Appendix 1 Protocol Systematic Review Patient-Safety Interventions.

Research question:
What are effective interventions to reduce the rate of adverse events and preventable deaths in hospitals?

Data Sources:
PubMed (including The National library of medicine**,** MEDLINE)
EMBASE
CINAHL
PsycInfo
The Cochrane Library (including the Cochrane Database of Systematic Reviews (CDSR), Database of Abstracts on Reviews and Effectiveness (DARE), Cochrane Controlled Trial Register (CCTR), NHS Economic Evaluation Database (NHS-EED) and Health Technology Assessment Database (HTA))

Selection criteria:
Patients/setting

- Hospitalized patients

Interventions

- Patient-safety interventions are described as interventions, strategies, practices, behavior, actions, procedures, or structures which are aimed to improve patient safety by reducing unintended patient harm as a result of the process of healthcare (adverse events). The interventions should contain 1 or more components (described in the article) that aimed to reduce adverse patient outcomes. The intervention had to compare the effectiveness of a specific patient-safety intervention to other interventions or control.

Control

- Usual hospital care

Outcomes

- At least one or more objectively measured changes in patient-safety outcomes, adverse events, at the patient level (e.g. adverse drug events, mortality, infections, pneumonia, etc) during hospital stay and adverse events that occurred within the first 12 months after hospital stay. Systematic reviews that only report process errors (e.g. diagnostic errors, no hand hygiene, medication/prescribing errors) and errors in structure (e.g. stress and fatigue of health care providers, no safety culture) are not included. Moreover, consequences of adverse events in terms of extra treatment(s), increased length of stay and readmission are not the focus

Type of studies

- Systematic reviews/meta-analysis of primary studies which provide evaluative results of patient safety interventions and comply to the Cochrane Effective Practice and Organisation of Care (EPOC) review group methodological criteria

Languages

- English-language systematic reviews

Data collection and analysis

- See A. Abstract and full text selection form on page 2
- See B. Quality assessment form on page 3 and 4
- See C. Data abstraction form on page 5, 6 and 7

A. FORM FOR ABSTRACT AND FULL TEXT SELECTION

Reviewers	
Name Reviewer 1	
Name Reviewer 2	
Date	

Study	
ID Study	
Authors, year	
Title	

Selection Criteria	
1. ***Study design*** Systematic review, review or meta- analysis ***Yes (include)*** Systematic review of primary research, systematic reviews of systematic reviews, systematic comparative review. Abstract specifies "systematic review" or "meta analysis" as a term. ***No (exclude)*** Primary studies, editorials, letters, comments, expert opinions, unsystematic reviews, narrative reviews (without systematic elements or which don't report methodology), synthesis of non-empirical work, such as guidelines or conceptual articles, reviews of methodology, research protocol articles, critical review.	○ Yes ○ No ○ Unclear
2. ***Setting/Patients*** Intervention is targeted at hospitalized patients and involved health care providers ***Yes (include)*** Acute care, in-hospital care, in both developed as developing countries, systematic reviews including hospital care and other settings, unless effect measures are available for the hospital setting separately ***No (exclude)*** Residential care, nursing homes, dental care, psychiatry, mental care, homecare, primary care, paramedics, tertiary care, public health	○ Yes ○ No ○ Unclear
3. ***Interventions*** Effect evaluation of patient safety interventions, which are aimed to prevent unintended patient harm ***Yes (include)*** A full description of the intervention should be reported. At least the following: title, abstract, aim needs to refer to the patient safety intervention. ***No (exclude)*** No description of the intervention is given. Components of the intervention are unclear. Review of non-interventional studies.	○ Yes ○ No ○ Unclear
4. ***Outcomes*** Effectiveness of a patient safety intervention is measured at patient level ***Yes (include)*** Quantitative outcome(s) on patient level including adverse events, adverse drug events, infections, pneumonia, mortality ***No (exclude)*** Outcome at professional level (performance of professionals; healthcare professional behavior, team climate). Errors in process (diagnostic errors, no hand hygiene, medication/prescribing errors) and errors in structure/ healthcare delivery systems (stress and fatigue of health care providers, no safety culture)	○ Yes ○ No ○ Unclear
5. ***Evidence*** The methodology (including search strategy and design of included studies) is reported ***Yes (include)*** Review contains methodological justification for search strategy and report about the quality of included studies. ***No (exclude)*** No methodological justification for search strategy and the quality of included studies is not reported.	○ Yes ○ No ○ Unclear

CONCLUSION REVIEWER If no to any of the above questions, then **exclude**. If yes or unclear to all, then **include** for full text review.	○ INCLUDE ○ EXCLUDE

B. FORM FOR QUALITY ASSESSMENT OF SYSTEMATIC REVIEWS

1. Reviewers	
a) Name reviewer	
b) Name second reviewer	
c) Date	

2. Study	
a) Title	
b) Authors	
c) Source and year	

3. Quality rating*	
1) Was an ''a priori'' design provided? The research question and inclusion criteria should be established before the conduct of the review. *Note: Need to refer to a protocol, ethics approval, or pre-determined/a priori published research objectives to score a "yes."*	☐ Yes (1) ☐ No (0) ☐ Can't answer (0) ☐ Not applicable (0)
2) Was there duplicate study selection and data extraction? There should be at least two independent data extractors and a consensus procedure for disagreements should be in place. *Note: 2 people do study selection, 2 people do data extraction, consensus process or one person checks the other's work.*	☐ Yes (1) ☐ No (0) ☐ Can't answer (0) ☐ Not applicable (0)
3) Was a comprehensive literature search performed? At least two electronic sources should be searched. The report must include years and databases used. Key words and/or MESH terms must be stated, and where feasible, the search strategy should be provided. All searches should be supplemented by consulting current contents, reviews, textbooks, specialized registers, or experts in the particular field of study, and by reviewing the references in the studies found. *Note: If at least 2 sources + one supplementary strategy used, select "yes" (Cochrane register/Central counts as 2 sources; a grey literature search counts as supplementary).*	☐ Yes (1) ☐ No (0) ☐ Can't answer (0) ☐ Not applicable (0)
4) Was the status of publication (i.e., grey literature) used as an inclusion criterion? The authors should state that they searched for reports regardless of their publication type. The authors should state whether or not they excluded any reports (from the systematic review), based on their publication status, language etc. *Note: If review indicates that there was a search for "grey literature" or "unpublished literature," indicate "yes." SIGLE database, dissertations, conference proceedings, and trial registries are all considered grey for this purpose. If searching a source that contains both grey and non-grey, must specify that they were searching for grey/unpublished lit.*	☐ Yes (1) ☐ No (0) ☐ Can't answer (0) ☐ Not applicable (0)
5) Was a list of studies (included and excluded) provided? A list of included and excluded studies should be provided. *Note: Acceptable if the excluded studies are referenced. If there is an electronic link*	☐ Yes (1) ☐ No (0)

to the list but the link is dead, select "no."	☐ Can't answer (0) ☐ Not applicable (0)
6) Were the characteristics of the included studies provided? In an aggregated form, such as a table, data from the original studies should be provided on the participants, interventions, and outcomes. The ranges of characteristics in all the studies analyzed, e.g., age, race, sex, relevant socioeconomic data, disease status, duration, severity, or other diseases should be reported. *Note: Acceptable if not in table format as long as they are described as above.*	☐ Yes (1) ☐ No (0) ☐ Can't answer (0) ☐ Not applicable (0)
7) Was the scientific quality of the included studies assessed and documented? ''A priori'' methods of assessment should be provided (e.g., for effectiveness studies if the author(s) chose to include only randomized, double-blind, placebo-controlled studies, or allocation concealment as inclusion criteria); for other types of studies, alternative items will be relevant. *Note: Can include use of a quality scoring tool or checklist, e.g., Jadad scale, risk of bias, sensitivity analysis, etc., or a description of quality items, with some kind of result for EACH study ("low" or "high" is fine, as long as it is clear which studies scored "low" and which scored "high"; a summary score/range for all studies is not acceptable).*	☐ Yes (1) ☐ No (0) ☐ Can't answer (0) ☐ Not applicable (0)
8) Was the scientific quality of the included studies used appropriately in formulating conclusions? The results of the methodological rigor and scientific quality should be considered in the analysis and the conclusions of the review, and explicitly stated in formulating recommendations. *Note: Might say something such as "the results should be interpreted with caution due to poor quality of included studies." Cannot score "yes" for this question if scored "no" for question 7.*	☐ Yes (1) ☐ No (0) ☐ Can't answer (0) ☐ Not applicable (0)
9) Were the methods used to combine the findings of studies appropriate? For the pooled results, a test should be done to ensure the studies were combinable, to assess their homogeneity (i.e., Chi-squared test for homogeneity, I2). If heterogeneity exists, a random effects model should be used and/or the clinical appropriateness of combining should be taken into consideration (i.e., is it sensible to combine?). *Note: Indicate "yes" if they mention or describe heterogeneity, i.e., if they explain that they cannot pool because of heterogeneity/variability between interventions.*	☐ Yes (1) ☐ No (0) ☐ Can't answer (0) ☐ Not applicable (0)
10) Was the likelihood of publication bias assessed? An assessment of publication bias should include a combination of graphical aids (e.g., funnel plot, other available tests) and/or statistical tests (e.g., Egger regression test). *Note: If no test values or funnel plot included, score "no". Score "yes" if mentions that publication bias could not be assessed because there were fewer than 10 included studies.*	☐ Yes (1) ☐ No (0) ☐ Can't answer (0) ☐ Not applicable (0)
11) Was the conflict of interest included? Potential sources of support should be clearly acknowledged in both the systematic review and the included studies. *Note: To get a "yes," must indicate source of funding or support for the systematic review AND for each of the included studies.*	☐ Yes (1) ☐ No (0) ☐ Can't answer (0) ☐ Not applicable (0)
12) Total score	

* Based on the AMSTAR criteria for Quality assessment of systematic reviews (Shea *et al. BMC Medical Research Methodology* 2007 **7**:10 doi:10.1186/1471-2288-7-10)
Additional notes (in italics) made by Michelle Weir, Julia Worswick, and Carolyn Wayne based on conversations with Bev Shea and/or Jeremy Grimshaw in June and October 2008 and July and September 2010. (http://amstar.ca/docs/AMSTARguideline.pdf)

C. DATA EXTRACTION FORM

1. Reviewers	
a) Name reviewer	
b) Date	
c) Cross-checked	

2. Study	
a) ID study	
b) Title	
c) Authors	
d) Source and year	

3. Objective and methods	
a) Objective/Aim of the review	
b) Number of studies included in the SR	
c) Time range of included studies	From: To:
d) Number of 'relevant' studies included (for the data analysis of this SR)	
e) Target population/participants	
f) Total no. of participants (sum of all 'relevant' included studies)	
g) Design/scientific quality of included studies	No. of Randomized controlled trials (RCTs): No. of non-randomised controlled clinical trials: No. of controlled before-and-after studies:

	No. of interrupted time series: No. of uncontrolled before-after studies and observational studies, including cohort study, case-control studies, cross-sectional studies, case studies:
h) Design/scientific quality of 'relevant' studies included (for the data analysis of this SR)	No. of Randomized controlled trials (RCTs): No. of non-randomised controlled clinical trials: No. of controlled before-and-after studies: No. of interrupted time series: No. of uncontrolled before-after studies and observational studies, including cohort study, case-control studies, cross-sectional studies, case studies:

4. Intervention	
i) Description of intervention (details/ comments)	

5. Outcome measurements	
j) Outcome measure 1	Definition: Qualitative/descriptive data: Quantitative/pooled results/combined ratios (e.g. risk rate):
k) Outcome measure 2	Definition: Qualitative/descriptive data: Quantitative/pooled results/combined ratios (e.g. risk rate):
l) Outcome measure 3	Definition: Qualitative/descriptive data: Quantitative/pooled results/combined ratios (e.g. risk rate):
m) Outcome measure 4	Definition: Qualitative/descriptive data: Quantitative/pooled results/combined ratios (e.g. risk rate):
n) Outcome measure 5	Definition: Qualitative/descriptive data: Quantitative/pooled results/combined ratios (e.g. risk rate):

o) Outcome measure 6	Definition: Qualitative/descriptive data: Quantitative/pooled results/combined ratios (e.g. risk rate):
p) Process evaluation (i.e., barriers and drivers for the implementation of the intervention)	

6. Limitations of the systematic review	
q) Description of limitations	Reported by the authors: Reported by us (researchers/reviewers):

7. Authors' key conclusions	
r) What conclusion did the authors make based on their findings? (e.g. first or last sentence of discussion/conclusion section)	

8. Other	
s) Comments/ remarks	