

Inhalt

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I. Baseline Assessment (Visit 1)

1. ASA (American Society of Anesthesiologists)

- I A normal healthy patient
- II A patient with mild systemic disease which does not limit physical activity
- III A patient with severe systemic disease which limits physical activity
- IV A patient with severe systemic disease that is a constant threat to life
- V A patient who is not expected to survive for 24 hours without the operation

2. Steroid use for chronic condition

Defined as regular administration of oral or parenteral corticosteroid medications or immunosuppressants for a chronic medical condition, within the 30 days prior to surgery, or at the time the patient is being considered as a candidate for surgery. A one-time pulse, limited short course, or a taper of less than 10 days duration would not qualify. Long-interval injections of long-acting agents would qualify.

3. Ascites within 30 days prior to intervention

The presence of fluid accumulation in the peritoneal cavity was noted on physical examination, abdominal ultrasound, or abdominal CT/MRI within 30 days prior to surgery. Documentation must state either active or a history of liver disease or must state secondary to malignancy.

4. Systemic Sepsis

- **SIRS**: clinical reaction with at least two of the following symptoms
 - o Temperature: $\geq 38^{\circ}\text{C}$ or $\leq 36^{\circ}\text{C}$
 - o Heart rate: $\geq 90/\text{min}$
 - o Breathing rate: $\geq 20/\text{min}$ or Hyperventilation in blood gas analysis
 - o Leucocytes: $> 12.000/\mu\text{l}$ or $< 4000/\mu\text{l}$
- **Sepsis**
 - o SIRS + assumed or proven infection
- **Septic shock**
 - o Sepsis with need of catecholamine-therapy in hypotension (MAP $< 65\text{mmHg}$) despite adequate volume-therapy

Remark: In 2016 new sepsis criteria have been introduced. Criteria used here are the prior ones, according to the NSQIP surgical risk calculator.

5. Disseminated Cancer

The patient has a primary cancer that has metastasized to a major organ AND meets at least one of the following:

- o Active treatment for the cancer within one year of the surgery date. If the surgical procedure is the treatment for the metastatic cancer, answer "Yes".
- o The patient has elected not to receive treatment for the metastatic disease
- o The patient's metastatic cancer has been deemed untreatable

Report the following cancers as Disseminated Cancer: Disseminated Cancer: Acute Lymphocytic Leukaemia (ALL), Acute Myelogenous Leukaemia (AML) and Stage IV Lymphoma.

Do not report the following as disseminated Cancer: Chronic Lymphocytic Leukaemia (CLL), Chronic Myelogenous Leukaemia (CML), Stages I through III Lymphomas or Multiple Myeloma.

6. Hypertension requiring medication

The patient has a diagnosis of HTN in the medical record and will require antihypertensive medication(s) within 30 days prior to surgery.

7. Congestive heart failure?

Only newly diagnosed CHF within the previous 30 days or a diagnosis of chronic CHF with signs or symptoms of CHF in the 30 days prior to surgery fulfils this definition.

8. Dyspnoea

Meant is the patients' dyspnoea status when they were in their usual state of health, prior to the onset of the acute illness, within the 30 days prior to the time the patient was being considered a candidate for surgery.

9. History of severe COPD

Chronic obstructive pulmonary disease (such as emphysema and/or chronic bronchitis) resulting in one or more of the following:

- Functional disability from COPD (for example, dyspnoea, inability to perform ADLs)
- Hospitalization in the past for treatment of COPD
- Chronic bronchodilator therapy with oral or inhaled agents
- FEV1 of <75% of predicted
- Do not include patients whose only pulmonary disease is asthma
- Do not include patients with diffuse interstitial fibrosis or sarcoidosis

10. Dialysis

Patient suffers from acute or chronic renal failure requiring treatment with peritoneal dialysis, haemodialysis, hemofiltration, haemodiafiltration, or ultrafiltration within 2 weeks prior to surgery. If a patient requires dialysis, but refuses it, the answer to this variable will be "Yes."

11. Acute renal failure

Acute renal failure is defined as a clinical condition associated with rapid decline of kidney function. The patient meets one of the following criteria:

- Increased blood urea nitrogen (BUN) on two measurements AND two Cr results > 3mg/dl
- Surgeon or physician has documented Acute Renal Failure AND one of the following:
 - Increased BUN on two measurements
 - Two Cr results > 3mg/dl

12. Mini Cog

- Mini-Cog is a 3-minute instrument that can increase detection of cognitive impairment in older adults
- The questionnaire can be found on our website https://pose-trial.org/?page_id=20 as Appendix 3
- Please follow the instructions explained in the Appendix
- In case a person is unable to execute the Mini Cog due to his or her **physical condition** (e.g. a broken dominant arm) please ask him or her to describe how he would draw a clock, to tell you all the numbers on the clock face as well as to describe where he would place the hands to depict 10 past 11.

13. Timed Up & Go test

- Timed Up & Go test can be found on our website https://pose-trial.org/?page_id=20 Appendix 4
- Please follow the instructions explained in the Appendix

II. Surgery Day (Visit 2)

1. Advanced intraoperative monitoring

- **BIS:** Bispectral index monitor is used to monitor depth of anaesthesia
- **NIRS:** Near infrared spectroscopy is a non invasive optical technology to determine tissue oxygenation.
- **Invasive RR:** invasive blood pressure measurement (via arterial catheter)
- **CVP:** central venous pressure
- **TEE:** transoesophageal echocardiography
- Pulmonary artery catheter
- Cardiac output via arterial wave form analysis

2. Severity of surgery

- **Minor:** e.g. skin-lesions or small skin tumours, biopsies, draining breast abscess, brief diagnostic and therapeutic procedures like arthroscopy without intervention
- **Intermediate:** Primary repair of inguinal hernia, excising varicose veins in the leg, tonsillectomy or adeno-tonsillectomy, knee arthroscopy, cataract surgery, uvuloplasty, minimally invasive repair of vaginal prolapse, vaginal hysterectomy, tendon repair of hand etc.
- **Major:** Total abdominal hysterectomy, endoscopic resection of prostate, lumbar discectomy, thyroidectomy, total joint replacement, lung operations, colon resection, radical neck dissection etc.

3. Urgency of surgery

- **Elective:** Intervention that is scheduled in advance because it does not involve a medical emergency
- **Urgent:** Intervention required within < 48 hrs
- **Emergency:** Non-elective Intervention performed when the patient's life or well-being is in direct jeopardy

4. Surgical wound classification

- **Clean:** Elective, not emergency, non-traumatic, primarily closed; no acute inflammation; no break in technique; respiratory, gastrointestinal, biliary and genitourinary tracts not entered.
- **Clean-contaminated:** Urgent or emergency case that is otherwise clean; elective opening of respiratory, gastrointestinal, biliary or genitourinary tract with minimal spillage (e.g. appendectomy) not encountering infected urine or bile; minor technique break.
- **Contaminated:** Non-purulent inflammation; gross spillage from gastrointestinal tract; entry into biliary or genitourinary tract in the presence of infected bile or urine; major break in technique; penetrating trauma <4 hours old; chronic open wounds to be grafted or covered.
- **Dirty:** Purulent inflammation (e.g. abscess); preoperative perforation of respiratory, gastrointestinal, biliary or genitourinary tract; penetrating trauma >4 hours old.

III. Follow-up on POD 30 (Visit 3)

1..In hospital outcome according to the ACS NSQIP

a. Cardiac complication

- **Cardiac arrest:** The absence of cardiac rhythm or presence of a chaotic cardiac rhythm requiring the initiation of CPR, which includes chest compressions
- **Myocardial infarction:** Defined according to the American Heart Association:
 - Acute rise and/or fall of cardiac troponin, with at least **one value** above the 99th percentile upper reference limit (unless clearly explained by non-ischemic aetiology e.g. pulmonary embolism, sepsis, renal failure, severe acute neurological disease)
 - **AND** at least **one** of the following:
 - Symptoms of ischaemia, **OR**
 - New/ presumed new significant ST-segment-T wave changes or new left bundle branch block, **OR**
 - Development of pathological Q-waves in the electrocardiography (ECG), **OR**
 - Imaging evidence (e.g. new loss of viable myocardium/ wall motion abnormality), **OR**
 - Identification by angiography or autopsy

For patients, who underwent Coronary artery bypass grafting:

- Acute rise of cardiac troponin > 10 x 99th percentile upper reference limit
- **AND**
 - New pathological Q-waves or new left bundle branch block in the ECG, **OR**
 - Imaging evidence (e.g. new loss of viable myocardium/ wall motion abnormality) **OR**
 - Identification by angiography or autopsy

b. Pneumonia

Infection of the lungs, diagnosed using **both radiologic** (i.e., infiltrate, consolidation or opacity, cavitation) and **clinical** (e.g. fever, leukopenia/leukocytosis, culture results, patient symptoms) criteria.

c. Pulmonary embolism

Radiological diagnosis or signs of pulmonary embolism in the autopsy

d. Return to Operating Room

Return to the operating room for additional surgery that was not planned at the time of the initial surgery.

e. Stroke

Defined as a new focal or generalized neurological deficit of >24h duration in motor, sensory, or coordination functions with compatible brain imaging and confirmed by a neurologist. Or signs of stroke in the autopsy. Transient ischemic attack is not considered as acute stroke.

f. Acute kidney injury

Acute kidney injury is defined according to the AKIN classification as AKI stage ≥ 2 .

- This means increase of creatinine >2-3x from baseline within the hospital stay **OR**
- Urine output less than 0.5 ml kg⁻¹ per hour for more than 12 hours **OR**
- Signs of acute kidney injury in the autopsy.

Acute renal failure requiring dialysis: A patient who did not require dialysis preoperatively, worsening of renal dysfunction postoperatively requiring hemodialysis, peritoneal dialysis, hemofiltration, haemodiafiltration, or ultrafiltration.

g. Venous thromboembolism/ blood clot

- The identification of a new thrombus within the venous system, described in studies as present in the superficial or deep venous systems but requires therapy.
- This diagnosis is confirmed by a duplex, venogram, CT scan or other imaging modality, AND the patient requires treatment with anticoagulation therapy and/ or placement of a vena cava filter or clipping of the vena cava.

h. Surgical site infection

- **Superficial Incisional SSI:** infection that involves only skin or subcutaneous tissue of the incision. It also includes either: purulent drainage, positive culture, signs/symptoms of infection and the incision is deliberately opened by the surgeon or diagnosis by the attending physician.
- **Deep Incisional SSI:** infection that appears to be related to the operation and involves deep soft tissues (for example, fascial and muscle layers) of the incision. It also includes either: purulent drainage, spontaneous dehiscence, deliberate opening by the surgeon, abscess involving the deep incision, or diagnosis by the attending physician.
- **Organ Space SSI:** infection that involves any part of the anatomy (for example, organs or spaces), other than the incision, which was opened or manipulated during an operation. It also includes either: purulent drainage, positive culture, abscess, or diagnosis by the attending physician.

i. Wound disruption

- A wound disruption is a surgical complication in which a wound ruptures along a surgical incision.

j. Systemic Sepsis

- **SIRS:** clinical reaction with at least two of the following symptoms
 - Temperature: $\geq 38^{\circ}\text{C}$ or $\leq 36^{\circ}\text{C}$
 - Heart rate: $\geq 90/\text{min}$
 - Breathing rate: $\geq 20/\text{min}$ or Hyperventilation in blood gas analysis
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- **Sepsis**
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k. Urinary tract infection

Bladder infection, diagnosed using a combination of clinical symptoms and laboratory confirmation (e.g., urine culture, pyuria, positive dipstick) or initiation of appropriate antimicrobial therapy.

l. Discharge to Post-Acute Care

Includes discharge to one of the following facilities: A skilled care facility that was not home previously (sub-acute hospital, skilled nursing home/facility, transitional care unit, long term care facility, or ventilator bed)

- An unskilled care facility that was not home previously (unskilled nursing home or assisted facility)
- Rehab (inpatient rehabilitation facility including rehabilitation distinct part units of a hospital)
- Separate acute care facility

2. (Actual) Functional Status

This question refers to the actual functional status 30 days after intervention.

- **Independent:** The patient does not require assistance from another person for any activities of daily living. This includes a person who is able to function independently with prosthetics, equipment, or devices.
- **Partially dependent:** The patient requires some assistance from another person for activities of daily living.
- **Totally dependent:** The patient requires total assistance for all activities of daily living.

3. Brief screen for cognitive impairment (BSCI)

- A three-item screen for cognitive impairment due to dementia
- Three words (dog, apple, house) are read to the interviewee soon after the start of the interview. The subject is asked to repeat them and remember them.
- After two minutes the person is asked again to repeat the three words
- Score: from 0 (worst score, none of the three words correctly recalled) to 3 (perfect score, all three words recalled correctly)

[Hill et al, 2005, Validation of a Brief Screen for Cognitive Impairment (BSCI) Administered by Telephone for Use in the Medicare Population]

4. Any complications after hospital discharge assessed by telephone interview

Please ask only for the following 4 complications:

- Cardiac (Cardiac arrest, myocardial infarction)
- Pulmonary (Pneumonia, pulmonary embolism)
- Stroke
- Acute kidney injury

Please note: They will be only rated as present if they led to hospital re-admission or death, or additionally in case of kidney injury, if it led to renal replacement therapy