

Patient outcomes definition guide for the International Surgical Outcomes Study (ISOS)

Definitions and grading of complications

The following definitions and gradings are provided for guidance where the nature and severity of a possible complication following surgery is uncertain.

Acute Kidney Injury (AKI)

Stage	Serum creatinine	Urine output
Mild	Increase of 1.5-1.9 times baseline value within 7 days or ≥ 0.3 mg/dL ($30 \mu\text{mol/L}$) within 48 hours	≤ 0.5 ml/kg/h for 6-12 hours
Moderate	Increase of 2.0-2.9 times baseline value within 7 days	≤ 0.5 ml/kg/h for 12 hours
Severe	Increase of 3.0 times baseline within 7 days or increase in serum creatinine to ≥ 4.0 mg/dL ($\geq 350 \mu\text{mol/L}$) with an acute rise of >0.5 mg/dL ($>50 \mu\text{mol/L}$) or initiation of renal replacement therapy	≤ 0.3 ml/kg/h for 24 hours or Anuria for 12 hours

Guidance: Baseline serum creatinine must be measured before surgery but an estimated value can be used if the patient does not have chronic kidney disease.

Acute Respiratory Distress Syndrome (ARDS)

Respiratory failure, or new or worsening respiratory symptoms, commencing within one week of surgery; and a chest radiograph or computed tomography scan which demonstrates bilateral opacities not fully explained by effusions, lobar/lung collapse, or nodules; and respiratory failure not fully explained by cardiac failure or fluid overload. Need objective assessment (e.g. echocardiography) to exclude hydrostatic oedema if no risk factor present.

Severity grading:

Mild: $\text{PaO}_2:\text{FiO}_2$ between 200 and 300 mmHg with PEEP or CPAP ≥ 5 cmH₂O

Moderate: $\text{PaO}_2:\text{FiO}_2$ between 100 and 200 mmHg with PEEP ≥ 5 cmH₂O

Severe: $\text{PaO}_2:\text{FiO}_2 \leq 100$ mmHg with PEEP ≥ 5 cmH₂O

Guidance:

If altitude is higher than 1000 m, a correction factor should be calculated as follows: $(\text{PaO}_2:\text{FiO}_2 \times [\text{barometric pressure}/760 \text{ mmHg}])$. PEEP, positive end-expiratory pressure; CPAP, non-invasive continuous positive airways pressure

Anastomotic leak

Leak of luminal contents from a surgical connection between two hollow viscera. The luminal contents may emerge either through the wound or at the drain site, or they may collect near the anastomosis, causing fever, abscess, septicaemia, metabolic disturbance and/or multiple-organ failure. The escape of luminal contents from the site of the anastomosis into an adjacent localised area, detected by imaging, in the absence of clinical symptoms and signs should be recorded as a sub-clinical leak.

Severity grading:

Mild: Results in only temporary harm and would not usually require specific clinical treatment.

Moderate: More serious complication but one which does not usually result in permanent harm or functional limitation. Usually requires clinical treatment.

Severe: Results in significant prolongation of hospital stay and/or permanent functional limitation or death. Almost always requires clinical treatment.

Arrhythmia

Electrocardiograph (ECG) evidence of cardiac rhythm disturbance.

Severity grading:

Mild: Results in only temporary harm and would not usually require specific clinical treatment.

Moderate: More serious complication but one which does not usually result in permanent harm or functional limitation. Usually requires clinical treatment.

Severe: Results in significant prolongation of hospital stay and/or permanent functional limitation or death. Almost always requires clinical treatment.

Cardiac arrest

The cessation of cardiac mechanical activity, as confirmed by the absence of signs of circulation. ECG changes may corroborate the incidence of cardiac arrest.

Severity grading: None

Pulmonary oedema

Evidence of fluid accumulation in the alveoli due to poor cardiac function.

Severity grading:

Mild: Results in only temporary harm and would not usually require specific clinical treatment.

Moderate: More serious complication but one which does not usually result in permanent harm or functional limitation. Usually requires clinical treatment.

Severe: Results in significant prolongation of hospital stay and/or permanent functional limitation or death. Almost always requires clinical treatment.

Gastro-intestinal bleed

Unambiguous clinical or endoscopic evidence of blood in the gastro-intestinal tract. Upper gastrointestinal bleeding is that originates from the oesophagus, stomach and duodenum. Lower gastro-intestinal bleeding originates from the small bowel and colon.

Severity:

Mild: Results in only temporary harm and would not usually require specific clinical treatment.

Moderate: More serious complication but one which does not usually result in permanent harm or functional limitation. Usually requires clinical treatment.

Severe: Results in significant prolongation of hospital stay and/or permanent functional limitation or death. Almost always requires clinical treatment.

Bloodstream infection

An infection which is not related to infection at another site and which meets either of the following criteria:

- 1) Patient has a recognised pathogen cultured from blood cultures which is not related to an infection at another site
- 2) Patient has at least one of the following signs or symptoms: fever ($>38^{\circ}\text{C}$), chills, or hypotension and at least one of the following:
 - a) common skin contaminant cultured from two or more blood cultures drawn on separate occasions
 - b) common skin contaminant cultured from at least one blood culture from a patient with an intravascular line, and a physician starts antimicrobial therapy
 - c) positive blood antigen test

Severity:

Mild: Results in only temporary harm and would not usually require specific clinical treatment.

Moderate: More serious complication but one which does not usually result in permanent harm or functional limitation. Usually requires clinical treatment.

Severe: Results in significant prolongation of hospital stay and/or permanent functional limitation or death. Almost always requires clinical treatment.

Myocardial infarction

Increase in serum cardiac biomarker values (preferably cardiac troponin) with at least one value above the 99th percentile upper reference limit and at least one of the following criteria:

- Symptoms of ischaemia
- New or presumed new ST-segment or T-wave ECG changes or new left bundle branch block
- Development of pathological Q-waves on ECG
- Radiological or echocardiographic evidence of new loss of viable myocardium or new regional wall motion abnormality
- Identification of an intra-coronary thrombus at angiography or autopsy

Severity grading:

Mild: Results in only temporary harm and would not usually require specific clinical treatment.

Moderate: More serious complication but one which does not usually result in permanent harm or functional limitation. Usually requires clinical treatment.

Severe: Results in significant prolongation of hospital stay and/or permanent functional limitation or death. Almost always requires clinical treatment.

Pneumonia

Chest radiographs with new or progressive and persistent infiltrates, or consolidation, or cavitation, and at least one of the following:

- a) fever ($>38^{\circ}\text{C}$) with no other recognized cause
- b) leucopaenia ($<4,000$ white blood cells/ mm^3) or leucocytosis ($>12,000$ white blood cells/ mm^3)
- c) for adults >70 years old, altered mental status with no other recognised cause

...and at least two of the following:

- new onset of purulent sputum or change in character of sputum, or increased respiratory secretions, or increased suctioning requirements
- new onset or worsening cough, or dyspnoea, or tachypnoea
- rales or bronchial breath sounds
- worsening gas exchange (hypoxia, increased oxygen or ventilator demand)

Guidance: Two radiographs are required for patients with underlying pulmonary or cardiac disease. The definition may be used to identify ventilator associated pneumonia.

Severity:

Mild: Results in only temporary harm and would not usually require specific clinical treatment.

Moderate: More serious complication but one which does not usually result in permanent harm or functional limitation. Usually requires clinical treatment.

Severe: Results in significant prolongation of hospital stay and/or permanent functional limitation or death. Almost always requires clinical treatment.

Post-operative haemorrhage

Blood loss occurring within 72 hours after the end of surgery which would normally result in transfusion of blood. Gastro-intestinal bleeding is defined above.

Severity:

Mild: Not applicable

Moderate: More serious complication but one which does not usually result in permanent harm or functional limitation. Usually requires clinical treatment.

Severe: Results in significant prolongation of hospital stay and/or permanent functional limitation or death. Almost always requires clinical treatment.

Pulmonary embolism (PE)

A new blood clot or thrombus within the pulmonary arterial system.

Guidance: Appropriate diagnostic tests include scintigraphy and CT angiography. Plasma D-dimer measurement is not recommended as a diagnostic test in the first three weeks following surgery.

Severity:

Mild: Results in only temporary harm and would not usually require specific clinical treatment.

Moderate: More serious complication but one which does not usually result in permanent harm or functional limitation. Usually requires clinical treatment.

Severe: Results in significant prolongation of hospital stay and/or permanent functional limitation or death. Almost always requires clinical treatment.

Stroke

Embolic, thrombotic, or haemorrhagic cerebral event with persistent residual motor, sensory, or cognitive dysfunction (e.g. hemiplegia, hemiparesis, aphasia, sensory deficit, impaired memory).

Severity:

Mild: Results in only temporary harm and would not usually require specific clinical treatment.

Moderate: More serious complication but one which does not usually result in permanent harm or functional limitation. Usually requires clinical treatment.

Severe: Results in significant prolongation of hospital stay and/or permanent functional limitation or death. Almost always requires clinical treatment.

Surgical site infection (superficial)

Infection involving only superficial surgical incision which meets the following criteria:

- 1) Infection occurs within 30 days after surgery and
- 2) Involves only skin and sub-cutaneous tissues of the incision and
- 3) The patient has at least one of the following:
 - a) purulent drainage from the superficial incision
 - b) organisms isolated from an aseptically obtained culture of fluid or tissue from the superficial incision and at least one of the following signs or symptoms of infection: pain or tenderness, localized swelling, redness, or heat, or superficial incision is deliberately opened by surgeon and is culture positive or not cultured. A culture-negative finding does not meet this criterion.
 - c) diagnosis of a incisional surgical site infection by a surgeon or attending physician

Severity:

Mild: Results in only temporary harm and would not usually require specific clinical treatment.

Moderate: More serious complication but one which does not usually result in permanent harm or functional limitation. Usually requires clinical treatment.

Severe: Results in significant prolongation of hospital stay and/or permanent functional limitation or death. Almost always requires clinical treatment.

Surgical site infection (deep)

An infection which involves both superficial and deep parts of surgical incision and meets the following criteria:

- 1) Infection occurs within 30 days after surgery if no surgical implant is left in place or one year if an implant is in place and
- 2) The infection appears to be related to the surgical procedure and involves deep soft tissues of the incision (e.g. fascial and muscle layers) and
- 3) The patient has 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 and is culture-positive or no cultures were taken whilst the patient has at least one of the following signs or symptoms of infection: fever ($>38^{\circ}\text{C}$) or localized pain or tenderness. A culture-negative finding does not meet this criterion.
 - c) an abscess or other evidence of infection involving the deep incision is found on direct examination, during surgery, or by histopathologic or radiologic examination
 - d) diagnosis of a deep incisional surgical site infection by a surgeon or attending physician

Severity:

Mild: Results in only temporary harm and would not usually require specific clinical treatment.

Moderate: More serious complication but one which does not usually result in permanent harm or functional limitation. Usually requires clinical treatment.

Severe: Results in significant prolongation of hospital stay and/or permanent functional limitation or death. Almost always requires clinical treatment.

Surgical site infection (organ/space)

An infection which involves any part of the body excluding the fascia or muscle layers and meets the following criteria:

- 1) Infection occurs within 30 days after surgery and
- 2) The infection appears to be related to the surgical procedure and involves any part of the body, excluding the skin incision, fascia, or muscle layers, that is opened or manipulated during the operative procedure and
- 3) The patient has at least one of the following:
 - a) purulent drainage from a drain that is placed through a stab wound into the organ/space
 - b) organisms isolated from an aseptically obtained culture of fluid or tissue in the organ/ space
 - c) an abscess or other evidence of infection involving the organ/space that is found on direct examination, during reoperation, or by histopathologic or radiologic examination
 - d) diagnosis of an organ/space surgical site infection by a surgeon or attending physician

Severity:

Mild: Results in only temporary harm and would not usually require specific clinical treatment.

Moderate: More serious complication but one which does not usually result in permanent harm or functional limitation. Usually requires clinical treatment.

Severe: Results in significant prolongation of hospital stay and/or permanent functional limitation or death. Almost always requires clinical treatment.

Urinary tract infection

An infection associated with at least one of the following signs or symptoms which should be identified within a 24 hour period:

Fever (>38 °C), urgency, frequency, dysuria, suprapubic tenderness, costovertebral angle pain or tenderness with no other recognised cause

and a positive urine culture of $\geq 10^5$ colony forming units/mL with no more than two species of microorganisms.

Severity:

Mild: Results in only temporary harm and would not usually require specific clinical treatment.

Moderate: More serious complication but one which does not usually result in permanent harm or functional limitation. Usually requires clinical treatment.

Severe: Results in significant prolongation of hospital stay and/or permanent functional limitation or death. Almost always requires clinical treatment.

Treatment for post-operative complications

To allow us to grade the severity of complications using different systems we need information describing the treatment of the **most severe complication** the patient developed. The treatment categories are explained defined below:

Drug therapy, blood transfusion or parenteral nutrition: please mark 'yes' if the patient received any of these treatments because they developed a complication.

Surgery or radiological procedure: This refers to surgery in an operating room and not minor bedside procedures. An example of a radiological treatment would be ultrasound or CT guided abscess drainage. Please mark 'yes' if the patient received any of these because they developed a complication.

Critical care admission: We have defined a critical care unit as a facility *routinely capable* of admitting patients who require invasive ventilation overnight. This does not mean an individual patient requires ventilation to be admitted to such a unit. Please mark 'yes' if the patient was admitted to critical care because they developed a complication. If the patient was already in critical care when the complication developed, please mark 'yes' if this resulted in a longer stay in critical care.

Hospital resource use after surgery

We will collect some basic data to describe the treatment resources patients received after surgery.

Hours in Post-Anaesthetic Care Unit after surgery: A post-anaesthetic recovery unit is dedicated facility for the care of all patients immediately following surgery under anaesthesia. Some patients may stay overnight. Please record the duration of stay in hours.

Days in critical care after surgery: Defined above. Total number of days in critical care within the first 30 days after surgery. May include multiple admissions and planned admission to critical care immediately after surgery.

Days in hospital after surgery: Total number of days in hospital after surgery.

Status at 30 days after surgery: Did the patient die within 30 days of surgery?