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Adverse Events Toolkit: Clinical Guidance for Identifying Harm

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ACRONYMS

Catheter-associated Urinary Tract Infection (CAUTI)

Centers for Disease Control and Prevention (CDC)

Chronic Obstructive Pulmonary Disease (COPD)

Colony-forming Unit (CFU)

Computerized Tomography (CT)

Computerized Tomography Pulmonary Angiogram (CTPA)

Deep Vein Thrombosis (DVT)

Diabetic Ketoacidosis (DKA)

Electrocardiogram (EKG)

Emergency Department (ED)

Fraction of Inspired Oxygen (FiO2)

Global Trigger Tool (GTT)

Glomerular Filtration Rate (GFR)

Hyperosmolar Hyperglycemic Nonketotic Syndrome (HHNS)

Infectious Diseases Society of America (IDSA)

Institute for Healthcare Improvement (IHI)

Intensive Care Unit (ICU)

International Normalized Ratio (INR)

Intravenous (IV)

Mean Arterial Pressure (MAP)

National Healthcare Safety Network (NHSN)

Office of Inspector General (OIG)

Percutaneous Endoscopic Gastrostomy (PEG)

Positive End-expiratory Pressure (PEEP)

Post Anesthesia Care Unit (PACU)

Pulmonary Embolism (PE)

Sliding Scale Insulin (SSI)

Society for Healthcare Epidemiology of America (SHEA)

ST-segment Elevation Myocardial Infarction (STEMI)

Tissue Plasminogen Activator (tPA)

Transient Ischemic Attack (TIA)

Ventilator-associated Event (VAE)

White Blood Cells (WBC)

INTRODUCTION

This toolkit resource provides details about how clinical experts assessed specific conditions and injuries related to common types of harm events while conducting our medical record reviews. It also includes information about the "triggers" (i.e., clinical clues of harm) our reviewers used to screen for possible harm events in hospitals. The toolkit describes the clinical guidance used in a recent report, *Adverse Events in Hospitals: A Quarter of Medicare Patients Experienced Harm in October 2018*, OEI-06-18-00400, and builds upon a series of reports about adverse events in hospitals and other health care settings. Of the 18 reports currently in this series, 7 studies used nurses and physicians to review medical records to identify adverse events (each focused on a different health care setting).

Companion Resource

For the methodology used during OIG's medical record reviews, see our companion resource: *Adverse Events Toolkit: Medical Record Review Methodology*.

The goal of our medical record reviews was to establish a national, point-in-time rate of patient harm. This methodology builds on the Global Trigger Tool (GTT) methodology developed by the Institute for Healthcare Improvement (IHI) which we adapted and used for screening and flagging medical records for possible patient harm.[1] A companion resource, *Adverse Events Toolkit: Medical Record Review Methodology*, details about our methodological approach and decision criteria.

During the course of our reviews, we recorded internal decisions, researched clinical literature and guidelines, interviewed experts in various fields, and conducted routine calls to gain consensus among reviewers on decisions regarding what constitutes harm and how to categorize harm events.

The "Specific Conditions and Injuries" section provides guidance on harm identification and categorization for 29 conditions encountered during our medical record reviews. These include conditions and injuries that were commonly found in our reviews and for which we provided specific guidance to our reviewers. As such, the list is not comprehensive of all types of patient harm events.

The "Hospital Trigger Tool" section includes the triggers we used for flagging potential harm events in hospitals. We use triggers like clinical clues within the medical record that may indicate harm (e.g., abnormal laboratory values or falls). In addition, the Appendix in this resource include the trigger tool worksheets that reviewers used in different health care settings.

The clinical information presented is current as of October 2018, our last adverse events medical record review. We did not reassess all clinical guidelines when drafting this toolkit. As such, users should seek out the most recent clinical guidance and standards of care and apply those to their adverse event determinations.

Standards

We conducted this work in accordance with the Quality Standards for Inspection and Evaluation issued by the Council of the Inspectors General on Integrity and Efficiency.

Legal Notice

This toolkit is a technical resource and is not intended to be used to determine compliance with any laws, regulations, or other guidance. It is not intended to, and does not create, any rights, privileges, or benefits, substantive or procedural, enforceable by a party against the United States; its agencies or instrumentalities; its officers or employees; or any other person. OIG does not endorse external content or material linked in this toolkit.

SPECIFIC CONDITIONS AND INJURIES

The tables below provide guidance on harm identification and categorization for 29 conditions encountered during the course of our medical record reviews. For each condition, we provide a definition and information about how to identify and describe harm events.[2] In addition, we have sections on where in the medical record relevant information is likely to be found (section called "Key Medical Record Documents") and tips on what to document to facilitate quality assurance efforts (section called "Quality Assurance Documentation"). Where applicable, we provide the most commonly associated triggers and useful references for each condition and injury.

Abnormal electrolytes

Abnormal electrolytes

Condition Definition

Abnormal electrolytes are imbalances of electrolytes in the body, most notably sodium and potassium. Certain medical conditions can contribute to abnormal electrolyte levels such as severe dehydration and heart and kidney disease. Also see "Fluid overload."

Harm Determination

We require that the patient show signs or symptoms (e.g., confusion, shortness of breath, electrocardiogram (EKG) changes, etc.) of abnormal electrolytes, and the reviewer should confirm that the abnormal electrolytes are not caused by underlying disease. These events can occur as a result of medical care or an omission of care. For example, certain medications, supplements, or tube feedings can contribute to an imbalance of electrolytes. An omission of care would include a delay or failure to treat a patient with abnormal electrolytes. In general, asymptomatic laboratory tests are considered clues of harm but are not usually considered a harm event. Exceptions to this rule include hyperkalemia for which we would consider potassium (K+) ≥6.0 mEq/mL a harm event regardless of signs and symptoms.

Preventability

Abnormal electrolytes may be a **preventable** event if:

- Patients received excessive diuretics or supplements (e.g., potassium chloride) and
- An imbalance was exacerbated by inadequate monitoring or substandard or delayed intervention to treat or prevent abnormal electrolyte levels.

Abnormal electrolytes may be a **nonpreventable** event if:

- A medically complex patient with significant underlying disease (e.g., chronic kidney disease or end stage renal disease on hemodialysis, end stage congestive heart failure) that predisposed them to abnormal electrolytes and made therapeutic intervention challenging.

Abnormal electrolytes

Key Medical Record Documents

Reviewers may find documentation of abnormal electrolytes in the following sections of the patient's medical record:

- Laboratory results,
- Progress notes (physician and nurse notes), and
- Medication administration record (any medications prescribed to correct electrolytes such as sodium polystyrene sulfonate or sodium zirconium cyclosilicate).

Quality Assurance Documentation

For abnormal electrolytes, the following factors may be helpful in ensuring consistency and accuracy:

- Signs and symptoms such as nausea and/or vomiting, confusion, weakness, and arrhythmia (as measured by EKG changes), and
- Medication administration record for medications (e.g., diuretics) and supplements (e.g., potassium) that providers gave the patient.

Associated Trigger(s)

See M13 Sodium polystyrene (kayexalate administration) or potassium greater than or equal to (≥) 6 mEq/L.

Acute kidney injury

Acute kidney injury

Condition Definition

Acute kidney injury is the sudden loss of the kidneys' ability to remove waste, also referred to as acute renal failure. Similarly, acute renal insufficiency is poor kidney function due to reduced blood flow which could progress to acute kidney failure. Acute kidney injury may be caused by severe dehydration, the use of IV contrast during an imaging study, excessive blood loss, antibiotics, overuse of NSAIDs, and other factors.

Harm Determination

We consider an acute kidney injury a harm event when one of the following criteria is met:

1) Serum creatinine level is 1.5 times greater than at baseline,
2) GFR decreases by more than 25 percent, or
3) Urine output is less than 0.5 mL/Kg/h for 6 hours.[3]

Acute kidney injury

Signs and symptoms are not required in calling the acute kidney injury a harm event if the above criteria are met. These criteria are based on the acute kidney injury indicators from the RIFLE criteria (see third reference below).

We rule out the natural progression of disease as the cause of an acute kidney injury in patients with pre-existing conditions, such as chronic renal disease, before considering it a harm event.

Preventability

Acute kidney injury may be a **preventable** event if:

- The patient received excessive diuretics or other medications, such as NSAIDs,
- Providers failed to provide timely intervention to prevent or treat acute kidney injury particularly in cases where the patient exhibited signs and symptoms such as severe dehydration,
- The patient's fluids were not carefully titrated, or
- Clinical practice guidelines were not followed (see "References" below).

Acute kidney injury may be a **nonpreventable** event if:

- The patient was highly susceptible to acute kidney injury (e.g., poor renal perfusion) or
- The patient required medication (e.g., diuretics or IV contrast) for diagnosis or treatment of another health condition where the benefits of treatment outweighed the risks of acute kidney injury.

In cases involving IV contrast-induced acute kidney injury, reviewers may want to assess whether providers followed guidelines from the "Kidney Disease: Improving Global Outcomes" (KDIGO) workgroup. This may include assessing whether the patient was provided standard volume administration with IV normal saline prior to undergoing a coronary angiography, limiting the volume of contrast administered, avoiding high-osmolar contrast media in patients with impaired baseline renal function, and stopping nephrotoxic medications, especially NSAIDs.

Key Medical Record Documents

Reviewers may find documentation of an acute kidney injury in the following sections of the patient's medical record:

- History and physical,
- Medication administration record,
- Laboratory results,
- Progress notes (physician and nurse notes),
- Consultation notes with focus on nephrology,
- Intake and output, and
- Dialysis notes.

Acute kidney injury

Quality Assurance Documentation

For acute kidney injuries, the following factors may be helpful in ensuring consistency and accuracy:

- The prior lowest (baseline) compared to the highest or peak (at the time event occurred) serum creatinine and
- The creatinine and GFR measures (including the baseline measure and percent reduction) as well urine output and days/times involved.

Associated Trigger(s)

See the following triggers:

- C4 Acute dialysis and
- M5 Rising blood urea nitrogen (BUN) or serum creatinine greater than (>) 1.5 times baseline.

References

- Bellomo, et al., "Acute renal failure definition, outcome measures, animal models, fluid therapy and information technology needs: the Second International Consensus of the Acute Dialysis Quality Initiative (ADQI) Group," *Critical Care*, Volume 8, Issue 4, August 2004, Figure 1.
- Kidney Disease: Improving Global Outcomes (KDIGO) Acute Kidney Injury Work Group, "KDIGO Clinical Practice Guideline for Acute Kidney Injury," *Kidney International Supplements*, Volume 2, Issue 1, March 2012.
- Lopes, J.A., and Jorge, S., "The RIFLE and AKIN Classifications for Acute Kidney Injury: A Critical and Comprehensive Review," *Clinical Kidney Journal*, Volume 6, Issue 1, February 2013.

Acute myocardial infarction

Acute myocardial infarction

Condition Definition

Acute myocardial infarction is myocardial necrosis resulting from acute obstruction of a coronary artery. Common signs and symptoms may include pressure-like substernal pain and the sudden onset of unexplained dyspnea with or without associated symptoms (e.g., nausea and vomiting, dizziness, palpitations, diaphoresis). Acute myocardial infarction includes both acute ST-segment elevation myocardial infarction (STEMI) and non-ST-segment elevation myocardial infarction (NSTEMI). Diagnosis and treatment strategies vary between STEMI and NSTEMI.

A STEMI occurs when one or more of the coronary arteries that supply the heart with blood become occluded. A STEMI can be diagnosed through EKG interpretation and a cardiac marker test (i.e., elevated troponin and creatine kinase levels).

Acute myocardial infarction

A NSTEMI is diagnosed similarly but does not include ST-segment elevation on the EKG or a new left bundle branch block. In contrast to a STEMI, a NSTEMI involves a partial occlusion rather than a complete occlusion of a coronary artery and can be treated by nitroglycerin.

Harm Determination

We consider an acute myocardial infarction a harm event if caused or exacerbated by the medical care provided or exacerbated by an omission of care. Although an acute myocardial infarction typically occurs as a result of underlying heart disease, a harm event may occur as the result of a high-risk procedure. Reviewers should evaluate any acute myocardial infarction that was new or present on admission to determine whether appropriate diagnosis and treatment was provided.

An omission of care, such as a delay in providing immediate care, may result in an extension of a myocardial infarction or re-infarction. Such omissions may result in worsening of the patient's condition with prolonged ischemia and further damage to the heart.

Preventability

An acute myocardial infarction may be a **preventable** event if:

- A patient is admitted with an evolving myocardial infarction and the providers fail to recognize or treat, resulting in an infarct extension and clinical deterioration.

An acute myocardial infarction may be a **nonpreventable** event if:

- The acute myocardial infarction is a complication of a high-risk procedure (e.g., high-risk percutaneous coronary intervention) where the potential benefits outweighed the risks, and providers followed evidence-based practices with timely and appropriate intervention (e.g., immediate catheterization), in which case the harm is considered not preventable.

Key Medical Record Documents

Reviewers may find documentation of an acute myocardial infarction in the following sections of the patient's medical record:

- Medication administration record for appropriate intervention, such as nitrates and morphine, and documentation of thrombolytics, such as tPA,
- Laboratory tests for cardiac enzymes, such as troponin,
- Progress notes (physician and nurse notes),
- Cardiologist's assessment,
- Rapid response team notes,
- EKG and if indicated, telemetry strips, and
- Interventional cardiologist procedural notes, such as percutaneous coronary intervention.

Acute myocardial infarction

Quality Assurance Documentation

For acute myocardial infarction, the following factors may be helpful in ensuring consistency and accuracy:

- Patient signs and symptoms (e.g., complaints of chest pain) and date/time of onset, date/time of diagnostic tests, and if symptoms are present on admission a determination if there was a delay in intervention,
- Test results of an echocardiogram, including ejection fraction, cardiac enzyme tests (troponin levels), and other tests (e.g., cardiac catheterization, cardiac MRI, etc.), and
- Any high-risk procedures that may have contributed to extension of acute myocardial infarction.

Associated Trigger(s)

See the following triggers:

- C3 Code/arrest/rapid response team and
- S9 Abnormal post-operative troponin level, including sensitive or highly sensitive troponin I or troponin T.

References

- O'Gara, et al., "2013 ACCF/AHA Guideline for the Management of ST-Elevation Myocardial Infarction, A Report of the American College of Cardiology Foundation/American Heart Association Task Force on Practice Guidelines," *Circulation*, Volume 127, Issue 4, January 2013. Available at https://www.ahajournals.org/doi/full/10.1161/CIR.0b013e3182742cf6.
- Amsterdam, et al., "2014 AHA/ACC Guideline for the Management of Patients with Non-ST-Elevation Acute Coronary Syndromes, A Report of the American College of Cardiology Foundation/American Heart Association Task Force on Practice Guidelines," *Circulation*, Volume 130, Issue 25, December 2014. Available at https://doi.org/10.1161/CIR.0000000000000134.

Allergic reaction

Allergic reaction

Condition Definition

An allergic reaction occurs when the immune system reacts to a substance (an allergen). Some reactions may be severe, such as anaphylaxis, a life-threatening condition. Others may be less severe, such as skin rashes.

Allergic reaction

Harm Determination

Allergic reactions may result from medications, food, bandages, or other allergen exposures. Allergic reactions are considered a harm event if any intervention is required, including discontinuing exposure to the allergen (such as medication). We considered an allergic reaction that occurs in the hospital harm regardless of whether the allergy was known in advance.

Preventability

An allergic reaction may be a **preventable** event if:

- The patient with a known allergy history is given a medication or exposed to an allergen or
- The patient was given a medication that was not indicated.

An allergic reaction may be a **nonpreventable** event if:

- The patient without a known allergy history to an allergen experiences an allergic reaction.

Key Medical Record Documents

Reviewers may find documentation of allergic reactions in the following sections of the patient's medical record:

- Medication administration record,
- Progress notes (physician and nurse notes),
- Rapid response team notes, and
- Patient education documentation—review if there is education documented for new medication or for a new allergy.

Quality Assurance Documentation

For allergic reactions, the following factors may be helpful in ensuring consistency and accuracy:

- Any signs and symptoms (e.g., skin rash) the patient developed related to their stay,
- Any treatment or intervention required as a result of signs and symptoms of an allergic reactions,
- Whether the patient's medical history listed any allergic reactions to medication or substances that the patient reacted to during their stay for determining preventability, and
- The type and severity of the allergic reaction (e.g., rash, hives, anaphylaxis).

Associated Trigger(s)

See M7 Diphenhydramine use.

Aspiration

Aspiration

Condition Definition

Aspiration is the accidental inhalation of foreign material (food, liquid, or gastric contents) into the airway. This could cause difficulty breathing or lead to an infection of the respiratory tract (aspiration pneumonia or bronchitis).

Harm Determination

We considered significant aspiration with resulting respiratory impairment or infections as a harm event. This harm event may include aspiration pneumonia, bronchitis, or acute respiratory distress.

Preventability

Consider the patient's underlying condition, history of aspiration, and appropriateness of prevention efforts when determining preventability for aspiration.

Aspiration may be a **preventable** event if:

- The patient with a known risk of aspiration was not given an appropriate diet or the head of the bed was not elevated.

Aspiration may be a **nonpreventable** event if:

- The patient had a history of recurrent aspiration or dysphagia due to underlying disease (e.g., severe stroke, end stage Parkinsonism) and/or required the use of a percutaneous endoscopic gastrostomy (PEG) tube or other gastrostomy and/or jejunostomy tube and aspirated despite providers following preventative measures such as appropriate evaluation, prevention, or intervention for aspiration (e.g., swallowing evaluation, appropriate diet, elevation of head of bed).

Key Medical Record Documents

Reviewers may find documentation of aspiration in the following sections of the patient's medical record:

- Progress notes (physician and nurse notes),
- Pulmonologist's or gastroenterologist's consult notes,
- Dietician consult—a patient might need a change in their current diet d/t aspiration; for example, indication of a clear liquid diet, full liquid diet, pureed diet, or other modified consistencies (liquids and solids),
- Speech and language pathology evaluations, including swallowing evaluations, and
- Radiology reports.

Quality Assurance Documentation

For aspiration, the following factors may be helpful in ensuring consistency and accuracy:

Aspiration

- History of recurrent aspiration,
- History or evidence of dysphagia associated with underlying disease or use of a PEG tube, other gastrostomy tube, or other enteral tube,
- History of significant stroke, head or neck cancer, or advanced Parkinsonism or other neuromuscular impairment with symptoms of dysphagia and aspiration, and
- Appropriate prevention or intervention.

Associated Trigger(s)

See C17 Aspiration.

Catheter-associated urinary tract infection

Catheter-associated urinary tract infection

Condition Definition

A catheter-associated urinary tract infection (CAUTI) is an infection of any part of the urinary system, including the urethra, bladder, ureters, and kidneys.

Harm Determination

We used CDC's epidemiological definition of a CAUTI and the Infectious Diseases Society of America's (IDSA's) clinical definition of a CAUTI to determine the presence of harm. (See "References" below for links to CDC and IDSA guidelines.) Our reviewers followed the CDC definition but when patients had a CAUTI that did not meet the CDC definition we directed our reviewers to consider whether the CAUTI met the IDSA's clinical definition in determining whether the CAUTI was a harm event attributable to the care provided.

- CDC epidemiological definition—A patient must meet the following criteria: (1) patient had an indwelling urinary catheter in place for more than 2 consecutive days and the catheter was either present on the day of the event or removed the day before; (2) patient had at least one of the following signs or symptoms: fever (>38°C), suprapubic tenderness, or costovertebral angle pain or tenderness; and (3) patient had a positive urine culture of ≥100,000 CFU/ml with no more than 2 species of microorganisms. *Candida* as well as a report of "yeast" that is not otherwise specified is excluded from meeting the CDC's definition.[4]
- IDSA clinical definition—A patient must meet the following criteria: (1) patient had an indwelling urethral, indwelling suprapubic, or intermittent catheterization; (2) patient had symptoms or signs compatible with UTI without another identifiable source of bacteria; and (3) patient had a culture growth of ≥1,000 CFU/mL of uropathogenic bacteria from a catheter-collected urine specimen. Symptoms include fever, hypotension, or other vital sign

and/or laboratory changes (elevated WBC), suprapubic or costovertebral angle tenderness, and otherwise unexplained systemic symptoms such as altered mental status.[5, 6]

In addition to the definitions above, a spontaneous urinary tract infection that develops without an associated device or intervention is usually not considered a harm event. Asymptomatic bacteriuria associated with a urinary catheter is not considered a harm event. Asymptomatic bacteremia associated with the same microorganism in the urine, however, may be used to confirm a UTI when symptoms are not present.

See "Hospital-acquired infection" for other information related to broader infection determinations.

Preventability

A CAUTI is almost always considered **preventable** when the appropriate infection prevention precautions are employed.

A CAUTI may be a **nonpreventable** event if appropriate prevention precautions are clearly documented or if the patient is particularly susceptible to the infection.

In determining preventability, we recommend that reviewers consult the resource *Guideline for Prevention of Catheter-Associated Urinary Tract Infection*, under references.

Key Medical Record Documents

Reviewers may find documentation of a CAUTI in the following sections of the patient's medical record:

- Medication administration record—look for new antibiotics that may have been started,
- Progress notes (physician and nurse notes),
- Consultation notes, e.g., infectious disease and urology,
- Documentation on insertion and care for urinary catheters,
- Intake and output, and
- Nursing care plans—look for initiation and continuation of urinary catheter preventative care and management.

Quality Assurance Documentation

For CAUTIs, the following factors may be helpful in ensuring consistency and accuracy:

- All organisms with their colony count from an appropriately collected urine culture (the culture that is the basis of the CAUTI event),
- Signs and symptoms, and
- Date and type of the most recent urinary catheterization (in/out, continuous).

Associated Trigger(s)

See C12 Hospital-acquired infections and C5 Positive culture (e.g., blood, urine, stool).

Catheter-associated urinary tract infection

References

- Gould, et al., *Guideline for Prevention of Catheter-Associated Urinary Tract Infection* (2009), Healthcare Infection Control Practices Advisory Committee, June 2009. Available at https://www.cdc.gov/infectioncontrol/pdf/guidelines/cauti-guidelines-H.pdf.
- CDC, "Urinary Tract Infection (Catheter-Associated Urinary Tract Infection [CAUTI] and Non-Catheter-Associated Urinary Tract Infection [UTI]) Events," January 2023. Available at https://www.cdc.gov/nhsn/pdfs/pscmanual/7psccauticurrent.pdf.
- Lo, et al., "Strategies to Prevent Catheter-Associated Urinary Tract Infections in Acute Care Hospitals: 2014 Update," *Infection Control and Hospital Epidemiology*, Volume 35, No. S2, May 2014.
- Hooton, et al., "Diagnosis, prevention, and treatment of catheter-associated urinary tract infection in adults: 2009 International Clinical Practice Guidelines from the Infectious Diseases Society of America," *Clinical Infectious Diseases*, Volume 50, Issue 5, February 2010.

Clostridioides difficile infection

Clostridioides difficile infection

Condition Definition

A *Clostridioides difficile* (*C. diff*) infection is caused by a bacterium known as *C. diff* that can cause symptoms ranging from diarrhea to life-threatening inflammation of the colon.

Harm Determination

We considered a *C. diff* infection a harm event if diagnosed on or after the fourth calendar day after admission when the admission day is calendar day 1.[7] *C. diff* infections that develop within the first 3 calendar days are considered present on admission and are not counted as harm events. *C. diff* infections should be confirmed by a stool test.

In determining whether a *C. diff* infection was properly treated, review the patient medication record to determine if the patient received first-line treatment of oral vancomycin or whether the patient received metronidazole which is no longer considered the first-line treatment. For fulminant *C. diff*, the 2018 guidelines recommend oral vancomycin.[8]

See "Hospital-acquired infection" for other information related to broader infection determinations.

Preventability

A *C. diff* infection is usually considered likely **preventable** because *C. diff* can often be prevented by following appropriate infection control procedures. See "References" for clinical guidelines related to diagnosis and treatment of *C. diff* infections.

Clostridioides difficile infection

A *C. diff* infection is considered **not preventable** if the patient had a *C. diff* infection in the past 6 months. About one in six patients who have been previously infected with *C. diff* will contract a relapse infection in the subsequent 2 to 8 weeks from the original infection.[9]

Key Medical Record Documents

Reviewers may find documentation of a *C. diff* infection in the following sections of the patient's medical record:

- History and physical, especially for history of *C. diff* and prior antibiotic usage,
- Medication administration record—review for risk factors such as prior antibiotics and proton pump inhibitors (PPI), and medications to treat *C. diff*,
- Laboratory results specific to *C. diff*,
- Progress notes (physician and nurse notes), and
- Infectious disease specialist and gastroenterologist consultation notes.

Quality Assurance Documentation

For *C. diff* infections, the following factors may be helpful in ensuring consistency and accuracy:

- Signs and symptoms of *C. diff* infection such as clinically significant diarrhea (three or more loose stools in 24 hours), severe abdominal pain, and blood in the stool,
- Results and date and time of diagnostic tests for laboratory diagnosis of *C. diff* infection such as NAAT and EIA screening for GDH or a positive culture from a rectal swab,
- Patient's medical history of a prior *C. diff* infection,
- Medication administration record for indication of whether the recommended first-line evidence-based practice was given, and
- Antibiotic history during prior or current hospitalization.

Associated Trigger(s)

See the following triggers:

- M1 *Clostridioides difficile* positive stool test,
- C12 Hospital-acquired infections, and
- C5 Positive culture (e.g., blood, urine, stool).

References

- Gupta, et al., "Diagnosis and Treatment of Clostridium difficile Infection," *JAMA*, Volume 320, No. 10, September 2018.
- CDC, "Multidrug-Resistant Organism & Clostridioides difficile Infection (MDRO/CDI) Module," January 2023. Available at https://www.cdc.gov/nhsn/PDFs/pscManual/12pscMDRO_CDADcurrent.pdf.

Clostridioides difficile infection

- Johnson, et al., "Clinical Practice Guideline by the Infectious Diseases Society of America (IDSA) and Society for Healthcare Epidemiology of America (SHEA): 2021 Focused Update Guidelines on Management of *Clostridioides difficile* Infection in Adults," *Clinical Infectious Diseases*, Volume 73, Issue 5, September 2021.

Conjunctivitis

Conjunctivitis

Condition Definition

Conjunctivitis is the inflammation or infection of the transparent membrane (conjunctiva) that lines the eyelid and covers the white part of the eyeball. Conjunctivitis may be caused by either a bacterial/viral source or an allergic reaction to a foreign source.

Harm Determination

We considered conjunctivitis a harm event if it met the criteria listed under "Hospital-acquired infection."

Preventability

Bacterial or viral conjunctivitis is usually considered **preventable** with proper hygiene and cleaning of bedsheets, pillowcases, and towels.

Allergic conjunctivitis is typically **not preventable** if the patient had no documented previous history of the allergen (e.g., medication).

Key Medical Record Documents

Reviewers may find documentation of conjunctivitis in the following sections of the patient's medical record:

- History and physical—specifically, allergic drug history or significant exposures,
- Medication administration record—new medications, such as creams and topicals, that might have been started to combat the infection, and
- Progress notes (physician and nurse notes).

Quality Assurance Documentation

For conjunctivitis, the following factors may be helpful in ensuring consistency and accuracy:

- Type of conjunctivitis as allergic, viral, or bacterial,
- Any antibiotics provided to the patient, and
- Patient's history of allergies or prior eye conditions.

Conjunctivitis

Associated Trigger(s)

See C12 Hospital-acquired infections.

Constipation

Constipation

Condition Definition

Constipation is generally defined as having fewer than three bowel movements per week or difficulty having bowel movements. Constipation may be caused by medication (e.g., opioids), diet, or general immobility. Obstipation is a severe form of constipation, where a person cannot pass stool or gas. This is a condition that may lead to obstruction.

Harm Determination

In general, we considered prolonged constipation greater than 3 days with the patient experiencing discomfort (e.g., pain, hard stools, or bloating) with difficulty passing stools a harm event. Many hospitalized patients experiencing constipation require bowel care protocols (e.g., sennosides, mobility, hydration, or stool softeners), but this is not a harm unless the required bowel care is not provided.

Ileus is the slowing down or stopping of peristalsis, muscle contractions that move digested food through a patient's intestines. Post-abdominal surgery patients may experience prolonged ileus up to 5 days. If it is greater than 5 days, patient harm should be considered. Ileus is often diagnosed by physical exam and X-ray. It may be associated with symptoms of bloating, vomiting, constipation, cramps, and loss of appetite. Ileus and constipation may not be a harm attributable to the hospital if the patient had a history of chronic constipation, if it was present on admission, and if appropriate preventative care was provided.

Preventability

Prolonged constipation is considered likely **preventable** if the patient did not receive the appropriate preventative bowel regimen (e.g., medication that was indicated with correct dosage).

Prolonged constipation is considered likely **not preventable** if the patient received the appropriate preventative bowel regimen.

Key Medical Record Documents

Reviewers may find documentation of constipation in the following sections of the patient's medical record:

- Medication administration record,
- Progress notes (physician and nurse notes),

Constipation

- Gastroenterologist consultation notes, and
- Nursing care plans.

Quality Assurance Documentation

For constipation, the following factors may be helpful in ensuring consistency and accuracy:

- Any medication (e.g., opioids, anticholinergics, tricyclic antidepressants, multi-vitamin infusion with iron) with a noted side effect of prolonged constipation including the dates(s) and dose(s) preceding the constipation event,
- If the constipation was related to a post-abdominal surgery,
- Whether a bowel regimen to prevent or treat the constipation was in place,
- The documented frequency of bowel movements,
- Patient signs and symptoms, and
- Any abdominal X-rays taken during the patient's hospital stay.

Associated Trigger(s)

See Appendix B for OIG's nursing home trigger tool worksheet at C25 Prolonged constipation.

Delirium or other change in mental status

Delirium or other change in mental status

Condition Definition

Delirium is a mental status change characterized solely by a disturbance in attention and awareness that is accompanied by a change in cognition that cannot be accounted for by a pre-existing or evolving neurocognitive disorder.

Harm Determination

We considered delirium or change in mental status that occurs during the hospital stay a harm event if not caused by underlying disease (e.g., pre-existing dementia). We did not consider intentional sedation causing mental status change as a harm event, such as medications provided as comfort measures for end-of-life care or to agitated patients.

Preventability

Reviewers should consider a patient's prior medical history, age, and other risk factors when determining whether delirium or other change in mental status was preventable. Reviewers should also consider whether the medication(s) and dosage, with a known risk for causing delirium, that was provided to the patient was indicated and appropriate for the patient's disease or condition.

Delirium or other change in mental status

Reviewers should consider whether high-risk patients received appropriate preventative treatment, such as non-pharmacological and other medical interventions to reduce the risk of delirium (e.g., agitation management, frequent mobility, orientation, and sleep management, ensuring the patient has glasses and hearing aids on, and fluid and electrolyte management and that pain is appropriately managed). In the intensive care unit, this also includes noise management, family and caregiver visits, and daily cessation of sedatives combined with daily spontaneous breathing trials if the patient is on a ventilator, when the patient's clinical condition allows.

Delirium or other change in mental status may be a **preventable** event if:

- The patient did not receive an evidence-based approach to delirium prevention based on medical record documentation.

Delirium or other change in mental status may be a **nonpreventable** event if:

- The patient received appropriate delirium preventative measures based on medical record documentation, including appropriate sedation, such as benzodiazepines and opioids.

Key Medical Record Documents

Reviewers may find documentation of delirium or other change in mental status in the following sections of the patient's medical record:

- History and physical for whether patient had a history of dementia or confusion,
- Medication administration record for delirium-causing medications such as benzodiazepines or opioids,
- Laboratory results (e.g., electrolytes, liver function tests, and blood glucose),
- Progress notes (physician and nurse notes), and
- Nursing care plans for evidence of preventative measures.

Quality Assurance Documentation

For delirium or other change in mental status, the following factors may be helpful in ensuring consistency and accuracy:

- Signs and symptoms of delirium or other mental status change,
- Any medications (e.g., opioids and psychotropics) that may have contributed to delirium or other mental status change including the names, dose(s), and date(s) the medication was given prior to the event,
- Any significant signs and symptoms, and
- Any resulting injuries (e.g., fall with fracture).

Associated Trigger(s)

See the following triggers:

- C1 Acute mental status change and

Delirium or other change in mental status

- M8 Flumazenil use.

Diabetic ketoacidosis and hyperosmolar syndrome

Diabetic ketoacidosis and hyperosmolar syndrome

Condition Definition

Complications of diabetes may include diabetic ketoacidosis (DKA) and hyperosmolar hyperglycemic nonketotic syndrome (HHNS). DKA is an acute metabolic complication of diabetes characterized by hyperglycemia, hyperketonemia, and metabolic acidosis. HHNS is a metabolic complication of diabetes mellitus characterized by severe hyperglycemia, extreme dehydration, hyperosmolar plasma, and altered consciousness.

Harm Determination

We considered DKA and HHNS harm events if they occurred or developed during the patient's hospitalization. This may be related to inadequate management of the patient's diabetes. In addition, we do not typically consider asymptomatic cases of hyperglycemia as harm events except if diabetes develops due to the administration of steroids to a non-diabetic patient and the diabetes becomes permanent.

Preventability

Reviewers should consider if the patient received an appropriate fluid and insulin regimen to treat hyperglycemia which led to DKA or HHNS.

DKA or HHNS may be a **preventable** event if it was exacerbated by poor management of uncontrolled diabetes during the patient's hospital stay.

DKA or HHNS may be a **nonpreventable** event if the patient was highly susceptible due to multiple comorbidities and if the patient received evidence-based treatment.

Key Medical Record Documents

Reviewers may find documentation of DKA and HHNS in the following sections of the patient's medical record:

- Medication administration record (e.g., insulin regimen and intravenous fluids),
- Laboratory results (e.g., frequent blood glucose checks),
- Progress notes (physician and nurse notes), and
- Consultation notes.

Diabetic ketoacidosis and hyperosmolar syndrome

Quality Assurance Documentation

For DKA and HHNS, the following factors may be helpful in ensuring consistency and accuracy:

- Signs and symptoms of DKA and HHNS,
- Diabetic management that may have led to DKA or HHNS, and
- Interventions, such as insulin and IV fluid management (especially the last few doses before the harm event).

Associated Trigger(s)

See C18 Care—other and M15 Medication—other.

Diarrhea

Diarrhea

Condition Definition

Diarrhea is loose, watery, and generally more-frequent bowel movements. Diarrhea has many causes, and they are generally divided into infectious and non-infectious (e.g., medication-induced) causes. Infectious diarrhea may be further described as severe, bloody, and watery diarrheas.[10] Medication-induced diarrhea manifests as a side effect of a medication (e.g., magnesium products and antibiotics).

Harm Determination

We considered diarrhea a harm event when a patient experienced three or more watery stools per day not caused by underlying disease, such as inflammatory bowel disease.

We considered medication-induced diarrhea a harm event. However, calling medication-induced diarrhea a harm event depends on the degree, signs, symptoms, and clinical context. Reviewers should try to determine whether diarrhea resulted in dehydration, whether it required an intervention, and the frequency of the diarrheal stools. Diarrhea related to tube feeding or surgery would also likely be considered harm.

We considered infectious diarrhea a harm if the infection was acquired during the hospital stay. (See "*Clostridioides difficile* infection" and "Hospital-acquired infection" for more details.)

Preventability

Diarrhea may be a **preventable** event if:

- It was caused by excessive administration of certain medications (e.g., antibiotics, magnesium oxide) or excessive nutritional tube feedings or

- It was hospital-acquired infectious diarrhea caused by inadequate infection prevention measures.

Diarrhea may be a **nonpreventable** event if:

- It was caused by medication required for treating the patient because providers may have foreseen diarrhea as an expected side effect of the medications but that the risk of diarrhea was outweighed by the benefits of treatment.

Key Medical Record Documents

Reviewers may find documentation of diarrhea in the following sections of the patient's medical record:

- History and physical,
- Medication administration record,
- Laboratory results (e.g., blood and stool cultures),
- Progress notes (physician and nurse notes),
- Gastroenterologist and/or infectious disease specialist consultation notes, and
- Nursing care plans.

Quality Assurance Documentation

For diarrhea, the following factors may be helpful in ensuring consistency and accuracy:

- Signs and symptoms of a potential infection,
- Patient's recent history of diarrhea,
- Any intestinal surgery performed during the stay, and
- Any medications or nutritional feedings that can cause diarrhea.

Although the etiology of diarrhea may be unknown, noting the presence of these factors may help differentiate diarrhea caused by underlying disease from that caused by care provided to the patient.

Associated Trigger(s)

See M1 *Clostridioides difficile* positive stool test.

Reference

- Shane, et al., "2017 Infectious Diseases Society of America Clinical Practice Guidelines for the Diagnosis and Management of Infectious Diarrhea," *Clinical Infectious Diseases*, Volume 65, Issue 12, December 2017.

Endotracheal intubation injury

Endotracheal intubation injury

Condition Definition

Endotracheal intubation is a process whereby a provider inserts a tube through the patient's mouth or nose and then into their trachea to assist with breathing during general anesthesia or to sustain breathing that is compromised by illness or injury. Extubation and reintubation are procedures involving the removal (extubation) or reinsertion (reintubation) of the tube.

Harm Determination

We considered injuries and complications associated with any intubation or reintubation (e.g., respiratory distress) as harm events. Traumatic intubation injuries may include aspiration, laceration to the airway, vocal cord injury, dental injury, a collapsed or perforated lung, infection, and other severe complications.

We considered reintubation itself a potential harm event depending on the patient's care plan. Reintubation following planned extubation as a trial for self-breathing or a planned transition to bilevel positive airway pressure (BPAP) would not typically be considered a harm event. We always considered premature or accidental extubation with subsequent acute respiratory failure a harm and we considered an associated reintubation or BPAP a life-sustaining intervention (i.e., H-level harm). If reintubation was necessary, but not life-sustaining, we considered assigning a lower level of harm.

Preventability

Most airway complications (including post-intubation respiratory distress, pulmonary aspiration, and esophageal intubation) and failed airway management are due to a lack of preparedness, assessment, planning, communication, teamwork skills, and situational awareness.

An endotracheal intubation injury may be considered a **preventable** event if due to the factors mentioned above such as incorrect tube insertion caused by a lack of preparedness. Self-extubation may also be preventable if evidence-based precautions (such as restraints) were not followed.

An endotracheal intubation injury may be considered a **nonpreventable** event if this harm occurs with a frail (e.g., elderly) patient or a patient with unfavorable airway anatomy.

Key Medical Record Documents

Reviewers may find documentation of endotracheal intubation injury in the following sections of the patient's medical record:

- Laboratory results (e.g., arterial blood gasses, oxygen saturation),
- Chest X-ray for possible pneumothorax or appropriateness of tube placement,
- Progress notes (physician and nurse notes),
- Pulmonologist and/or intensivist consultation notes,
- Vital signs documentation,

Endotracheal intubation injury

- Rapid response team notes—review if a code was called on a patient in response to unresponsiveness or if the patient was found not breathing, and
- Emergency department notes.

Quality Assurance Documentation

For endotracheal intubation injuries, the following factors may be helpful in ensuring consistency and accuracy:

- Any accidental re-intubation or extubation as this may indicate potential harm occurred,
- Warning signs of an intubation injury such as a patient who experienced difficulty breathing and aspiration with unusual breathing sounds and chest pain, and
- The extent of the injury and complications related to improper insertion to determine the severity of the harm.

Associated Trigger(s)

See the following triggers:

- C15 Any procedure complication,
- S4 Intubation/reintubation/bilevel positive airway pressure (BPAP) in post anesthesia care unit (PACU), and
- I4 Intubation/reintubation.

Excessive bleeding

Excessive bleeding

Condition Definition

Excessive bleeding can result from platelet disorders, coagulation or blood vessel defects, or injury from medical care or omission of care. This includes occult or overt (visible) bleeding.

Harm Determination

Our reviewers considered excessive bleeding a harm event when it was not caused by underlying disease or due to an injury prior to admission. Excessive bleeding caused by a surgical complication or the result of medical therapy (e.g., anticoagulant-related) is considered a harm event. There must be hemodynamic manifestation or evidence of excessive bleeding, such as documented physiologic vital sign changes (e.g., tachycardia, hypotension, orthostatic signs/symptoms), to be considered harm.

Excessive bleeding

Reviewers should check for indicators of excessive bleeding such as:

- Precipitous drops in hemoglobin and hematocrit levels (absolute drop to hemoglobin less than 7.0 Gm and/or hematocrit less than 21%) within less than 72 hours,
- An unplanned transfusion or use of blood products,
- Elevated partial thromboplastin time greater than 100 seconds,
- International normalized ratio (INR) greater than six,
- Guaiac-positive stools, and
- Administration of vitamin K or factor Xa reversal agents (andexanet alfa and idarucizumab).

Transfusions require clinical judgment to determine whether they were interventions resulting from a harm event. Transfusion of many units or transfusions indicative of blood loss beyond anticipated amounts within the first 24 hours of surgery, intra-operatively and post-operatively, would likely be related to a peri-operative bleeding event or unintentional trauma to a blood vessel. The other following occurrences may be evidence of harm:

- Bleeding due to a medical device or medication during hospitalization and that requires transfusion,
- Surgery requiring more than two units of blood (in operating room or within 24 hours of surgery), except for trauma surgery, cardiovascular, and complex spine surgeries in which up to four to six or more units may be given,
- Platelets or fresh frozen plasma being transfused, and
- Blood being transfused 2 or more days after surgery.

If a patient was bleeding on admission and underwent a surgery, a transfusion(s) may be required which we would not consider a harm event.

Preventability

Excessive bleeding may be a **preventable** event if:

- Test results indicate supratherapeutic levels due to excessive anticoagulation as the cause,
- The patient received medication that was contraindicated, not indicated, or in an incorrect dosage that contributed to excessive bleeding, or
- There was inadequate monitoring and a delay in treating the excessive blood loss.

Excessive bleeding may be a **nonpreventable** event if:

- The patient received medication that was indicated, monitored, given at the appropriate dosage and interval, and was not contraindicated with other medications but contributed to excessive bleeding.

Excessive bleeding

Key Medical Record Documents

Reviewers may find documentation of excessive bleeding in the following sections of the patient's medical record:

- History and physical,
- Medication administration record,
- Laboratory results,
- Progress notes (physician and nurse notes),
- Procedure or operative notes,
- Surgery and/or hematology consultation notes,
- Nursing care plans, and
- Discharge/transition of care summary.

Quality Assurance Documentation

For excessive bleeding, the following factors may be helpful in ensuring consistency and accuracy:

- Signs and symptoms (e.g., tachycardia or hypotension),
- Clinical severity of the bleed,
- Any laboratory tests indicative of a bleed, such as a precipitous drop in hemoglobin (<7 gms) and hematocrit levels (<21%) within 72 hours, and
- Any intervention or treatment provided to the bleeding patient, such as blood transfusions or vitamin K administration.

Associated Trigger(s)

See triggers below:

- C2 Transfusion or use of blood products,
- C7 Abrupt or significant decrease in hemoglobin or hematocrit,
- M2 Partial thromboplastin time (PTT) greater than (>) 100 seconds,
- M3 International normalized ratio (INR) greater than (>) 6, and
- M6 Vitamin K, factor Xa reversal agents (andexanet alfa, idarucizumab administration).

Fall with injury

Fall with injury

Condition Definition

A fall with injury, minor or serious, that occurs within the hospital. Examples of such injury include fractures, lacerations, closed head injuries, contusions, skin tears, and sprains.

Harm Determination

We only considered a fall in the hospital a harm event if there is a documented injury. A fall in a care setting may be the result of medications or a lack of adequate monitoring. Our reviewers relied on their clinical judgment to determine whether an injury was associated with a fall. Significant pain that impacted patient care, such as the patient being unable to ambulate, was considered a fall with injury. All falls must be reviewed for possible injuries.

Preventability

A fall with injury may be a **preventable** event if:

- The patient was left unattended and standard precautions (e.g., interventions based on fall risk screening, walker, bedrail positions, call button, bed alarm, monitoring, etc.) were not implemented to prevent a fall, especially for those at higher fall risk, or
- The fall was related to excessive medication, based upon Beers criteria, medication that was not indicated, or high-risk medication combinations such as benzodiazepines, opiates, and anti-cholinergics that were given in close proximity.

A fall with injury may be a **nonpreventable** event if:

- Appropriate precautions were implemented based on medical record documentation or the patient was not compliant (e.g., refused to use a call button for assistance to the bathroom).

Key Medical Record Documents

Reviewers may find documentation of a fall with injury in the following sections of the patient's medical record:

- History and physical,
- Medication administration record to determine if sedating medications contributed to the fall,
- Radiology results—review if any X-ray was performed to confirm injuries resulting from the fall,
- Progress notes (physician and nurse notes),
- Consultant notes,
- Procedure or operative notes (e.g., possible fracture repair),
- Nursing care plans—look for fall prevention measures, and
- Morse or other fall scale assessment documentation.

Fall with injury

Quality Assurance Documentation

For a fall with injuries, the following factors may be helpful in ensuring consistency and accuracy:

- Whether fall-risk precautions were in place,
- The extent of the injury (e.g., dislocations, fractures, lacerations, skin tears, sprains, hematomas) associated with the fall and pain severity interfering with/preventing physical therapy, and
- Contributing factors leading to the fall, such as documented excessive medication use.

Associated Trigger(s)

See C8 Fall or other trauma.

Fluid overload

Fluid overload

Condition Definition

Fluid or volume overload (also called hypervolemia) is typically associated with underlying disease, such as heart failure, kidney failure, or cirrhosis. However, IV-induced fluid overload can also occur if the patient receives more fluid than can be excreted. This includes an overload of transfusions and other fluids. If left untreated, fluid overload can lead to worsening of heart, kidney, and lung function and ultimately death. Also see "Abnormal electrolytes."

Harm Determination

We considered fluid overload a harm event when it was not caused by underlying disease. For fluid overload to be considered harm, the patient must also have signs and symptoms, which may include discomfort (e.g., stomach bloating, cramping, and headaches), edema (swelling), hypertension, dyspnea (shortness of breath), rapid weight gain, and pulmonary edema. A fluid overload harm event may occur when IV fluid is given at a higher rate or larger volume than can be absorbed or excreted. Certain medications that cause fluid retention or increased sodium intake from nutritional tube feedings can also contribute to fluid overload, which may also be considered harm events. Fluid overload may also be exacerbated by an omission of care (e.g., failure to recognize or act on signs and symptoms, such as monitoring weight gain), which may be a harm event.

Preventability

Fluid overload is considered a **preventable** event if the patient received excessive fluids manifested by weight gain not caused by underlying disease or if there was an omission of care (failure to recognize or treat).

Fluid overload may be a **nonpreventable** event if the patient was highly susceptible (e.g., patient in renal failure) to the fluid overload and if providers administered IV fluids at the appropriate volume

Fluid overload

and rate. In some cases, the benefits of treatment may outweigh the risks of fluid overload which we consider not preventable.

Key Medical Record Documents

Reviewers may find documentation of fluid overload in the following sections of the patient's medical record:

- History and physical,
- Laboratory results,
- Progress notes (physician and nurse notes),
- Intake and output, and
- Daily weight documentation.

Quality Assurance Documentation

For fluid overload, the following factors may be helpful in ensuring consistency and accuracy:

- The patient's medical history, especially related to congestive heart failure (CHF) which may establish whether the fluid overload is due to underlying disease, and any treatments for CHF or fluid overload,
- Signs and symptoms such as edema, hypertension, dyspnea, and weight gain,
- Laboratory tests for blood or urine electrolyte levels and diagnostic tests such as a chest X-ray, and
- Medications, IV fluids, transfusions, or nutritional tube feedings.

Associated Trigger(s)

See C18 Care—other and M15 Medication—other.

Hospital-acquired infection

Hospital-acquired infection

Condition Definition

An infection is caused by pathogenic microorganisms and can lead to local or systemic symptoms. Common symptoms of infection include fever, rash, diarrhea, fatigue, muscle aches, coughing, difficulty breathing, confusion, sore throat, and pain with urination.

Harm Determination

In general, we considered an infection that developed after the second calendar day in the hospital (when the day of admission is calendar day one) a harm event. In contrast, an infection that develops

within the first 2 calendar days is considered present on admission and we do not count it as a harm event. However, if a patient is admitted with an ongoing infection and then deteriorates while in the hospital due to an omission of care or failure to diagnosis the infection, this may be considered a harm event.

There are exceptions to the above rule. An infection resulting from certain medical devices placed during the hospital stay (including devices placed during a contiguous emergency, observation, or outpatient surgery/procedure) may be considered hospital-acquired within 2 days after admission if the device was identified as the primary source of infection. Another exception is a *C. diff* infection which requires 3 or more days after admission to be considered hospital acquired. (See "*Clostridioides difficile* infection" for more information.)

Reviewers should also carefully interpret laboratory test results for positive cultures in blood, urine, or stool samples of pathogenic microorganisms. Abnormal laboratory test results without signs/symptoms (e.g., asymptomatic bacteriuria) are generally not considered harm. For example, if a patient has an indwelling urinary catheter and a positive urine culture that is 100,000 CFU per ml without pain or fever or change in mental status, it is not considered harm. Reviewers should also be careful with possible bacterial contaminants documented in laboratory results as these are not considered infections.

In determining whether an infection was a harm event, we recommend that reviewers follow infection-specific guidelines provided by the CDC and reiterated in the links below:

- Catheter-associated urinary tract infection (CAUTI),
- *Clostridioides difficile* (*C. diff*) infection,
- Vascular catheter-associated infection infection,
- Surgical site infection, and
- Ventilator-associated event.

A list of other infections included in this toolkit are listed and linked below:

- Conjunctivitis,
- Skin or soft tissue infection, and
- Sepsis.

The above lists are not exhaustive of all possible hospital-acquired infections, so reviewers should rely on their clinical judgment and consult infectious disease specialists where needed.

Preventability

A hospital-acquired infection is generally considered a **preventable** event if providers did not follow proper infection control processes. If providers did not appropriately treat an existing infection, this may also be considered preventable. Several hospital-acquired infections tracked by the CDC are largely deemed preventable through the application of evidence-based guidelines, "Preventability" for those infections (see list above).[11]

Hospital-acquired infection

A hospital-acquired infection may be a **nonpreventable** event if the patient had a similar recent infection or was otherwise at higher risk. This includes recurring *C. diff* infections where patients may be at higher risk for infections that may not be preventable (see "*Clostridioides difficile* infection" for more details). Higher-risk patients include frail patients such as those in an immunocompromised state (e.g., patients on cancer therapy or with human immunodeficiency virus).

Key Medical Record Documents

Reviewers may find documentation of hospital-acquired infections in the following sections of the patient's medical record:

- Medication administration record,
- Laboratory results, especially cultures and white blood cells (WBC) with differential,
- Radiology results,
- Progress notes (physician and nurse notes),
- Infectious disease specialist and other consultation notes, and
- Relevant invasive devices documentation.

Quality Assurance Documentation

For hospital-acquired infections, the following factors may be helpful in ensuring consistency and accuracy:

- Type, timing, and device (e.g., central line, urinary catheter, dialysis access device, etc.),
- Site of infection (e.g., bones, lungs, skin, etc.),
- Signs and symptoms associated with infection with dates of occurrence,
- If relevant, urine culture—include CFU/mL (e.g., 100,000 CFU/mL for microorganisms), and
- If relevant, blood culture—identify microorganism and how many blood cultures were positive (e.g., methicillin-resistant *Staphylococcus aureus* 2/3).

Associated Trigger(s)

See C12 Hospital-acquired infections and C5 Positive culture (e.g., blood, urine, stool).

References

See "References" for specific infections listed above.

Hypoglycemia

Hypoglycemia

Condition Definition

Hypoglycemia is an abnormally low level of blood glucose.

Harm Determination

We considered a blood glucose level below 50 mg/dL due to medication or surgery (e.g., bariatric surgery) a harm event even without signs or symptoms. A blood glucose level above 50 mg/dL may be considered a harm event if the patient experienced a sudden drop in levels (e.g., 200 mg/dL to 60 mg/dL) with documented signs and symptoms of low blood glucose. For non-diabetic patients who experience blood glucose levels below 50 mg/dL, reviewers should rule out underlying disease (e.g., liver failure, insulinoma) before considering it a harm event.

Reviewers should also consider the method used to obtain the patient's blood glucose level to avoid overcounting glycemic control events. Low blood glucose for patients experiencing low blood flow states (i.e., severe hypotension or code situations) may be inaccurate if identified through a finger-stick. Reviewers should confirm these potential events by checking the medical record for serum glucose level. If multiple episodes of hypoglycemia occur within 24 hours, we recommend counting it as a single event.

Preventability

Reviewers should consider the patient's insulin regimen and timeframe of the event when determining preventability for hypoglycemia. If the patient experienced a prior episode of hypoglycemia, reviewers should check whether providers appropriately adjusted the level of insulin given to the patient, as indicated, to determine whether the recurrence of such episodes were preventable.

Reviewers should also consider whether there was adequate glucose monitoring. If patients were on IV insulin, adequate monitoring includes glucose level checks every 30 minutes to 2 hours and if the patient was not eating every 4 to 6 hours.[12]

For patients undergoing surgery, reviewers should consider these additional elements in their determinations on whether:

- Oral hypoglycemic agents such as metformin were withheld on the day of surgery and
- Intermediate-acting or long-acting insulin (or pump basal insulin) was reduced on the morning of the surgery in accordance with national clinical guidelines (50 percent of intermediate-acting or 60 to 80 percent of long-acting analog or pump dose).[13]

Hypoglycemia may be a **preventable** event if the patient was only receiving sliding scale insulin (SSI) instead of multi-modal (basal bolus with correctional) insulin.[14]

Hypoglycemia may be a **nonpreventable** event if the episode occurred within the first 2 calendar days after admission, when the admission date was calendar day 1, and if providers followed correct dosing and monitoring.

Hypoglycemia

Key Medical Record Documents

Reviewers may find documentation of hypoglycemia and insulin administration that may have led to hypoglycemia in the following sections of the patient's medical record:

- Medication administration record to determine the insulin dosage that may have led to hypoglycemia and management of the hypoglycemic event,
- Laboratory results (e.g., daily glucose checks, glucose lab results),
- Progress notes (physician and nurse notes),
- Dietician consultation notes, and
- Diabetic flow sheets, if available.

Quality Assurance Documentation

For hypoglycemia, the following factors may be helpful in ensuring consistency and accuracy:

- Insulin dosage prior to the hypoglycemic event, whether SSI or multimodal (basal bolus) insulin regimen with dates, times, and dose, and
- Prior hypoglycemic events with date(s)/time(s), insulin regimen (including whether SSI or multimodal (basal bolus) with dates, times, and dose), and whether the insulin regimen was modified.

Associated Trigger(s)

See M4 Glucose less than (<) 50 mg/dL.

References

- American Diabetes Association, "Diabetes Care in the Hospital: Standards of Medical Care in Diabetes—2018," *Diabetes Care*, Volume 41, Issue Supplement 1, January 2018. Accessed at https://care.diabetesjournals.org/content/41/Supplement_1/S144 on December 3, 2021.
- Handelsman, et al., "American Association of Clinical Endocrinologists and American College of Endocrinology – Clinical Practice Guidelines For Developing A Diabetes Mellitus Comprehensive Care Plan – 2015," *Endocrine Practice*, Volume 2, Supplement 1, April 2015.
- Seaquist, et al., "Hypoglycemia and Diabetes: A Report of a Workgroup of the American Diabetes Association and The Endocrine Society," *Diabetes Care*, Volume 36, May 2013.

Hypotension

Hypotension

Condition Definition

Hypotension is abnormally low blood pressure. Hypotension may be related to underlying disease, such as a heart condition, sepsis, pregnancy, or an endocrine disorder. However, it can also be caused by dehydration or medication.

Harm Determination

We considered hypotension with signs or symptoms (lightheadedness, dizziness, confusion, or fainting) a harm event. Reviewers should look for evidence that the hypotension was associated with a medical intervention (e.g., medications) because hypotension associated with underlying disease is not considered a harm event. Reviewers should be careful not to define a normal low blood pressure as a harm event—elderly patients may have systolic blood pressure of 80-90 mmHg when prone. Additionally, if low blood pressure is the desired endpoint in treatment of heart failure, it should not be considered harm. In contrast, treatment, or intervention, such as an abrupt withdrawal of medication, to address hypotension may also signify a possible harm event if the patient exhibits signs and symptoms.

Exceptions to the guideline on signs and symptoms, stated above, apply to patients who are recumbent in an ICU or under sedation (e.g., during a surgical procedure). We consider hypotension as a harm in these patients if they meet one of the following criteria:

- The patient experiences a mean arterial pressure (MAP) of <60 mmHg which is indicative of low perfusion (note that a one-time reading of a MAP of <60 mmHg may represent an error and need further investigation) and
- The patient experiences a MAP of <65 mmHg requiring treatment (e.g., vasopressors and IV saline bolus) or requiring sustained treatment and monitoring for 15 minutes or more.

Preventability

Hypotension may be a **preventable** event if:

- It was the result of a medication error (e.g., excessive dosage of an opioid or polypharmacy),
- It was part of a larger cascade of harms where the initial event (e.g., untreated infection or myocardial infarction) was determined to be preventable, or
- It was prolonged because providers did not immediately intervene before the patient's condition worsened.

Hypotension may be a **nonpreventable** event if:

- The patient had multiple comorbidities or an advanced age that predisposed the patient to hypotensive episodes complicating their care or
- The hypotension was caused by certain medications (e.g., anesthesia) or high-risk procedures that were needed for treatment, but in which the benefits outweighed the risks of harm.

Hypotension

Key Medical Record Documents

Reviewers may find documentation of hypotension in the following sections of the patient's medical record:

- Medication administration record (e.g., antihypertensive, nitrates, diuretics that may have contributed to hypotension),
- Laboratory results,
- Progress notes (physician and nurse notes), and
- Procedure or operative notes and/or anesthesia records including pre-operative, intra-operative, and post-operative records of vital signs and medication.

Quality Assurance Documentation

For hypotension, the following factors may be helpful in ensuring consistency and accuracy:

- Any MAP measurements (calculated or invasive monitoring) before and after medication use including those recorded during surgeries and procedures that may show an abrupt decrease in blood pressure,
- Any medications and their dosages that may have contributed to hypotension and potential causes such as excessive blood loss or oversedation,
- Any signs and symptoms such as near syncope, orthostasis, weakness, dizziness, or mental status change,
- Any interventions (e.g., vasopressors, flattening the bed, reverse Trendelenburg, starting IVs, etc.) that were provided to treat hypotension and the time of treatment, and
- The setting in which the hypotension occurred, such as if the patient was in the operating room under general anesthesia or was recovering in bed, or relevant signs and symptoms.

Associated Trigger(s)

See M11 Abrupt decrease in blood pressure.

Nausea and vomiting

Nausea and vomiting

Condition Definition

Nausea and vomiting are not diseases but rather are symptoms of many different conditions, including gastrointestinal infections, food poisoning, migraines, or more significant diseases such as heart attack, kidney failure, or liver disorders. They can also be side effects from medication or certain treatments or procedures.

Nausea and vomiting

Harm Determination

We considered nausea and vomiting a harm event when the episodes were prolonged, resulted in dehydration or projectile vomiting, occurred multiple times in a short time frame, or required significant intervention. However, one or two episodes of nausea and vomiting that are treated successfully with anti-emetics are not typically harm events. Reviewers should confirm that the nausea and vomiting have a clinical cause that is related to the care provided or lack thereof and not the result of underlying disease.

Preventability

Clinically significant nausea and vomiting may be a **preventable** event if anti-emetics are not provided prior to or in conjunction with medications (e.g., chemotherapy) or procedures known to cause nausea and vomiting as a side effect of treatment. If the nausea and vomiting persisted and providers did not provide anti-emetics, leading to dehydration, we considered the nausea and vomiting preventable.

Nausea and vomiting may be **not preventable** when due to medications and procedures and if appropriately diagnosed and treated.

Key Medical Record Documents

Reviewers may find documentation of nausea and vomiting in the following sections of the patient's medical record:

- Laboratory tests (e.g., electrolytes, BUN, and serum creatinine),
- Medication administration record, especially for medications that may have caused nausea and vomiting and for treatment with anti-emetics,
- Progress notes (physician and nurse notes), and
- Consultation notes (e.g., gastroenterologist, hematologist, or oncologist).

Quality Assurance Documentation

For nausea and vomiting, the following factors may be helpful in ensuring consistency and accuracy:

- Onset, frequency, and duration of vomiting,
- Anti-emetics (dates/times),
- Causes of vomiting (e.g., medication or procedures),
- Any projectile vomiting, and
- Laboratory tests, such as electrolytes, BUN, and serum creatinine.

Associated Trigger(s)

See M10 Anti-emetic use.

Pressure injury

Pressure injury

Condition Definition

Pressure injuries, also called decubitus ulcers or bedsores, involve ulceration of tissue deprived of adequate blood supply by prolonged pressure. Pressure injuries are classified into four stages: Stage 1 is intact skin with non-blanchable redness; Stage 2 is a shallow ulcer or blister indicating damage to the epidermis; Stage 3 is damage extending through all layers of the skin; and Stage 4 is damage through all the layers of the skin and underlying muscle, tendons, or bone. Pressure injuries are unstageable when the extent of the tissue damage cannot be confirmed because it is obscured by slough or eschar. Deep tissue pressure injuries are persistent, non-blanchable deep red, maroon, or purple discolorations of the skin revealing a dark wound or blood-filled blister.[15]

Harm Determination

We considered a pressure injury that develops during the patient's hospital stay a harm event. A pressure injury that was present on admission and increases in stage while in the hospital's care is also considered a harm event. Stage I pressure injuries are only considered harm events if the stage is specifically documented or if there is documentation of non-blanchable redness in the description. Multiple pressure injuries may be counted as separate harm events if the location is geographically different (e.g., sacrum and heel) because the cause is different. However, bilateral injuries (e.g., right and left buttocks) should be counted as a single event.

We considered any pressure injury or skin breakdown, particularly those attributed to a medical device (e.g., prosthetic limb), a harm event. In some cases, these events may develop into skin and soft tissue infections.

Regarding severity, reviewers should reserve G-level severity for Stage 4 pressure injuries unless special circumstances are documented such as a Stage 3 pressure injury that becomes infected, leading to permanent damage to the tissue under the skin.

Preventability

A pressure injury may be a **preventable** event if:

- Providers did not implement preventative measures (e.g., risk assessment, regular turning, positioning, specialty mattresses, etc.) for pressure injuries, especially with high-risk patients (e.g., those who are bed-ridden or immobile).

A pressure injury may be a **nonpreventable** event if:

- The patient was non-compliant with regular turning and other safety measures or
- Providers employed documented preventative measures, but the patient still developed pressure injuries due to their high susceptibility.

In determining preventability, we recommend that reviewers consult the following resources under "References": *Pressure Injury Prevention Points* and the *Braden Scale Protocols by Level of Risk*.

Pressure injury

Key Medical Record Documents

Reviewers may find documentation of pressure injury in the following sections of the patient's medical record:

- History and physical to determine if present on admission or stage on admission,
- Progress notes (physician and nurse notes),
- Wound care assessment,
- Wound/ostomy team's assessment notes,
- Braden scale assessment results—these could be found in the nursing assessments, and
- Dressing change documentation—this would likely be in the wound care notes.

Quality Assurance Documentation

For pressure injuries, the following factors may be helpful in ensuring consistency and accuracy:

- Stage(s) of the pressure injury (including stage on admission and progression to a higher stage),
- Date(s) and location of the pressure injury,
- Date(s) and description(s) of a significant increase in severity defined as increase in size of at least 1 cm in any dimension and/or with documentation such as "larger" or "deeper," and
- Preventative measures (listed above).

Associated Trigger(s)

See C9 Pressure injury/skin breakdown from medical device.

References

- National Pressure Injury Advisory Panel, "National Pressure Ulcer Advisory Panel (NPUAP) announces a change in terminology from pressure ulcer to pressure injury and updates the stages of pressure injury," Press Release, April 2016. Available at https://cdn.ymaws.com/npiap.com/resource/resmgr/online_store/npiap_pressure_injury_stages.pdf.
- National Pressure Injury Advisory Panel, *Pressure Injury Prevention Points*, 2016. Available at https://cdn.ymaws.com/npiap.com/resource/resmgr/online_store/1a._pressure-injury-preventi.pdf.
- Braden, B., *Braden Scale Protocols by Level of Risk*, 2001. Available at https://www.in.gov/fssa/ddrs/files/Braden_Scale_Risk_Levels_OR-FM-HS-PU-1411-6-09.pdf.

Sepsis

Sepsis

Condition Definition

Sepsis is a life-threatening organ dysfunction caused by a dysregulated host response to infection. Septic shock is a subset of sepsis and occurs when underlying circulatory and cellular metabolism abnormalities are profound enough to substantially increase mortality.[16]

Harm Determination

We considered sepsis that develops during the hospitalization a harm event. If a patient was admitted to the hospital with an infection and was not provided adequate treatment, we considered the infection a harm event when it led to sepsis or further patient deterioration such as organ dysfunction and septic shock.

Reviewers should also be aware of false positives for bloodstream infections caused by contaminated blood cultures.[17, 18] Skin bacterial contaminants in blood cultures may lead to false positives for bloodstream infections. Bacterial contaminants are usually found in only one blood culture (e.g., one of three cultures). If a common bacterial contaminant is found in repeated blood cultures, with the same bacteria, it may be considered a harm event. Common skin contaminants include diphtheroid (*Corynebacterium* spp.), *Bacillus* spp. (excluding *Bacillus anthracis*), *Propionibacterium* spp., and coagulase-negative *staphylococci* (including *Staphylococcus epidermidis*).

See "Hospital-acquired infection" for information related to broader infection determinations.

Preventability

Sepsis may be a **preventable** event if:

- Providers did not follow best practices or employ infection prevention measures or
- Providers failed to recognize sepsis or take immediate action to treat sepsis.

Sepsis may be a **nonpreventable** event if:

- The patient was in a severely immunocompromised state (e.g., patients on cancer therapy, or with human immunodeficiency virus).

We suggest using current Surviving Sepsis Campaign guidelines when determining preventability of sepsis events (see second reference). Bundle elements include:

- Measuring lactate levels (remeasuring if initial lactate is >2 mmol/L),
- Obtaining blood culture prior to the administration of antibiotics,
- Administering antibiotics within 1 hour of sepsis or septic shock recognition,
- Rapidly administering 30 ml/Kg crystalloid for hypertension or lactate >4 mmol/L within the first 3 hours, and
- Applying vasopressors if the patient is hypotensive during fluid resuscitation to maintain MAP >65 mmHg.[19]

Sepsis

Key Medical Record Documents

Reviewers may find documentation of sepsis in the following sections of the patient's medical record:

- Medication administration record (e.g., antibiotics),
- Laboratory tests and cultures related to Surviving Sepsis Campaign bundle above,
- Progress notes (physician and nurse notes),
- Procedure or operative notes including invasive decides that may represent an etiology of sepsis,
- Consultation notes,
- Vital signs, and
- Rapid response team's notes.

Quality Assurance Documentation

For sepsis, the following factors may be helpful in ensuring consistency and accuracy:

- Signs and symptoms of an infection,
- Blood culture results including date and time,
- Intervention (e.g., antibiotic administration) including date and time,
- The device (e.g., IV line or urinary catheter) associated with sepsis,
- Any surgery or procedures that may have contributed to sepsis or led to the development of sepsis from a local infection, and
- Any documentation necessary to demonstrate compliance with sepsis bundle.

Associated Trigger(s)

See C12 Hospital-acquired infections and C5 Positive culture (e.g., blood, urine, stool).

References

- Singer, et al., "The Third International Consensus Definitions for Sepsis and Septic Shock (Sepsis-3)," JAMA, Volume 315, No. 8, February 2016. Available at https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4968574/pdf/nihms794087.pdf.
- Levy, et al., "The Surviving Sepsis Campaign Bundle: 2018 Update," *Critical Care Medicine*, Volume 46, Number 6, June 2018. Available at https://doi.org/10.1097/CCM.0000000000003119.

Skin or soft tissue infection

Skin or soft tissue infection

Condition Definition

Skin and soft tissue infections vary by cause, location, and severity. A skin or soft tissue infection involves microbial invasion of the skin and skin structure and may include signs and symptoms such as purulent discharge, abscesses, crusting, and blisters. More severe infections include advancing cellulitis and necrotizing soft tissue infections.

Fungal skin infections are commonly caused by yeast (such as *Candida*) or dermatophytes, such as *Epidermophyton*, *Microsporum*, and *Trichophyton*. Fungal skin infections may manifest as irritated skin with itching, scaliness, or redness.

A skin infection may also be caused by intertrigo, which is inflammation of the skin caused by irritation and skin breakdown (e.g., maceration) in areas where two skin surfaces rub against each other. This can sometimes occur in patients who are immobile or who wear medical devices such as prosthetic limbs, splints, and braces.

Harm Determination

In general, we considered a skin or soft tissue infection, including those caused by fungus or intertrigo, a harm event if it met the criteria listed under "Hospital-acquired infection." We would consider intertrigo that led to a yeast infection (e.g., *Candida*) a harm event.

Preventability

A skin or soft tissue infection may be a **preventable** event if:

- Providers did not employ infection prevention measures (e.g., application of emollients, antifungals, or drying agents) for patients at high-risk for infection or
- Providers did not provide appropriate antibiotics or antifungals to treat the infection.

A skin or soft tissue infection may be a **nonpreventable** event if:

- Providers employed infection preventative measures,
- The infection was experienced by patient at higher risk (e.g., immunocompromised, frail, morbidly obese, advanced age, etc.), or
- Moisture control was difficult to maintain in difficult areas (e.g., groin).

Key Medical Record Documents

Reviewers may find documentation of skin or soft tissue infection in the following sections of the patient's medical record:

- Medication administration record (e.g., antibiotics or antifungals),
- Progress notes (physician and nurse notes),
- Skin/wound assessment,

Skin or soft tissue infection

- Wound/ostomy team documentation, and
- Infectious disease specialist consultation notes.

Quality Assurance Documentation

For skin and soft tissue infections, the following factors may be helpful in ensuring consistency and accuracy:

- The site of the infection,
- Whether it was a superficial or deeper infection,
- Culture results,
- Antibiotics or antifungals provided,
- Patient risk factors (e.g., immobility), and
- Whether appropriate preventative measures (listed above) were in place to help avoid infection.

Associated Trigger(s)

See C12 Hospital-acquired infections.

Skin tear

Skin tear

Condition Definition

A skin tear is a wound caused by shear, friction, and/or blunt force resulting in separation of skin layers. A skin tear can be partial-thickness (separation of the epidermis from the dermis) or full-thickness (separation of both the epidermis and dermis from underlying structures).[20]

Harm Determination

We considered a skin tear that resulted from a fall or other trauma a harm event. However, a skin tear without documentation of an accompanying fall or other injury requires clinical judgement before being considered a harm event. For example, multiple skin tears in a non-frail patient with normal skin upon admission may be considered a temporary harm. But a few minor skin tears in a fragile elderly patient who is on steroids and bed-ridden are most likely not harm.

Preventability

A skin tear may be a **preventable** event if:

- Providers did not follow appropriate precautions to prevent falls that led to the skin tear, particularly with high-risk patients, or

- It was the result of the patient being unnecessarily exposed to objects or surfaces (e.g., bedrail) that contributed to the skin tear or breakdown.

A skin tear may be a **nonpreventable** event if:

- Providers followed appropriate precautions (such as cushioning/padding against the patient's bedrail), but the patient still experienced a skin tear from a fall or other trauma (e.g., hitting a bedrail).

Reviewers may want to consult the Prevention and Management of Skin Tears in Aged Skin guidelines developed by International Skin Tear Advisory Panel for helping determine preventability.[21]

Key Medical Record Documents

Reviewers may find documentation of a skin tear in the following sections of the patient's medical record:

- History and physical to determine if the skin tear was present on admission or risk factors for skin tears, such as chronic steroid use,
- Progress notes (physician and nurse notes), and
- Wound/ostomy team's assessment notes.

Quality Assurance Documentation

For skin tears, the following factors may be helpful in ensuring consistency and accuracy:

- The size and extent of the skin tear, such as the length and depth of the tear in centimeters or inches,
- The cause of the skin tear, such as if the tear was caused by a fall or other trauma with injury,
- Any safety precautions and treatment provided to the patient for the skin tear, and
- Any underlying medical condition of the patient increasing risk for skin tears.

Associated Trigger(s)

See C8 Fall or other trauma and C18 Care—other.

Reference

- LeBlanc, et al., *International Skin Tear Advisory Panel, Best Practices for the Prevention and Management of Skin Tears in Aged Skin*, Wounds International, 2018. Available at https://woundsinternational.com/best-practice-statements/istap-best-practice-recommendations-prevention-and-management-skin-tears-aged-skin/.

Stroke

Stroke

Condition Definition

An acute stroke is a cerebrovascular accident caused by interrupted blood flow to the brain with signs and symptoms that can include sudden numbness or weakness in the face, arm, or leg, or on one side of the body, sudden confusion with trouble speaking and understanding speech, problems seeing in one or both eyes or loss of vision in a visual field, trouble walking including dizziness, loss of balance, or lack of coordination, and a sudden severe headache with no known cause. A stroke can lead to permanent brain damage or death. There are different types of strokes such as an acute ischemic stroke (caused by an obstructed blood vessel), a hemorrhagic stroke (caused by a bleeding blood vessel), and a transient ischemic attack.

Harm Determination

Although a stroke is often the result of underlying disease (e.g., hypertension), it can also be caused by medication or surgery. We consider a stroke caused by medication provided during the course of care a harm event. A stroke that occurs prior to admission or as the result of underlying disease should also be evaluated for omissions of care or treatment errors as failure to provide prompt and appropriate care may be a factor in an extension of the stroke. An extension of the stroke that is due to an omission of care may be considered a harm event. An example of an omission of care event is a delay in diagnosis which results in tissue plasminogen activator (tPA)—or anticoagulants, antiplatelets, or other thrombolytics—not being provided within the appropriate window.

Preventability

A stroke may be a **preventable** event if:

- The stroke was the result of a medical error or a significant delay/omission of care. For example, if a patient was admitted with signs and symptoms of a stroke and providers failed to recognize the stroke and therefore failed to provide appropriate care to prevent further deterioration, this would be categorized as a preventable harm event.

A stroke may be a **nonpreventable** event if:

- Providers followed evidence-based practices with timely and appropriate intervention (e.g., administration of anticoagulants) but harm resulted (e.g., excessive central nervous system bleed) nonetheless or
- The stroke occurred in a patient who may be at higher risk for stroke complications, such as those with multiple comorbidities.

Key Medical Record Documents

Reviewers may find documentation of a stroke in the following sections of the patient's medical record:

- History and physical,
- Medication administration record,

Stroke

- Brain imaging results,
- Progress notes (physician and nurse notes),
- Rapid response or stroke team's notes,
- Cardiovascular surgery or procedure record, and
- Transfer notes—if the patient was transferred to a higher level of care.

Quality Assurance Documentation

For strokes, the following factors may be helpful in ensuring consistency and accuracy:

- The time from the onset of stroke signs and symptoms to intervention,
- Whether hospital staff provided appropriate and timely care (e.g., an IV infusion of tPA for this life-threatening condition), and
- The results of the CT head scan for determining the extent of the harm (e.g., cerebral edema), treatment needs, and the patient's prognosis.

Associated Trigger(s)

See C13 In-hospital stroke or transient ischemic attack (TIA).

Reference

- Powers, et al., "2018 Guidelines for the Early Management of Patients with Acute Ischemic Stroke, A Guideline for Healthcare Professionals from the American Heart Association/American Stroke Association," *Stroke*, Volume 49, Issue 3, March 2018. Accessible at https://www.ahajournals.org/doi/pdf/10.1161/STR.0000000000000158.

Surgical site infection

Surgical site infection

Condition Definition

A surgical site infection is an infection that occurs near or at the surgical incision site and/or deeper underlying tissue spaces and organs. A surgical site infection may be superficial, or it could involve a more severe deep tissue surgical infection.

Harm Determination

We considered a surgical site infection a harm event if the infection occurred within 30 days of a surgical procedure (or within 90 days for procedures involving implanted materials) per CDC guidelines on the surveillance periods for surgical site infections following selected operative procedure categories.[22] In contrast to some organizations that track only specific surgical site infections, we consider any surgical site infection that developed post-operatively as a harm event if it was attributable to a surgery or procedure. We also consider post-operative infections that required

readmission for treatment a harm event. We also consider deep post-operative surgical wound infections related to a previous hospitalization as almost always attributable to the original surgery and we would therefore consider it a harm from the patient's prior stay. However, reviewers should also rule out any infection present at the time of surgery.

Preventability

We recommend that reviewers consult the CDC guidelines for the prevention of surgical site infections in the references below.

A surgical site infection may be a **preventable** event if:

- The infection was related to inadequate infection prevention (such as lack of or inappropriate antimicrobial prophylaxis) and poor care management such as inadequate monitoring or inadequate surgical/procedural incision care in the post-operative period or
- The infection was related to a surgical technique that contributed to wound dehiscence or another complication (e.g., retained object) that led to an infection.

A surgical site infection may be a **nonpreventable** event if providers applied infection prevention precautions and appropriate care and:

- The patient was highly susceptible to an infection (e.g., obese, on cancer therapy, or immunocompromised) or
- The surgery or procedure was high-risk (e.g., organ transplantation or involving prolonged surgical time), increasing the likelihood of a complication and resulting infection.

Key Medical Record Documents

Reviewers may find documentation of a surgical site infection in the following sections of the patient's medical record:

- History and physical for documentation of recent surgery,
- Laboratory results (e.g., wound cultures and WBC with differential),
- Medication administration record (e.g., antibiotics),
- Progress notes (physician and nurse notes),
- Consultation notes,
- Vital signs (e.g., fever, blood pressure, respiratory rate),
- Invasive devices documentation, and
- Procedure or operative notes.

Quality Assurance Documentation

For surgical site infections, the following factors may be helpful in ensuring consistency and accuracy:

- Wound cultures indicating the presence of pathogenic microorganisms,

Surgical site infection

- White blood cell count (per specialty guidelines to differentiate inflammatory from infected fluid),
- Purulent discharge from the incision site,
- Other documented signs and symptoms (e.g., fever, delirium, etc.) of an infection,
- The day and time of diagnosis,
- Any resulting wound dehiscence or complication,
- Operative notes documenting the infected surgical wound,
- Antibiotic coverage prior to and after the procedure,
- Wound care, and
- Placement of a wound vacuum to assist with wound healing.

Associated Trigger(s)

See the following triggers:

- C12 Hospital-acquired infections,
- C5 Positive culture (e.g., blood, urine, stool), and
- S11 Any operative complication.

References

- CDC, "Surgical Site Infection Event," January 2022. Available at CDC, "Surgical Site Infection Event," January 2023. Available at https://www.cdc.gov/nhsn/pdfs/pscmanual/9pscssicurrent.pdf.
- Berríos-Torres, et al., "Centers for Disease Control and Prevention Guideline for the Prevention of Surgical Site Infection, 2017," *JAMA Surgery*, Volume 152, Number 8, August 2017. Available at doi:10.1001/jamasurg.2017.0904.

Vascular access device complication

Vascular access device complication

Condition Definition

A vascular access device is a type of catheter that provides either permanent or non-permanent access to blood vessels. Although used for treatment, these types of devices have the potential to cause harm to the patient when there is a failure or complication associated with the device.[23] (For infections related to vascular access devices, see "Vascular catheter-associated infection.")

Vascular access device complication

Harm Determination

We considered a vascular access device that is permanent or totally implanted (e.g., a port implanted for chemotherapy), and that becomes clotted or otherwise defective, as a harm event even without signs and symptoms. A non-permanent vascular access device (e.g., a peripherally inserted central catheter line or a peripheral IV) that becomes clotted, requiring removal and reinsertion, is not considered a harm event unless there is other patient harm such as a hematoma, vein thromboses with signs and symptoms (e.g., pain, swelling), or infection.

Preventability

A vascular access device complication may be a **preventable** event if:

- The cause of the harm was related to incorrect placement/insertion and securement of the vascular access device.

A vascular access device complication may be a **nonpreventable** event if:

- The patient was particularly frail with significant hemodynamic problems or
- Placement of the device was difficult due to complex anatomic placement.

Key Medical Record Documents

Reviewers may find documentation of a vascular access device complication in the following sections of the patient's medical record:

- Progress notes (physician and nurse notes),
- Consultation notes (e.g., vascular surgeon),
- Anesthesia records,
- Interventional radiology procedure notes, and
- Vascular access device documentation.

Quality Assurance Documentation

For vascular access device complications, the following factors may be helpful in ensuring consistency and accuracy:

- The type of vascular access device,
- A description of the failure,
- Signs or symptoms,
- Any associated complications, and
- Contributing factors that led to the harm.

Associated Trigger(s)

See C15 Any procedure complication and S11 Any operative complication.

Vascular access device complication

References

- Spencer, T.R., "Securing vascular access devices," American Nurses Association, September 2018. Available at https://www.myamericannurse.com/securing-vascular-access-devices/.
- Hudson, et al., *Pathogenesis and Prevention of Vascular Access Failure, Vascular Access Surgery - Tips and Tricks*, IntechOpen, January 2019. Available at https://www.intechopen.com/chapters/65268.

Vascular catheter-associated infection

Vascular catheter-associated infection

Condition Definition

A vascular catheter-associated infection is associated with a catheter used for access to a blood vessel. This includes all types of vascular catheter devices encompassing central venous lines, midlines, peripheral IVs, arterial lines, and heart-lung bypass machines for extracorporeal membrane oxygenation (ECMO). This occurs when pathogenic microorganisms (e.g., bacteria, viruses, fungi) enter the bloodstream through vascular catheter devices.

An example of a vascular catheter-associated infection is a central line-associated bloodstream infection (CLABSI). CDC distinguishes a CLABSI as an epidemiologic definition which differs from its clinical definition of a catheter-related bloodstream infection (CRBSI) which is specific to laboratory testing that thoroughly identifies the catheter as the source of the bloodstream infection.[24]

Harm Determination

In general, we considered a vascular catheter-associated infection a harm event if it met the criteria listed under "Hospital-acquired infection" and the infection source is associated with a vascular catheter.

Specific to CLABSI, per CDC's NHSN criteria, this is considered a serious harm if the patient had a bloodstream infection and had a central line within the 48-hour period before the development of the infection, and that the infection was not related to another site.[25] (See "Hospital-acquired infection" for more information on identifying infections.)

Reviewers should also be aware of false positives for bloodstream infections caused by contaminated blood cultures.[26, 27] See "Sepsis" for more information about false positives.

(Note that CDC guidelines are continuously updated, so reviewers should follow the most recent guidelines.)

Vascular catheter-associated infection

Preventability

A vascular catheter-associated infection is usually considered a **preventable** event if the appropriate infection prevention precautions had been followed—for example, the use of a catheter checklist and "time out" to ensure adherence to infection prevention practices at the time of central venous catheter insertion and the use of an aseptic technique, including the use of a cap, mask, sterile gown, sterile gloves, and a large sterile sheet for the insertion of the catheter.

A vascular catheter-associated infection may be a **nonpreventable** event if providers employed appropriate infection prevention precautions, but the patient still contracted an infection or the patient was highly susceptible to an infection due to an immunocompromised state.

In determining preventability, we suggest consulting guidelines on preventing CLABSIs that were developed by the Society for Healthcare Epidemiology of America (SHEA), CDC, and IDSA.[28] See "References" below for more information.

Key Medical Record Documents

Reviewers may find documentation of a vascular catheter-associated infection in the following sections of the patient's medical record:

- Medication administration record (e.g., antibiotics),
- Laboratory reports (e.g., blood cultures and WBC with differential),
- Progress notes (physician and nurse notes),
- Infection control notes, and
- Consultation notes (e.g., infectious disease).

Quality Assurance Documentation

For vascular catheter-associated infections, the following factors may be helpful in ensuring consistency and accuracy:

- The type of vascular catheter,
- Site of the catheter,
- Duration of catheter placement,
- Laboratory microorganism findings including the site, date, and time of the blood culture test results, and
- Any signs and symptoms with dates as a result of the infection.

Associated Trigger(s)

See C12 Hospital-acquired infections and C5 Positive culture (e.g., blood, urine, stool).

Vascular catheter-associated infection

References

- Buetti, et al., "Strategies to prevent central line-associated bloodstream infections in acute-care hospitals: 2022 Update," *Infection Control & Hospital Epidemiology*, Volume 43, Issue 5, April 2022. Available at https://www.ncbi.nlm.nih.gov/pmc/articles/PMC9096710/.
- CDC, "Bloodstream Infection Event (Central Line-Associated Bloodstream Infection and Non-central Line Associated Bloodstream Infection)," January 2023. Available at https://www.cdc.gov/nhsn/pdfs/pscmanual/4psc_clabscurrent.pdf.

Ventilator-associated event

Ventilator-associated event

Condition Definition

A ventilator-associated event (VAE) often involves ventilator-associated pneumonia and aspiration (see "Aspiration" for further details). A ventilator is a machine that is used to help a patient breathe by providing oxygen through the patient's mouth or nose or through a tracheostomy. Ventilator-associated pneumonia is a lung infection that develops in a person who is breathing with mechanical assistance from a ventilator.

Harm Determination

We considered a VAE a harm if it met the CDC's NHSN criteria.[29] These criteria distinguish VAE into three levels:

1) a ventilator-associated condition,
2) an infection-related ventilator-associated complication, and
3) possible ventilator-associated pneumonia.

We considered any event that met one of these three criteria a harm event. Below, we summarize this guidance.

To be considered as having a ventilator-associated condition, the patient must be mechanically ventilated for at least 4 calendar days. When considering ventilator-associated harm, the day of intubation and initiation of mechanical ventilation is day 1. A VAE is considered hospital-acquired if the patient had a baseline period of stability or improvement for at least 2 calendar days and then one of the following occurred:

- The patient experienced an increase in daily minimum fraction of inspired oxygen (FiO2) of ≥20 points over the daily minimum of FiO2 of the first day in the baseline period, sustained for 2 or more calendar days, or

- The patient experienced an increase in daily minimum positive end-expiratory pressure (PEEP) values of ≥3 cm of H2O over the daily minimum PEEP of the first day in the baseline period, sustained for 2 or more calendar days.

An infection-related ventilator-associated complication occurs when the infection was contracted on or after calendar day 3 of mechanical ventilation and within 2 calendar days before or after the onset of worsening oxygenation with both of the following criteria being met:

- The patient's body temperature was above 38°C or lower than 36°C or WBC ≥12,000 cells/mm^3 or WBC ≤4,000 cells/mm^3, and
- Providers gave the patient a new antimicrobial agent(s) to treat the infection for 4 or more qualifying antimicrobial days (see CDC guidance for list of specimens).

Possible ventilator-associated pneumonia occurs when the above criteria are met and if one of the following is met:

- There is a positive culture of one or more specimens,
- Purulent respiratory secretions with specimens present, or
- There is a positive diagnostic test for the presence of a disease-causing microorganism.

For a complete description of the above criteria, see the NHSN guidelines.

See "Hospital-acquired infection" for more information related to broader infection determinations.

(Note that CDC guidelines are continuously updated, so reviewers should follow the most recent guidelines.)

Preventability

A ventilator-associated event is usually considered a **preventable** event if the appropriate infection prevention precautions had been followed. For example, daily toothbrushing, oral care with chlorhexidine, subglottic secretion drainage, head of bed elevation if possible, and other best practices involving mechanically ventilated patients can help prevent infection.

A ventilator-associated event may be a **nonpreventable** event if the providers employed appropriate infection prevention precautions, but the patient still contracted an infection or the patient was highly susceptible to an infection due to an immunocompromised state.

In determining preventability, we suggest consulting guidelines on preventing ventilator-associated pneumonia that were developed by SHEA, CDC, and IDSA.[30]

Key Medical Record Documents

Reviewers may find documentation of a ventilator-associated event in the following sections of the patient's medical record:

- Medication administration record (e.g., antibiotics),
- Laboratory results (e.g., respiratory and/or blood cultures, WBC with differential),

- Radiology results (e.g., chest imaging),
- Progress notes (physician and nurse notes),
- Consultation notes (e.g., pulmonologists and intensivists),
- Respiratory therapy notes, and
- Ventilator-related ongoing documentation of FiO2, PEEP, and arterial blood gasses measurement.

Quality Assurance Documentation

For ventilator-associated events, the following factors may be helpful in ensuring consistency and accuracy:

- Type and duration of mechanical ventilation,
- Bronchoscopic culture findings including the date and time of the test results,
- Trending FiO2 or PEEP measurements and WBC,
- The patient's body temperature during the time of the event as this may indicate an infection or oxygenation issue,
- Any signs and symptoms as a result of the infection, and
- Chest CT image changes.

Associated Trigger(s)

See the following triggers:

- I1 Hospital-acquired pneumonia onset,
- C12 Hospital-acquired infections, and
- S7 Mechanical ventilation greater than (>) 24 hours post-operatively.

References

- Klompas, et al., "Strategies to prevent ventilator-associated pneumonia, ventilator-associated events, and nonventilator hospital-acquired pneumonia in acute-care hospitals: 2022 Update," *Infection Control & Hospital Epidemiology*, First View, May 2022. Available at https://pubmed.ncbi.nlm.nih.gov/35589091/.
- CDC, "Ventilator-Associated Event (VAE)," January 2023. Available at https://www.cdc.gov/nhsn/pdfs/pscmanual/10-vae_final.pdf.

HOSPITAL TRIGGER TOOL

Researchers conducting medical record reviews may want to explore the use of trigger tools and how they can be used in patient harm identification. We use triggers as clinical clues within the medical record that may indicate harm occurred.[31] Our review methodology includes the use of a Global Trigger Tool (GTT), which was modified from the Institute for Healthcare Improvement's (IHI's) GTT. We adapted and refined our triggers specific to each setting, such as nursing homes. (See the Appendix for the trigger tool worksheets we used across different settings.) For more information about the medical record review methodology, see the companion resource, *Adverse Events Toolkit: Medical Record Review Methodology*.

Below, we provide the list of triggers used in our hospital-focused reviews, including definitions and interpretation that may be useful for reviewers. Although largely based on triggers developed by IHI for hospitalized patients, we added to and modified the original list based on our experience conducting medical record reviews. We also refer to related sections in the toolkit to identify specific conditions and injuries that may be commonly associated with the triggers listed below. The triggers are grouped into four modules: 1) care, 2) medication, 3) surgical, and 4) intensive care.

Care Module Triggers

This module consists of 18 triggers related to the general care of patients during their hospital stay.

#	Care Module Triggers
C1	Acute mental status change
C2	Transfusion or use of blood products
C3	Code/arrest/rapid response team
C4	Acute dialysis
C5	Positive culture (e.g., blood, urine, stool)
C6	Studies for emboli, pulmonary embolism (PE) or deep vein thrombosis (DVT) such as D-Dimer, computerized tomography (CT) pulmonary angiogram (CTPA), or lung ventilation-perfusion scan
C7	Abrupt or significant decrease in hemoglobin or hematocrit
C8	Fall or other trauma
C9	Pressure injury/skin breakdown from medical device
C10	Readmission within 30 days
C11	Restraint use
C12	Hospital-acquired infections
C13	In-hospital stroke/transient ischemic attack (TIA)
C14	Transfer to higher level of care
C15	Any procedure complication
C16	Urinary retention
C17	Aspiration
C18	Care—other

Sources: Triggers C2 through C15 and C18 are based on the triggers found in Griffin, F.A., and Resar, R.K., *IHI Global Trigger Tool for Measuring Adverse Events* (Second Edition), Institute for Healthcare Improvement Innovation Series, 2009. Triggers C1, C16, and C17 are based on the triggers found in Adler, L., Moore, J., and Federico F., *IHI Skilled Nursing Facility Trigger Tool for Measuring Adverse Events*, Institute for Healthcare Improvement, November 2015.

C1 Acute mental status change

Medication adverse drug events can cause profound changes in mental status (e.g., delirium caused by opioid analgesics or ICU psychosis) and are considered patient harm. Look for mental status changes related to medical care. Reviewing the prescriber orders, vital signs, the medication administration record, and progress notes (e.g., nurse, physician/allied health) is useful. Treatment that results in intentional sedation is likely not a harm event (e.g., comfort measures for end-of-life patients, medication administered to calm agitated patients, or medication given to induce sleep). (See Specific Conditions and Injuries—Delirium or other change in mental status for more information.)

C2 Transfusion or use of blood products

Procedures may require intra-operative transfusions of blood products for replacement of blood lost. Any transfusion of a blood product should be investigated for causation, including excessive bleeding (surgical or anticoagulant-related), or unintentional trauma of a blood vessel. Transfusion of many units or transfusions indicative of blood loss beyond expectation, intra-operatively, within the first 24 hours after surgery and the later post-operative period, may be related to a perioperative harm event. Patients receiving anticoagulants who require transfusion of fresh frozen plasma and platelets may have experienced an excessive bleeding event. (Also see Trigger C7—Abrupt or significant decrease in hemoglobin or hematocrit and Specific Conditions and Injuries—Excessive bleeding for more information on bleeding and transfusions.)

C3 Code/arrest/rapid response team

All "codes," calls for an emergency response (e.g., code team or rapid response), and cardiac or pulmonary arrests need to be carefully reviewed because they may have been caused by harm events or be harm events themselves. Reviewers should check for medication-related issues. Not all codes/arrests/rapid responses are patient harm, as some may be progression of underlying disease. For example, sudden cardiac arrhythmia resulting in cardiac arrest may not be a harm event if due to an underlying cardiac condition. A code resulting from a medication and/or inadequate or delayed care is a harm event.

C4 Acute dialysis

A requirement for dialysis may be the result of a disease process or a harm event. Examples of harm events include radiological intravenous dye or drug-induced acute kidney injury reflected by rising serum creatinine and/or reduction of urinary output or glomerular filtration rate (GFR). (Also see Trigger M5—Rising blood urea nitrogen (BUN) or serum creatinine greater than (>) 1.5 times baseline and see Specific Conditions and Injuries—Acute kidney injury for more information.)

C5 Positive culture (e.g., blood, urine, stool)

A positive culture at any time during the hospitalization must be investigated as an indicator of a possible harm event—a hospital-associated infection. Generally, harm events associated with this trigger will include infections that are diagnosed on or after the third calendar day after admission as a result of existing device infections (e.g., CAUTI, pacemaker wire, etc.) or other hospital-associated infections. New devices inserted upon admission associated with infection are usually harm events. (See Trigger C12—Hospital-acquired infections and Specific Conditions and Injuries—Hospital-acquired

infection for more information.) A *C. diff* infection is considered a harm event if it was diagnosed on or after the fourth calendar day when the admission day is calendar day 1. (See Trigger M1—*Clostridioides difficile* positive stool test.)

However, abnormal laboratory test results without signs/symptoms (e.g., asymptomatic bacteriuria) are generally not considered harm. For example, if a patient has an indwelling urinary catheter and a positive urine culture that is 100,000 CFU per ml without pain or fever or change in mental status, it is not considered harm.

Positive blood cultures related to underlying disease (such as community-acquired pneumonia progressing to sepsis) would not be indicative of a harm event unless the progression leads to a complication due to an omission of care. Reviewers should bear in mind that possible bacterial contaminants documented in laboratory results are not considered infections. (See Specific Conditions and Injuries—Sepsis and Specific Conditions and Injuries—Vascular catheter-associated infection for more information.)

C6 Studies for emboli, pulmonary embolism (PE) or deep vein thrombosis (DVT) such as D-Dimer, computerized tomography (CT) pulmonary angiogram (CTPA), or lung ventilation-perfusion scan

Development of DVT or PE during a hospital stay should be considered a harm event unless it is clearly related to a disease process (examples include cancers such as brain, ovary, pancreas, colon, stomach, lung and kidney, leukemia, or lymphoma or clotting disorders). However, any failure to provide prophylaxis, when indicated, is an omission of care. Although there are options regarding the best prophylactic treatment to prevent a DVT or PE from occurring in the hospital, the review should focus on the context of the case concerning possible failure to provide prophylaxis or providing inadequate prophylaxis. The failure to prevent the PE or DVT when the indicated prophylaxis is provided may not be preventable but is still a harm event.

C7 Abrupt or significant decrease in hemoglobin or hematocrit

An excessive drop in hemoglobin or hematocrit, equivalent to an absolute drop to hemoglobin <7.0 Gm and/or hematocrit <21%, or unplanned transfusion with documented physiologic vital sign changes (e.g., tachycardia, hypotension, orthostatic signs/symptoms), should be investigated if the decrease occurs within a short period of time (e.g., 72 hours or less). Significant drops in hemoglobin or hematocrit are considered patient harm if they are the result of a medical treatment (e.g., aspirin, non-steroidal anti-inflammatory drugs, and anticoagulants) or a procedure complication. (See Specific Conditions and Injuries—Excessive bleeding for more information.)

C8 Fall or other trauma

Any fall in the care setting that causes injury, regardless of cause, is a harm event, whereas a fall without injury is not a harm event. A fall in a care setting represents a failure of care or may be the result of medications, equipment failure, or lack of adequate monitoring. Documented injuries could include dislocations, fractures, lacerations, skin tears, sprains, hematomas, and/or significant pain (e.g., pain limiting patient ambulation). Most falls are not harm events, but all falls must be reviewed for possible injuries. Any other or unexplained trauma or injuries that were not present on admission require medical record review to determine if they represent a harm event. (See Specific Conditions and Injuries—Fall with injury for more information.)

C9 Pressure injury/skin breakdown from medical device

Pressure injuries that develop or advance in stage during a patient's hospital stay are harm events. For example, a pressure injury that is a Stage 1 on arrival but escalates to Stage 2 during the indexed hospital stay is an event. We recommend using the National Pressure Injury Advisory Panel (NPIAP) staging guidelines. (See Specific Conditions and Injuries—Pressure injury for more information.)

For Stage 1 pressure injuries that develop during the patient's stay, screeners should refer only cases specifically described as non-blanchable redness, not just redness. For example, if a patient has light-toned skin with non-blanchable redness as evidenced by the provider notes or skin assessment chart with Stage 1 indicated by the provider and requiring treatment, this should be flagged for review. There may be cases where screeners are unable to determine non-blanchable redness due to dark-toned skin or insufficient documentation; in these cases, reviewers should use their clinical judgment or follow up with medical experts to collect such documentation where appropriate.

For pressure injuries described as "worsening" without an increase in stage, reviewers should assess the record for any documentation of a significant increase in the size of the pressure injury of at least 1 cm in any dimension and/or with documentation such as "larger" or "deeper." Reviewers should also flag any pressure injuries progressing to the need for amputation as this may be a harm event.

Any skin breakdown that was not present on admission should also be considered a trigger for harm, particularly those attributed to a medical device (e.g., prosthetic limb).

C10 Readmission within 30 days

Any readmission associated with an index admission could be attributed to a harm event. A harm event may not manifest itself until after the patient has been discharged from the hospital, especially if the length of stay was short. Examples of harm events may include unplanned readmissions for a post-operative infection, development of DVT, or a PE complication.

C11 Restraint use

Restraint use includes both physical and chemical (use of medication to control behavior) restraints. Whenever physical or chemical restraints are used, review the documented reasons, and evaluate the possible relationship between the use of physical or chemical restraints and confusion from drugs or falls as this would indicate patient harm.

C12 Hospital-acquired infections

This trigger encompasses a broad category of patient harm that includes infections that are diagnosed on or after the third calendar day after admission, such as vascular catheter-associated bloodstream infections, sepsis from other device infections (e.g., CAUTI), or any other hospital-associated infection. In general, an infection is not attributable to the hospital admission if diagnosed within the first 2 calendar days (where the admission day is the first calendar day), as these are often related to devices inserted during the preceding hospitalization or are infections acquired prior to the admission.

There are exceptions to the above 2-day rule. If a new device was inserted during the patient's hospitalization, any resulting infection would be attributable to the hospital stay, even if within the first 2 calendar days. (See Specific Conditions and Injuries—Hospital-acquired infection for more information.) In ad*dition,* a C. diff infection diagnosis on or after the fourth calendar day after admission is considered hospital-acquired. (See *Clostridioides difficile* infection for more information.)

In reviewing the record for a hospital-acquired infection, reviewers should check laboratory results for positive cultures growing pathogenic microorganisms from blood, urine, sputum, other body fluid, or stool samples. A positive blood culture at any time during the hospital stay should be investigated as an indicator of a harm event (see Trigger C5—Positive culture (e.g., blood, urine, stool)). However, abnormal laboratory test results without signs/symptoms (e.g., asymptomatic bacteriuria) are generally not indicative of harm. For example, if a patient has an indwelling urinary catheter and a positive urine culture that is 100,000 CFU per ml without pain or fever or change in mental status, it is not considered harm. Reviewers should bear in mind that possible bacterial contaminants documented in laboratory results are not considered infections.

In identifying infection harm events, we recommend that reviewers follow guidelines from the Centers for Disease Control and Prevention's National Healthcare Safety Network (CDC/NHSN) when determining whether an infection may be associated with a medical device or exposure to pathogens in the facility. Below is a list of some common healthcare-associated infections, see links for specific infection condition guidance.

- Catheter-associated urinary tract infection (CAUTI),
- *Clostridioides difficile* (*C. diff*) infection,
- Vascular catheter-associated infection,
- Surgical site infection, and
- Ventilator-associated event.

A wider list of other possible healthcare-associated infections is included at the Specific Conditions and Injuries—Hospital-acquired infection section.

C13 In-hospital stroke or transient ischemic attack (TIA)

Stroke or transient ischemic attack is often due to an underlying disease process. However, these conditions may also result from medical care or omission of care. Examples include the failure to maintain adequate anticoagulation prophylaxis (e.g., in patients with atrial fibrillation) as demonstrated by non-therapeutic levels (omission of care) or as a result of intracranial bleeding related to a medication intervention (an act of commission). (See Specific Conditions and Injuries—Stroke for more information and other requirements.)

C14 Transfer to higher level of care

Transfers of patients to a higher level of care (e.g., to a telemetry or ICU) should be reviewed for a potential harm event. If the patient was transferred due to an exacerbation of an underlying condition (e.g., COPD), this is not considered a harm event unless secondary to an act of omission or commission causing the patient's clinical deterioration. A transfer itself is not harm but may signify that harm occurred.

C15 Any procedure complication

A complication resulting from any procedure (e.g., a procedure on the floor, such as catheterization or central line placement) is a harm event. A procedure note may not indicate complications, especially if the complication occurs hours or days after the procedure note has been dictated. Therefore, reviewers should watch for complications noted in coding, the discharge summary, or other progress notes.

Occurrences such as unintentional tube removal (or removal by patient) are considered quality of care issues if there are no related signs and symptoms. If signs and symptoms occur (as would be expected with unplanned removal of endotracheal or thoracotomy tubes), these may be harm events and should be referred for review. (See examples at Specific Conditions and Injuries—Endotracheal intubation injury and Specific Conditions and Injuries—Vascular access device complication.)

C16 Urinary retention

Urinary retention is the inability to empty the bladder. Acute urinary retention is usually an emergent condition and may be the result of medical intervention, such as medication or removal of an indwelling urinary catheter, such as a Foley catheter. Both acute and chronic urinary retention may also be due to an underlying patient condition (e.g., prostate enlargement) which is not considered a harm event. Patients with urinary retention are at greater risk for other harm events such as falls, infections, and changes in mental status.

C17 Aspiration

Aspiration of foreign material into the airway may be the result of abnormal swallowing or other contributory events. All harm resulting from aspiration, such as aspiration pneumonia, bronchitis, or acute respiratory distress, is considered harm regardless of whether it was preventable. (See Specific Conditions and Injuries—Aspiration for more information and other requirements.)

C18 Care—other

Frequently when the record is reviewed, patient harm is uncovered that does not relate to any trigger. Any other potential care-related harm event can be placed under this "other" trigger.

Medication Module Triggers

This module consists of 15 triggers related to patients who received medication during their hospital stay.

#	Medication Module Triggers
M1	*Clostridioides difficile* positive stool test
M2	Partial thromboplastin time (PTT) greater than (>) 100 seconds
M3	International normalized ratio (INR) greater than (>) 6
M4	Glucose less than (<) 50 mg/dL
M5	Rising blood urea nitrogen (BUN) or serum creatinine greater than (>) 1.5 times baseline
M6	Vitamin K, factor Xa reversal agents (andexanet alfa, idarucizumab administration)
M7	Diphenhydramine use
M8	Flumazenil use
M9	Naloxone use
M10	Anti-emetic use
M11	Abrupt decrease in blood pressure
M12	Abrupt medication stop
M13	Sodium polystyrene (kayexalate administration) or potassium greater than or equal to (≥) 6 mEq/L
M14	Abnormal drug levels
M15	Medication—other

Sources: Triggers M1 through M10, M12, and M15 are based on the triggers found in Griffin, F.A., and Resar, R.K., *IHI Global Trigger Tool for Measuring Adverse Events* (Second Edition), Institute for Healthcare Improvement Innovation Series, 2009. Triggers M11, M13, and M14 are based on the triggers found in Adler, L., Moore, J., and Federico F., *IHI Skilled Nursing Facility Trigger Tool for Measuring Adverse Events*, Institute for Healthcare Improvement, November 2015.

M1 *Clostridioides difficile* positive stool test

C. diff, if diagnosed on or after the fourth calendar day after admission when the admission day is calendar day 1, is a harm event. The diagnosis of a *C. diff* infection should be suspected in patients with clinically significant diarrhea, which is defined as three or more loose stools in 24 hours.[32] However, there are other causes of medication-associated diarrhea such as from magnesium hydroxide. A *C. diff* infection should also be suspected in cases of ileus as well as relevant risk factors including recent antibiotic use, hospitalization, and advanced patient age. (See Trigger C12—Hospital-acquired infections for flagging these infections and Specific Conditions and Injuries—*Clostridioides difficile* infection for more information and other requirements.)

M2 Partial thromboplastin time (PTT) greater than (>) 100 seconds

Elevated PTT measurements occur when patients are on heparin. Reviewers should look for evidence of bleeding to determine if a harm event has occurred. Elevated PTT in itself is not a harm event—there must be manifestation such as bleeding, a significant drop in hemoglobin or hematocrit levels, or bruising. (See Specific Conditions and Injuries—Excessive bleeding for more information and other requirements.)

M3 International normalized ratio (INR) greater than (>) 6

Elevated INR laboratory tests above normal are not considered patient harm unless associated with signs and symptoms of bleeding. Reviewers should look for evidence of bleeding to determine if patient harm has occurred. (See Specific Conditions and Injuries—Excessive bleeding for more information and other requirements.)

M4 Glucose less than (<) 50 mg/dL

A blood glucose level below 50 mg/dL due to a medication or surgery is considered a harm event with or without signs and symptoms. (See Specific Conditions and Injuries—Hypoglycemia for more information and other requirements.)

- In cases with signs and symptoms, reviewers should search for lethargy and shakiness documented in nursing notes and diabetic flow sheet as well as the administration of glucose, orange juice, or other interventions. If symptoms are present when there is a significant drop in blood glucose due to a glycemic medication, even when blood glucose is greater than 50 mg/dL this may be a harm event. Review diabetic/blood glucose flow sheets, nursing notes, laboratory tests, and the medication administration record for symptoms associated with use of insulin or oral hypoglycemic(s).

- In cases without signs and symptoms, an abnormal laboratory result is considered harm if blood glucose is less than 50 mg/dL. Patients may have physiologic changes that may not be documented or recognized by the patient due to cognitive impairment.

M5 Rising blood urea nitrogen (BUN) or serum creatinine greater than (>) 1.5 times baseline

Reviewers should check laboratory records for rising levels of serum creatinine. If a change of 1.5 times greater than baseline creatinine levels is found, GFR decreases by more than 25 percent, or urine output

is less than 0.5 mL/Kg/h for 6 hours, then these are indicators for acute kidney injury, which is considered patient harm.[33] (These indicators are based on the RIFLE criteria.)[34] To determine serum creatinine baseline, it may be helpful to review laboratory tests, if available, from preceding hospitalization or within the patient's discharge summary, history, and physical or other hospital records. Reviewers should also check the medication administration records for medications known to cause acute kidney injury. (See Specific Conditions and Injuries—Acute kidney injury for more information and other requirements.)

M6 Vitamin K, factor Xa reversal agents (andexanet alfa, idarucizumab administration)

Reviewers should screen the medication administration record and physician orders to check if vitamin K or factor Xa reversal agents (listed above) were used as a response to a bleed while on an anticoagulant, prolonged prothrombin time, or elevated INR levels. Any of the above may signal a harm event. If either laboratory value (prothrombin time or INR) is high, review the chart for evidence of bleeding. Look in the laboratory reports for a drop in hematocrit or for guaiac-positive stools. Check the progress notes for evidence of excessive bruising or gastrointestinal bleeding. Although less likely, a hemorrhagic stroke or other internal bleeding may have occurred. If any of these are found, this is likely a harm event. (See Specific Conditions and Injuries—Excessive bleeding for more information and other requirements.)

M7 Diphenhydramine use

Diphenhydramine is frequently used for allergic reactions to drugs but can also be ordered as a sleep aid or for seasonal allergies. If the drug has been administered, review the record for potential patient harm, such an allergic reaction to a drug, or confusion, which is a side effect of the medication. (See Specific Conditions and Injuries—Allergic reactions for more information and other requirements.)

M8 Flumazenil use

Flumazenil reverses the side effect of benzodiazepine drugs manifested by confusion and abrupt hypotension. (See Specific Conditions and Injuries—Delirium or other change in mental status for more information and other requirements.)

M9 Naloxone use

Naloxone is a powerful opioid antagonist. Usage likely represents patient harm from excess opioid administration, as this may result in a spectrum of clinical signs and symptoms ranging from oversedation to respiratory failure.

M10 Anti-emetic use

Nausea and vomiting commonly are the result of medications, medical conditions, and surgery. Providers often administer anti-emetics to patients to prevent or treat nausea and vomiting. Nausea and vomiting that interferes with feeding and post-operative recovery is an indicator of patient harm. In addition, if nausea and vomiting delays discharge, or is associated with dehydration or projectile vomiting, this is also an indicator of patient harm. One or two episodes treated successfully with anti-emetics would suggest no harm event. Reviewer judgment is needed to determine whether harm occurred. (See Specific Conditions and Injuries—Nausea and vomiting for more information and other requirements.)

M11 Abrupt decrease in blood pressure

An abrupt decrease in blood pressure in which the systolic blood pressure drops to less than 90 mmHg may represent patient harm. The hypotension may be related to a patient harm secondary to medications including anti-hypertensive medications, muscle relaxants, pain medications, sedatives, or excess diuretics, or alternatively it may related to sepsis or a cascade due to significant bleeding. Reviewers should review medical record for symptoms such as:

- near syncope,
- orthostasis,
- weakness,
- dizziness, or
- mental status change.

Reviewers should also look for actions such as paging a physician, flattening the bed, reverse Trendelenburg, or starting IVs, which may affect the preventability determination. Note that some patients, e.g., patients who are recumbent in ICU or sedated in bed elsewhere, may not have symptoms, but will have potential signs due to lack of blood pressure such as cold extremities or pale complexion. (See Specific Conditions and Injuries—Hypotension for more information, other requirements, and exceptions.)

M12 Abrupt medication stop

"Abrupt" is best described as an unexpected stop. Although the discontinuation of medications is a common finding in the record, abruptly stopping medications is a trigger that requires further investigation for cause. A sudden change in patient condition requiring medication adjustment may be related to patient harm. However, discontinuation of an intravenous antibiotic to switch to oral is not unexpected and therefore not likely to reveal patient harm. Reviewers should check the physician orders and medication administration records for evidence indicating an abrupt medication stop.

M13 Sodium polystyrene (kayexalate administration) or potassium greater than or equal to (≥) 6 mEq/L

Sodium polystyrene sulfonate (kayexalate) is used in the treatment of hyperkalemia (elevated potassium) by aiding in the removal of excess potassium from the body. Hyperkalemia should be flagged as possible patient harm for any potassium levels greater than or equal to 6.0 mEq/L, regardless of whether there are associated signs and symptoms. Administration of kayexalate (oral or IV potassium) may be in response to an overdose, which would be a harm event. Reviewers should check for any documented causes of hyperkalemia and whether the patient had been receiving potassium, angiotensin-converting enzyme, or aldosterone inhibitor medications. (See Specific Conditions and Injuries—Abnormal electrolytes for more information and other requirements.)

M14 Abnormal drug levels

If laboratory tests are sub-therapeutic (below lower therapeutic limit) or supra-therapeutic (above upper therapeutic limit), review the hospital medical record progress notes for documentation of a potential harm event. Examples include inadequate seizure medication serum level leading to a seizure or an elevated aminoglycoside serum drug level that leads to acute kidney injury.

M15 Medication—other

Frequently when the record is reviewed, patient harm is uncovered that does not fit a trigger. Any other potential medication-related harm event can be placed under this "other" trigger.

Surgical Module Triggers

This module consists of 11 triggers related to patients who had a surgical procedure during their hospital stay.

#	Surgical Module Triggers
S1	Unplanned return to surgery
S2	Unplanned change in procedure
S3	Unplanned admission to intensive care post-operation
S4	Intubation/reintubation/bilevel positive airway pressure (BPAP) in post anesthesia care unit (PACU)
S5	Unplanned X-ray/CT scan/magnetic resonance imaging (MRI) or other imaging intra-operatively or in PACU
S6	Intra-operative or post-operative death
S7	Mechanical ventilation greater than (>) 24 hours post-operatively
S8	Intra-operative epinephrine, norepinephrine, naloxone, or flumazenil
S9	Abnormal post-operative troponin level, including sensitive or highly sensitive troponin I or troponin T
S10	Injury, unplanned repair, or removal of organ
S11	Any operative complication

Source: Triggers S1 through S11 are based on the triggers found in Griffin, F.A., and Resar, R.K., *IHI Global Trigger Tool for Measuring Adverse Events* (Second Edition), Institute for Healthcare Improvement Innovation Series, 2009.

S1 Unplanned return to surgery

If surgery was not clearly planned prior to the first surgery, reviewers should consider it unplanned, and review for a possible harm event. An example of a harm event would be a patient having internal bleeding following surgery which required a second surgery to explore the cause of the bleeding and to stop the bleeding.

S2 Unplanned change in procedure

An unexpected change in a surgical procedure may be due to a device or equipment failure which would be a harm if it caused an injury or adverse outcome. It could also be a sign of a complication which would be considered a harm event. When the surgical procedure indicated on post-operative notes is different from the surgical procedure planned in the pre-operative notes or documented in the surgical consent, a reviewer should look for details as to why the change occurred. If it is not clearly indicated that the procedure was planned, consider that it was unplanned and review for a possible harm event.

S3 Unplanned admission to intensive care post-operation

Admission to an ICU can be a normal post-operative journey or it may be unexpected. However, unexpected admissions to an ICU following an operation may be related to harm events stemming from the operation. For example, admission to the ICU following coronary artery bypass surgery may be expected, but admission following knee replacement would be unusual. The reviewer should determine why an ICU admission occurred. If it is not clearly indicated that the admission is planned, consider it unplanned and review for a possible harm event.

S4 Intubation/reintubation/bilevel positive airway pressure (BPAP) in post anesthesia care unit (PACU)

Anesthesia, sedatives, aspiration, or pain medications can cause respiratory depression requiring the use of a BPAP or reintubation post-operatively in a PACU, which would be a harm event. Reviewers should check for these interventions following surgery and procedures. (See Trigger I4—Intubation/ reintubation and Specific Conditions and Injuries—Endotracheal intubation injury for more information and other requirements.)

S5 Unplanned X-ray/CT scan/magnetic resonance imaging (MRI) or other imaging intra-operatively or in PACU

Imaging of any kind that is not routine for a given surgery or procedure requires investigation. Imaging due to suspicion of retained items or due to an incorrect instrument or sponge count would be an indicator of patient harm. The identification of a retained item necessitating an additional procedure or suture removal and re-exploration during the same surgery is considered a harm event. If the retained item is identified and removed during the same surgery, without any additional evidence of harm or re-operation to the patient, this is not considered a harm event. If it is not clearly indicated that the imaging is planned, consider it unplanned and review for a possible harm event.

S6 Intra-operative or post-operative death

All deaths that occur intra-operatively should be considered harm events unless the surgery was heroic with death as a likely outcome. Post-operative deaths will require review of the record for specifics, but in general all post-operative deaths will be harm events.

S7 Mechanical ventilation greater than (>) 24 hours post-operatively

If the patient requires unplanned mechanical ventilation beyond 24 hours after a surgery or procedure, then an intra-operative or post-operative harm event should be considered. If short-term mechanical ventilation was planned following cardiac, major thoracic, and certain abdominal procedures, then this is not considered a harm event. Patients with pre-existing pulmonary or muscular disease may experience more difficulty weaning from a ventilator post-operatively, but this should not automatically exclude the possibility of a harm event. Reviewers must use clinical judgment to determine whether an event occurred or whether the ventilator was necessitated due to underlying disease. (See Specific Conditions and Injuries—Ventilator-associated event for more information and other requirements.)

S8 Intra-operative epinephrine, norepinephrine, naloxone, or flumazenil

These medications (listed above) are not routinely administered intra-operatively. Review anesthesia and operative notes to determine the reason for administration. Hypotension caused by bleeding or oversedation are examples of harm events that might be treated with these medications.

S9 Abnormal post-operative troponin level, including sensitive or highly sensitive troponin I or troponin T

A post-operative increase in troponin levels following non-cardiac surgery may indicate a cardiac harm event. Reviewers will need to use clinical judgment to determine whether a harm event has occurred. Note that renal failure is often a non-cardiac cause of an elevated troponin level.

S10 Injury, unplanned repair, or removal of organ

Injury, unplanned repair, or removal of an organ during or following a procedure or surgery is a harm event. The removal or repair must be part of the planned procedure; otherwise, this is a harm event

and likely the result of a surgical harm event such as an accidental injury. Reviewers should check the operative notes and post-operative notes for evidence that the procedure included the repair or removal of any organ.

S11 Any operative complication

This refers to any of a number of complications, including but not limited to PE, DVT, pressure injury, myocardial infarction, renal failure, etc. Any operative complication is a harm event but may not be preventable. This includes post-operative complications stemming from the procedure.

Intensive Care Module Triggers

This module consists of five triggers related to patients who spent part of their hospital stay in an ICU.

#	Intensive Care Module Triggers
I1	Hospital-acquired pneumonia onset
I2	Readmission or unplanned admission to intensive care
I3	In-unit procedure
I4	Intubation/reintubation
I5	ICU—other

Source: Triggers I1 through I4 are based on the triggers found in Griffin, F.A., and Resar, R.K., *IHI Global Trigger Tool for Measuring Adverse Events* (Second Edition), Institute for Healthcare Improvement Innovation Series, 2009. OIG added trigger I5 to capture harm events that do not fit in one of the other four intensive care module triggers.

I1 Hospital-acquired pneumonia onset

Any pneumonia diagnosed in the ICU should be flagged as an indicator of patient harm and should be reviewed by a physician. In general, an infection starting in any hospital unit (not only the ICU) may be considered attributable to the admission if it occurs on or after the third calendar day after admission. Readmissions, to either the hospital or the ICU, could also represent a healthcare-associated infection from a previous hospitalization. Ventilator-associated pneumonia in the ICU is considered a harm event. (See Specific Conditions and Injuries—Ventilator-associated event for more information and other requirements.)

I2 Readmission or unplanned admission to intensive care

Any admission to an ICU can be part of a normal post-operative plan or it may be unexpected. Unexpected ICU admissions are often related to operative harm events. Any readmission to the ICU should be reviewed for a possible harm event. For example, admission to the ICU following an aortic aneurysm repair may be expected, but admission following knee replacement would be unusual. (Also see Trigger S3—Unplanned admission to intensive care post-operation.)

I3 In-unit procedure

Any procedure performed in the ICU requires investigation as unplanned procedures may be indicative of patient harm events. Reviewers should look at all the bedside procedures and/or procedures done while the patient was in the ICU. Complications are commonly not included on the dictated procedure note but may be evident by the subsequent care.

I4 Intubation/reintubation

Any intubation or reintubation while in the ICU should be reviewed for possible associated harm event(s). Reviewers should check for these interventions during the patient's ICU stay. (See Trigger S4—Intubation/reintubation/bilevel positive airway pressure (BPAP) in post anesthesia care unit (PACU) and Specific Conditions and Injuries—Endotracheal intubation injury for more information and other requirements.)

I5 ICU—other

Use this trigger for ICU events detected but not related to one of the Intensive Care triggers listed above.

APPENDIX

Trigger Tool Worksheet for Hospitals

	Care Triggers
C1	Acute mental status change
C2	Transfusion or use of blood products
C3	Code/arrest/rapid response team
C4	Acute dialysis
C5	Positive culture (e.g., blood, urine, stool)
C6	Studies for emboli, PE or DVT such as D-Dimer, CT pulmonary angiogram (CTPA), or lung ventilation-perfusion scan
C7	Abrupt or significant decrease in hemoglobin or hematocrit
C8	Fall or other trauma
C9	Pressure injury/skin breakdown from medical device
C10	Readmission within 30 days
C11	Restraint use
C12	Hospital-acquired infections
C13	In-hospital stroke/TIA
C14	Transfer to higher level of care
C15	Any procedure complication
C16	Urinary retention
C17	Aspiration
C18	Care—other

	Medication Triggers
M1	*Clostridioides difficile* positive stool test
M2	Partial thromboplastin time greater than (>) 100 seconds
M3	International normalized ratio (INR) greater than (>) 6
M4	Glucose less than (<) 50 mg/dL
M5	Rising BUN or serum creatinine greater than (>) 1.5 times baseline
M6	Vitamin K, factor Xa reversal agents (andexanet alfa, idarucizumab administration)
M7	Diphenhydramine use
M8	Flumazenil use
M9	Naloxone use
M10	Anti-emetic use
M11	Abrupt decrease in blood pressure
M12	Abrupt medication stop
M13	Sodium polystyrene (kayexalate administration) or potassium greater than or equal to (≥) 6 mEq/L
M14	Abnormal drug levels
M15	Medication—other

	Surgical Triggers
S1	Unplanned return to surgery
S2	Unplanned change in procedure
S3	Unplanned admission to intensive care post-op
S4	Intubation/reintubation/BPAP in post anesthesia care unit (PACU)
S5	Unplanned X-ray/CT scan/MRI or other imaging intra-op or in PACU
S6	Intra-op or post-op death
S7	Mechanical ventilation greater than (>) 24 hours post-operatively
S8	Intra-op epinephrine, norepinephrine, naloxone, or flumazenil
S9	Abnormal post-operative troponin level, including sensitive or highly sensitive troponin I or troponin T
S10	Injury, unplanned repair, or removal of organ
S11	Any operative complication

	Intensive Care Unit Triggers
I1	Hospital-acquired pneumonia onset
I2	Readmission or unplanned admission to intensive care
I3	In-unit procedure
I4	Intubation/reintubation
I5	Intensive care unit—other

Source: OIG, *Adverse Events in Hospitals: A Quarter of Medicare Patients Experienced Harm in October 2018*, OEI-06-18-00400, May 2022.

Trigger Tool Worksheet for Skilled Nursing Facilities

	Care Triggers		Medication Triggers
C1	Acute mental status change	**M1**	Abnormal electrolytes
C2	Aspiration	**M2**	Abrupt medication stop
C3	Call to physician or family members	**M3**	Anti-emetic use
C4	Code or emergency medical services (EMS)	**M4**	Diphenhydramine use
C5	Death	**M5**	Elevated INR
C6	Drop in hemoglobin/hematocrit	**M6**	Epinephrine use
C7	Studies for emboli: PE or DVT	**M7**	Glucose <50, glucagon or dextrose supplement
C8	Fall	**M8**	Abrupt onset hypotension
C9	Family complaint	**M9**	Naloxone use
C10	Any infection	**M10**	Sodium polystyrene (kayexalate administration)
C11	New or increased diuretics	**M11**	Abnormal drug levels
C12	High or low body temperature	**M12**	Thrombocytopenia
C13	In (SNF) stroke or TIA	**M13**	Total WBC <3000
C14	New onset of incontinence	**M14**	Vitamin K administration (phytonadione)
C15	Insertion or use of urinary catheter	**M15**	Antibiotics started in SNF
C16	Significant change in status assessment in MDS (SCSA)	**M16**	Increasing pain medication needs
C17	Resident incident or accident	**M17**	Administration of parenteral fluid
C18	Pressure injury	**M18**	Rising ALT/AST liver function test
C19	ED visit	**M19**	Medication—other
C20	Transfer to acute care hospital or observation (OBS) unit		**Procedure Triggers**
C21	Restraint use	**P1**	Post-operative/postprocedure complication
C22	Rising serum creatinine	**P2**	Procedure reintubation/BPAP/new continuous positive airway pressure (CPAP)
C23	Urinary retention	**P3**	Procedure—other
C24	New onset diarrhea		
C25	Prolonged constipation		
C26	Diagnostic radiology or imaging studies		
C27	Care—other		

Source: OIG, *Adverse Events in Skilled Nursing Facilities: National Incidence Among Medicare Beneficiaries*, OEI-06-11-00370, February 2014.

Trigger Tool Worksheet for Inpatient Rehabilitation Facilities

	Care Triggers		Medication Triggers
C1	Acute mental status change	**M1**	Abnormal electrolytes
C2	Aspiration	**M2**	Abrupt medication stop
C3	Call to physician or family members	**M3**	Anti-emetic use
C4	Code, rapid response team (RRT), or emergency medical services (EMS)	**M4**	Diphenhydramine use
C5	Death	**M5**	Elevated INR
C6	Drop in hemoglobin/hematocrit	**M6**	Glucose <50, glucagon or dextrose supplement
C7	Studies for emboli, PE or DVT	**M7**	Abrupt onset hypotension
C8	Fall	**M8**	Naloxone use
C9	Family complaint	**M9**	Sodium polystyrene (kayexalate administration)
C10	Any infection	**M10**	Abnormal drug levels
C11	New or increased diuretics	**M11**	Thrombocytopenia
C12	High or low body temperature	**M12**	Total WBC <3000 or >12,000
C13	In IRF stroke or TIA	**M13**	Vitamin K administration (phytonadione)
C14	New onset of incontinence	**M14**	Antibiotics started in IRF
C15	Insertion or use of urinary catheter	**M15**	Increasing pain medication needs
C16	Functional independence measure™ (FIM™ score) decrease or no change from admission to discharge	**M16**	Administration of parenteral fluid
C17	Patient incident or accident	**M17**	Medication—other
C18	Pressure injury		**Procedure Triggers**
C19	ED visit	**P1**	Post-operative/postprocedure complication
C20	Transfer to acute care hospital or observation (OBS) unit or unplanned transfer to another IRF	**P2**	Procedure reintubation/new BPAP/new CPAP
C21	Restraint use	**P3**	Procedure—other
C22	Rising serum creatinine		
C23	Urinary retention		
C24	New onset diarrhea		
C25	Prolonged constipation		
C26	Diagnostic radiology or imaging studies		
C27	Care—other		

Source: OIG, *Adverse Events in Rehabilitation Hospitals: National Incidence Among Medicare Beneficiaries*, OEI-06-14-00110, July 2016.

Trigger Tool Worksheet for Long-term Care Hospitals

	Care Triggers		Medication Triggers
C1	Acute mental status change	**M1**	Abnormal electrolytes
C2	Aspiration	**M2**	Abrupt medication stop
C3	Call to physician or family members	**M3**	Anti-emetic use
C4	Code, rapid response team (RRT), or emergency medical services (EMS)	**M4**	Diphenhydramine use
C5	Death	**M5**	Elevated INR or partial thromboplastin time (PTT) greater than 100 seconds
C6	Drop in hemoglobin/hematocrit or unplanned transfusion	**M6**	Glucose <50, glucagon or dextrose supplement given
C7	Studies for emboli, PE, or DVT	**M7**	Abrupt onset hypotension
C8	Fall	**M8**	Naloxone use
C9	Family complaint	**M9**	Flumazenil use
C10	Any infection	**M10**	Epinephrine/Norepinephrine use
C11	New or increased diuretics	**M11**	Sodium Polystyrene (kayexalate administration)
C12	High or low body temperature	**M12**	Abnormal drug levels
C13	In long-term care hospitals (LTCH) stroke or TIA	**M13**	Thrombocytopenia
C14	New or worsening onset of incontinence	**M14**	Total WBC < 3000 or >12,000
C15	Insertion or use of urinary catheter	**M15**	Vitamin K administration (phytonadione)
C16	Patient incident or accident	**M16**	Antibiotics started in LTCH
C17	Pressure ulcer	**M17**	Beginning or increasing pain medication
C18	Emergency department visit	**M18**	New administration of parenteral fluid
C19	Unplanned transfer to acute care hospital (including admission through emergency department or to an observation unit	**M19**	Rising aminotransferase (ALT) / aspartate aminotransferase (AST)—Liver Function Test
C20	Restraint use	**M20**	Medication—other
C21	Rising serum creatinine or acute dialysis		**Procedure Triggers**
C22	Urinary retention	**P1**	Post-operative or postprocedure complication
C23	New onset diarrhea	**P2**	Procedure intubation, reintubation, recanulation, new BPAP, or new CPAP
C24	Prolonged constipation or obstipation	**P3**	Post-operative or postprocedure troponin level of greater than 1.5 ng/ml
C25	Diagnostic radiology or imaging studies	**P4**	Procedure—other
C26	New or worsening contracture		
C27	Transfer to higher level of care within facility		
C28	Care—other		

Source: OIG, *Adverse Events in Long-Term-Care Hospitals: National Incidence Among Medicare Beneficiaries*, OEI-06-14-00530, November 2018.

Trigger Tool Worksheets for Indian Health Service Hospitals

Adult and Perinatal Indian Health Service Hospital Triggers			
	Care Triggers		**Medication Triggers (continued)**
C1	Acute mental status change	**M8**	Diphenhydramine use
C2	Transfusion or use of blood products	**M9**	Flumazenil use
C3	Code; cardiac or pulmonary arrest; or rapid response team activation	**M10**	Naloxone use
C4	Positive culture	**M11**	Anti-emetic administration
C5	Studies for emboli, PE, or DVT, such as D-Dimer, CTPA, or lung ventilation-perfusion scan	**M12**	Sodium polystyrene (kayexalate administration)
C6	Death	**M13**	Abrupt onset hypotension
C7	Drop in hemoglobin/hematocrit	**M14**	Abnormal drug levels
C8	Fall or other trauma	**M15**	Abrupt medication stop
C9	Pressure injuries or other skin breakdown	**M16**	Thrombocytopenia
C10	Readmission within year	**M17**	Use of traditional herbs, rituals, or botanicals
C11	Restraint use	**M18**	Medication—other
C12	Healthcare-associated infections		**Intensive Care Unit Triggers**
C13	Total WBC <3000 (or >12,000)	**I1**	Pneumonia onset
C14	New or increased diuretics	**I2**	Readmission to intensive care
C15	Hospital stroke or TIA at hospital	**I3**	In-unit procedure
C16	Transfer to higher level of care	**I4**	Intubation/reintubation
C17	Any procedure complication	**I5**	Intensive care unit—other
C18	Urinary retention		**Surgical Triggers**
C19	New onset diarrhea	**S1**	Return to surgery
C20	Prolonged constipation	**S2**	Change in surgical procedure
C21	Care—other	**S3**	Unplanned admission to intensive care post-operation
	Medication Triggers	**S4**	Intubation/reintubation/BPAP in PACU
M1	*Clostridioides difficile* positive stool	**S5**	Unplanned X-ray intra-op or in PACU
M2	Abnormal electrolytes	**S6**	Intra-op or post-op death
M3	Partial thromboplastin time >100 seconds	**S7**	Mechanical ventilation >24 hours post-op
M4	INR >6	**S8**	Intra-op epinephrine, norepinephrine, naloxone, or flumazenil
M5	Glucose <50, glucagon or dextrose supplement For pediatric patients, glucose <40 mg/dl during 1st year of life; and <50 mg/dl after 1st year	**S9**	Abnormal post-operative troponin level, including highly sensitive troponin T (hs-cTnT), above the upper limit of normal
M6	Rising serum creatinine, decreasing urine output, GFR, or acute dialysis	**S10**	Removal, injury, or repair of organ
M7	Vitamin K administration (phytonadione)	**S11**	Any operative complication

Adult and Perinatal Indian Health Service Hospital Triggers (continued)			
	Perinatal Triggers		**Perinatal Triggers (continued)**
P1	Delivery prior to 39 weeks gestation	**P15**	Corticosteroid administration
P2	Apgar <7 at 5 min.	**P16**	Labetalol, hydralazine, or nifedipine administration
P3	Admission to NICU >24 hours	**P17**	Unplanned Caesarean section
P4	Transfer to a higher level of care	**P18**	Perinatal—other
P5	3rd or 4th degree lacerations		**Long-term/Non-acute Care Triggers**
P6	Prolonged fetal heart rate decelerations	**LT-C1**	Insertion or use of urinary catheter
P7	Platelet count <50,000	**LT-C2**	Acute deterioration while in long-term or non-acute status
P8	Specialty consult	**LT-C3**	Diagnostic radiology or imaging studies while in long-term or non-acute status
P9	Instrumented delivery	**LT-C4**	Long-term/non-acute care—other
P10	General anesthesia		**Long-term/Non-acute Medication Triggers**
P11	Cord gases ordered	**LT-M1**	Antibiotics started while in long-term or non-acute status
P12	Gestational diabetes	**LT-M2**	Starting or increasing pain medication needs while in long-term or non-acute status
P13	Terbutaline administration	**LT-M3**	Administration of parenteral fluid while in long-term or non-acute status
P14	Administration of uterotonic agents (such as methylergonovine, and 15-methyl-prostaglandin in the postpartum period)	**LT-M4**	Long-term/non-acute care medication module—other

Source: OIG, *Incidence of Adverse Events in Indian Health Service Hospitals*, OEI-06-17-00530, December 2020.

Pediatric Indian Health Service Hospital Triggers			
	Medications/Fluids Triggers		**Hospital Transfer/Outcomes Triggers**
Ped_M1	Warfarin triggers: INR >6	**Ped_T1**	Readmission within year
Ped_M2	Serum creatinine doubling	**Ped_T2**	Any code or arrest, or rapid response team activation
Ped_M3	Nephrotoxin use (e.g., aminoglycosides, cyclosporine, tacrolimus, vancomycin) and doubling creatinine (Cr)	**Ped_T3**	All inpatient deaths
Ped_M4	Elevated drug levels (antiepileptics): phenytoin (>30 mcg/ml) or abnormally low (<10 mcg/ml)	**Ped_T4**	Hospital transfer/outcomes—other
Ped_M5	Elevated drug levels (antiepileptics): oxcarbazepine (>45 mcg/ml) or abnormally low (<3 mcg/ml)		**Healthcare-associated Infection Triggers**
Ped_M6	Total bilirubin >25 mg/dl (<28 days old)	**Ped_I1**	Positive *Clostridioides difficile* test (>4th calendar day from admission)
Ped_M7	Hepatotoxic medications and elevated liver enzymes (AST, ALT) >3 x normal	**Ped_I2**	Oral vancomycin
Ped_M8	Hypoglycemia <40 mg/dl during the first year of life; <2 mmol/L or 50 mg/dl) after the first year of life	**Ped_I3**	Positive blood culture
Ped_M9	Abrupt medication stops	**Ped_I4**	Positive urine culture
Ped_M10	Flumazenil administration	**Ped_I5**	Positive respiratory or GI viral infection (on or after the 3rd calendar day from admission)
Ped_M11	Opiate-related constipation with intermittent laxative use	**Ped_I6**	Surgical site infection
Ped_M12	Naloxone administration	**Ped_I7**	Healthcare-associated infection—other
Ped_M13	Pediatric medication—other		**Surgical Triggers**
	Hospital Care Environment Triggers	**Ped_S1**	Drop of hemoglobin (Hgb) or hematocrit (Hct) of >25% in less than 24 hours
Ped_H1	Fall	**Ped_S2**	Mechanical ventilation >48 hours post-operatively
Ped_H2	Infiltrations: infiltration/extravasation or phlebitis documentation	**Ped_S3**	Operative time >6 hours (non-cardiac patients)
Ped_H3	Infiltrations: hyaluronidase administration	**Ped_S4**	Intra-operative epinephrine, norepinephrine, or phenylephrine (non-cardiac patients)
Ped_H4	Pressure injury documentation (≥Stage 1)	**Ped_S5**	Return to surgery
Ped_H5	Embolus/thrombus documentation	**Ped_S6**	Change in procedure
Ped_H6	Pediatric hospital care environment—other	**Ped_S7**	Pediatric surgical module—other
	NICU/PICU Triggers		**Long-term/Non-acute Care Triggers**
Ped_N1	Readmission to ICU within 24 hours after discharge/transfer	**LT-C1**	Insertion or use of urinary catheter
Ped_N2	Transfer to higher level of care	**LT-C2**	Acute deterioration while in long-term or non-acute status
Ped_N3	Unplanned endotracheal extubating	**LT-C3**	Diagnostic radiology or imaging studies while in long-term or non-acute status
Ped_N4	Failed endotracheal extubation (reintubation within 24 hours of planned extubation)	**LT-C4**	Long-term/non-acute care—other
Ped_N5	Racemic epinephrine administration (patients mechanically ventilated within last 24 hours)		
Ped_N6	NICU/ PICU—other		

Pediatric Indian Health Service Hospital Triggers (continued)			
	Long-term/Non-acute Medication Triggers		
LT-M1	Antibiotics started while in long-term or non-acute status	**LT-M3**	Administration of parenteral fluid while in long-term or non-acute status
LT-M2	Starting or increasing pain medication needs while in long-term or non-acute status	**LT-M4**	Long-term/non-acute care medication module—other

Source: OIG, *Incidence of Adverse Events in Indian Health Service Hospitals*, OEI-06-17-00530, December 2020.
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[18] CDC, "Implementation Resources for Hospitals," last reviewed October 2021. Accessed at https://www.cdc.gov/antibiotic-use/core-elements/hospital/implementation.html on January 30, 2023.

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[22] CDC, "Surgical Site Infection Event (SSI)," January 2023. Available at https://www.cdc.gov/nhsn/pdfs/pscmanual/9pscssicurrent.pdf.

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[26] CDC, "Bloodstream Infection Event (Central Line-Associated Bloodstream Infection and Non-central Line Associated Bloodstream Infection)," January 2022. Accessed at https://www.cdc.gov/nhsn/pdfs/pscmanual/4psc_clabscurrent.pdf on July 12, 2022.

[27] CDC, "Implementation Resources for Hospitals," last reviewed October 2021. Accessed at https://www.cdc.gov/antibiotic-use/core-elements/hospital/implementation.html on January 30, 2023.

[28] Buetti, et al., "Strategies to prevent central line-associated bloodstream infections in acute-care hospitals: 2022 Update," *Infection Control & Hospital Epidemiology*, Volume 43, Issue 5, April 2022. Accessed at https://doi.org/10.1017/ice.2022.87 on June 14, 2023.

[29] CDC, "Ventilator-Associated Event (VAE)," January 2022. Accessed at https://www.cdc.gov/nhsn/pdfs/pscmanual/10-vae_final.pdf on July 12, 2022.

[30] Klompas, et al., "Strategies to prevent ventilator-associated pneumonia, ventilator-associated events, and nonventilator hospital-acquired pneumonia in acute-care hospitals: 2022 Update," *Infection Control & Hospital Epidemiology*, First View, May 2022. Accessed at https://doi.org/10.1017/ice.2022.88 on May 25, 2023.

[31] Other providers and researchers may define triggers differently. For example, automated triggers employed for electronic health records may function as both a screening method and a predictive tool to identify potential patient harm. In contrast, in our retrospective medical record review we use triggers to screen for patient harm.

[32] Shane, et al., "2017 Infectious Diseases Society of America Clinical Practice Guidelines for the Diagnosis and Management of Infectious Diarrhea," *Clinical Infectious Diseases*, Volume 65, Issue 12, December 2017. Accessed at https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5850553/ on May 25, 2023.

[33] Reviewers may want to consult NIH's clinical tools to calculate glomerular filtration rate (GFR). See NIH, "Glomerular Filtration Rate (GFR) Calculators." Accessed at www.niddk.nih.gov/health-information/professionals/clinical-tools-patient-management/kidney-disease/laboratory-evaluation/glomerular-filtration-rate-calculators on February 14, 2022.

[34] Our clinician reviewers used the Risk, Injury, Failure, Loss of kidney function and End-stage kidney disease (RIFLE) classification for acute kidney injury. Reviewers considered the "risk" class criteria an indication of harm. See Bellomo, et al., "Acute renal failure - definition, outcome measures, animal models, fluid therapy and information technology needs: the Second International Consensus of the Acute Dialysis Quality Initiative (ADQI) Group," *Critical Care*, Volume 8, Issue 4, August 2004. Accessed at https://www.ncbi.nlm.nih.gov/pmc/articles/PMC522841/ on May 25, 2023.