Searches

# ▲	MEDLINE Searches	Results
1	((preventable or avoidable or unnecessary or untoward or ameliorable) adj2 (harm or complication* or omission)).mp.	1668
2	exp Medical Errors/cl, mt, pc, st, sn [Classification, Methods, Prevention & Control, Standards, Statistics & Numerical Data]	23681
3	exp medical error/pc or medical error.mp.	19329
4	"Drug-Related Side Effects and Adverse Reactions"/	28899
5	((Adverse drug or adverse medication) adj1 (event* or incident or reaction* or effect* or outcome*)).mp.	18911
6	Human error*.mp.	1603
7	((service* or system* or communication* or organization* or organisation* or treatment or therap* or diagnos*) adj1 (weak* or fail* or error* or mistake* or delay*)).mp.	129170
8	(adverse* adj1 (event* or outcome* or complication* or effect* or reaction*)).mp.	285222
9	((psychological or emotional or physical) adj1 (harm or complication*)).mp.	1129
10	patient safety.mp. or Patient Safety/	26908
11	(death* or accident or serious incident* or injur* or adverse event*).mp.	1770259
12	10 and 11	4389
13	(never event* or near miss*).mp.	1797
14	(iatrogenic adj (harm or injur* or complication*)).mp.	2862
15	Patient Harm/ or patient harm.mp.	914
16	Diagnostic Errors/	38362
17	(preventable or avoidable or unnecessary or untoward or ameliorable).mp.	76388
18	2 or 3 or 4 or 5 or 6 or 7 or 8 or 9 or 12 or 13 or 14 or 15 or 16	441852
19	17 and 18	7129

20	1 or 19	8482
21	Prevalence/ or prevalence.mp.	547386
22	incidence.mp. or Incidence/	698801
23	Epidemiologic Studies/	8042
24	exp Case-Control Studies/	897333
25	(epidemiologic* adj (study or studies)).mp.	78191
26	case control.mp.	282010
27	exp Cohort Studies/	1765445
28	Cross-Sectional Studies/	259191
29	(cohort adj (study or studies)).mp.	302778
30	Cohort analy*.mp.	5992
31	(follow up adj (study or studies)).mp.	634329
32	longitudinal.mp.	237282
33	Retrospective.mp.	730249
34	Prospective.mp.	648409
35	(observ* adj1 (study or studies)).mp.	88143
36	(analytical adj (study or studies)).mp.	3110
37	(comparative adj (study or studies)).mp.	1977764
38	(evaluation adj (study or studies)).mp.	379513
39	Meta-analysis/	82995
40	((Systematic or narrative) adj review).mp.	75440
41	Clinical Trial/ or Randomized Controlled Trial/	798769
42	or/23-41	4859990
43	20 and 42	3466

44	21 or 22	1176178
45	20 and 44	1662
46	43 or 45	4150
47	limit 46 to (english language and yr="2000 -Current")	3090

	EMBASE Searches	Results
1	((preventable or avoidable or unnecessary or untoward or ameliorable) adj2 (harm or complication* or omission)).mp.	2681
2	exp medical error/pc or medical error.mp.	20146
3	"Drug-Related Side Effects and Adverse Reactions"/	147260
4	((Adverse drug or adverse medication) adj1 (event* or incident or reaction* or effect* or outcome*)).mp.	1311288
5	Human error*.mp.	2936
6	((service* or system* or communication* or organization* or organisation* or treatment or therap* or diagnos*) adj1 (weak* or fail* or error* or mistake* or delay*)).mp.	253754
7	(adverse* adj1 (event* or outcome* or complication* or effect* or reaction*)).mp.	484261
8	((psychological or emotional or physical) adj1 (harm or complication*)).mp.	1776
9	patient safety.mp. or Patient Safety/	95003
10	(death* or accident or serious incident* or injur* or adverse event*).mp.	2716696
11	9 and 10	19087
12	(never event* or near miss*).mp.	3290
13	(iatrogenic adj (harm or injur* or complication*)).mp.	4529
14	Patient Harm/ or patient harm.mp.	2140
15	Diagnostic Errors/	44515
16	(preventable or avoidable or unnecessary or untoward or ameliorable).mp.	113295
17	Epidemiologic Studies/	199895
18	exp Case-Control Studies/	134951
19	(epidemiologic* adj (study or studies)).mp.	95355
20	case control.mp.	185587

21	exp Cohort Studies/	341127
22	Cross-Sectional Studies/	103615
23	(cohort adj (study or studies)).mp.	213334
24	Cohort analy*.mp.	343331
25	(follow up adj (study or studies)).mp.	58024
26	longitudinal.mp.	286746
27	Retrospective.mp.	896288
28	Prospective.mp.	818727
29	(observ* adj1 (study or studies)).mp.	163996
30	(analytical adj (study or studies)).mp.	5391
31	(comparative adj (study or studies)).mp.	771045
32	(evaluation adj (study or studies)).mp.	35313
33	Meta-analysis/	138129
34	((Systematic or narrative) adj review).mp.	209731
35	Clinical Trial/ or Randomized Controlled Trial/	1150050
36	2 or 3 or 4 or 5 or 6 or 7 or 8 or 11 or 12 or 13 or 14 or 15	1848097
37	16 and 36	18155
38	1 or 37	20108
39	or/17-35	4317801
40	38 and 39	6944
41	limit 40 to (yr="2000 -Current" and article)	3037

	PsycINFO Searches	**Results**
1	((preventable or avoidable or unnecessary or untoward or ameliorable) adj2 (harm or complication* or omission)).mp.	146
2	exp medical error/pc or medical error.mp.	272
3	((Adverse drug or adverse medication) adj1 (event* or incident or reaction* or effect* or outcome*)).mp.	1437
4	Human error*.mp.	848

5	((service* or system* or communication* or organization* or organisation* or treatment or therap* or diagnos*) adj1 (weak* or fail* or error* or mistake* or delay*)).mp.	8136
6	(adverse* adj1 (event* or outcome* or complication* or effect* or reaction*)).mp.	28802
7	((psychological or emotional or physical) adj1 (harm or complication*)).mp.	1356
8	patient safety.mp. or Patient Safety/	3413
9	(death* or accident or serious incident* or injur* or adverse event*).mp.	195024
10	8 and 9	617
11	(never event* or near miss*).mp.	472
12	(iatrogenic adj (harm or injur* or complication*)).mp.	133
13	Patient Harm/ or patient harm.mp.	150
14	(preventable or avoidable or unnecessary or untoward or ameliorable).mp.	11017
15	2 or 3 or 4 or 5 or 6 or 7 or 10 or 11 or 12 or 13	40899
16	14 and 15	577
17	1 or 16	695
18	limit 17 to (english language and yr="2000 -Current")	620
19	limit 18 to "0100 journal"	498

eTable 1: Severity and main types of preventable patient harm.

Severity	**Definition and examples**
Mild harm	Patient outcome is symptomatic, symptoms are mild, loss of function or harm is minimal or intermediate but short term, and no or minimal intervention is required; it is typically resolved within one month
Moderate harm	Patient outcome is symptomatic, requiring intervention, an increased length of stay, or temporary disability or loss of function; it is typically resolved within one year.
Severe harm/death	Patient outcome is symptomatic, requiring life-saving/major, shortening life expectancy, causing death or major permanent or long term harm or loss of function; results in death or permanent disability.
Types	**Content/examples**
Medication management	Adverse drug events and adverse drug reactions which occurred in prescribing/ordering of medication stage, administration stage, dispensing and monitoring stage.
Non-drug therapeutic management	Incidents caused by suboptimal healthcare management such as inappropriate treatment and delegation, delay or failure in tracking and monitoring, wrong referral, or wrong use of healthcare resource.
Diagnosis	Missed, wrong, delayed or inappropriate diagnostic incidents resulting from failure to capture documented signs, symptoms, and laboratory tests, not ordering an indicated diagnostic test or not undertaking adequate patient assessment.
Invasive medical procedures	Errors, complications or injuries before, during or after invasive clinical procedures such as complications in central catheters, endoscopes, bronchoscopies, pacemakers, central line placement, intervention radiology, haematoma following venepuncture, bleeding or low saturation after tracheostomy.
Surgical procedures	Errors or avoidable complications occurring during the operation or shortly after the operation such as infection, accidental tissue damage, bleeding, dysrhythmia, laceration of organ/blood vessel, urine retention, atelectasis, pericardial/pleural effusion, myocardial infraction.
Healthcare-acquired infections	Infections occurring after medical procedures such as an infection in the surgical wound, nosocomial urinary tract infection, fungal sepsis, or central line associated blood stream infection.

eTable 2: Characteristics of included studies (n=~~72~~)

Study ID	Country	Design	Setting	N	Population	method
Agarwal et al, 2010	USA	Cross-sectional	Intensive Care	734	Children/ adolescents	Patient record review
Aibar et al, 2015	Spain	Retrospective	Obstetrics	836	Adults	Patient record review
Amaral et al, 2015	Canada	Prospective	Intensive Care	247	Adults	Patient record review
Aranas-andres et al, 2008/2009	Spain	Retrospective	Hospitals	5,624	Adults	Patient record review
Aranaz-andres et al, 2011	Argentina, Colombia, Mexico, Peru	Cross-sectional	Hospitals	11,379	Adults	Patient record review
Aranaz-andres et al, 2012	Spain	Cross-sectional	Primary Care	96,047	Adults	Health providers inserted data on a reporting system approach
Baines et al, 2013	Netherlands	Retrospective	Hospitals	4,023	Adults	Patient record review
Baker et al, 2004	Canada	Retrospective	Hospitals	4,164	Adults	Patient record review
Bartlett et al, 2008	Canada	Retrospective	Hospitals	2,355	Adults	Patient record review
Blais et al, 2013	Canada	Retrospective	Hospitals	1261	Adults	Patient record review
Calder et al, 2010	Canada	Prospective	Emergency Department	503	Adults	Patient record review
Calder et al, 2015	Canada	Prospective	Emergency Department	13,495	Adults	Patient record review
Davis et al, 2013	New Zealand	Retrospective	Hospitals	6,579	Adults	Patient record review
Florea et al, 2010	Canada	Retrospective	Obstetrics	6,752	Adults	Patient record review
Forster et al, 2003	Canada	Prospective	Hospitals	400	Older adults	Patient record review
Forster et al, 2006	Canada	Prospective	Obstetrics	425	Adults	Patient record review
Forster et al, 2007	Canada	Prospective	Intensive Care	207	Adults	Clinical surveillance
Forster at al, 2008	Canada	Prospective	Emergency Department	328	Adults	Patient record review
Forster et al, 2011	Canada	Prospective	Hospitals	1,406	Adults	Clinical surveillance
Fowler et al, 2008	USA	Prospective	Hospitals	2,582	Adults	Patient survey
Friedman et al, 2008	Canada	Prospective	Emergency Department	292	Adults	Patient record review
Halfon et al, 2017	Sweden	Cross-sectional	Surgical unit	600	Adults	Patient record review
Halfon et al, 2017	Sweden	Cross-sectional	Hospitals	400	Adults	Patient record review
Healey et al, 2002	USA	Prospective	Surgical unit	3,395	Adults	Patient record review
Hendrie et al, 2007	Australia	Retrospective	Emergency Department	3,332	Adults	Patient record review
Hendrie et al, 2017	Australia	Case-control	Emergency Department	2,167	Adults	Patient record review
Herrera et al, 2005	Mexico	Retrospective	Hospitals	4,555	Adults	Patient record review

Hoorgervorst-schiilp et al, 2015	Netherlands	Retrospective	Hospitals	2,975	Adults	Patient record review
Hwang et al, 2014	South Korea	Retrospective	Hospitals	629	Adults	Patient record review
Kable et al, 2002	Australia	Retrospective	Surgical unit	17,179	Adults	Patient record review
Kennerly et al, 2014	USA	Prospective	Hospitals	9,017	Adults	Patient record review
Khan et al, 2016	USA	Prospective	Hospitals	383	Children/ adolescents	Patient survey
Larsen et al, 2007	USA	Retrospective	Intensive Care	259	Children/ adolescents	Patient record review
Letaief et al, 2010	Tunisia	Retrospective	Hospitals	620	Adults	Patient record review
Lipitz-Snyderman et al, 2017	USA	Retrospective	Oncology	400	Adults	Patient record review
Maflow et al, 2012	Canada	Cross-sectional	Hospitals	3669	Children/ adolescents	Patient record review
Mayor et al, 2018	UK	Retrospective	Hospitals		adults	Patient record review
Mendes et al, 2009	Brazil	Retrospective	Hospitals	1,103	Adults	Patient record review
Merino et al, 2012	Spain	Retrospective	Intensive Care	1,017	Adults	Health providers survey
Merten et al, 2013 (a)	Netherlands	Retrospective	Hospitals	4744	Adults	Patient record review
Merten et al, 2013 (b)	Netherlands	Retrospective	Hospitals	3173	Older adults	Patient record review
Michel et al, 2004 (a)	France	Cross-sectional	Hospitals	778	Adults	Survey of health providers
Michel et al, 2004 (b)	France	Prospective	Hospitals	778	Adults	Survey of health providers
Michel et al, 2004 (c)	France	Retrospective.	Hospitals	778	Adults	Survey of health providers
Montserrat-Capella et al, 2015	Mexico. Peru, brazil, Colombia	Prospective	Emergency Department	2,080	Adults	Patient record review
~~**Montserrat-Capella et al, 2015**~~	~~Mexico. Peru, brazil, Colombia~~	~~Retrospective~~	~~Emergency Department~~	~~2,080~~	~~Adults~~	~~Patient record review~~
Najjar et al, 2013	Israel	Retrospective	Hospitals	640	Adults	Patient record review
Nilsson et al, 2012	Sweden	Retrospective	Hospitals	128	Adults	Patient record review
Nilsson et al, 2016	Sweden	Retrospective	Surgical unit	3,301	Adults	Patient record review
Nilsson et al, 2018	Sweden	Retrospective	Hospitals	64,917	Adults	Patient record review
Nuckols et al, 2007	USA	Retrospective	Hospitals	2244	Adults	Patient record review
Pucher et al, 2013	UK	Retrospective	Hospitals	1,752	Adults	Patient record review
Rafter et al, 2015	Ireland	Retrospective	Hospitals	1,574	Adults	Patient record review
Rajasekaran et al, 2016	India	Prospective	Hospitals	4,906	Adults	Patient record review
Rothschild et al, 2005	USA	Retrospective	Intensive Care	391	Adults	Patient record review
Sari et al, 2007/2008	UK	Retrospective	Hospitals	1,006	Adults	Patient record review

Sari et al, 2015	Iran	Retrospective	Hospitals	1,162	Adults	Patient record review
Soop et al, 2009	Sweden	Retrospective	Hospitals	1,967	Adults	Patient record review
Sousa et al, 2014	Portugal	Retrospective	Hospitals	1,669	Adults	Patient record review
Stockwell et al, 2015	USA	Retrospective	Hospitals	600	Children/ adolescents	Patient record review
Stockwell et al, 2017	USA	Retrospective	Hospitals	3790	Children/ adolescents	Patient record review
Suarez et al, 2014	Spain	Retrospective	Hospitals	1,440	Older adults	Patient record review
Thomas et al, 2000 (a)	USA	Retrospective	Hospitals	4,000	Older adults	Patient record review
Thomas et al, 2000 (b)	USA	Retrospective	Hospitals	7,200	Adults	Patient record review
Vincent et al, 2001	UK	Retrospective	Hospitals	1,014	Adults	Patient record review
Weingart et al, 2005	USA	Prospective	Hospitals	228	Adults	Patient survey
Williams et al, 2008	UK	Retrospective	Hospitals	354	Adults	Patient record review
Wilson et al, 2012	8 African countries	Retrospective	Hospitals	15,548	Adults	Patient record review
Woods et al, 2006	USA	Retrospective	Hospitals	879	Children/ adolescents	Patient record review
Zegers et al, 2009	Netherlands	Retrospective	Hospitals	7,926	Adults	Patient record review
De Wet et al, 2009	UK	Retrospective	Primary Care	500	Adults	Patient record review

eTable 3: The assessment of preventable patient harm across studies (N=72)

Study ID	Assessment process	Definition of harm	Severity of preventable harm	Type of preventable harm
Agarwal et al, 2010	**2-stage process**: Initially nurses or physicians reviewed records for the presence/absence of 22 triggers for potential harm. Each identified trigger prompted an in depth investigation for the presence of harm. The findings of the in-depth investigation were presented to a pharmacist and physician who made the final decision. A consensus procedure was used among the reviewers about causation, preventability and severity of harm and the final determination was made by intensive care physician in case of discrepancy.	**Harm:** An injury, large or small, caused by the use (including non-use) of a drug, test, or medical treatment identified during the PICU stay. **Preventable harm:** may have been avoidable, given the appropriate implementation of evidence-based medicine and/or appropriate use of available resources.	n/r	n/r
Aibar et al, 2015	**2-stage process:** Initially trained nurses reviewed records using criteria listed in a validated screening guide for for the presence/absence of patient harm. Next a team of external reviewers (physicians) reviewed the patient records who met at least one of the criteria in the screening guide and made the final decision regarding causation, preventability and severity of patient harm. Consensus for preventability was facilitated with the use of a **score of 4 or higher in a standard 6-point Likert scale.**	**Harm:** Any unforeseen and unexpected accident recorded in the medical record that cause injury and/or disability and/or prolonged the hospital stay and/or led to death which was the result of health care and not the patient's underlying condition. **Preventable harm:** Any event causing harm to the patient that was perceived to be more related to the healthcare management rather than to the patient's underlying condition.	Permanent injury or death =severe, a new consultation, surgical treatment, medication or admission to a hospital=moderate.	Clinical procedure; Surgical procedure;
Amaral et al, 2015	**2-stage consensus process:** Initially trained nurses reviewed records using criteria listed in a validated screening guide for for the presence/absence of patient harm. Next a team of external reviewers (physicians) reviewed the patient records who met at least one of the criteria in the screening guide and made the final decision regarding causation, preventability and severity of patient harm. Consensus for preventability was facilitated with the use of a score of **4 or higher in a standard 6-point Likert scale.**	**Harm:** Any unplanned injury arising as a direct consequence of healthcare leading to increased morbidity (requirement for new treatments, prolongation of hospital stay or disability at hospital discharge) or mortality and unexplainable by the patient's underlying condition. **Preventable harm:** decided on the basis of whether it could have been avoided if errors of omission or commission did not occur.	Causing death of the patient or permanent disability= severe; lengthened hospital stay = moderate mild=others were considered slight.	n/r
Aranas-andres et al, 2008/2009	**2-stage consensus process:** Initially trained nurses reviewed records using criteria listed in a validated screening guide for for the presence/absence of patient harm. Next a team of external reviewers (physicians) reviewed the patient records who met at least one of the criteria in the screening guide and made the final decision regarding causation, preventability and severity of patient harm. Consensus for preventability was facilitated with the use of a score of **4 or higher in a standard 6-point Likert scale.**	**Harm:** Any unforeseen and unexpected accident recorded in the medical record that cause injury and/or disability and/or prolonged the hospital stay and/or led to death which was the result of health care and not the patient's underlying condition. **Preventable harm:** Any event causing harm to the patient that was perceived to be more related to the healthcare management rather than to the patient's underlying condition.	Causing death of the patient or permanent disability= severe; lengthened hospital stay = moderate mild=others were considered slight.	Medication; Diagnosis; Clinical procedure; Infections;

Aranaz-andres et al, 2011	**2-stage consensus process:** Initially trained nurses or physicians reviewed records using criteria listed in a validated screening guide for for the presence/absence of 19 triggers or criteria. Next a team of external reviewers (physicians) reviewed the patient records who met at least one of the criteria in the screening guide and made the final decision following consensus.	**Harm:** any event causing harm to the patient that was perceived to be more related to the healthcare management rather than to the patient's underlying condition. **Preventable harm:** any event causing harm to the patient that was perceived to be more related to the healthcare management rather than to the patient's underlying condition.	Causing death of the patient or permanent disability= severe; lengthened hospital stay = moderate mild=others were considered slight.	n/r
Aranaz-andres et al, 2012	**1-stage process:** The primary care health professionals (physicians and nurses) had to report any condition that might indicate harm on a reporting system approach and include their assessments in terms of whether harm was caused by the healthcare (causation) and preventability. Consensus for preventability was facilitated with the use of a score of **4 or higher in a standard 6-point Likert scale.**	**Harm:** Any incident causing harm to the patient and related to the healthcare provided rather than a consequence of the patients' underlying condition. A validated causality measure was used using a 6-point scale (score of 4 and above). **Preventable harm:** Any event causing harm to the patient that was perceived to be more related to the healthcare management rather than to the patient's underlying condition.	Permanent injury or death =severe, a new consultation, surgical treatment, medication or admission to a hospital=moderate.	Medication; Therapeutic management; Clinical procedure; Infections;
Baines et al, 2013	**2-stage process.** Initially trained nurses reviewed records using criteria listed in a validated screening guide for for the presence/absence of 16 triggers or criteria. Next physicians reviewed the patient records who met at least one of the criteria in the screening guide and made the final decision about causation, preventability and severity of harm. Consensus for preventability was facilitated with the use of a score of **4 or higher in a standard 6-point Likert scale**	**Harm:** An unintended injury resulting in a longer stay in hospital, a temporary or permanent disability, or death which was caused by healthcare management rather than the patient's disease.	Causing death of the patient or permanent disability= severe; lengthened hospital stay = moderate mild=others were considered slight.	Medication; Diagnosis; Clinical procedure; Surgical procedure;
Baker et al, 2004	**2-stage process**: Initially trained nurses reviewed records using criteria listed in a validated screening guide for for the presence/absence of 16 triggers or criteria. Next physicians reviewed the patient records who met at least one of the criteria in the screening guide and made the final decision about causation, preventability and severity of harm. Consensus for preventability was facilitated with the use of a score of **4 or higher in a standard 6-point Likert scale.**	**Harm:** An unintended injury resulting in a longer stay in hospital, a temporary or permanent disability, or death which was caused by healthcare management rather than the patient's disease.	Moderate=temporary impairment of function lasting up to a year; severe= permanent impairment of function or death.	n/r
Bartlett et al, 2008	**1-stage process:** The primary care health professionals (physicians and nurses) had to report any condition that might indicate harm on a reporting system and include their assessments in terms of whether harm was caused by the healthcare (causality) and preventability. Consensus for preventability was facilitated with the use of a score of **4 or higher in a standard 6-point Likert scale**	**Harm:** Any incident causing harm to the patient and related to the healthcare provided rather than a consequence of the patients' underlying condition. A validated causality measure was used using a 6-point scale (score of 4 and above). **Preventable harm:** Any event causing harm to the patient that was perceived to be more related to the healthcare management rather than to the patient's underlying condition.	n/r	Medication; Therapeutic management;
Blais et al, 2013	**2-stage process**. Initially trained nurses reviewed records using criteria listed in a validated screening guide for for the presence/absence of 24 triggers or criteria. Next physicians reviewed the patient records who met at least one of the criteria in the screening guide and made the final decision about causation, preventability and severity of harm. Consensus	**Harm:** An injury, harm or complication that results in disability, death or increased use of healthcare resources, and that is caused by health care rather than by the client's underlying disease process.	Moderate=temporary impairment of function lasting up to a year; severe= permanent impairment of function or death.	n/r

	for preventability was facilitated with the use of a score of **4 or higher in a standard 6-point Likert scale**			
Calder et al, 2010	**2-stage process:** Medical students using a standard list of flagged outcomes indicating potential harm reviewed patient records. Next, an independent physician panel made judgement for causation, preventability and severity of patient harm using consensus procedures for records meeting at least one criterion in stage 1.	**Harm:** Flagged outcome associated with ED management. **Preventable harm**: Caused by a health care management problem such as a diagnostic issue, management issue, unsafe disposition decision, suboptimal follow-up, medication adverse effect or procedural complication.	n/r	Medication; Diagnosis; Therapeutic management; Clinical procedure;
Calder et al, 2015	**2-stage process.** Initially trained nurses reviewed records using criteria listed in a validated screening guide for for the presence/absence of 18 screening criteria. Next physicians reviewed the patient records who met at least one of the criteria in the screening guide and made the final decision about causation, preventability and severity of harm. Consensus for preventability was facilitated with the use of a score of **4 or higher in a standard 6-point Likert scale**	**Harm**: an adverse outcome related to the care received during the index visit. **Preventable harm:** caused by healthcare management problem such as a diagnostic issue, management issue, unsafe disposition decision or suboptimal follow-up.	Moderate=temporary impairment of function lasting up to a year; severe= permanent impairment of function or death.	n/r
Davis et al, 2013	**2-stage process.** Initially trained nurses reviewed records using criteria listed in a validated screening guide for for the presence/absence of 18 screening criteria. Next physicians reviewed the patient records who met at least one of the criteria in the screening guide and made the final decision about causation, preventability and severity of harm using consensus procedures.	**Harm:** an unintended injury resulting in disability and caused by healthcare management rather than the underlying disease process.an unintended injury resulting in disability. **Preventable harm:** an error in healthcare management due to failure to follow accepted practice at an individual or system level.	Serious=permanent disability (lasting more than 1 year) or death.	Diagnosis; Therapeutic management; Clinical procedure; Surgical procedure;
Florea et al, 2010	**2-stage process.** Initially trained nurses reviewed records using criteria listed in a validated screening guide for for the presence/absence of a list of standard screening criteria. Next obstetricians reviewed the patient records who met at least one of the criteria in the screening guide and made the final decision using implicit criteria for preventability and severity of harm using consensus procedures.	**Harm:** associated with communication errors e.g. caused to the mother or baby with communication, record keeping and wrong results. **Preventable harm:** Specific factors were considered in the determination of preventability, such as whether standard protocols were followed, or whether there were obvious errors in clinical performance or communication.	n/r	n/r
Forster et al, 2003	**2-stage process:** Initially trained nurses reviewed records using criteria listed in a validated screening guide for for the presence/absence of a list of 18 triggers. Next physicians reviewed the patient records who met at least one of the criteria in the screening guide and made the final decision about causation, preventability as severity of harm using consensus procedures. The two reviewers used implicit criteria for preventability and if they did not agree a third experienced reviewer was involved.	**Harm:** an injury resulting from medical management rather than the underlying disease. **Preventable harm:** an injury that could have been avoided, that is, an injury judged to probably be the result of an error or a system design flaw. The two reviewers used implicit criteria for preventability and if they did not agree a third experienced reviewer was involved.	Mild=laboratory abnormality only, one day of symptoms; moderate= several days of symptoms, non-permanent disability, Serious=permanent disability, or death.	Mild=laboratory abnormality only, one day of symptoms; moderate= several days of symptoms, non-permanent disability, Serious=permanent disability, or death.
Forster et al, 2006	**2-stage process:** Initially trained nurses reviewed records using criteria listed in a validated screening guide for for the presence/absence of a list of 18 triggers. Next physicians reviewed the patient records who met at least one of the criteria in the screening guide and made the final decision about causation, preventability and severity of harm using consensus procedures. The two reviewers used implicit criteria for	**Harm:** an adverse outcome due to health care management as opposed to progression of natural disease. **Preventable harm:** urged to be avoidable by means available in routine practice.	n/r	n/r

	preventability and if they did not agree a third experienced reviewer was involved.			
Forster et al, 2007	**2-stage process:** Initially trained nurses identified potential incidents of patient harm in clinical occurrences. Next physicians reviewed the flagged cases who met at least one of the criteria in the screening guide and made the final decision about causation, preventability and severity of harm using consensus procedures. Cases of harm were reviewed by the panel using implicit criteria to determine if they were avoidable with the available resources and currently accepted practices.	**Harm:** patient injuries caused by medical care. For each adverse clinical occurrence, the review panel determined whether the occurrence was truly an event in which the patient's status changed. **Preventable harm:** avoidable with the available resources and currently accepted practices.	Mild=laboratory abnormality only, one day of symptoms; moderate= several days of symptoms, non-permanent disability, Serious=permanent disability, or death.	Mild=laboratory abnormality only, one day of symptoms; moderate= several days of symptoms, non-permanent disability, Serious=permanent disability, or death.
Forster at al, 2008	**2-stage process:** Initially trained nurses reviewed records using criteria listed in a validated screening guide for for the presence/absence of a list of 18 triggers. Next physicians reviewed the patient records who met at least one of the criteria in the screening guide and made the final decision about causation, preventability as severity of harm using consensus procedures. The two reviewers used implicit criteria for preventability and if they did not agree a third experienced reviewer was involved.	**Harm:** an adverse outcome due to health care management as opposed to progression of natural disease. **Preventable harm:** judged to be avoidable by means available in routine practice.	'significant', 'severe', 'life-threatening', or 'fatal.	'significant', 'severe', 'life-threatening', or 'fatal.
Forster et al, 2011	**2-stage process**: Initially trained nurses identified potential incidents of patient harm in clinical occurrences. Next physicians reviewed the flagged cases who met at least one of the criteria in the screening guide and made the final decision about causation, preventability and severity of harm using consensus procedures. Cases of harm were reviewed by the panel using implicit criteria to determine if they were avoidable with the available resources and currently accepted practices.	**Harm:** patient injuries caused by medical care. For each adverse clinical occurrence, the review panel determined whether the occurrence was truly an event in which the patient's status changed. **Preventable harm:** avoidable with the available resources and currently accepted practices.	Mild=laboratory abnormality only, one day of symptoms; moderate= several days of symptoms, non-permanent disability, Serious=permanent disability, or death.	Mild=laboratory abnormality only, one day of symptoms; moderate= several days of symptoms, non-permanent disability, Serious=permanent disability, or death.
Fowler et al, 2008	**2-stage process:** Initially interviewers conducted a patient survey where participants were asked standard questions for common sources of problems during their hospital stay and were prompted against a list of 11 common medical and surgical complications. Next, independent trained reviewers rated the print-out copies of the interviews. The two reviewers used implicit criteria to reach consensus preventability and if they did not agree a third experienced reviewer was involved.	**Harm: v**ents leading to intensive care treatment or death caused by medical care rather than the patients' underlying condition. **Preventable harm:** Cases of harm were reviewed by the reviewers to determine if they were avoidable with the available resources and currently accepted care practices in average Hospital in the US .	Severe=intensive care treatment or death.	Severe=intensive care treatment or death.
Friedman et al, 2008	**2-stage process:** Initially interviewers conducted a patient survey where participants were asked 4 standard questions for their ED experience followed by prompt questions if the response was positive. Next, print-out copies were reviewed by two independent trained reviewers and ED physicians. The two reviewers used implicit criteria to reach consensus preventability and if they did not agree a third experienced reviewer was involved.	**Harm:** unintended injury or complication caused by health care management rather than the patient's underlying disease.	Serious=permanent injury or death, moderate=a new consultation, surgical treatment, medication or admission.	Serious=permanent injury or death, moderate=a new consultation, surgical treatment, medication or admission.

Halfon et al, 2017	2-stage process. Initially trained nurses or physicians reviewed the patient case notes to identify using a modified version of the Adverse Patient Occurrence inventory to identify potential incidents of harm. Next, experienced physicians reviewed all potential incidents for causation, preventability, types and severity. Consensus was reached on the basis of a priori preventability judgement being attributed to each cause, based on a literature review and study team consensus.	Harm: injury or unintended complication caused by healthcare rather than by the patient's disease and resulting in permanent or temporary disability at time of discharge, death or prolonged hospital stay of at least 1 day.	n/r	n/r
Halfon et al, 2017	**2-stage process:** Initially trained nurses or physicians reviewed the patient case notes to identify using a modified version of the Adverse Patient Occurrence inventory to identify potential incidents of harm. Next, experienced physicians reviewed all potential incidents for causation, preventability, types and severity. Consensus was reached on the basis of a priori preventability judgment being attributed to each cause, based on a literature review and study team consensus.	**Harm:** Injury or unintended complication caused by healthcare rather than by the patient's disease and resulting in permanent or temporary disability at time of discharge, death or prolonged hospital stay of at least 1 day.	n/r	n/r
Healey et al, 2002	**2-stage process:** Initially surgical unit personnel reviewed the patient case notes to identify potential incidents of harm. Next, surgeons reviewed all potential incidents uncial consensus were reached for preventability.	**Harm:** Unintended injury or complication resulting in disability, death, prolong hospital stay and caused by health care management rather than patient disease. Preventable harm: if there were deficiencies in care as assessed by surgeon's peer groups.	n/r	n/r
Hendrie et al, 2007	**2-stage process:** Initially two registrars with 10 years' postgraduate experience reviewed the patient case notes to identify potential incidents of harm for the first 200 records. Afterward the process was by one reviewer following satisfactory inter-rater agreement in a proportion of charts. If there were any concerns, a panel of reviewers was involved. Consensus for preventability was facilitated with the use of a score of **3 or higher in a standard 6-point Likert scale.**	**Harm:** (i) an unintended injury or complication, which (ii) resulted in disability, death, prolongation of the hospital stay, or prolongation of the natural history of the disease; and (iii) is caused by health care management rather than the patient's disease.	Serious=permanent injury or death; Moderate: new consultation, surgical treatment, medication or admission.	n/r
Hendrie et al, 2017	**2-stage process:** Initially two registrars with 10 years' postgraduate experience reviewed the patient case notes to identify potential incidents of harm for the first 200 records. Afterward the process was by one reviewer following satisfactory inter-rater agreement in a proportion of charts. If there were any concerns, a panel of reviewers was involved. Consensus for preventability was facilitated with the use of a score of **3 or higher in a standard 6-point Likert scale.**	**Harm:** (i) an unintended injury or complication, which (ii) resulted in disability, death, prolongation of the hospital stay, or prolongation of the natural history of the disease; and (iii) is caused by health care management rather than the patient's disease.	n/r	n/r
Herrera et al, 2005	**2-stage process:** Experienced trained physicians reviewed the patient records to identify potential incidents of harm based on a standard protocol. If there were any concerns about specific cases, a second senior reviewer was involved to decide about preventability.	**Harm:** an unintended injury or complication resulting in disability, death, prolong hospital stay and caused by health care management rather than patient disease.	n/r	Medication; Diagnosis; Therapeutic management; Surgical procedure; Infections;
Hoorgervorst -schiilp et al, 2015	**2-stage process:** Initially trained nurses screened the patient records using 16 standard screening criteria indicating potential harm. Next, experienced physicians reviewed all medical records meeting at least one criterion in stage 1. Consensus for preventability was facilitated with the use of a score of **4 or higher in a standard 6-point Likert scale.**	**Harm:** (i) an unintended injury or complication, which (ii) resulted in disability, death, prolongation of the hospital stay, or prolongation of the natural history of the disease; and (iii) is caused by health care management rather than the patient's disease. Preventable harm: care given fell below the current	n/r	n/r

		level of expected performance for practitioners or systems.		
Hwang et al, 2014	**2-stage process:** Initially quality improvement specialist screened the patient records using 53 standard triggers indicating potential harm. Next, experienced physician reviewed 60 randomly selected medical records to confirm inter-rater reliability. Consensus for preventability was facilitated with the use of a score of **4 or higher in a standard 6-point Likert scale.**	**Harm:** Occurred because of medical care or services rather than as a cause of underlying diseases or medical conditions. AEs related to the active delivery of care (acts of commission), but excluded those by acts of omission related to substandard care.	Mild, moderate, severe and death.	n/r
Kable et al, 2002	**2-stage process:** Initially quality improvement specialist screened the patient records using standard triggers indicating potential harm. Next, experienced physician reviewed a number of randomly selected medical records to confirm inter-rater reliability.	**Harm:** an 'unintended injury or complication which results in disability, death or prolongation of hospital stay, and is caused but health care management rather than the patient's disease'.	Severe=permanent injury or death, moderate=a new consultation, surgical treatment, medication or admission.	n/r
Kennerly et al, 2014	**2-stage process.** Initially quality improvement specialist screened the patient records using standard triggers indicating potential harm. Next, experienced physician reviewed a number of randomly selected medical records to confirm inter-rater reliability. Consensus for preventability was facilitated with the use of a score of **3 or higher in a 5point Likert scale.**	**Harm:** an 'unintended injury or complication which results in disability, death or prolongation of hospital stay, and is caused but health care management rather than the patient's disease.	Severe=permanent injury or death, moderate=a new consultation, surgical treatment, medication or admission.	Medication; Surgical procedure; Infections;
Khan et al, 2016	**2-stage process:** Written survey by patients followed by physician assessment. Initially, parents were surveyed to report whether their child experienced a mistake (ie, an error), any negative effects from the mistake (ie, a harmful error, also known as a preventable AE), and details of the incident. Next, two independent experienced reviewers screened the results of survey and made decisions following consensus.	**Harm:** which was associated with prolonging admission. **Preventable harm:** Preventable harm was defined as negative effects from the medical mistake (ie, a harmful error), and details of the incident.	n/r	
Larsen et al, 2007	**2-stage process:** Initially quality improvement specialist screened the patient records using standard triggers indicating potential harm. Next, experienced physician reviewed a number of randomly selected medical records to confirm inter-rater reliability.	**Harm:** an 'unintended injury or complication which results in disability, death or prolongation of hospital stay, and is caused but health care management rather than the patient's disease'.	Severe=permanent injury or death, moderate=a new consultation, surgical treatment, medication or admission.	Medication; Infections;
Letaief et al, 2010	**2-stage process:** Initially trained nurses screened the patient records using 18 standard screening criteria indicating potential harm. Next, two experienced physicians reviewed all medical records meeting at least one criterion in stage 1 and made a final judgement.	**Harm:** injury related to medical management, in contrast to complications of disease. Medical management includes all aspects of care, including diagnosis and treatment, failure to diagnose or treat, and the systems and equipment used to deliver care. Preventable harm: occurred because recommendations for care were not followed.	Mild=recovery within 1 month, Moderate= resolved within 12 months, Serious=permanent impairment, degree of disability ,50%, death.	
Lipitz-Snyderman et al, 2017	**2-stage process:** Initially trained nurses screened the patient records using 73 standard triggers indicating potential harm. Next, two experienced physicians reviewed all medical records meeting at least one trigger in stage 1 and made a final judgement. Consensus for preventability was facilitated with the use of a **score of 50% or higher in a 3-point Likert scale.**	**Harm:** An act of commission or omission rather than the underlying disease or condition of the patient. Harm was deemed preventable if it resulted from clinical care that was inconsistent with standard oncology practice or from a treatment-related complication that should have been anticipated.	n/r	n/r

Maflow et al, 2012	**2-stage process:** Initially trained nurses screened the patient records using 73 standard triggers indicating potential harm. Next, two experienced physicians reviewed all medical records meeting at least one trigger in stage 1 and made a final judgement. Consensus for preventability was facilitated with the use of a score of **50% or higher in a 3-point Likert scale.**	**Harm:** An act of commission or omission rather than the underlying disease or condition of the patient. Harm was deemed preventable if it resulted from clinical care that was inconsistent with standard oncology practice or from a treatment-related complication that should have been anticipated.	n/r	n/r
~~**Mayor et al, 2018**~~	~~2-stage process: Initially trained nurses screened the patient records using 18 standard screening criteria indicating potential harm. Next, two experienced physicians reviewed all medical records meeting at least one criterion in stage 1 to confirm whether harm was present, its preventability, location, classification, causes. If there was no agreement between the two reviews, a consensus procedure took place to reach a final judgement. Consensus for preventability was facilitated with the use of a score of **3 or higher in a 5point Likert scale.**~~	~~**Harm:** Unintended injury or complication causing temporary or permanent disability and/or increased length of stay (LOS) and resulting from health-care management~~	~~n/r~~	~~n/r~~
Mayor et al, 2018	2-stage process: Initially trained nurses screened the patient records using 18 standard screening criteria indicating potential harm. Next, two experienced physicians reviewed all medical records meeting at least one criterion in stage 1 to confirm whether harm was present, its preventability, location, classification, causes. If there was no agreement between the two reviews, a consensus procedure took place to reach a final judgement**.** Consensus for preventability was facilitated with the use of a score of **3 or higher in a 5point Likert scale.**	**Harm:** Unintended injury or complication causing temporary or permanent disability and/or increased length of stay (LOS) and resulting from health-care management.	n/r	n/r
Mendes et al, 2009	**2-stage process:** Initially trained nurse's o screened the patient records using a standard list of triggers indicating potential harm. Next, an experienced physician reviewed all medical records meeting at least one trigger in stage 1 and made a final judgment.	**Harm:** Unintended injury or harm resulting in death, temporary or permanent disability or dyes-function, or prolonged hospital stay that arises from health care .	n/r	
Merino et al, 2012	**2-stage process:** A pair of nurse and physician in each participating site completed a questionnaire about incidents of harm. Next experienced investigators made judgments about the causation and preventability of harm using implicit criteria.	**Harm:** Impairment of structure or function of the body and/or any deleterious effect arising there from, including disease, injury, suffering, disability and death, and may be physical, social or psychological	Mild=recovery within 1 month, Moderate= resolved within 12 months, Serious=permanent impairment, degree of disability 50%, death.	n/r
Merten et al, 2013 (a)	**3-stage process:** Initially trained nurses screened the patient records using 18 standard screening criteria indicating potential harm. Next, two experienced physicians reviewed all medical records meeting at least one criterion in stage 1 to confirm whether harm was present, its preventability, location, classification, causes. If there was no agreement between the two reviews, a consensus procedure took place to reach a final judgement. Consensus for preventability was facilitated with the use of a score of **4 or higher in a 6-point Likert scale.**	**Harm:** (i) an unintended physical or mental injury, which (ii) resulted in the prolongation of hospital stay, temporary or permanent disability or death, and was (iii) caused by healthcare management rather than the underlying disease. **Preventable harm**: resulting from an error in management due to failure to follow accepted practice at an individual or system level. Accepted practice was taken to be 'the current level of expected performance for the average practitioner or system that manages the condition in question'.	n/r	Medication; Diagnosis; Therapeutic management; Clinical procedure; Surgical procedure;

Merten et al, 2013 (b)	**3-stage process.** Initially trained nurses screened the patient records using 18 standard screening criteria indicating potential harm. Next, two experienced physicians reviewed all medical records meeting at least one criterion in stage 1 to confirm whether harm was present, its preventability, location, classification, causes. If there was no agreement between the two reviews, a consensus procedure took place to reach a final judgement. Consensus for preventability was facilitated with the use of a score of **4 or higher in a 6-point Likert scale.**	**Harm:** (i) an unintended physical or mental injury, which (ii) resulted in the prolongation of hospital stay, temporary or permanent disability or death, and was (iii) caused by healthcare management rather than the underlying disease. **Preventable harm:** resulting from an error in management due to failure to follow accepted practice at an individual or system level. Accepted practice was taken to be 'the current level of expected performance for the average practitioner or system that manages the condition in question'.	n/r	Medication; Diagnosis; Therapeutic management; Clinical procedure; Surgical procedure;
Michel et al, 2004 (a)	**2-stage process.** Nurses interviewed the head nurse or consulted the patient records using 17 standard trigger criteria indicating potential harm. Next, for patients who screened positive, the investigator screened the doctor who was responsible of their care. Consensus for preventability was facilitated with the use of a score of **4 or higher in a 6point Likert scale.**	**Harm:** An unintended injury caused by medical management rather than by a disease process and which resulted in death, life threatening illness, disability at time of discharge, admission to hospital, or prolongation of hospital stay. **Preventable harm:** would not have occurred if the patient had received ordinary standards of care appropriate for the time of the study.	n/r	n/r
Michel et al, 2004 (b)	**2-stage process:** The detection investigators visited the ward on day one of the survey and on two other occasions during the first seven days, then once a week for up to a month. The doctor involved in the prospective method visited the ward at the end of the first week then when the last patient was discharged or on day 30 if patients were still present. Thus patients with adverse events detected on the first day were confirmed by two different doctors one week apart. Consensus for preventability was facilitated with the use of a score of **4 or higher in a 6point Likert scale.**	**Harm:** An unintended injury caused by medical management rather than by a disease process and which resulted in death, life threatening illness, disability at time of discharge, admission to hospital, or prolongation of hospital stay. **Preventable harm:** would not have occurred if the patient had received ordinary standards of care appropriate for the time of the study.	n/r	n/r
Michel et al, 2004 (c)	For the retrospective method, review of the medical records began 30 days after the cross sectional method. Consensus for preventability was facilitated with the use of a score of **4 or higher in a 6-point Likert scale.**	**Harm:** An unintended injury caused by medical management rather than by a disease process and which resulted in death, life threatening illness, disability at time of discharge, admission to hospital, or prolongation of hospital stay. **Preventable harm:** Would not have occurred if the patient had received ordinary standards of care appropriate for the time of the study.	n/r	n/r
Montserrat-Capella et al, 2015	**2-stage process**: Initially trained nurses reviewed records using criteria listed in a validated screening guide for for the presence/absence of harm. Next a team of external reviewers (physicians) reviewed the patient records who met at least one of the criteria in the screening guide and made the final decision. Consensus for preventability was facilitated with the use of a score of **4 or higher in a 6point Likert scale.**	**Harm:** an unintended injury caused by medical management rather than by a disease process and which resulted in death, life threatening illness, disability at time of discharge, admission to hospital, or prolongation of hospital stay. **Preventable harm:** would not have occurred if the patient had received ordinary standards of care appropriate for the time of the study.	Mild=recovery within 1 month, Moderate= resolved within 12 months, Serious=permanent impairment, degree of disability ,50%, death.	Medication; Therapeutic management;

~~**Montserrat-Capella et al, 2015**~~	~~**2-stage process:** Initially trained nurses reviewed records using criteria listed in a validated screening guide for for the presence/absence of harm. Next a team of external reviewers (physicians) reviewed the patient records who met at least one of the criteria in the screening guide and made the final decision. Consensus for preventability was facilitated with the use of a score of **3 or higher in a 5point Likert scale.**~~	~~**Harm:** Any health care-associated incident which caused harm, with a causation score of at least 4. Causation was scored by reviewers using a 6-point scale, with 1 being no or minimal evidence and 6 practically certainly evidence of health care-related contributory factors causing the harm.~~	~~Mild=recovery within 1 month, Moderate= resolved within 12 months, Serious=permanent impairment, degree of disability ,50%, death.~~	~~n/r~~
Najjar et al, 2013	**2-stage process:** Initially independent trained nurses reviewed records using standard triggers for the presence/absence of harm. Next, they met to reach consensus and a third reviewer (physicians confirmed the causation, preventability and severity of the harm in patient records who met at least one of the criteria in the screening guide and made the final decision. Consensus for preventability was facilitated with the use of a score of **4 or higher in a 6-point Likert scale.**	**Harm:** resulting from medical care, not due to the underlying disease or the intended consequences of treatment.	n/r	Medication; Surgical procedure; Infections;
Nilsson et al, 2012	**2-stage process:** Initially independent trained nurses reviewed records using standard triggers for the presence/absence of harm in a proportion of records and then they continued independently, they met to reach consensus for any disagreements. Next, experienced physicians confirmed the causation, preventability and severity of the harm in patient records who met at least one of the criteria in the screening guide and made the final decision. Consensus for preventability was facilitated with the use of a score of **4 or higher in a 6-point Likert scale.**	**Harm:** Any health care-associated incident which caused harm, with a causation score of at least 4. Causation was scored by reviewers using a 6-point scale, with 1 being no or minimal evidence and 6 practically certainly evidence of health care-related contributory factors causing the harm.	n/r	Therapeutic management; Clinical procedure; Surgical procedure; Infections;
Nilsson et al, 2016	**2-stage process.** Initially independent trained nurses reviewed records using standard triggers for the presence/absence of harm in a proportion of records and then they continued independently, they met to reach consensus for any disagreements. Next, experienced physicians confirmed the causation, preventability and severity of the harm in patient records who met at least one of the criteria in the screening guide and made the final decision. Consensus for preventability was facilitated with the use of a score of **2 or higher in a 4-point Likert scale.**	**Harm:** Any health care-associated incident which caused harm, with a causation score of at least 4. Causation was scored by reviewers using a 6-point scale, with 1 being no or minimal evidence and 6 practically certainly evidence of health care-related contributory factors causing the harm.	Level of harm according to National Coordination Council for Medication Error Reporting and Prevention (NCC MERP) index*. Only Categories E–I is included in Global Trigger Tool.	n/r
Nilsson et al, 2018	**2-stage process:** Initially independent trained nurses reviewed records using standard triggers for the presence/absence of harm in a proportion of records. Next, experienced physicians confirmed the causation, preventability and severity of the harm in patient records who met at least one of the criteria in the screening guide and made the final decision using a national handbook. Consensus for preventability was facilitated with the use of a score of **2 or higher in a 4-point Likert scale.**	**Harm:** Any health care-associated incident which caused harm, with a causation score of at least 4. Causation was scored by reviewers using a 6-point scale, with 1 being no or minimal evidence and 6 practically certainly evidence of health care-related contributory factors causing the harm.	Level of harm according to National Coordination Council for Medication Error Reporting and Prevention (NCC MERP) index*. Only Categories E–I is included in Global Trigger Tool.	n/r
Nuckols et al, 2007	**2-stage process:** Record review by internist followed by interpreter agreement in a proportion (10%) of charts by a second internist. Consensus for preventability was facilitated with the use of a score of **2 or higher in a 3-point Likert scale.**	**Harm:** An unintended event the event resulted in patient harm (prolongation of hospital stays, disability at discharge and/or extra cost of treatment) caused by healthcare rather than by disease process alone.	n/r	Medication; Diagnosis; Clinical procedure; Surgical procedure;

Pucher et al, 2013	**2-stage proses:** Initially independent trained nurses reviewed records for the presence/absence of harm in a proportion of records and then they continued independently. Next, they met to discuss their rating and reach consensus for any disagreements.	**Harm:** An unintended injury or harm resulting in death, temporary or permanent.	n/r	n/r
Rafter et al, 2015	**2-stage process:** Initially nurses reviewed records for the presence/absence of 18 triggers for potential harm. Each identified trigger prompted an in depth investigation for the presence of harm. Next, physicians when through the records which met at least one trigger and reached final decisions for the causation, preventability and severity of the harm. Consensus for preventability was facilitated with the use of a score of **4 or higher in a 6-point Likert scale.**	Harm: An unintended injury or complication resulting in disability at the time of discharge, prolonged hospital stay or death and that was caused by healthcare management rather than by the underlying disease process	n/r	n/r
Rajasekaran et al, 2016	**2-stage process:** Initially independent trained nurses reviewed surgeons using standard triggers for the presence/absence of harm. Next, senior consultant surgeon confirmed the causation, preventability and severity of the harm in patient records who met at least one of the criteria in the screening guide and made the final decision.	**Harm:** An unintended injury or harm resulting in death, temporary or permanent.	n/r	n/r
Rothschild et al, 2005	**2-stage process:** Initially independent trained nurses reviewed surgeons using standard triggers for the presence/absence of harm. Next, senior consultant surgeon confirmed the causation, preventability and severity of the harm in patient records who met at least one of the criteria in the screening guide and made the final decision. Consensus for preventability was facilitated with the use of a score of **3 or higher in a 5-point Likert scale.**	**Harm:** Any injury due to medical management, rather than the underlying disease.	n/r	Medication; Diagnosis; Therapeutic management; Clinical procedure;
Sari et al, 2007/2008	**2-stage process:** Initially trained nurses or physicians reviewed records using criteria listed in a validated screening guide for for the presence/absence of 18 triggers or criteria. Next a team of external reviewers (physicians) reviewed the patient records who met at least one of the criteria in the screening guide and made the final decision. Consensus for preventability was facilitated with the use of a score of **4 or higher in a 6-point Likert scale.**	**Harm**: Any event causing harm to the patient that was perceived to be more related to the healthcare management rather than to the patient's underlying condition. **Preventable harm:** Any event causing harm to the patient that was perceived to be more related to the healthcare management rather than to the patient's underlying condition.	Mild=Impairment or disability resolved within a month; Moderate= impairment or disability resolved within 12 months; serious= permanent disability or patient death.	Medication; Diagnosis; Therapeutic management; Clinical procedure; Surgical procedure; Infections;
Sari et al, 2015	**2-stage process:** Initially trained nurses or physicians reviewed records using criteria listed in a validated screening guide for for the presence/absence of 18 triggers or criteria. Next a team of external reviewers (physicians) reviewed the patient records who met at least one of the criteria in the screening guide and made the final decision. Consensus for preventability was facilitated with the use of a score of **4 or higher in a 6-point Likert scale.**	**Harm**: Any event causing harm to the patient that was perceived to be more related to the healthcare management rather than to the patient's underlying condition. **Preventable harm:** Any event causing harm to the patient that was perceived to be more related to the healthcare management rather than to the patient's underlying condition.	Mild=Impairment or disability resolved within a month; Moderate= impairment or disability resolved within 12 months; serious= permanent disability or patient death.	
Soop et al, 2009	**3-stage process:** Initially trained nurses screened the patient records using 18 standard screening criteria indicating potential harm. Next, two experienced physicians reviewed all medical records meeting at least one criterion in stage 1 to confirm whether harm was present, its preventability, location, classification, causes. If there was no agreement between the two reviews, a consensus procedure took place to reach a	**Harm:** (i) an unintended physical or mental injury, which (ii) resulted in the prolongation of hospital stay, temporary or permanent disability or death, and was (iii) caused by healthcare management rather than the underlying disease.	Severity: Serious=permanent disability or death	Medication; Diagnosis; Clinical procedure; Surgical procedure; Infections;

	final judgement. Consensus for preventability was facilitated with the use of a score of **4 or higher in a 6-point Likert scale.**	**Preventable harm:** Resulting from an error in management due to failure to follow accepted practice at an individual or system level.		
Sousa et al, 2014	**2-stage proses:** Initially trained nurses or physicians reviewed records using criteria listed in a validated screening guide for for the presence/absence of 18 triggers or criteria. Next a team of external reviewers (physicians) reviewed the patient records who met at least one of the criteria in the screening guide and made the final decision. Consensus for preventability was facilitated with the use of a score of **4 or higher in a 6-point Likert scale.**	**Harm:** An unintended event the event resulted in patient harm (prolongation of hospital stays, disability at discharge and/or extra cost of treatment) caused by healthcare rather than by disease process alone.	Mild=Impairment or disability resolved within a month; Moderate= impairment or disability resolved within 12 months; serious= permanent disability or patient death.	n/r
Stockwell et al, 2015	**2-stage process:** Initially trained nurses or physicians reviewed records using standard triggers. Next a team of external reviewers (physicians) reviewed the triggers who met at least one of the criteria in the screening guide and made the final decision. Consensus for preventability was facilitated with the use of a score of **3 or higher in a 6-point Likert scale.**	**Harm:** An unintended event the event resulted in patient harm (prolongation of hospital stays, disability at discharge and/or extra cost of treatment) caused by healthcare rather than by disease process alone	Mild=Impairment or disability resolved within a month; Moderate= impairment or disability resolved within 12 months; serious= permanent disability or patient death.	n/r
Stockwell et al, 2017	**2-stage process:** Initially trained nurses or physicians reviewed records using 27 standard triggers. Next a team of external reviewers (physicians) reviewed the triggers who met at least one of the criteria in the screening guide and made the final decision regarding causation, preventability and severity. Consensus for preventability was facilitated with the use of a score of **4 or higher in a 6-point Likert scale.**	**Harm:** An unintended event the event resulted in patient harm (prolongation of hospital stays, disability at discharge and/or extra cost of treatment) caused by healthcare rather than by disease process alone. **Preventable harm:** Breach of standard professional behaviour or technique was identified; necessary precautions were not taken; event was preventable by modification of behaviour, technique or care.	n/r	n/r
Suarez et al, 2014	A team of two nurses and one physician reviewed the triggers in the medical records of patients and made consensus decisions about causation, preventability and severity of harm. Consensus for preventability was facilitated with the use of a score of **3 or higher in a 6-point Likert scale.**	**Harm:** "unintended physical injuries resulting from medical care that require additional monitoring, treatment, or hospitalization, or that result in death."	Mild=Impairment or disability resolved within a month; Moderate= impairment or disability resolved within 12 months; serious= permanent disability or patient death.	Medication; Diagnosis; Therapeutic management; Surgical procedure; Infections;
Thomas et al, 2000 (a)	**2-stage process:** Initially trained nurses or physicians reviewed records using criteria listed in a validated screening guide for for the presence/absence of 18 triggers or criteria. Next a team of external reviewers (physicians) reviewed the patient records who met at least one of the criteria in the screening guide and made the final decision.	**Harm:** An injury that was caused by medical management (rather than the underlying disease) and that prolonged the hospitalization, produced a disability at the time of discharge, or both.	Mild=Impairment or disability resolved within a month; Moderate= impairment or disability resolved within 12 months; serious= permanent disability or patient death.	Medication; Diagnosis; Therapeutic management; Clinical procedure; Surgical procedure;
Thomas et al, 2000 (b)	**2-stage process:** Initially trained nurses or physicians reviewed records using criteria listed in a validated screening guide for for the presence/absence of 18 triggers or criteria. Next a team of external reviewers (physicians) reviewed the patient records who met at least one of the criteria in the screening guide and made the final decision.	**Harm:** An injury that was caused by medical management (rather than the underlying disease) and that prolonged the hospitalization, produced a disability at the time of discharge, or both.	Mild=Impairment or disability resolved within a month; Moderate= impairment or disability resolved within 12 months;	Medication; Diagnosis; Therapeutic management; Clinical procedure; Surgical procedure;

			serious= permanent disability or patient death.	
Vincent et al, 2001	2-stage process: Initially trained nurses or physicians reviewed records using criteria listed in a validated screening guide for for the presence/absence of 18 triggers. Next a team of external reviewers (physicians) reviewed the patient records who met at least one of the criteria in the screening guide and made the final decision cause, preventability, place and date of occurrence, type of harm. Consensus for preventability was facilitated with the use of a score of **4 or higher in a 6-point Likert scale.**	Harm: An injury that was caused by medical management (rather than the underlying disease) and that prolonged the hospitalization, produced a disability at the time of discharge, or both.	Mild=Impairment or disability resolved within a month; Moderate= impairment or disability resolved within 12 months; serious= permanent disability or patient death.	n/r
Weingart et al, 2005	**2-stage process:** Written survey completed by patients followed by physician assessment. Initially, parents were surveyed to report whether their child experienced a mistake (ie, an error), any negative effects from the mistake (ie, a harmful error, also known as a preventable AE), and details of the incident. Next, two independent experienced reviewers screened the results of survey and made decisions following consensus.	**Harm:** Injuries because of medical care rather than the natural history of the illness. Preventable harm caused by errors involving parties, and process of care deficiencies.	Mild=Impairment or disability resolved within a month; Moderate= impairment or disability resolved within 12 months; serious= permanent disability or patient death.	n/r
Williams et al, 2008	**2-stage process:** Initially trained nurses or physicians reviewed records using criteria listed in a validated screening guide for for the presence/absence of 15 triggers. Next a team of external reviewers (physicians) reviewed the patient records who met at least one of the criteria in the screening guide and made the final decision cause, preventability, place and date of occurrence, type of harm	**Harm:** Unintended injury or complication which led to temporary or permanent disability and/or increased length of stay or death and which was caused by healthcare management.	n/r	n/r
Wilson et al, 2012	**2-stage process:** Initially trained nurses or physicians reviewed records using criteria listed in a validated screening guide for for the presence/absence of 18 triggers or criteria. Next a team of external reviewers (physicians) reviewed the patient records who met at least one of the criteria in the screening guide and made the final decision. Consensus for preventability was facilitated with the use of a score of **4 or higher in a 6-point Likert scale.**	**Harm:** Unintended injury that resulted in temporary or permanent disability or death (including increased length of stay or readmission) and that was associated with healthcare management rather than the underlying disease process	n/r	Clinical procedure; Surgical procedure;
Woods et al, 2006	**2-stage process:** Initially trained nurses reviewed records using criteria listed in a validated screening guide for for the presence/absence of 18 triggers or criteria. Next, physicians reviewed the patient records who met at least one of the criteria in the screening guide and made the final decision. Consensus for preventability was facilitated with the use of a score of **4 or higher in a 6-point Likert scale.**	**Harm:** Injury caused by medical intervention or management, rather than the disease process, which either prolonged the hospital stay or caused disability at discharge. **Preventable harm:** Where there was enough information currently available to have prevented the event using currently accepted practices.	Mild=Impairment or disability resolved within a month; Moderate= impairment or disability resolved within 12 months; serious= permanent disability or patient death.	Diagnosis; Therapeutic management; Clinical procedure; Surgical procedure;
Zegers et al, 2009	3-stage process: Initially trained nurses screened the patient records using 18 standard screening criteria indicating potential harm. Next, two experienced physicians reviewed all medical records meeting at least one criterion in stage 1 to confirm whether harm was present, its preventability, location, classification, causes. If there was no agreement between the two reviews, a consensus procedure took place to reach a	**Harm:** (i) an unintended physical or mental injury, which (ii) resulted in the prolongation of hospital stay, temporary or permanent disability or death, and was (iii) caused by healthcare management rather than the underlying disease.	Mild=Impairment or disability resolved within a month; Moderate= impairment or disability resolved within 12 months; serious= permanent disability or patient death.	Medication; Diagnosis; Therapeutic management; Clinical procedure; Surgical procedure;

	final judgement. Consensus for preventability was facilitated with the use of a score of **4 or higher in a 6-point Likert scale.**	**Preventable harm:** An error in management due to failure to follow accepted practice at an individual or system level.		
De Wet et al, 2009	**2-stage process:** f two independent trained auditors using a standard preformat. Afterwards they met to compare and discuss their individual findings until a consensus agreement was reached. .	**Harm:** Injury resulting from medical management rather than the underlying disease. **Preventable harm:** An error in healthcare management due to failure to follow accepted practice at an individual or system level.	Mild=Impairment or disability resolved within a month; Moderate= impairment or disability resolved within 12 months; serious= permanent disability or patient death.	Medication; Diagnosis; Therapeutic management; Surgical procedure; Infections;

eTable 4: Critical appraisal ratings

Study ID	Q1	Q2	Q3	Q4	Q5	Q6	Q7	Q8	Q9	Total
Agarwal 2010	1	1	0	1	1	0	1	1	0	6
Aibar 2015	1	1	1	1	1	0	0	0	1	6
Amaral 2015	0	1	1	1	1	1	1	1	1	8
Aranas-andres 2008/2009	1	1	1	1	1	1	1	1	1	9
Aranaz-andres 2011	1	1	1	1	1	1	0	0	1	7
Aranaz-andres 2012	1	1	1	1	1	1	0	0	1	7
Baines 2013	1	1	1	1	1	1	1	1	1	9
Baker 2004	1	1	1	1	1	1	0	0	1	7
Bartlett 2008	1	1	1	1	1	1	1	1	1	9
Blais 2013	1	1	0	1	0	1	1	1	1	7
Calder 2015	0	0	0	0	0	1	1	1	0	3
Calder 2010	0	1	1	1	1	1	1	1	1	8
Davis 2013	1	1	1	1	1	1	0	0	0	6
Florea 2010	0	1	1	0	1	1	1	1	0	6
Forster 2003	1	1	1	1	1	1	1	1	0	8
Forster 2006	1	1	1	1	1	1	1	1	0	8
Forster 2007	1	1	1	1	1	1	0	0	0	6
Forster 2008	1	1	1	1	1	1	1	0	0	7
Forster 2011	1	1	1	0	1	1	1	0	1	7
Fowler 2008	1	1	1	1	1	1	1	0	0	7
Friedman 2008	1	1	1	1	1	1	1	1	0	8
Halfon 2017	1	1	1	1	1	0	1	1	0	7
Halfon 2017	1	1	1	1	1	0	1	1	0	7
Healey 2002	1	1	1	1	0	0	1	1	0	6
Hendrie 2007	1	1	1	0	0	1	0	0	1	5
Hendrie 2017	1	1	1	0	1	1	1	1	1	8
Herrera 2005	1	0	1	0	1	1	1	1	0	6
Hoorgervorst-schiilp 2015	1	1	0	1	1	1	1	1	1	8
Hwang 2014	1	0	1	1	1	0	1	1	1	7
Kable 2002	1	1	1	1	1	1	1	1	1	9
Kennerly 2014	1	1	1	0	1	1	0	1	1	7
Khan 2016	1	1	1	0	1	0	1	1	0	7
Larsen 2007	1	1	0	1	1	0	1	1	1	7

Letaief 2010	1	0	1	0	1	1	1	1	1	7
Lipitz-Snyderman 2017	1	1	1	0	1	1	0	1	1	7
Matlow 2012	1	1	1	1	1	1	0	0	1	7
~~Mayor 2015~~	~~1~~	~~1~~	~~1~~	~~1~~	~~1~~	~~1~~	~~0~~	~~1~~	~~1~~	~~2~~
Mayor 2018	1	1	1	1	1	1	0	1	1	2
Mendes 2009	1	1	1	0	1	0	1	1	1	7
Merino 2012	1	1	1	1	1	1	1	1	1	9
Merten 2013a	1	1	0	1	1	1	1	1	1	8
Merten 2013b	1	1	0	1	1	1	0	1	1	7
Michel 2004a	1	1	1	1	1	1	0	0	1	7
Michel 2004b	1	1	1	1	0	1	1	1	1	8
Michel 2004c	1	1	1	1	1	0	1	0	1	7
Montserrat-capella 2015a	1	1	0	1	0	1	1	0	1	7
~~Montserrat-capella 2015b~~	~~0~~	~~1~~	~~0~~	~~1~~	~~0~~	~~1~~	~~1~~	~~1~~	~~1~~	~~6~~
Najjar 2013	1	1	1	1	1	0	1	1	1	8
Nilsson 2012	1	1	1	1	1	1	1	1	1	9
Nilsson 2016	1	1	1	0	1	1	1	1	1	8
Nilsson 2018	1	1	1	1	1	1	1	1	1	2
Nuckols 2007	1	1	1	0	1	0	1	1	1	7
Pucher 2013	1	1	1	1	1	1	1	1	0	8
Rafter 2017	1	1	1	0	1	1	1	0	1	7
Rajasekaran 2016	1	1	1	0	1	1	0	1	1	7
Rothschild 2005	1	1	1	1	1	0	1	1	1	8
Sari 2007/2008	1	1	1	0	1	1	1	0	1	7
Sari 2015	1	1	1	1	1	1	1	1	1	9
Soop 2009	1	1	1	1	1	1	1	0	1	8
Sousa 2014	1	1	1	1	1	1	1	0	1	8
Stockwell 2015	1	1	1	0	1	1	0	1	1	7
Stockwell 2018	1	1	1	0	0	1	0	0	1	6
Suarez 2014	1	1	1	1	1	0	1	1	1	8
Thomas 2000a	1	1	1	1	1	1	1	1	0	8
Thomas 2000a	1	1	1	1	1	1	1	1	0	8
Vincent 2001	1	0	1	1	1	1	1	1	1	8
Weingart 2005	1	0	1	1	0	1	1	1	0	6
Williams 2008	1	0	1	1	0	1	1	1	0	6
Wilson 2012	1	0	1	1	1	1	1	1	1	8
Woods 2006	1	1	1	1	0	1	1	0	1	8

Zegers 2008	1	1	1	0	1	1	1	0	1	7
De Wet 2009	0	1	1	1	1	1	1	1	0	7