Death*	2 (<1%)	0	0	0	0	0	0	0	0	0	0
Septic Shock	2 (<1%)	0	1	0	1	0	0	0	1	1	0
Cardiac Arrest req. CPR	1 (<1%)	0	0	0	1	0	0	0	0	1	0
Iatrogenic Pneumothorax	1 (<1%)	0	1	0	0	0	1	0	0	0	0
On Ventilator > 48 hours	1 (<1%)	0	0	0	1	0	0	0	0	0	1
Unplanned Intubation for Resp/Cardiac	1 (<1%)	0	1	0	0	0	0	0	0	1	0
TOTAL:	303 (30%)	144	148	2	7	32	233	11	15	7	3
Literature and expert-defined AEs											
Urinary Retention	234 (23%)	196	38	0	0	219	11	0	4	0	0

Adverse Event	Total AEs (n=1,010 in 734 surgeries)	IHI Harm Rating					Clavien-Dindo Classification					
		E	F	G	H		Grade I	Grade II	Grade IIIa	Grade IIIb	Grade IVa	Grade IVb
Hematoma	87 (9%)	60	27	0	0		56	13	5	13	0	0
Wound Disruption/ Dehiscence	81 (8%)	74	7	0	0		65	13	1	2	0	0
Persistent Nausea/Vomiting	25 (2%)	11	14	0	0		16	9	0	0	0	0
Bleeding requiring any units packed red blood cells or transfusions < 72 hours after surgery	20 (2%)	0	19	0	1		0	17	1	1	1	0
Intraoperative Iatrogenic Injuries	17 (2%)	8	9	0	0		3	3	1	10	0	0
Allergy	13 (1%)	12	1	0	0		5	8	0	0	0	0
Adverse Drug Event	6 (1%)	6	0	0	0		5	1	0	0	0	0
Dental Occurrences	1 (<1%)	0	1	0	0		0	0	1	0	0	0
Unplanned Intubation	1 (<1%)	1	0	0	0		1	0	0	0	0	0
TOTAL:	485 (48%)	368	116	0	1		370	75	9	30	1	0
“Other” AEs determined by nurse and surgeon review												
Other Organ System Occurrence	123 (12%)	65	58	0	0		67	41	7	8	0	0
Other Wound Occurrence	81 (8%)	56	25	0	0		28	47	5	1	0	0
Other Cardiac Occurrence	9 (1%)	3	6	0	0		1	6	2	0	0	0
Other Respiratory Occurrence	5 (<1%)	0	5	0	0		0	5	0	0	0	0
Other Urinary Occurrence	3 (<1%)	1	2	0	0		0	3	0	0	0	0
Other CNS Occurrence	1 (<1%)	0	1	0	0		0	0	0	1	0	0
TOTAL:	222 (22%)	125	97	0	0		96	102	14	10	0	0

NOTE: For explanations of the harm and complication ratings refer to Table 1. IHI=Institute for Healthcare Improvement; SSI=Surgical Site Infection; CNS=Central nervous system.

* Death is the rated “T” on the IHI harm scale and classified as Grade V by Clavien-Dindo. These columns are not shown in the table.