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Appendices

Describing adverse events in medical inpatients using the Global Trigger Tool

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Appendix 1: Description of the triggers

Modules and variables	Description
Care (C)	
Transfusion or use of blood products	Transfusion of red blood cells, blood platelets, fresh frozen plasma or use of blood products (e.g., albumin, Intratect®, Privigen®) during hospitalisation. Excessive bleeding (surgical, anticoagulant-related), unintentional trauma of a blood vessel etc. are examples of possible AEs.
CPR or MET activation or severe health deterioration	Rapid response team (resuscitation) or MET activation, severe health deterioration during hospitalisation. In the first 24 hours postoperatively it is very likely to be an AE. However, some CPR / MET activations can be related to the progression of a disease.
Acute dialysis	(New) acute dialysis during hospital stay. Drug-induced renal failure or reaction to the administration of a contrast medium for radiological procedures are example of possible AEs.
Positive culture	Patients with positive blood and urine cultures, as well as positive cultures from, for example, wound swaps or bronchoscopy. Excluded are positive urine cultures with mixed flora and antimicrobial activity if this was the only positive result. Generally, a positive culture 48–72 h after admission is considered as an in-hospital AE.
X-Ray or Doppler studies for emboli (lung) or DVT	Suspected or confirmed DVT or pulmonary embolism on admission / during hospitalisation. Confirmed DVT or lung emboli are considered as AEs. Excluded are emboli related to a disease process such as cancer or clotting disorders.
Decrease in haemoglobin or haematocrit ≥25%	Decrease in haemoglobin or haematocrit of >25% within 72 h or less during hospitalisation. A decrease itself or a decrease associated with a disease process is not an AE. An AE may be a bleeding event related to the use of anticoagulants, aspirin or a surgical complication.
Patient fall[b]	A fall is defined as an event, where a person unintentionally hits the floor or a lower level[*]. An in-hospital fall may be the result of medication, equipment failure or inadequate staffing. Falls resulting in injury (e.g., bruises, pain, fracture) are considered as an AE. Any fall that occurred outside the hospital is included, as the fall might be the result of medical treatment.
Pressure ulcers	Pressure ulcer or decubitus occurrence on admission and/or during hospitalisation, category 1–4. Categories 2–4 are considered as an AE. Redness of the skin described without specification and with no blanching is considered as pressure ulcer category 1.
Readmission within 30 days	Unplanned readmission within 30 days of discharge from the university hospital (e.g., unplanned readmission from rehabilitation centres to the university hospital are included as well). An emergency department visit within 30 days of discharge is not considered as a readmission. An unplanned readmission within 30 days of discharge is considered as an AE.

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Restraint use	Restraints used (e.g., bed safety guards, sensor mats, 1:1 round the clock bedside care) during hospital stay. A relationship between the use of restraints and confusions from drugs etc. indicate an AE.
Infections	Any infection occurring during admission, such as central venous infection, urinary tract infection, pneumonia, postoperative infection. Generally, infections occurring 48–72 h after admission are considered as in-hospital AEs. Infections that caused admission to the hospital were included as well.
Stroke	Any strokes or transient ischaemic attacks occurring before or during hospitalisation. If treatments (anticoagulation) and procedures (surgical, conversion of atrial fibrillation) have likely contributed to a stroke it is considered as an AE.
Transfer to higher level of care	Transfer to a higher level of care within the institution (telemetry, intermediate care, intensive care unit). All transfers to a higher level of care after surgery are included as well. All transfers are likely to be the result of an AE as patient's clinical condition may have deteriorated due to an AE.
Any procedure complication	Any procedure complications present on admission or during hospitalisation. A complication resulting from any procedure is considered as an AE.
Other	Any event that does not fit a trigger from the "care" and "medication" module.
Medication (M)	
Clostridium difficile-positive stool	*C. difficile*-positive stool. *C. difficile*-positive stool is considered an AE if a history of antibiotic use is present. Generally, a positive trigger 48–72 h after admission is considered as an in-hospital AE.
aPTT >100 seconds	aPTT higher than 100 seconds when patients are on heparin during hospitalisation. Elevated aPTT itself is not an AE – there must be manifestations such as bleeding, bruising, etc. Blood in stool without further diagnosis of its cause is not considered as AE.
INR >4	INR higher than 4 on admission / during hospitalisation. An elevated INR itself is not an AE – there must be manifestations such as bleeding, bruising, etc. and previously administered anticoagulants. Blood in stool without further diagnosis of its cause is not considered as AE.
Glucose ≤3 or ≥15 mmol/l	Glucose less than 3 mmol/l or higher than 15 mmol/l. Symptoms can be lethargy or shakiness. If the patient is symptomatic and there is an association with use of insulin or hypoglycaemics, it is considered as an AE. Administration of glucose, orange juice or any other intervention itself is not considered as an AE.
Serum creatinine two times over baseline	Change of laboratory results two times greater than baseline levels during hospitalisation. It is considered an AE if is caused by medication known to cause renal toxicity. If causes are physical, such as a pre-existing renal disease that leads to renal failure, it is not an AE but rather the progression of disease.
Vitamin K administration	Any administration of Vitamin K (Konakion®) during hospitalisation. If Vitamin K was used as a response to a prolonged INR and there is evidence of bleeding (bruising, gastrointestinal bleed), it is an AE.
Antihistamine administration	Administration of antihistamine during hospitalisation. Often used drug brands in the hospital are: Aerius®, Bilaxten®, Feniallerg®, Itinerol®, Tavegyl®, Telfast® or Xyzal®. An antihistamine is frequently used for allergic reactions to drugs but can also be ordered as sleep aid or preoperative/pre-procedure medication or for seasonal allergies. An allergic reaction to a drug or blood transfusion administered during hospitalisation or prior to admission is considered as AE.
Flumazenil administration	Administration of flumazenil (Anexate®) during hospitalisation. Flumazenil reverses the effect of benzodiazepine drugs. Prolonged sedation or severe hypotension are examples of possible AEs.
Naloxone administration	Administration of naloxone (Naloxon Orpha®) during hospitalisation. Combi-medication with naloxone such as Targin® are excluded. Nalaxone is an antagonist of narcotics. Usage likely represents an AE except in the case of drug abuse or self-inflicted overdose.
Anti-emetic administration	Anti-emetic administration (e.g., Primperan®, Motilium®, Emend®, Ondansetron Teva®) during hospitalisation. Nausea and vomiting that interfere with feeding or postoperative recovery, or delay discharge may suggest an AE.

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Oversedation/hypotension	Vital signs: hypotension (blood pressure <90 mm Hg). Chart notes: sedation or lethargy (German: “somnolent”, “lethargisch”, “schläfrig”). Hypotension and/or sedation/lethargy related to the administration of a sedative, analgesic or muscle relaxant may suggest an AE.
Abrupt medication stop	Abruptly stopped medications (>4) during hospitalisation. A sudden change in patient condition requiring adjustment of medication is often related to an AE.
Surgical (S)	
Troponin levels >1.5 ng/l or µg/ml[ab]	Troponin levels higher than 1.5 ng/l on admission / during hospitalisation. High troponin levels may indicate a cardiac event.
Any operative complication	Any number of perioperative complications during hospitalisation or prior to admission.
Self-developed triggers	
Sudden change in cognitive function	A sudden change or fluctuation in mental status such as attention, thinking, level of consciousness, memory, emotions or sleep-wake rhythm prior to admission or during hospitalisation. This may indicate delirium, which is considered as an AE.
Phlebitis or extravasation injury	Redness, induration, swelling or pain close by the vein and/or injection site during hospitalisation. Thrombophlebitis is considered as an AE.
Delay in discharge	Delay of discharge written in the patient record during hospital stay. A delay of discharge due to a medical condition may indicate an AE.
AE = adverse event; aPTT = activated partial thromboplastin time CPR = cardiopulmonary resuscitation; DVT = deep vein thrombosis; INR = international normalised ratio; MET = medical emergency team * Reference: Frank O, Schwendimann R. Sturzprävention - Orientierungshilfe und Empfehlungen. Schriftenreihe Patientensicherheit, Nr. 2, Schweiz, 2008	

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Appendix 2: Type, prevalence and severity of adverse events present on admission, for categories E to I only

Type of AE	Prevalence of AEs (n = 240)		Severity of AEs according to NCC MERP (E-I)*, n (%)				
	n	% (CI)	E	F	G	H	I
Infections	125	52.1 (45.6–58.6)	33 (26.4)	80 (64.0)	4 (3.2)	7 (5.6)	1 (0.8)
Fall	29	12.1 (8.2–16.9)	5 (17.2)	14 (48.3)	4 (13.8)	5 (17.2)	1 (3.5)
Abnormal blood values	18	7.5 (4.5–11.6)	4 (22.2)	10 (55.6)	2 (11.1)	2 (11.1)	0 (0.0)
Neurological reaction	13	5.4 (2.9–9.1)	1 (7.7)	11 (84.6)	0 (0.0)	0 (0.0)	1 (7.7)
Skin/tissue damage	12	5.0 (2.6–8.6)	8 (66.7)	1 (8.3)	3 (25.0)	0 (0.0)	0 (0.0)
Others	11	4.6 (2.3–8.1)	2 (18.2)	8 (72.7)	0 (0.0)0	1 (9.1)	0 (0.0)
Pressure ulcers	10	4.2 (2.0–7.5)	8 (80.0)	1 (10.0)	1 (10.0)	0 (0.0)	0 (0.0)
Thrombosis/embolism	9	3.8 (1.7–7.0)	1 (11.1)	5 (55.6)	2 (22.2)	1 (11.1)	0 (0.0)
Pain	8	3.3 (1.4–6.5)	0 (0.0)	8 (100.0)	0 (0.0)	0 (0.0)	0 (0.0)
Stroke / transient ischaemic attack	8	3.3 (1.4–6.5)	0 (0.0)	0 (0.0)	2 (25.0)	5 (62.5)	1 (12.5)
Bleeding	6	2.5 (0.9–5.4)	1 (16.7)	3 (50.0)	0 (0.0)	2 (33.3)	0 (0.0)
Nausea/vomiting	6	2.5 (0.9–5.4)	0 (0.0)	6 (100.0)	0 (0.0)	0 (0.0)	0 (0.0)
Loss of weight / reduced nutrient uptake	6	2.5 (0.9–5.4)	3 (50.0)	3 (50.0)	0 (0.0)	0 (0.0)	0 (0.0)
Inaccurate vital signs	5	2.1 (0.7–4.8)	1 (20.0)	4 (80.0)	0 (0.0)	0 (0.0)	0 (0.0)
Diarrhoea	3	1.2 (0.3–3.6)	2 (66.7)	1 (33.3)	0 (0.0)	0 (0.0)	0 (0.0)
Constipation	3	1.2 (0.3–3.6)	0 (0.0)	3 (100.0)	0 (0.0)	0 (0.0)	0 (0.0)
Surgical complications	2	0.8 (0.1–3.0)	0 (0.0)	2 (100.0)	0 (0.0)	0 (0.0)	0 (0.0)
Weakness	2	0.8 (0.1–3.0)	1 (50.0)	1 (50.0)	0 (0.0)	0 (0.0)	0 (0.0)
Allergic reaction	1	0.4 (0.0–2.3)	1 (100.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Threat / violence	1	0.4 (0.0–2.3)	0 (0.0)	1 (100.0)	0 (0.0)	0 (0.0)	0 (0.0)

AE = adverse event; CI = confidence interval; NCC MERP = The National Coordinating Council for Medication Error Reporting and Prevention Index

* NCC MERP Categories E–I (harm to patients); E = Temporary harm to the patient and required intervention, F = Temporary harm to the patient and required initial or prolonged hospitalisation, G = Permanent patient harm, H = Intervention required to sustain life, I = Patient death. (Reference: National Coordinating Council for Medication Error Reporting and Prevention (NCC MERP). Types of medication errors 2001 (cited 2019 June 17). Available from: https://www.nccmerp.org/types-medication-errors.)

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Appendix 3: Type, prevalence and severity of events during hospitalisation

Type of AE	Prevalence of Events (n = 240)		Severity of events according to NCC MERP* (n)					
	n	% (CI)	A–D	E	F	G	H	I
Skin/tissue damage	125	52.1 (45.6–58.6)	101	24	0	0	0	0
Inaccurate vital signs	88	36.7 (30.6–43.1)	79	7	1	0	1	0
Infections	81	33.8 (27.8–40.1)	19	26	28	2	5	1
Constipation	57	23.8 (18-5–29.6)	56	0	0	0	1	0
Neurological reaction	56	23.3 (18.1–29.2)	1	14	34	2	5	0
Abnormal blood value	56	23.3 (18.1–29.2)	44	5	6	0	1	0
Pressure ulcers	47	19.6 (14.8–25.2)	29	18	0	0	0	0
Readmission	36	15.0 (10.7–20.2)	0	0	34	0	2	0
Bleeding	29	12.1 (8.2–16.9)	8	13	5	1	2	0
Fall	22	9.2 (5.8–13.5)	16	4	1	1	0	0
Nausea/vomiting	20	8.3 (5.2–12.6)	12	7	1	0	0	0
Diarrhoea	14	5.8 (3.2–9.6)	4	6	4	0	0	0
Urinary retention	14	5.8 (3.2–9.6)	13	0	1	0	0	0
Surgical complications	14	5.8 (3.2–9.6)	1	5	2	1	5	0
Pain	10	4.2 (2.0–7.5)	10	0	0	0	0	0
Allergic reaction	9	3.8 (1.7–7.0)	1	7	0	0	1	0
Loss of weight / reduced nutrient uptake	8	3.3 (1.4–6.5)	1	1	6	0	0	0
Stroke / transient ischaemic attack	6	2.5 (0.9–5.4)	0	0	2	1	3	0
Suicidal/self-harming behaviour	2	0.8 (0.1–3.0)	0	1	1	0	0	0
Thrombosis/embolism	2	0.8 (0.1–3.0)	0	1	1	0	0	0
Anaesthesia-associated	2	0.8 (0.1–3.0)	0	0	0	0	2	0
Dehydration	1	0.4 (0.0–2.3)	1	0	0	0	0	0
Others	87	36.2 (30.2–42.7)	54	7	16	1	4	5

AE = adverse event; CI = confidence interval; NCC MERP = The National Coordinating Council for Medication Error Reporting and Prevention Index

* NCC MERP Categories E–I (harm to patients); E = Temporary harm to the patient and required intervention, F = Temporary harm to the patient and required initial or prolonged hospitalisation, G = Permanent patient harm, H = Intervention required to sustain life, I = Patient death. (Reference: National Coordinating Council for Medication Error Reporting and Prevention (NCC MERP). Types of medication errors 2001 (cited 2019 June 17). Available from: https://www.nccmerp.org/types-medication-errors.)

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Appendix 4: Type, prevalence, severity and preventability of adverse events during hospitalisation

Continuation of table 3 in the main article

Type of AE	Prevalence of AEs (n = 240)		Severity of AEs according to NCC MERP (E–I)* (n)					Preventability of AEs† Preventable %
	n	% (CI)	E	F	G	H	I	
Inaccurate vital signs	9	3.8 (1.7–7.0)	7	1	0	1	0	22.2
Allergic reaction	8	3.3 (1.4–6.5)	7	0	0	1	0	12.5
Nausea/vomiting	8	3.3 (1.4–6.5)	7	1	0	0	0	0.0
Loss of weight / reduced nutrient uptake	7	2.9 (1.2–5.9)	1	6	0	0	0	37.5
Stroke / transient ischaemic attack	6	2.5 (0.9–5.4)	0	2	1	3	0	16.7
Fall	6	2.5 (0.9–5.4)	4	1	1	0	0	50.0
Anaesthesia associated	2	0.8 (0.1–3.0)	0	0	0	2	0	0.0
Suicidal/self-harming behaviour	2	0.8 (0.1–3.0)	1	1	0	0	0	0.0
Thrombosis/embolism	2	0.8 (0.1–3.0)	1	1	0	0	0	0.0
Urinary retention	1	0.4 (0.0–2.3)	0	1	0	0	0	100.0
Constipation	1	0.4 (0.0–2.3)	0	0	0	1	0	0.0
Dehydration	0	0.0 (0.0–1.5)	0	0	0	0	0	0.0
Pain	0	0.0 (0.0–1.5)	0	0	0	0	0	0.0

AE = adverse event; CI = confidence interval; NCC MERP = The National Coordinating Council for Medication Error Reporting and Prevention Index

* NCC MERP Categories E–I (harm to patients); E = Temporary harm to the patient and required intervention, F = Temporary harm to the patient and required initial or prolonged hospitalisation, G = Permanent patient harm, H = Intervention required to sustain life, I = Patient death. (Reference: National Coordinating Council for Medication Error Reporting and Prevention (NCC MERP). Types of medication errors 2001 (cited 2019 June 17). Available from: https://www.nccmerp.org/types-medication-errors.)

† Preventability: probably preventable and preventable are regarded as "preventable" AEs.

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