**Appendix B: Data abstraction tool**

**File information**

Anonymous Record number + stay number:

Patient’s date of birth:

Admission date:

Discharge date:

**Verification of Patient information**

Age

Sex

Admission type

Residence before admission

Destination

Length of stay

 *Patient admitted from another acute care hospital: exclude medical record*

**Adequacy of the medical record** Yes No

* Nursing progress notes
* Documentation procedures
* Discharge notes, including medication prescriptions

*When 2/3 missing from medical record: inadequate; exclude medical record*

Weight (if available):

**Co-morbidities**

**Co-morbidity Present Not present Missing**

Congestive heart failure

Arrhythmia

Valvular disease

Disease of pulmonary circulation

Peripheral vascular disease

Hypertension

Paralysis

Other neurological disorders

Chronic pulmonary disease

Diabetes without chronic complication

Diabetes with chronic complications

Hypothyroidism

Renal failure

Liver disease

Peptic ulcer disease

AIDS

Lymphoma

Metastatic cancer

Solid tumour without metastasis

Rheumatoid arthritis

Coagulopathy

Obesity

Weight loss

Fluid and electrolyte disorders

Chronic blood loss anaemia

Deficiency anaemias

Alcohol abuse

Drug abuse

Psychoses

Depression

**Decubitus (one criteria is required per decubitus ulcer)**

**Grade 1**: Non-blanchable erythema of intact skin; discolouration of the

skin, warmth, oedema, induration, or hardness may also be used as

indicators, particularly in individuals with darker skin

**Grade 2**: Partial thickness skin loss involving epidermis, dermis, or both.

The ulcer is superficial and presents clinically as an abrasion or blister

**Grade 3**: Full thickness skin loss involving damage to or necrosis of

subcutaneous tissue that may extend down to, but not through underlying

fascia

**Grade 4**: Extensive destruction, tissue necrosis, or damage to muscle,

bone, or supporting structures with or without full thickness skin loss

Decubitus in medical record, no further specification

No clinical criteria for decubitus

**102 Adverse events KCE Reports S**

**Deep vein thrombosis/Pulmonary embolism (DVT/PE) (at least one criteria is**

**required)**

Surgical procedure performed.

New pulmonary embolism based on abnormal pulmonary angiography

High-probability ventilation/perfusion scintigraphy or perfusion scintigraphy alone:

single or multiple wedge-shaped perfusion defects with or without matching chest

roentgenographic abnormalities; wedge-shaped areas of overperfusion usually coexist

New pulmonary embolism based on spiral CT

Diagnostic echocardiography: visualization of embolized thrombi in the central

pulmonary arteries or in right heart chambers

Indirect evidence of pulmonary embolism with echocardiography in case of massive

PE and hemodynamic instability

Ultrasonography positive for DVT of the lower extremity or positive venogram

DVT/PE in medical record, no further specification

No clinical criteria for DVT/PE

**Postoperative sepsis (at least one criteria is required)**

Surgical procedure performed 􀀀

***Infection***: Inflammatory reaction due to the presence of microorganisms or

the invasion of otherwise sterile tissue by microorganisms 􀀀

***Sepsis***: Systemic reaction to infection. The systemic reaction is defined by two or

more of the following conditions as a result of infection:

* Temperature > 38 °C or < 36 °C 􀀀
* Heart rate > 90/min 􀀀
* Respiration rate > 20/min or PaCO2 < 32 mmHg 􀀀
* Leukocytes > 12,000/l or < 4,000/l or > 10% immature forms 􀀀

# Severe sepsis

* Sepsis associated with a new organ dysfunction *or* 􀀀
* Sepsis associated with hypoperfusion (e.g., lactate acidosis, oliguria

(< 30 ml/h or < 0.5 ml/kg/h), or an acute alteration in mental status) *or* 􀀀

* Sepsis associated with hypotension (systolic arterial pressure <

90 mmHg, MAP (mean arterial pressure) < 60 mmHg, or a

decrease in systolic blood pressure of ≥ 40 mmHg from baseline

in the absence of other causes for hypotension) 􀀀

***Septic shock***

Persistent arterial hypotension unexplained by other causes

Hypotension = systolic arterial pressure < 90 mmHg, MAP < 60

mmHg or a reduction in systolic blood pressure of ≥ 40 mmHg from

baseline, despite adequate volume resuscitation, in the absence of

other causes for hypotension 􀀀

Sepsis in medical record, no further specification 􀀀

No clinical criteria for sepsis 􀀀

**KCE Reports S Adverse events 103**

**Ventilator associated pneumonia (VAP) (at least one criteria is required)**

Parenchymal lung infection occurring more than 48-72 hours

after initiation of mechanical ventilation 􀀀

**and**

At least **2 of 3** clinical feat:

* Fever greater than 38°C 􀀀
* Leukocytosis (> 10,000/µl) or leukopenia (< 4,000/µl) 􀀀
* Purulent tracheal secretions (bacteria or inflammatory cells) 􀀀

Ventilator associated pneumonia in medical record, no further specification 􀀀

No clinical criteria for ventilator associated pneumonia 􀀀

**Postoperative wound infection (at least one criteria is required)**

Surgical procedure performed 􀀀

Incisional infection as evidenced by superficial drainage and positive gram

stain for white blood cells 􀀀

Incisional infection as evidenced by documentation of red (erythema) and hot

or swollen and painful incision site, and clinician note of purulent drainage of

infection site 􀀀

Incisional infection as evidenced by superficial drainage, positive gram stain for

white blood cells, and clinician note of purulent drainage of infection site 􀀀

Incisional infection as evidenced by documentation of red (erythema) and hot

or swollen and painful incision site, and fever, leukocytosis, or left shift 􀀀

Deep infection as evidenced by drainage and positive gram stain for white

blood cells 􀀀

Deep infection as evidenced by fever, leukocytosis, or left shift; and x-ray,

CT scan, or ultrasound evidence of abscess at anatomical site of surgical incision 􀀀

Deep infection as evidenced by creptitus in the wound on physical exam; or x-ray,

CT scan, or ultrasound evidence of gas at anatomical site or surgical incision, and

documentation of red (erythema) and hot or swollen and painful incision site with fever 􀀀

Postoperative wound infection in medical record, no further specification 􀀀

No clinical criteria for postoperative wound infection 􀀀

**Adverse events recording:**

a) Was there a patient injury or complication? 􀀀 Yes 􀀀 No

if yes, what kind ?

Decubitus 􀀀 DVT/PE 􀀀

Sepsis 􀀀 VAP 􀀀

Postoperative wound infection 􀀀 Other 􀀀

If other, specify : \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Did that complication present at the time of admission? 􀀀 Yes 􀀀 No

b) Was the patient’s injury/complication caused by:

Health-care management 􀀀

Health-care management interacting

with disease process 􀀀

Solely by disease process 􀀀

Not documented 􀀀

Not applicable 􀀀

c) Did the injury or complication result in disability at the time of discharge and/or a

prolonged hospital stay (or re-admission or out-patient treatment) or death?

(at least one possibility)

No disability 􀀀

Harm that contributed to or resulted in temporary harm to the patient

and required intervention 􀀀

Harm that contributed to or resulted in prolonged hospitalization 􀀀

Harm that contributed to or resulted in permanent patient disability 􀀀

Harm that required intervention to sustain life 􀀀

Harm that contributed to or resulted in the death of a patient 􀀀

Harm after discharge (at home) 􀀀

Not documented 􀀀

Not applicable 􀀀

d) Estimation of extra length of stay as a consequence of the adverse event:

Amount of days:

e) Existence of potential quality problems:

Inadequate preparation for surgery 􀀀

Problem with technical care during a surgical procedure 􀀀

Problem with anaesthesia care before or during a surgical procedure 􀀀

Problem with medications administered 􀀀

Failure to monitor patient condition or medications 􀀀

Delay in services or treatment 􀀀

Failure to respond to abnormal findings 􀀀

Failure to provide preventive care (e.g., prophylactic antibiotic

or anticoagulation) 􀀀

Failure to recognize procedure contraindication 􀀀

Failure to recognize medication contraindication 􀀀

Poor communication or coordination of care 􀀀

Inadequate or inappropriate equipment or facilities 􀀀

Inadequate or inappropriate staffing 􀀀

Not documented 􀀀

Not applicable 􀀀

f) Consider the extent to which health-care management rather than the disease process is

responsible for the adverse event.

1. Virtually no evidence for management causation/system failure 􀀀
2. Slight-to-modest evidence for management causation 􀀀
3. Management causation unlikely; less than 50-50a but close call 􀀀
4. Management causation more likely than not, more than 50-50b but close call 􀀀
5. Moderate/strong evidence for management causation 􀀀
6. Valid evidence for management causation 􀀀

aManagement causation not quite likely: less, but close to 50%

bManagement causation more likely than not : more, but close to 50%

**S Adverse events 105**

g) Extent the adverse event is preventable

1. Not preventable: virtually no evidence for preventability 􀀀

2. Low preventability: slight-to-modest evidence for preventability 􀀀

3. Low preventability: preventability not likely, less than 50-50 but close call 􀀀

4. High preventability: preventability more likely than not, more than 50-50

 but close call 􀀀

5. High preventability: strong evidence for preventability 􀀀

6. High preventability: valid evidence for preventability 􀀀

h) Date of adverse event (dd/mm/yyyy):

 Day of procedure that caused the adverse event:

If available, time of day: Morning 􀀀

 Afternoon 􀀀

 Evening 􀀀

Time of adverse event (24-hour clock):

i) Specialty caring for patient

Specialty patient care Specialty adverse event occurrence

**Medical admission**

Cardiology – CCU 􀀀 􀀀

Dermatology 􀀀 􀀀

Endocrinology 􀀀 􀀀

Gastroenterology 􀀀 􀀀

Geriatrics 􀀀 􀀀

Haematology 􀀀 􀀀

Immunology and allergy 􀀀 􀀀

Infectious disease 􀀀 􀀀

Internal medicine 􀀀 􀀀

Medical oncology 􀀀 􀀀

Medical ophthalmology 􀀀 􀀀

Nephrology 􀀀 􀀀

Neurology 􀀀 􀀀

Pulmonary disease 􀀀 􀀀

Rheumatology 􀀀 􀀀

Other (specify) \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

**Surgical admission**

Anaesthesiology 􀀀 􀀀

Cardiac surgery 􀀀 􀀀

Colon/rectal surgery 􀀀 􀀀

General surgery 􀀀 􀀀

Neurosurgery 􀀀 􀀀

ENT surgery 􀀀 􀀀

Orthopaedic surgery 􀀀 􀀀

Plastic surgery 􀀀 􀀀

Thoracic surgery 􀀀 􀀀

Vascular surgery 􀀀 􀀀

Urologic surgery 􀀀 􀀀

Eye surgery 􀀀 􀀀

Other (specify) \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

**Emergency department** 􀀀 􀀀

**Intensive care**

Medical intensive care 􀀀 􀀀

Surgical intensive care 􀀀 􀀀

Uncertain 􀀀 􀀀

j) Area where the adverse event occurred:

􀀀 Emergency department

􀀀 Ward; specify \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

􀀀 Operating room

􀀀 Radiology

􀀀 Radiology – angiography

􀀀 Catheterisation lab

􀀀 Other (specify) \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

k) Additional care as a result of the adverse event

*Additional medical care*

Additional surgical intervention with general anaesthesia or regional anaesthesia

Additional surgical intervention under sedation

Technical procedure, non-operating room procedure

Consultation or preoperative assessment (additional)

Cardiac catheterisation

Angiography

Invasive diagnostic procedure

Any exam or test with control and nutritional or dietetic supervision

Additional treatment with frequency adjustment of dose and medical supervision

Clinical supervision by doctor (minimum 3 times per day)

Other: specify \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

*Additional nursing care*

Respiratory care: continuous or intermittent ventilator assistance (3 times per day)

Perfusion IV (continuous, intermittent, alimentation, medication)

Assessment of vital functions (every 2 hours for a min. 8 hours)

Daily hydroelectrolytic balance (input and output)

Operative or major posttraumatic wound care or drain care,

including care of operative site at least 3 times daily

(excluding permanent nasogastric tube or vesical drain)

Nursing supervision of clinical state of patient (minimum 3 times per day)

Isolation measures for prevention of contamination

Other: specify \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_