

Complication Criteria



The complications listed below follow common definitions and are cited when possible. A complication event may have more than one complication category. An example is a screw malposition with neurologic deficit, or Proximal Junctional Failure, which is a combination of Proximal Junctional Kyphosis and an additional complication (ie fracture, ligament failure, neuro deficit or all of the above.) The intent of this document is to build consensus where possible, understating that most but not all events are captured. This document is intended to be a living document and is expected to change and to be modified over time.

1. CANCER

Rationale: Spinal deformity surgery may use biologics that can improve the fusion rate but may also play a role in oncogenesis.

a. New Primary Cancer: Surveillance, Epidemiology and End Results (SEER) Criteria

Definition: New diagnosis of malignant or benign cancer especially those that may increase metastatic burden to spine (Breast, Lung, Prostate, Kidney, Thyroid). Common skin cancers are excluded, with the exception of melanoma.

b. Metastatic Spread

i Local (spine)

Definition: New diagnosis of metastatic spinal cancer, ie to axial skeletal system (spine and pelvis). The most common diagnosis in this location is usually Breast, Lung, Prostate, Kidney, or Thyroid cancer.

ii Distant (non-spine)

Definition: New diagnosis of solid organ cancer or appendicular skeletal metastatic disease that may increase metastatic burden to spine (especially Breast, Lung, Prostate, Kidney, Thyroid).

MEDICAL EVENTS

(Reportable if occurring during hospitalization or within 30 days of index/revision spine surgery discharge)

2. CARDIOPULMONARY

a. Arrhythmia

Definition: Symptomatic change in the normal cardiac rhythm of the patient. Note that if the patient has a baseline abnormal rhythm (i.e. AFIB) this would not be necessary to record. Bradycardia and tachycardia should only be recorded if they are prolonged, symptomatic and require a consultation by a medical doctor.

Criteria: An arrhythmia must be noted intraoperatively OR within 30 days after the primary procedure AND one of the following two scenarios (A or B) below: A. Documentation of ECG changes indicative of an arrhythmia, B. diagnosis of arrhythmia by a physician (medical doctor or cardiologist).

b. Myocardial infarction (MI)

Definition: Blockage of blood flow to the heart causing damage or death to part of the heart muscle.

Criteria: An acute myocardial infarction must be noted intraoperatively OR within 30 days after the primary procedure AND one of the following three scenarios (A or B or C) below: A. Documentation of ECG changes indicative of acute MI, B. New elevation in troponin greater than three times upper level of the reference range in the setting of suspected myocardial ischemia, C. medical or cardiac physician, diagnosis of myocardial infarction.

c. Congestive heart failure (CHF)

Definition: Symptomatic change that results in new cardiac dysfunction, and decreased ejection fraction. Note that if the patient has baseline abnormal function this would not be necessary to record unless it deteriorates.

Criteria: CHF must be noted intraoperatively OR within 30 days after the primary procedure AND one of the following three scenarios (A or B or C) below: A. Documentation of CHF with clinical symptoms of CHF including: venous congestion pulmonary edema, or lower extremity edema, B Diagnosis of CHF via diagnostic tests: ECG changes indicative of CHF, or Echocardiogram that demonstrates poor cardiac function with decreased ejection fraction, or angiogram, MR angiogram with a diagnosis of CHF, C. Diagnosis of CHF by a physician (medical doctor or cardiologist).

d. Deep Vein Thrombosis (DVT)

Definition: New diagnosis of blood clot or thrombus within the venous system (superficial or deep) which may be coupled with inflammation and is symptomatic.

Criteria: Must be noted within 30 days after the primary procedure AND one of the following A or B below: A. New Diagnosis of a [new] venous thrombosis (superficial or deep), confirmed by a duplex, venogram, CT scan, or B. any other definitive imaging modality (including direct pathology examination such as autopsy).

e. Pulmonary Embolism (PE)

Definition: Lodging of a blood clot in the pulmonary artery with subsequent obstruction of blood supply to the lung parenchyma. The blood clots usually originate from the deep leg veins or the pelvic venous system.

Criteria: A pulmonary embolism must be noted during or within 30 days after the primary procedure AND the following criteria, A AND B below: A. New diagnosis of a blood clot in a pulmonary artery, AND B. The patient has a V-Q scan interpreted as high probability of pulmonary embolism or a positive CT exam, TEE, pulmonary arteriogram, CT angiogram, or any other definitive imaging modality (including direct pathology examination such as autopsy).

f. Atelectasis

Definition: Atelectasis is pulmonary dysfunction that may occur following any surgical procedure due to alveolar collapse. It is usually asymptomatic, but if symptomatic should be recorded.

Criteria: Must be noted within 30 days after the primary procedure AND the following criteria, A AND B below: A. increased pulmonary dysfunction, diagnosis is clinical and may be accompanied by CXR, CT scans, with decreased oxygen saturation AND, B. diagnosis by a physician (medical doctor or pulmonologist).²

g. Acute Respiratory Distress Syndrome (ARDS)

Definition: Acute respiratory distress syndrome is pulmonary dysfunction that occurs in critically ill patients. The cause is intravascular pulmonary edema that is triggered by increased inflammation and permeability and is associated with sepsis, trauma or massive blood transfusions.

Criteria: Must be noted within 30 days after the primary procedure AND the following criteria, A AND B below: A. increased pulmonary dysfunction, diagnosis is clinical and may be accompanied by CXR, CT scans, ECG or Echocardiograms, AND B. diagnosis by a physician (medical doctor or pulmonologist). Other diagnostic criteria may include: (1) FiO₂ >50%; (2) Ventilator support for >48h; (3) PaO₂/FiO₂ ≤ 300 mm Hg; and (4) bilateral lung infiltrates on CXR.¹

h. Pleural Effusion

Definition: Pleural effusion is the accumulation of fluid in the pleural space. It is typically caused via extra capillary fluid leakage and introduction of fluid into this cavity. This accumulation may be spontaneous or due to a procedure (including surgical, or placement of venous or arterial lines near the chest.) It may be asymptomatic, but if symptomatic should be recorded.

Criteria: Must be noted within 30 days after the primary procedure AND the following three (A and B and C) criteria: A. clinical diagnosis of increased pulmonary dysfunction, AND B. fluid noted on post-operative CXR, or CT scans, AND C. diagnosis by a physician (medical doctor or pulmonologist).¹

i. Pneumothorax

Definition: Pneumothorax is the accumulation of air in the pleural space with no vascular bed surrounding the visceral pleura.² It is typically caused via disruption of the pleura and introduction of air into this cavity. This disruption may be spontaneous or due to a procedure (including surgical, or placement of venous or arterial lines near the chest.) It may be asymptomatic, but if symptomatic should be recorded.

Criteria: Must be noted within 30 days after the primary procedure AND the following three (A and B and C) criteria: A. clinical diagnosis of increased pulmonary dysfunction, AND B. air noted on post-operative CXR, or CT scans, AND C. diagnosis by a physician (medical doctor or pulmonologist).¹

3. CENTRAL NERVOUS SYSTEM

a. Delirium

Definition: A decrease in the normal cognitive function following the surgical procedure that is symptomatic, and different than expected due to patient's age or medications.

Criteria: Must be noted within 30 days after the primary procedure AND a clinical diagnosis that is characterized by an acute change in level of consciousness characterized by reduced ability to maintain attention to external stimuli, lethargy, or agitation, and disorganized thinking as manifested by rambling, irrelevant, or incoherent speech.³

b. Seizure

Definition: A disruption in normal brain activity that is due to abnormal, excessive, hypersynchronous discharges from an aggregate of central nervous system (CNS) neurons with manifestations ranging from convulsive activity to experiential phenomena not discernable by an observer.

Criteria: Diagnosis must be noted intraoperatively or within 30 days after the primary procedure AND one of the following A OR B below: A. diagnostic EEG with seizure activity, B. diagnosis confirmed by a neurology consultation.¹

c. Cerebral Vascular Accident (CVA)/Stroke

Definition: An interruption or severe reduction of blood supply to the brain resulting in severe dysfunction.

Criteria: A Stroke/Cerebral Vascular Accident (CVA) must be noted during or within 30 days after the primary procedure AND one of the following A OR B below: A. There is motor, sensory, or cognitive dysfunction which persists for 24 hours or more in the setting of a suspected stroke, OR B. abnormality on imaging studies suggestive of a CNS infarct, or CNS infarction confirmed by biopsy or autopsy.¹

d. Syndrome of Inappropriate Anti Diuretic Hormone (SIADH)

Definition: SIADH is defined as hyponatremia with inappropriately concentrated urine caused by excessive secretion of antidiuretic hormone.

Criteria: Must be noted within 30 days after the primary procedure AND the following criteria, A AND B below: A. Clinically significant SIADH presenting with anorexia, lethargy, irritability, confusion, weakness or personality changes, AND B. confirmed with laboratory testing.

4. GASTROINTESTINAL

a. Prolonged or Excessive Nausea/Vomiting

Definition: Nausea and/or vomiting following the index surgical procedure may be common. Report as a complication if it is excessive, resistant to medication, prolonged or persistent.

Criteria: a clinical diagnosis of nausea and/or vomiting causing significant distress and/or requiring medical management and prolonged hospital stay following the index surgery.

b. Prolonged Ileus

Definition: Ileus is defined as postoperative decrease in small bowel function causing the inability to tolerate an oral diet or abdominal distention following the index procedure.

Criteria: Prolonged postoperative ileus must be noted to occur on or after 48hrs postoperatively without prior resolution of POI AND at least one of the following: (i) nausea/vomiting, (ii) inability to tolerate an oral diet over the preceding 24 h period, (iii) the absence of flatus over the preceding 24 h period, (iv) abdominal distension and/or (v) radiological evidence of bowel distension without mechanical obstruction.⁵

c. Dysphagia

Definition: Dysphagia is difficulty moving food or liquid through the mouth, pharynx, and esophagus. The patient senses swallowed material sticking along the enteral path.⁴

Criteria: Must be noted within 30 days after the primary procedure AND a diagnosis of patient-reported dysphagia, clinically significant difficulty with swallowing.

d. Bowel Obstruction

Diagnosis: Bowel obstruction is mechanical blockage of the small or large bowel, usually causing abdominal distension, nausea and/or vomiting.

Criteria: Must be noted within 30 days after the primary procedure AND clinically significant nausea and/or vomiting caused by bowel obstruction confirmed on abdominal radiography or CT scanning.

e. Superior Mesenteric Artery (SMA) Syndrome

Definition: SMA syndrome is bowel ischemia caused by disruption in flow through the superior mesenteric artery that supplies the small intestine.

Criteria: Must be noted within 30 days after the primary procedure AND the following criteria, A AND B below: A. Clinically significant severe nausea and vomiting, and inability to take oral intake, AND B. Diagnosis of superior mesenteric artery-induced bowel obstruction on plain abdominal film or with an oral contrast study.⁶

f. Cholecystitis

Diagnosis: Cholecystitis is inflammation of the gallbladder caused by obstruction of the cystic duct.

Criteria: Must be noted within 30 days after the primary procedure AND the following criteria, A AND B below: A. diagnosed with clinical symptoms including RUQ or epigastric pain, nausea/vomiting, AND B. confirmation with ultrasound or radionuclide scan by an attending physician.

g. Gastro Intestinal (GI) Bleed

Definition: Blood loss through the gastrointestinal tract, including hematemesis, melena, or hematochezia. Occult GI bleeding may be identified in the absence of overt bleeding by special examination of the stool (e.g., guaiac testing), or symptoms of blood loss or anemia such as lightheadedness, syncope, angina, or dyspnea.

Criteria: Must be noted within 30 days after the primary procedure AND at least one of the following: bloody vomitus or stool, bleeding from the rectum. It may or may not be accompanied by Hct decrease >10%, or lightheadedness, syncope, angina, or dyspnea.¹

h. Liver Failure

Definition: Acute liver failure is defined as hepatic dysfunction following the index surgical procedure.

Criteria: Must be noted within 30 days after the primary procedure AND the following criteria, A AND B below: A. massive hepatic necrosis with impaired consciousness⁴, AND B. diagnosed by a physician (medical doctor or gastroenterologist).

i. Pancreatitis

Definition: The definition of pancreatitis is pancreatic injury causing steady, boring midepigastic pain radiating to the back that is frequently increased in the supine position, often associated with nausea and vomiting⁴.

Criteria: Must be noted within 30 days after the primary procedure AND the following criteria, A AND B AND C below. A. Presence of clinical symptoms of pancreatitis, AND B. serum amylase concentration >3X greater than normal, and C. diagnosed by a physician (medical doctor or gastroenterologist). It may or may not be confirmed with a CT scan.

5. INFECTIOUS (NON-SURGICAL WOUND)

a. Non-surgical Cellulitis

Definition: Non-surgical cellulitis is defined as non-spinal area of erythema, drainage or pain that is symptomatic.

Criteria: Criteria include erythema, drainage, or an open wound. Diagnosis can be made with Gram staining and culture however only yields a diagnosis in 20% of cases. Therefore, diagnosis is often clinical.⁴

b. Thrush

Definition: Thrush is an infection of the upper GI track that is characterized by white, adherent, painless, discrete or confluent patches in the mouth, tongue, or esophagus.⁴ It results from a disturbance of the normal bacterial flora of the esophagus.

Criteria: Must be noted within 30 days after the primary procedure AND a documentation in the medical record of a diagnosis of thrush, or the patient is treated with oral irrigation for the specific treatment of thrush.

c. Urinary Tract Infection (UTI)

Definition: An infection in the urinary tract (kidneys, ureters, bladder, and urethra).

Criteria: Must be noted within 30 days after the primary procedure AND patient must meet ONE of the following A OR B below:

A: A urine culture of > 100,000 colonies/ml urine with no more than two species of organisms. Signs and symptoms should be reported within 72 hours prior to a urine culture being sent or 24 hours after the culture was sent, AND one of the following six *criteria:* (i) fever (>38°C or 100.4°F) (ii) urgency (iii) frequency (iv) dysuria (v) suprapubic tenderness (vi) costovertebral angle pain or tenderness.

B: TWO of the following six criteria: (i) fever (>38°C or 100.4°F) (ii) urgency (iii) frequency (iv) dysuria (v) suprapubic tenderness (vi) costovertebral angle pain or tenderness AND At least one of the following: (i) Two urine cultures with repeated isolation of the same uropathogen with >100 colonies/ml urine in non-voided specimen. (ii) Urine culture with < 100,000 colonies/ml urine of single uropathogen in patient being treated with appropriate antimicrobial therapy. Signs and symptoms should be reported within 72 hours prior to a urine culture being sent or 24 hours after the culture was sent. (iii) Physician or Advanced Practitioner diagnosis (iv) Physician or Advanced Practitioner institutes appropriate antimicrobial therapy.

d. C. Diff

Definition: C. diff. colitis is diarrhea of varying severity, from mild to fulminant and life threatening. It results from a disturbance of the normal bacterial flora of the colon and colonization by C. diff., which releases toxins (A&B) that cause mucosal inflammation and damage.

Criteria: Must be noted within 30 days after the primary procedure AND the following criteria, A OR B below: A. There is documentation in the medical record of a positive C. diff laboratory test i.e. diarrhea (≥ 3 unformed stools per 24 h for ≥ 2 days) by detection of the organism, toxin A, or toxin B in stool or identification of pseudomembranes in the colon⁴, OR B. There is documentation in the record that the patient is receiving current treatment for C. diff.

e. Pneumonia

Definition: Pneumonia is an infection of one or both lungs caused by bacteria, viruses, fungi, or aspiration. Pneumonia can be community acquired or acquired in a healthcare setting.

Criteria: Must be noted within 30 days after the primary procedure AND Must meet Radiology (A) criteria AND ONE of the following TWO Signs/Symptoms/Laboratory (B1 OR B2) below:

A. Radiology: A chest radiological exam (X-ray or CT) demonstrating at least ONE of the following: (i) Infiltrate (ii) Consolidation (iii) Opacity (iv) Cavitation, AND

Signs/Symptoms/Laboratory B1: At least ONE of the following: (i) Fever (>38°C or >100.4°F) with no other recognized cause (ii) Leukopenia (<4,000 WBC) or leukocytosis (>12,000 WBC) AND At least ONE of the following: (i) Positive Bronchoalveolar lavage (BAL) (ii) Positive growth in blood culture not related to another source of infection (iii) Positive growth in culture of pleural fluid (iv) Positive quantitative culture from minimally contaminated lower respiratory tract (LRT) specimen (e.g., BAL or protected specimen brushing) OR

Signs/Symptoms/Laboratory B2 At least TWO of the following: (i) New onset of purulent sputum, or change in character of sputum, or increased respiratory secretions, or increased suctioning requirements (ii) New or worsening cough, dyspnea, or tachypnea (iii) Rales (crackles) or rhonchi (iv) Worsening gas exchange (e.g., O₂ desaturations (e.g., PaO₂/FiO₂ \leq 240), increased oxygen requirements, or increased ventilator demand) (v) Infection of the lung parenchyma confirmed by fever, sputum or bronchial cultures, CXR, and requiring treatment.¹

f. Sepsis

Definition: Sepsis takes a variety of forms and spans from relatively mild physiologic abnormalities to septic shock. Sepsis is the systemic response to infection. (SIRS; Systemic inflammatory response syndrome). Septic Shock: Septic Shock is more severe than sepsis. Sepsis is considered severe when it is associated with organ and/or circulatory dysfunction.

Criteria: Must be noted within 30 days after the primary procedure AND confirmed by a physician (medical doctor or infectious diseases specialist) AND have at least TWO of the following Five Clinical Signs of SIRS: (i) Temp high ($>38^{\circ}\text{C}$ or $>100.4^{\circ}\text{F}$) or low ($<36^{\circ}\text{C}$ or $<96.8^{\circ}\text{F}$) (ii) HR >90 bpm (iii) RR >20 breaths/min or PaCO₂ 12,000 cell/mm³ (iv) Leukopenia ($<4,000$ WBC) or leukocytosis ($>12,000$ WBC) or 10% immature (band) forms (v) Anion gap acidosis: this is defined by either: (check with your Lab on calculation) a. $[\text{Na} + \text{K}] - [\text{Cl} + \text{HCO}_3 \text{ (or serum CO}_2\text{)}]$. If this number is greater than 16, then an anion gap acidosis is present OR b. $\text{Na} - [\text{Cl} + \text{HCO}_3 \text{ (or serum CO}_2\text{)}]$. If this number is greater than 12, then an anion gap acidosis is present.

6. RENAL

a. Acute Kidney Injury:

Definition: Progressive Renal dysfunction is the reduced capacity of the kidney(s) to perform its function in comparison to the preoperative state.

Criteria: Progressive Renal Insufficiency OR Acute Renal Failure Requiring Dialysis must be noted within 30 days after the primary procedure AND the following criteria A1 OR A2, B1 OR B2 and C1 OR C2 for staging OR D, A1. Increase in serum creatinine of ≥ 0.3 mg per dL (26.52 μmol per L) or ≥ 1.5 - to 2-fold from baseline OR A2. <0.5 mL per kg per hour of urine output for more than six hours (Stage 1). B1. Increase in serum creatinine of 2- to 3-fold from baseline OR B2. <0.5 mL per kg per hour of urine output for more than 12 hours (Stage 2). C1. Increase in serum creatinine of threefold from baseline or ≥ 4.0 mg per dL (353.60 μmol per L) with an acute rise of at least 0.5 mg per dL (44.20 μmol per L) OR C2. <0.3 mL per kg per hour of urine output for 24 hours or anuria for 12 hours OR Renal replacement therapy required (Stage 3). D. An abrupt (within 48 hours) reduction in kidney function based on an elevation in serum creatinine level, a reduction in urine output, the need for renal replacement therapy (dialysis), or a combination of these factors.⁷

7. MUSCULOSKELETAL

Rationale: Spinal surgery may be causally related to various musculoskeletal complaints that affect our patients. These complaints are not necessarily related to the surgical event and may be distant from our surgical site. However, if these events are significant for our patients they should be captured even if remote from the index surgery.

a. Distant Site Spine Pain

Definition: patient reported pain that is near the spine that is not near the site of the surgical intervention. This pain should be non-neurologic and must be related to muscular or direct pain over the spine.

Criteria: diagnosis of distant site spine pain must be made both clinically by the attending surgeon AND B. confirmed with XR and advanced imaging (either MRI or CT scan) that this is not due to degeneration.

b. Distant Cervical Degeneration

Definition: Patient reported pain that is near the cervical spine that is not near the site of the previous surgical intervention. This pain may be either muscular with direct pain over the spine or may also have a neurologic component.

Criteria: Diagnosis of cervical degeneration must be made both clinically by the attending surgeon, AND B. confirmed with XR and advanced imaging (either MRI or CT scan).

c. Distant Thoracic Degeneration

Definition: Patient reported pain that is near the thoracic spine that is not near the site of the previous surgical intervention. This pain may be either muscular with direct pain over the spine or may also have a neurologic component.

Criteria: A AND B below: A. Diagnosis of thoracic degeneration must be made both clinically by the attending surgeon, AND B. confirmed with XR and advanced imaging (either MRI or CT scan).

d. Distant Lumbar Degeneration

Definition: Patient reported pain that is near the lumbar spine that is not near the site of the previous surgical intervention. This pain may be either muscular with direct pain over the spine or may also have a neurologic component.

Criteria: A AND B below: A. Diagnosis of lumbar degeneration must be made both clinically by the attending surgeon, AND B. confirmed with XR and advanced imaging (either MRI or CT scan).

e. Extremity Pain (non-neurologic)

Definition: Patient reported extremity pain that is not near the site of the previous surgical intervention and cannot be reasonably attributed to the surgical procedure.

Criteria: A AND B below: A. Diagnosis of extremity pain must be made clinically by the attending surgeon, AND B. This pain must be post-surgical and a new pain and diagnosis for the patient.

f. Large Joint Degeneration

Definition: Symptomatic degenerative changes in the hip, knee or shoulder that were not present prior to surgery.

Criteria: A AND B below: A. Diagnosis of clinically significant large joint degeneration must be made both clinically by the attending surgeon, AND B. confirmed with XR and advanced imaging (either MRI or CT scan).

g. Trochanteric Bursitis

Definition: Symptomatic inflammation of the trochanteric bursa causing lateral hip pain.

Criteria: A AND B below: A. Patient-reported pain with palpation over the greater trochanter at any time point following the index surgery, AND B. physician diagnosis of trochanteric bursitis.

h. SI Joint Pain

Definition: Pain originating from the sacroiliac joint.

Criteria: A AND B below: A. Patient-reported pain with palpation of the SI joint, AND B. Diagnosis of SI joint pain by the attending surgeon, AND C. at least 3 positive provocation tests (compression, distraction, thigh thrust, Gaenslen's test, and Patrick's sign).⁸

j. Total Hip Dislocation⁹

Definition: Dislocation of a total hip arthroplasty that may be associated with changes in pelvic alignment following deformity surgery.

Criteria: Dislocation must take place in a total hip Arthroplasty that was placed prior to the index surgical procedure or a subsequent revision surgery.

j. Distant Site Spine Fracture

Definition: Distant site spine fracture of an axial bony element following surgery, separate from the surgically fused vertebrae, which may be related to changes in alignment following deformity surgery.

Criteria: A AND B AND C below: A. traumatic or nontraumatic fracture of a vertebral element separate from the surgically fused vertebrae, AND B. diagnosed by an attending physician, AND C. confirmed with XR and advanced imaging (either MRI or CT scan). This is separate and distinct from PJK/PJF.

k. Non-spine Fracture

Definition: Fracture of any appendicular bony element that may be related to post-surgical changes in alignment or gait.

Criteria: A AND B below: A. traumatic or nontraumatic fracture of any appendicular bony element, AND B. confirmed with XR and advanced imaging (either MRI or CT scan).

Spine Surgical Events

8. IMPLANT RELATED EVENTS:

These may occur at any post-operative time point

a. Implant Prominence

Definition: Implant prominence is defined as symptomatic, palpable instrumentation beneath skin.

Criteria: A. Diagnosis of implant prominence includes patient-reported, symptomatically palpable or visible instrumentation beneath skin AND B. recorded by an attending physician.

b. Painful Implants

Definition: Painful implantation is defined as symptomatic pain originating from spinal instrumentation.

Criteria: A. Diagnosis of painful implantation includes patient-reported pain that can be reasonably attributed to spinal instrumentation AND B. recorded by an attending physician.

c. Screw malposition

Definition: Screw malposition is defined as screw placement in a less than ideal position causing clinically significant symptoms (i.e. pain, neurological deficit).

Criteria: A. The determination of screw malposition must be made by the attending surgeon AND B. findings on XR and/or advanced imaging (either MRI or CT scan) or neuromonitoring.

d. Dislodgement or Loosening

Definition: Implant dislodgement or loosening is defined as a change in the position or loss of integrity of the spinal instrumentation.

Criteria: A. Radiographic evidence of implant dislodgement or loosening AND B. clinically significant signs or symptoms.

e. Rod/Screw Breakage

Definition: Rod/screw breakage is defined as mechanical failure of rods or screws following the index surgical procedure or a subsequent revision surgical procedure.

Criteria: A. Diagnosis of rod/screw fracture must be made by the attending surgeon AND B. confirmed with XR and/or advanced imaging (either MRI or CT scan).

9. RADIOGRAPHIC EVENTS:

These may occur at any post-operative time point

a. Adjacent Segment Disease

Definition: Adjacent segment disease is defined as the presentation of new symptoms referable to a vertebral level adjacent to the instrumented UIV or LIV of the index surgical procedure.

Criteria: Diagnosis of adjacent segment disease is made by the following criteria, A AND/OR B below: A. Clinically significant symptoms attributable to new degenerative changes at the spinal level adjacent to a previously surgically treated level or levels in the spine.¹¹ AND/OR B. radiographic findings of degeneration that can include: (i) a decrease of more than 3 mm in disc height, (ii) an intervertebral angle at flexion less than -5° , or (iii) a progress of slippage greater than 3 mm.¹⁰

b. Pseudarthrosis

Definition: Pseudarthrosis is defined as the failure of bony union to form between two or more instrumented spinal vertebrae.

Criteria: Must be diagnosed at more than six months after fusion, and the following criteria A AND B below: A. (i) radio-lucent line (wider than 2mm) at the graft-vertebral body interface OR (ii) no trabeculae bridging the graft-vertebral body interface or settling ($>5\text{mm}$) of the graft; AND B. (i) more than 5 degrees of motion on F/E radiographs OR (ii) implant migration OR (iii) implant breakage OR (iv) progressive deformity.¹

c. Pedicle Fracture

Definition: Pedicle fracture is defined as the fracture of a spinal pedicle. This may occur during the placement of instrumentation, or may occur late either within the fused levels, or immediately adjacent to the fused spine.

Criteria: A. Diagnosis of pedicle fracture includes the fracture of a pedicle diagnosed radiographically via XR or advanced imaging, AND B. clinically significant signs or symptoms.

d. Heterotopic Ossification

Definition: Heterotopic ossification is defined as ectopic bone formation within soft tissue that is clinically significant or limits range of motion.

Criteria: A. (i) clinically significant pain or (ii) limited range of motion attributed to osteophytes or bony islands within soft tissue, AND B. that can be visualized on XR and/or advanced imaging (either MRI or CT scan).¹²

e. Proximal Junctional Kyphosis

Definition: Proximal junctional kyphosis is defined as kyphosis at the upper instrumented vertebrae that was not present or has worsened following spinal surgery.

Criteria: A. proximal junction sagittal Cobb angle from the UIV to the UIV+1 $\geq 10^\circ$ AND B. progression of the proximal junction sagittal Cobb angle at least 10° greater than the preoperative measurement.¹⁴

f. Distal Junctional Kyphosis

Definition: Distal junctional kyphosis is defined as symptomatic kyphosis at the lower instrumented vertebrae that was not present or is worsened from prior to surgery.

Criteria: A. distal junctional angle greater than 10° between the caudal endplate of the from the UIV to the UIV-1 AND B. at least 10° greater than the corresponding preoperative measurement.¹³

g. Vertebral Body Fracture

Definition: Vertebral body fracture is defined as traumatic or nontraumatic fracture of a vertebral body following the index surgery.

Criteria: A. clinically significant symptoms AND B. evidence of vertebral body fracture of either instrumented or non-instrumented vertebrae on XR and/or advanced imaging (either MRI or CT scan).

h. Interspinous Ligament Disruption

Definition: Interspinous ligament disruption is defined as a physical disruption to the interspinous ligament following the index surgery.

Criteria: Disruption of the interspinous ligament resulting in A. increasing clinical symptoms AND B. angular OR translational deformity as noted on XR and/or advanced imaging (either MRI or CT scan).

i. Sagittal Malalignment

Definition: Sagittal malalignment is defined as symptomatic sagittal alignment that is worsened from postoperative correction.

Criteria: A. a change in sagittal alignment compared with postoperative imaging AND B. clinically significant symptoms.

j. Coronal Malalignment

Definition: Coronal malalignment is defined as symptomatic sagittal alignment that is worsened from postoperative correction.

Criteria: A. a change in coronal alignment compared with postoperative imaging AND B. clinically significant symptoms.

10. NEUROLOGICAL EVENTS:

These may occur at any post-operative time point

a. UE Intraoperative Positioning Neuropathy

Definition: UE intraoperative positioning neuropathy is defined as peripheral neuropathy in the upper extremity newly onset following the index surgery.

Criteria: A. clinically significant neurologic dysfunction that can be attributed to positioning during surgery, AND B. diagnosed by the attending physician.

b. Femoral Cutaneous Neuralgia

Definition: Femoral cutaneous neuralgia is defined as compression of the femoral cutaneous nerve causing sensory deficit.

Criteria: A. Patient-reported complaint of hypesthesia of the anterior thigh in the distribution of the femoral cutaneous nerve, without motor weakness¹⁸ AND B. diagnosed by the attending physician.

c. Sensory Deficit/Neuropathy

Definition: Sensory deficit/neuropathy is defined as sensory deficit and/or neurologic dysfunction that can be attributed to the index surgical procedure.

Criteria: A. Newly onset sensory deficit or neuropathy following the index surgery, AND B. associated with vertebral levels that were surgically manipulated.

d. Motor Deficit

Definition: The definition of motor deficit is a decrease in motor function following the index surgery.

Criteria: A. a postoperative decrease in motor strength compared with preoperative measurements using the manual muscle test (MMT) scale AND B. attributed to instrumented spinal levels.²¹

e. Spinal Cord Injury/Myelopathy

Definition: Spinal cord injury/myelopathy is defined as symptomatic myelopathy or spinal cord injury at or adjacent to the level of the index surgery.

Criteria: A. Presence of greater than one long-tract sign localized to the cervical or thoracic spinal cord (Hoffman or Babinski sign, clonus, hyperreflexia, crossed abductor sign, and gait dysfunction) on physical examination AND B. absence of other neurologic condition(s) AND C at a level associated with the index surgery.¹⁵

f. Bowel/Bladder Dysfunction

Definition: Bowel/bladder dysfunction is defined as any clinically significant alteration in the patient's normal bowel and/or bladder habits.

Criteria: A. abnormal bowel and/or bladder function including but not limited to (diarrhea, constipation, polyuria, oliguria, infectious diarrhea) AND B. requiring medical intervention or lifestyle change¹⁷.

g. Retrograde Ejaculation

Definition: Retrograde ejaculation is retrograde flow of ejaculate in male patients due to nerve injury during anterior approach spinal surgery.

Criteria: A. patient-reported retrograde ejaculation after surgery with anterior exposure, OR B. can be confirmed by post-ejaculatory urinalysis.¹⁹

h. Visual Deficit

Definition: Visual deficit is defined by vision change or loss of vision following the index surgery.

Criteria: A. postoperative change or loss of vision following prone spine surgery, AND B. attributed to ischemic optic neuropathy, central retinal artery occlusion, central retinal vein occlusion, cortical blindness, direct compression, or acute angle closure glaucoma.²⁰

i. Recurrent Laryngeal Nerve Injury/Dysphonia

Definition: Recurrent laryngeal nerve injury is defined as dysphonia or hoarseness caused by injury to the recurrent laryngeal nerve during cervical spine surgery.

Criteria: A. Clinically significant vocal cord dysfunction following surgery AND B. that can be confirmed via laryngoscopic examination of the vocal cords.¹⁶

j. C5 Palsy

Definition: C5 Palsy is defined as an injury to the C5 nerve root during cervical spine surgery causing motor deficit.

Criteria: Postoperative motor palsy of the deltoid and biceps muscles in the upper extremity by ≥ 1 grades in the manual muscle test (MMT) without sensory disturbance.²²

h. Horner's Syndrome

Definition: Horner's syndrome is a deficit of sympathetic innervation of the eye causing the triad of ptosis, miosis, and anhidrosis.

Criteria: A. Development of ipsilateral pupillary miosis, facial anhidrosis, and ptosis, resulting from damage to cervical sympathetic trunk after an anterior approach to the cervical spine AND B. clinically significant signs or symptoms.²³

11. INTRAOPERATIVE EVENTS

a. Anesthesia Complication

Definition: Anesthesia complication is defined as complication that occurs as a result of anesthesia-related procedures or medications that were administered during the surgical procedure.

Criteria: A. Adverse anesthesia-related event including, but not limited to: cardiovascular, respiratory, or renal impairment with a causal relationship to anesthesia-related procedures (including IV placement, foley placement, arterial line placement) AND B. determined by an attending physician.

b. Massive Blood Loss

Definition: Massive blood loss is defined as significantly increased blood loss from what would be expected during the surgical procedure.

Criteria: greater than 4 liters of (estimated or calculated) blood loss during the surgical procedure.

c. Dural Tear

Definition & Criteria: Dural tear is defined as an unintentional violation of the dura that occurred during the surgery.

d. Unintended Extension of Fusion

Definition & Criteria: Unintended extension of fusion is defined as the unintentional fusion of additional vertebral levels during the surgical procedure.

e. Wrong Level Surgery

Definition & Criteria: Wrong level surgery is defined as a surgical procedure that was performed at a vertebral level different than originally intended.

f. Visceral Injury

Definition: Visceral injury is defined as injury to visceral organs relating to instrumentation placed during the index surgical procedure.

Criteria: A. visceral organ injury that occurs during surgery, OR B. postoperatively due to migration of instrumentation.²⁵

g. Vascular Injury

Definition: Vascular injury is defined as an unintentional injury to a vascular structure during the index surgical procedure.

Criteria: A. unintentional intraoperative vascular injury AND B. requiring repair and/or additional assistance during the index surgical procedure.

h. Lymphocele

Definition: Lymphocele is defined as a collection of lymphatic fluid causing clinically significant symptoms following the index surgical procedure.

Criteria: A. Retroperitoneal lymphedema resulting in mechanical compression, nutritional deficiency, or immunosuppression²⁴ AND B. visible on advanced imaging.

i. Retained Instrument/Sponge

Definition & Criteria: Retained instrument/sponge is defined as any instrumentation or surgical supplies (including drains) that are unintentionally left inside the surgical wound.

12. SURGICAL WOUND EVENT

a. Hematoma – superficial (seroma)

Definition: Seroma is defined as a collection of fluid beneath the skin at or near the site of incision from the index surgical procedure.

Criteria: Clinically significant pain or neurological symptoms attributed to a culture-negative seroma²⁶.

b. Hematoma – epidural

Definition: Epidural hematoma is defined as a collection of blood in the epidural space following the index surgical procedure.

Criteria: A. Blood accumulation that causes clinically significant symptoms AND B1. diagnosis of a hematoma with direct visualization OR B2. advanced imaging²⁷.

c. Wound Drainage

Definition: Wound drainage is defined as the drainage of serous fluid from the index surgical wound at a higher normal rate.

Criteria: Clinically significant drainage of serous fluid causing alteration in the typical postoperative wound management, according to the attending physician.

d. Dehiscence

Definition: Dehiscence is defined as the spontaneous reopening of a previously surgically closed wound.

Criteria: A spontaneous reopening of a surgically closed wound with total breakdown of the surgical closure compromising the integrity of the procedure, without infection.²⁷

e. Infection – Superficial

Definition: Superficial Incisional SSI is an infection that involves only skin or subcutaneous tissue of the surgical incision.

Criteria: An infection that involves only skin or subcutaneous tissue of the incision AND at least ONE of the following: A. Purulent drainage, with or without laboratory confirmation, from the superficial incision B. Organisms isolated from an aseptically obtained culture of fluid or tissue from the superficial incision C. Superficial incision is deliberately opened by the surgeon AND At least one of the following signs or symptoms of infection: (i) pain or tenderness (ii) localized swelling (iii) redness (iv) heat.

f. Infection – Deep

Definition: Deep Incisional SSI is an infection which involves deep soft tissues. Deep soft tissues are typically any tissue beneath skin and immediate subcutaneous fat, for example fascial and muscle layers.

Criteria: An infection that involves deep soft tissues AND at least ONE of the following: A. Purulent drainage from the deep incision but not from the organ/space component of the surgical site B. A deep incision spontaneously dehisces or is deliberately opened by a surgeon when the patient has at least one of the following signs or symptoms: fever (> 38° C), localized pain, or tenderness, unless the site is culture-negative C. An abscess or other evidence of infection involving the deep incision is found on direct examination, during reoperation, or by histopathologic or radiologic examination D. Diagnosis of a deep incision SSI by a surgeon or attending physician.

g. Incisional Hernia

Definition: Incisional hernia is defined as a herniation that occurs through a previously made incision in the abdominal wall.

Criteria: Presence of a bulge in the area of a postoperative abdominal scar that is perceptible or palpable by clinical examination or imaging²⁸.

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