

The following content was supplied by the author as supporting material and has not been copy-edited or verified by JBJS.

Appendix

TABLE E-1 Care-Module Trigger Events That May Indicate an Adverse Event Has Occurred

Trigger	Definition
Transfusion/use of blood products	C1-Transfusion of Blood or Use of Blood Products Procedures can require intraoperative transfusion of blood products for replacement of estimated blood lost, but this has become less common with “bloodless surgery.” Any transfusion of packed red blood cells or whole blood should be investigated for causation, including excessive bleeding (surgical or anticoagulant-related), unintentional trauma of a blood vessel, etc. Transfusion of many units or beyond expected blood loss within the first 24 hours of surgery, including intraoperatively and postoperatively, will likely be related to a perioperative adverse event. Cases in which excessive blood loss occurred preoperatively are typically not adverse events. Patients receiving anticoagulants who require transfusion of fresh frozen plasma and platelets have likely experienced an adverse event related to the use of anticoagulants.
Code, cardiac or pulmonary arrest, or rapid response team activation	All “codes,” cardiac or pulmonary arrests, and activation of Rapid Response Teams need to be carefully reviewed as this may be the culmination of an adverse event (check for medication-related issues). However, not all codes/arrests/team responses are adverse events as some may be related to progression of a disease process. For example, cardiac or pulmonary arrest intraoperatively or in the post anesthesia care unit should always be considered an adverse event. In the first 24 hours postoperatively, it is also very likely to be an adverse event. Conversely, a sudden cardiac arrhythmia resulting in cardiac arrest may not be an adverse event, but related to cardiac disease. Failure to recognize signs and symptoms would be an example of an error of omission and would not be counted as an adverse event unless the changes in patient condition were the result of some medical intervention
Acute dialysis	A new need for dialysis may be the course of a disease process or the result of an adverse event. Examples of adverse events might be drug-induced renal failure or reaction to the administration of a dye for radiographic procedures.
Positive blood culture	A positive blood culture at any time during the hospitalization must be investigated as an indicator of an adverse event, specifically a hospital-associated infection. Generally, adverse events associated with this trigger will include infections that are diagnosed 48 hours or more after admission, such as bloodstream line infections, sepsis from other device infections (e.g., catheter-associated urinary tract infection), or any other hospital-associated infection. Patients with positive blood cultures related to other disease (such as community acquired pneumonia progressing to sepsis) would not be considered to have adverse events.
X-ray or doppler studies for emboli or deep vein thrombosis	Development of a deep vein thrombosis (DVT) or pulmonary embolism (PE) during a hospital stay in most cases will be an adverse event. Rare exceptions may be those related to disease processes such as cancer or clotting disorders. However, in most patients this is harm related to medical care, even if all appropriate preventive measures appear to have been taken. If the hospitalization occurs due to a DVT or embolism, look for causation prior to admission that could be attributed to medical care such as a prior surgical procedure. The lack of prophylaxis with no DVT or PE is not an adverse event; it is an error of omission.
Decrease in hemoglobin or hematocrit of 25% or greater	Any decrease of 25% or greater in hemoglobin (Hg) grams or hematocrit (Hct) should be investigated, especially when occurring in a relatively short period of time such as 72 hours or less. Bleeding events are commonly identified by this trigger and may be related to use of anticoagulants or aspirin or a surgical misadventure. The decrease in Hg or Hct in itself is not an adverse event unless related to some medical treatment. A decrease associated with a disease process is not an adverse event.
Patient fall	A fall in a care setting represents a failure of care and may be the result of medications, equipment failure, or failure of adequate staffing. Any fall in the care setting that causes

	injury, regardless of cause, is an adverse event; a fall without injury is not an adverse event. Falls resulting in injury and admission to the hospital should be reviewed for causation. A fall that is the result of medical treatment (such as from medications) should be considered an adverse event, even if the fall occurred outside the hospital.
Pressure ulcers	Pressure or decubitus ulcers are adverse events. Chronic decubiti are adverse events if they occurred during a hospitalization. If the ulcers occurred in the outpatient setting, consider the etiology (over-sedation, etc.) to assess if an adverse event occurred.
Readmission within 30 days	Any readmission, particularly within 30 days of discharge, could be an adverse event. An adverse event may not manifest itself until after the patient has been discharged from the hospital, especially if the length of stay is minimal. Examples of adverse events may include surgical site infection, deep vein thrombosis, or pulmonary embolism.
Restraint use	Whenever restraints are used, review the documented reasons and evaluate the possible relationship between the use of restraints and confusion from drugs, etc., which would indicate an adverse event.
Healthcare-associated infections	Any infection occurring after admission to the hospital is likely an adverse event, especially those related to procedures or devices. Infections that cause admission to the hospital should be reviewed to determine whether they are related to medical care (e.g., prior procedure, urinary catheter at home or in long-term care) versus naturally occurring disease (e.g., community-acquired pneumonia).
In-hospital stroke	Transfers to a higher level of care within the institution, to another institution, or to your institution from another must be reviewed. All transfers are likely to be the result of an adverse event and a patient's clinical condition may have deteriorated secondary to an adverse event. Look for the reasons for the transfer. For example, in the case of admission to intensive care following respiratory arrest and intubation, if the respiratory arrest was a natural progression of an exacerbation of chronic obstructive pulmonary disease (COPD), then it would not be an adverse event; if it was caused by a pulmonary embolism that developed postoperatively or resulted from over-sedation of a patient with COPD, it would be an adverse event. A higher level of care may include telemetry, intermediate care, or a step-down unit if the patient is transferred from a general medical or surgical nursing unit.
Any procedure complication	A complication resulting from any procedure is an adverse event. Procedure notes frequently do not indicate the complications, especially if they occur hours or days after the procedure note has been dictated, so watch for complications noted in coding, the discharge summary, or other progress notes.
Other	Frequently when the record is reviewed, an adverse event is uncovered that does not fit a trigger. Any such event can be placed under this "Other" trigger. An event does not require a listed trigger to be counted as an event.

TABLE E-2 Medication Triggers Events That May Indicate an Adverse Event Has Occurred

Clostridium difficile positive stool	A positive C. difficile assay is an adverse event if a history of antibiotic use is present.
Partial thromboplastin time (PTT) greater than 100 seconds	Elevated PTT measurements occur when patients are on heparin. Look for evidence of bleeding to determine if an adverse event has occurred. Elevated PTT in itself is not an adverse event—there must be manifestation such as bleeding, drop in Hg or Hct, or bruising.
International normalized ratio (INR) greater than 6	Look for evidence of bleeding to determine if an adverse event has occurred. An elevated INR in itself is not an adverse event.
Glucose less than 50 mg/dl	Review for symptoms such as lethargy and shakiness documented in nursing notes, and the administration of glucose, orange juice, or other intervention. If symptoms are present, look for associated use of insulin or oral hypoglycemics. If the patient is not symptomatic, there is no adverse event.
Rising BUN or serum creatinine 2 times (2x) over baseline	Review laboratory records for rising levels of either BUN or serum creatinine. If a change of 2 times greater than baseline levels is found, review medication administration records for medications known to cause renal toxicity. Review physician progress notes and the history and physical for other causes of renal failure, such as pre-existing renal disease or diabetes, that could have put the patient at greater risk for renal failure; this would not be an adverse event, but rather the progression of disease.
Vitamin K administration	If Vitamin K was used as a response to a prolonged INR, review the record for evidence of bleeding. An adverse event has likely occurred if there are laboratory reports indicating a drop in hematocrit or guiac-positive stools. Check the progress notes for evidence of excessive bruising, gastrointestinal (GI) bleed, hemorrhagic stroke, or large hematomas as examples of adverse events.
Diphenhydramine (benadryl) administration	Diphenhydramine is frequently used for allergic reactions to drugs but can also be ordered as a sleep aid, a pre-op/pre-procedure medication, or for seasonal allergies. If the drug has been administered, review the record to determine if it was ordered for symptoms of an allergic reaction to a drug or blood transfusion administered either during the hospitalization or prior to admission—these are adverse events.
Romazicon (flumazenil) administration	Romazicon reverses the effect of benzodiazepine drugs. Determine why the drug was used. Examples of adverse events are severe hypotension or marked, prolonged sedation.
Naloxone (narcan) administration	Naloxone is a powerful narcotic antagonist. Usage likely represents an adverse event except in cases of drug abuse or self-inflicted overdose.
Anti-emetic administration	Nausea and vomiting commonly are the result of drug administrations both in surgical and non-surgical settings. Anti-emetics are commonly administered. Nausea and vomiting that interferes with feeding, postoperative recovery, or delayed discharge suggests an adverse event. 1 or 2 episodes treated successfully with anti-emetics would suggest no adverse event. Reviewer judgment is needed to determine whether harm occurred.
Over-sedation/hypotension	Review the physician progress, nursing, or multidisciplinary notes for evidence of oversedation and lethargy. Review vital signs records or graphics for episodes of hypotension related to the administration of a sedative, analgesic, or muscle relaxant. Intentional overdose is not considered an adverse event.
Abrupt medication stop	Although the discontinuation of medications is a common finding in the record, abruptly stopping medications is a trigger requiring further investigation for cause. A sudden change in patient condition requiring adjustment of medications is often related to an adverse event. “Abrupt” is best described as an unexpected stop or deviation from typical ordering practice; for example, discontinuation of an intravenous antibiotic for switch to oral is not unexpected.
Other	Use this trigger for adverse drug events detected but not related to 1 of the Medication triggers listed above.

TABLE E-3 Surgical Care Trigger Events That May Indicate an Adverse Event Has Occurred

Return to surgery	A return to the operating room can either be planned or unplanned, and both can be a result of an adverse event. An example of an adverse event would be a patient who had internal bleeding following the first surgery and required a second surgery to explore for the cause and to stop the bleeding. Even if the second surgery is exploratory but reveals no defect, this should be considered an adverse event.
Change in procedure	When the procedure indicated on the postoperative notes is different from the procedure planned in the preoperative notes or documented in the surgical consent, a reviewer should look for details as to why the change occurred. An unexpected change in procedure due to complications or device or equipment failure should be considered an adverse event, particularly if length of stay increases or obvious injury has occurred.
Admission to intensive care postoperatively	Admission to an intensive care unit can be either a normal postoperative journey or it may be unexpected. The unexpected admissions frequently are related to operative adverse events. For example, admission to intensive care following aortic aneurysm repair may be expected, but admission following knee replacement would be unusual. The reviewer needs to determine why intensive care admission occurred.
Intubation or reintubation or use of BiPap in post anesthesia care unit (PACU)	Anesthesia, sedatives, or pain medications can result in respiratory depression requiring the use of BiPap or reintubation postoperatively, which would be an adverse event.
X-ray intraoperatively or in post anesthesia care unit	Imaging of any kind that is not routine for the procedure requires investigation. An x-ray taken due to suspicion of retained items or incorrect instrument or sponge count would be a positive trigger. The identification of a retained item necessitating an additional procedure is an adverse event. If the retained item is identified and removed without any additional evidence of harm or reoperation to the patient, this is not considered an adverse event.
Intra- or postoperative death	All deaths that occur intraoperatively should be considered adverse events unless death is clearly expected and the surgery was of a heroic nature. Postoperative deaths will require review of the record for specifics, but in general all post-op deaths will be adverse events.
Mechanical ventilation greater than 24 hours postoperatively	Short-term mechanical ventilation postoperatively for cardiac, major thoracic, and certain abdominal procedures is planned. If the patient requires mechanical ventilation beyond 24 hours, an intraoperative or postoperative adverse event should be considered. Patients with pre-existing pulmonary or muscular disease may experience more difficulty in quickly weaning from a ventilator postoperatively, but this should not automatically exclude the possibility of an adverse event. Reviewers must use clinical judgment to determine whether the intraoperative and postoperative care was event free or part of the disease process.
Intraoperative administration of Epinephrine, Norepinephrine, Naloxone, or Romazicon	These medications are not routinely administered intraoperatively. Review anesthesia and operative notes to determine the reason for administration. Hypotension caused by bleeding or over-sedation are examples of adverse events that might be treated with these medications.
Postoperative increase in troponin levels greater than 1.5 nanogram/mL	A postoperative increase in troponin levels may indicate a cardiac event. Reviewers will need to use clinical judgment as to whether a cardiac event has occurred.
Injury, repair, or removal of organ during operative procedure	Review operative notes and postoperative notes for evidence that the procedure included repair or removal of any organ. The removal or repair must be part of the planned procedure or this is an adverse event and likely the result of surgical misadventure such as an accidental injury.
Occurrence of any operative complication	This refers to any of a number of complications, including but not limited to PE, DVT, decubiti, MI, renal failure, etc.

The IHI provides a definition of all trigger events to aid reviewers in determining if an adverse event has occurred.

TABLE E-4 The National Coordinating Council for Medication Error Reporting and Prevention Index as Used by the IHI for Reporting Level of Harm Following an Adverse Event

Level of Harm Category	Description
E	Temporary harm to patient and required treatment
F	Temporary harm to patient and required initial or prolonged length of stay
G	Permanent patient harm
H	Intervention required to sustain life
I	Patient death