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What is the quality of reporting on guideline, protocol or algorithm implementation in adult trauma centers: Protocol for a systematic review

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ABSTRACT

Introduction: Quality improvement (QI) activity is mandatory in trauma centers but there is no prescription for doing successful QI. Considerable variation in implementation strategies and inconsistent use of evidence-based protocols therefore exist across trauma centers. The quality of reporting on these strategies may limit the transferability of successful QI initiatives across centers. This systematic review will assess the quality of reporting on guideline, protocol or algorithm implementation within a trauma center in terms of the Revised Standards for Quality Improvement Reporting Excellence (SQUIRE 2.0).

Methods and analysis: We will search for English language articles published after 2010 in EMBASE, MEDLINE, CINAHL electronic databases, and the Cochrane Central Register of Controlled Trials. The database search will be supplemented by searching trial registries and grey literature online. Quantitative studies evaluating the effects on providers and/or patients of an implemented guideline, protocol or algorithm in a trauma setting will be included. The primary outcome will be obtained based on the18-items identified in the SQUIRE 2.0 guidelines. Secondary outcomes will include information on study design, guideline-type, population, control, outcomes and other necessary information for assessment of risk of bias or meta-analyses. All study titles, abstracts and full-text screening will be completed independently and in duplicate by the review team members. Data extraction and risk of bias assessment will also be done independently and in duplicate. Primary outcomes will be reported by narrative summaries and as percentage scores for each guideline item across included studies.

Ethics and dissemination: Results will be disseminated through scientific publication and conferences. Important implications for trauma center leaders and practitioners when planning future guideline implementations are expected.

Systematic review registration: PROSPERO registration number CRD42018084273

Strengths and limitations of this study:

- This is the first systematic review to assess the quality of quality improvement reporting by trauma centers where quality improvement activity is required.
- The results of this study will directly inform enhancements in quality improvement reporting by trauma centers and increase the transferability of their findings.
- A rigorous literature search and systematic review methodology will be used to identify relevant guideline implementation studies in the trauma care context.
- Indexing of quality improvement studies in the electronic databases is poor and inconsistent which may result in some studies not being captured in this review.

INTRODUCTION

Trauma centers are state or regionally designated hospitals that are resourced to provide specialized care for severely injured patients. In addition to being designated as such, trauma centers may also go through the process of accreditation or verification by an external body; the verification process utilizes standard criteria to ensure that trauma centers are suitably equipped to provide the highest quality trauma care.[1] Center verification criteria include engagement in quality improvement (QI) activity as part of a Performance Improvement and Patient Safety (PIPS) program.[1] A PIPS program is designed to monitor center performance and outcomes over time, with continuous improvement as the ultimate objective.

Despite the mandated existence of PIPS programs, patient outcomes across accredited trauma centers continue to be highly variable.[2-4] Differences in structures and processes of care across centers are hypothesized to contribute to these persistent variations in outcomes.[5] Trauma centers also report inconsistent use of evidence-based protocols, which may contribute to differences in quality of care across institutions.[6-8,] Finally, implementation of PIPS programs and QI strategies has varied considerably across centers; inadequacy of a center's PIPS program is the most frequent reason for failing verification review.[9] Identifying ways to support trauma centers in developing and implementing successful QI strategies is therefore critical.

One mechanism to support QI in trauma centers is the American College of Surgeons' Trauma Quality Improvement Program (TQIP).[10] Launched in 2010, TQIP provides performance data reports to enrolled trauma centers on their processes of care and patient outcomes relative to their peers using risk-adjusted benchmarking, as well as evidence-based guidelines. TQIP has also developed best practice guidelines in the areas of geriatric trauma management, massive transfusion in trauma, traumatic brain injury management, management of orthopedic trauma

and palliative care.[11] Each year, more than 1000 representatives of TQIP enrolled trauma centers meet to share successes and challenges in their QI efforts. Some centers have also published these successes in peer reviewed journals, for example reporting on reduction in rates of venous thromboembolism (VTE) and urinary tract infection (UTI).[12,13]

While successful QI strategies are increasingly published in the scholarly and grey literatures, the quality of that reporting may be playing an important role in the observed variation in the success of QI initiatives across centers. At this time we do not know if QI reporting in trauma is of sufficient detail or of high enough quality to enable replication or transferability to other centers. Even successful QI strategies, if inadequately reported, may result in failed initiatives at other centers wishing to implement them. The Revised Standards for Quality Improvement Reporting Excellence (SQUIRE 2.0) guidelines were developed to ensure the utility and quality of QI reporting in health care and to establish a common ground to share QI outcomes in the scholarly literature.[14] SQUIRE 2.0 is a checklist that guides reporting on QI methods and interventions. (Appendix I) The objective of our study is to assess the quality of reporting on trauma QI studies with reference to SQUIRE 2.0 and to provide recommendations for optimal reporting. Our research question is: In trauma centers, what is the quality of reporting on guideline, protocol or algorithm implementation within a hospital setting in terms of the Revised Standards for Quality Improvement Reporting Excellence (SQUIRE 2.0)?

METHODS AND ANALYSIS

This protocol was drafted using Preferred Reporting Items for Systematic Reviews and Meta-analysis Protocols (PRISMA-P) 2015.[15] See Appendix II. Registration of this protocol was completed in the International Prospective Register of Systematic Reviews (PROSPERO) on

January 15, 2018, registration number CRD42018084273. If protocol amendments are made, we will date and elaborate upon the rationale and details of such amendments in the final report

Eligibility criteria

Studies

We will include quantitative studies such as experimental studies (randomized clinical trials (RCTs), quasi-RCTs, non-RCTs); quasi-experimental studies (controlled before and after studies, interrupted time series); and, observational studies (cohort, case-control, registry studies). Only articles evaluating the effects on providers and/or patients of an implemented guideline, protocol or algorithm will be included. Studies will be excluded if they describe a guideline, protocol or algorithm implementation without evaluating its effects in a trauma setting. Qualitative studies, conference abstracts, proceedings, editorials and commentaries will be excluded.

Participants

Articles will be included in the review if the reported QI study is exclusively oriented to the care of injured adults (>18yrs) and focused on change involving health care practitioners within a hospital setting (i.e. trauma center).

Health care practitioners include the following:

- Surgeon (trauma, orthopedic, neurosurgery, plastics, vascular, urology)
- Physician (emergency medicine, anesthesiologist, radiologist, transfusion medicine, geriatrician, intensive care)
- Housestaff or trainee in any of the previously listed medical or surgical specialties

- Nurse or nurse practitioner
- Health professional student
- Physiotherapist
- Occupational therapist
- Speech therapist
- Pharmacist or pharmacy technician
- Social worker

Guideline, protocol or algorithm

Using the American College of Surgeons' Resources for Optimal Care of the Injured (2014) as a guide, we have defined a guideline, protocol or algorithm as any effort to reduce unnecessary variation in care through the development of a standardized tool and/or statement derived from evidence-based validated sources or best available literature and clinical experience.[1] Guidelines and protocols may be systematically developed consensus statements that are designed to assist in clinical decision-making within an institution, and consist of a step-by-step explanation of procedures for problem-solving or achieving a desired outcome.[16] Protocols are often displayed in an algorithm format and implemented as clinical pathways using provider education and/or computerized clinical decision support tools in the form of order sets or standardized consultation requests.

Setting

We will include reports of QI studies undertaken in any adult trauma center (Level I, II, or III). Clinical areas may include but are not limited to the trauma ward, trauma bay, emergency department, operating room, intensive care unit and angioembolization suite.

Information Sources – search strategy

The databases searched will include EMBASE, MEDLINE, CINAHL, and the Cochrane Central Register of Controlled Trials from 2010. The year 2010 was selected to coincide with the launch of TQIP which has made evidence-based guidelines widely available to trauma centers. The database search will be supplemented by searching trial registries (e.g., clinicaltrials.gov) and grey literature online. Only English articles will be considered due to limited language resources. There are no restrictions by country of study. If necessary we will contact study authors for data clarification and to identify additional studies. Lastly, we will hand search publications known for publishing QI in trauma namely the Journal of Trauma and Acute Care Surgery and Journal of Trauma Nursing. We will also hand search the references of included studies. An information specialist (LP) with expertise developing searches for QI systematic reviews will develop and implement the search (Appendix III – Search strategy).

Data management

A web-based software such as Covidence (https://www.covidence.org/) will be used for data management.

Study selection

A pilot test of 25 randomly selected citations will be conducted by all authors to verify the inclusion/exclusion criteria. Subsequently, all study titles and abstracts will be reviewed by two reviewers independently (Level I screening). Full texts of studies considered appropriate or uncertain for inclusion will be retrieved. Full-text articles will be reviewed by two reviewers independently (Level II screening). All discrepancies will be resolved by discussion or a third reviewer. Study selection process and reasons for exclusion will be reported.

Data collection

Data from included studies will be abstracted independently by two reviewers using a standardized data collection form to address the primary and secondary outcomes. Data to address the primary outcome will be obtained based on the18-items identified in the SQUIRE 2.0 guidelines (Appendix II – SQUIRE 2.0 guideline data collection form). Additional data will be collected to address the secondary outcomes, and will include information on study design, guideline-type, population, control, outcomes and other necessary information for assessment of risk of bias or meta-analyses. The data collection form will be pilot tested on a randomly selected 10% sample of included studies to ensure high inter-rater agreement between reviewers. Discrepancies will be resolved by discussion or with a third reviewer.

Outcomes

The primary outcome of interest is compliance with the SQUIRE 2.0 guidelines for reporting on guideline or protocol implementation. Secondary outcomes of interest are the qualitative assessment of risk of bias in non-randomized and randomized included studies. Other secondary

outcomes of interest are the reported effects of implemented guidelines on processes and/or patients outcomes.

Data synthesis

The flow of the screening process will be presented in a PRISMA flow diagram. A table in PICO format will present the characteristics of the included studies. Other important information will be included in the tables as needed. Primary outcomes, i.e., quality of reporting on QI study vis-à-vis SQUIRE 2.0 guideline items, will be presented descriptively by narrative summaries and as percentage scores for each guideline item across included studies. These data will be extracted by way of their absence or presence in the QI report (i.e., yes, no or unclear). Narrative summaries of sub-groups will also be provided for example of guideline-type, targeted deficiencies or providers (e.g. physicians, nurses, etc).

Risk of bias assessment will be performed independently in duplicate for each included study. Any disagreement will be resolved through discussion and consensus. For RCTs, we will use the Cochrane Collaboration's tool[17], which assesses bias in domains of sequence generation, allocation concealment, blinding of outcomes, incomplete outcome data, selective outcome reporting, and baseline imbalances. For cohort studies, risk of bias will be evaluated on the selection of the exposed and non-exposed cohorts, the comparability of the cohorts, the assessment of outcomes, and the adequacy of follow-up, using the Newcastle-Ottawa scale[18].

The outcomes of each intervention (the effects of the guideline implementation on processes and/or patients) will be synthesized in a table. Studies will be combined in meta-analyses if sufficient clinical, methodological, and statistical homogeneity is found. Clinical and

methodological heterogeneity across the studies will be assessed by examining the details of the subjects, the baseline data, the interventions and the outcomes to determine whether the studies are sufficiently similar or not. If meta-analyses are conducted, statistical heterogeneity will be determined using the I^2 statistic and the chi-square test. Pooling of overall estimates of effect will be performed using generic inverse variance weighting methods. Using these methods, each study estimate of the relative treatment will be given a weight that is equal to the inverse of the variance of the effect estimate (i.e., one divided by the standard error squared).

We will use computer software (RevMan 5.3, The Nordic Cochrane Centre, The Cochrane Collaboration, 2015 or similar) to carry out a quantitative analysis. If performed, meta-analyses will be conducted using a mixed-effect model. Reporting bias will be assessed with a funnel plot of the studies included in the review.

ETHICS AND DISSEMINATION

QI is required in trauma centers but needs to be effectively designed and implemented in order to achieve improvements in targeted outcomes. Trauma centers have variable success with QI that may be modifiable by enhancing the quality of QI reporting and thus the transferability of findings. It is therefore timely to review the quality of reporting by trauma centers that are implementing guidelines and protocols with a view to describe current gaps and opportunities. There are no ethical or safety concerns with this study. We will disseminate the results of this review through scientific publication and conferences. We expect our results to have important implications for trauma center leaders and practitioners when planning future guideline implementations.

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Contributions of protocol authors: LGC is the guarantor, conceived of the study and drafted the protocol. ABN, BH, AW and LDL provided expertise on trauma. LP developed the search strategy. LP and LDL provided expertise on systematic review methods. LGC, ABN, LP, BH, AW, DDP, AZ, LDL contributed to development of the selection criteria. LGC, ABN, LP, BH, AW, DDP, AZ, LDL provided critical revisions and approved the final version of the manuscript.

Competing interests statement: The authors declare no competing interests.

APPENDIX I – Data collection form based on SQUIRE 2.0

Revised Standards for Quality Improvement Reporting Excellence (SQUIRE 2.0)		
Data collection form		**Yes/No/Unclear**
TITLE AND ABSTRACT		
1. Title	Indicate that the manuscript concerns an initiative to improve healthcare (broadly defined to include the quality, safety, effectiveness, patient-centeredness, timeliness, cost, efficiency and equity of healthcare).	
2. Abstract	a. Provide adequate information to aid in searching and indexing. b. Summarise all key information from various sections of the text using the abstract format of the intended publication or a structured summary as background, local problem, methods, interventions, results, conclusions.	
INTRODUCTION	*WHY DID YOU START?*	
3. Problem description	Nature and significance of the local problem.	
4. Available knowledge	Summary of what is currently known about the problem, including relevant previous studies.	
5. Rationale	Informal or formal frameworks, models, concepts and/or theories used to explain the problem, any reasons or assumptions that were used to develop the intervention(s) and reasons why the intervention(s) was expected to work.	
6. Specific aims	Purpose of the project and of this report.	
METHODS	*WHAT DID YOU DO?*	
7. Context	Contextual elements considered important at the outset of introducing the intervention(s)	
8. Intervention(s)	a. Description of the intervention(s) in sufficient detail that other(s) could reproduce it. b. Specifics of the team involved in the work.	
9. Study of the intervention(s)	a. Approach chosen for assessing the impact of the intervention(s). b. Approach used to establish whether the observed outcomes were due to the intervention(s).	
10. Measures	a. Measures chosen for studying processes and outcomes of the intervention(s), including rationale for choosing them, their operational definitions and their validity and reliability b. Description of the approach to the ongoing assessment of contextual elements that contributed to the success, failure, efficiency and cost. c. Methods employed for assessing completeness and accuracy of data.	

11. Analysis	a. Qualitative and quantitative methods used to draw inferences from the data. b. Methods for understanding variation within the data, including the effects of time as a variable.
12. Ethical considerations	Ethical aspects of implementing and studying the intervention(s) and how they were addressed, including but not limited to formal ethics review and potential conflicts of interest.
RESULTS	*WHAT DID YOU FIND?*
13. Results	a. Initial steps of the intervention(s) and their evolution over time (e.g., time-line diagram, flow chart or table), including modifications made to the intervention during the project. b. Details of the process measures and outcomes. c. Contextual elements that interacted with the intervention(s). d. Observed associations between outcomes, interventions and relevant contextual elements. e. Unintended consequences such as unexpected benefits, problems, failures or costs associated with the intervention(s). f. Details about missing data.
DISCUSSION	*WHAT DOES IT MEAN?*
14. Summary	a. Key findings, including relevance to the rationale and specific aims. b. Particular strengths of the project.
15. Interpretation	a. Nature of the association between the intervention(s) and the outcomes. b. Comparison of results with findings from other publications. c. Impact of the project on people and systems. d. Reasons for any differences between observed and anticipated outcomes, including the influence of context. e. Costs and strategic trade-offs, including opportunity costs.
16. Limitations	a. Limits to the generalisability of the work. b. Factors that might have limited internal validity such as confounding, bias or imprecision in the design, methods, measurement or analysis. c. Efforts made to minimise and adjust for limitations.
17. Conclusions	a. Usefulness of the work.

	b. Sustainability. c. Potential for spread to other contexts. d. Implications for practice and for further study in the field. e. Suggested next steps.
OTHER INFORMATION	
18. Funding	Sources of funding that supported this work. Role, if any, of the funding organisation in the design, implementation, interpretation and reporting.

APPENDIX II – PRISMA-P checklist

PRISMA-P (Preferred Reporting Items for Systematic review and Meta-Analysis Protocols) 2015 checklist: recommended items to address in a systematic review protocol*

Section and topic	Item No	Checklist item	Information reported		Page number(s)
			Yes	No	
ADMINISTRATIVE INFORMATION					
Title: Identification	1a	Identify the report as a protocol of a systematic review	√		01
Update	1b	If the protocol is for an update of a previous systematic review, identify as such			N/A
Registration	2	If registered, provide the name of the registry (such as PROSPERO) and registration number	√		03
Authors: Contact	3a	Provide name, institutional affiliation, e-mail address of all protocol authors; provide physical mailing address of corresponding author	√		01
Contributions	3b	Describe contributions of protocol authors and identify the guarantor of the review	√		14
Amendments	4	If the protocol represents an amendment of a previously completed or published protocol, identify as such and list changes; otherwise, state plan for documenting important protocol amendments			N/A
Support: Sources	5a	Indicate sources of financial or other support for the review	√		14
Sponsor	5b	Provide name for the review funder and/or sponsor	√		14
Role of sponsor or funder	5c	Describe roles of funder(s), sponsor(s), and/or institution(s), if any, in developing the protocol	√		14
INTRODUCTION					
Rationale	6	Describe the rationale for the review in the context of what is already known	√		04-05
Objectives	7	Provide an explicit statement of the question(s) the review will address with reference to participants, interventions, comparators, and outcomes (PICO)	√		05
METHODS					
Eligibility criteria	8	Specify the study characteristics (such as PICO, study design, setting, time frame) and report characteristics (such as years considered, language, publication status) to be used as criteria for eligibility for the review	√		05-09
Information sources	9	Describe all intended information sources (such as electronic databases, contact with study authors, trial registers or other grey literature sources) with planned dates of coverage	√		08
Search strategy	10	Present draft of search strategy to be used for at least one electronic database, including planned limits, such that it could be repeated	√		Appendix III

Study records: Data management	11a	Describe the mechanism(s) that will be used to manage records and data throughout the review	√		08
Selection process	11b	State the process that will be used for selecting studies (such as two independent reviewers) through each phase of the review (that is, screening, eligibility and inclusion in meta-analysis)	√		08-09
Data collection process	11c	Describe planned method of extracting data from reports (such as piloting forms, done independently, in duplicate), any processes for obtaining and confirming data from investigators	√		09
Data items	12	List and define all variables for which data will be sought (such as PICO items, funding sources), any pre-planned data assumptions and simplifications	√		09-11
Outcomes and prioritization	13	List and define all outcomes for which data will be sought, including prioritization of main and additional outcomes, with rationale	√		09-10
Risk of bias in individual studies	14	Describe anticipated methods for assessing risk of bias of individual studies, including whether this will be done at the outcome or study level, or both; state how this information will be used in data synthesis	√		10
Data synthesis	15a	Describe criteria under which study data will be quantitatively synthesised	√		10-11
	15b	If data are appropriate for quantitative synthesis, describe planned summary measures, methods of handling data and methods of combining data from studies, including any planned exploration of consistency (such as I^2, Kendall's τ)	√		11
	15c	Describe any proposed additional analyses (such as sensitivity or subgroup analyses, meta-regression)	√		11
	15d	If quantitative synthesis is not appropriate, describe the type of summary planned			N/A
Meta-bias(es)	16	Specify any planned assessment of meta-bias(es) (such as publication bias across studies, selective reporting within studies)			N/A
Confidence in cumulative evidence	17	Describe how the strength of the body of evidence will be assessed (such as GRADE)			N/A

APPENDIX III - Search Strategy

Database: Ovid MEDLINE: Epub Ahead of Print, In-Process & Other Non-Indexed Citations, Ovid MEDLINE® Daily and Ovid MEDLINE® <1946-Present>

Search Strategy:

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1 trauma$.mp.
2 exp "Wounds and Injuries"/
3 injur$.tw.
4 or/1-3
5 Practice Guidelines as Topic/ [Guidelines]
6 Guidelines as Topic/
7 Guideline Adherence/
8 Critical Pathways/
9 Clinical Protocols/
10 Algorithms/
11 (practice adj guideline?).tw.
12 (clinical adj guideline?).tw.
13 (treatment adj guideline?).tw.
14 (diagnos$ adj guideline?).tw.
15 (management adj guideline?).tw.
16 (clinical adj algorithm?).tw.
17 (treatment adj algorithm?).tw.
18 (diagnos$ adj algorithm?).tw.
19 (management adj algorithm?).tw.
20 (clinical adj protocol?).tw.
21 (treatment adj protocol?).tw.
22 (diagnos$ adj protocol?).tw.
23 (management adj protocol?).tw.
24 (critical adj pathway?).tw.
25 (clinical adj pathway?).tw.
26 (treatment adj pathway?).tw.
27 (diagnos$ adj pathway?).tw.
28 (management adj pathway?).tw.
29 or/5-28
30 ((study adj12 protocol?) or (trial adj12 protocol?)).ti.
31 29 not 30
32 exp Hospitals/
33 Emergency Service, Hospital/
34 Trauma Centers/
35 Academic Medical Centers/
36 Intensive Care Units/
37 hospital$.tw.
38 (emergenc$ adj care).tw.
39 (emergenc$ adj department?).tw.

40 (emergenc$ adj unit?).tw.
41 (emergenc$ adj room?).tw.
42 (emergenc$ adj service?).tw.
43 "accident and emergency".tw.
44 "accident & emergency".tw.
45 (trauma adj center?).tw.
46 (trauma adj centre?).tw.
47 (trauma adj unit?).tw.
48 (trauma adj department?).tw.
49 "academic medical centre?".tw.
50 "academic medical center?".tw.
51 ICU?.tw.
52 (intensive adj care).tw.
53 or/32-52
54 randomized controlled trial.pt. [RCT fitler - validated]
55 randomized.mp.
56 placebo.mp.
57 Controlled Clinical Trial/ [quasi-expt-observ study filter]
58 Observational Study/
59 (descriptive adj3 stud$).tw.
60 (descriptive adj3 design).tw.
61 (descriptive adj3 analys?s).tw.
62 nonrandom$.tw.
63 non-random$.tw.
64 non-experiment$.tw.
65 nonexperiment$.tw.
66 (natural adj experiment?).tw.
67 (observational$ adj3 stud$).tw.
68 (observational$ adj3 design).tw.
69 (observational$ adj3 analys?s).tw.
70 quasirandom$.tw.
71 quasi-random$.tw.
72 quasiexperimental.tw.
73 quasi-experimental.tw.
74 exp Cohort Studies/
75 Registries/
76 Epidemiologic Methods/
77 limit 76 to yr=1971-1988
78 cohort$.tw.
79 (follow-up adj stud$).tw.
80 (followup adj stud$).tw.
81 (follow-up adj design).tw.
82 (followup adj design).tw.
83 (follow-up adj analys?s).tw.
84 (followup adj analys?s).tw.
85 (follow-up and base-line).tw.

86 (followup and baseline).tw.
87 longitudinal.tw.
88 ("long term" adj stud$).tw.
89 (longterm adj stud$).tw.
90 ("long term" adj design).tw.
91 (longterm adj design).tw.
92 ("long term" adj analys?s).tw.
93 (longterm adj analys?s).tw.
94 (population adj stud$).tw.
95 (population adj analys?s).tw.
96 prospective.tw.
97 retrospective.tw.
98 registry.tw.
99 registries.tw.
100 Cross-Sectional Studies/
101 (cross adj sectional).tw.
102 (incidence adj stud$).tw.
103 (prevalence adj stud$).tw.
104 (transversal adj stud$).tw.
105 exp Case-Control Studies/
106 Control Groups/
107 Matched-Pair Analysis/
108 (case$ adj3 control$).tw.
109 (case adj3 comparison$).tw.
110 (case$ and series).tw.
111 case-referent.tw.
112 (control$ adj3 stud$).tw.
113 (control adj group$).tw.
114 before-after.tw.
115 "before and after".tw.
116 (before adj after).tw.
117 (time adj series).tw.
118 Evaluation Studies/
119 Comparative Study/
120 Multicenter Study/
121 Pilot Projects/
122 Program Evaluation/
123 Validation Studies/
124 (comparative adj stud$).tw.
125 (comparison adj stud$).tw.
126 (evaluation adj stud$).tw.
127 effectiveness.tw.
128 intervention.tw.
129 (multicenter adj stud$).tw.
130 (multi-center adj stud$).tw.
131 (multicenter adj stud$).tw.

132 (multi-center adj stud$).tw.
133 (multidimensional adj stud$).tw.
134 (multi-dimensional adj stud$).tw.
135 (pre- adj5 post-).tw.
136 (pretest adj5 posttest).tw.
137 (program$ adj6 evaluat$).tw.
138 or/54-75,77-137
139 4 and 31 and 53 and 138
140 exp Animals/ not (exp Animals/ and Humans/)
141 139 not 140
142 limit 141 to yr="2010 -Current"
143 limit 142 to english language

BMJ Open

What is the quality of reporting on guideline, protocol or algorithm implementation in adult trauma centers: Protocol for a systematic review

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Primary Subject Heading:	Surgery
Secondary Subject Heading:	Health services research, Evidence based practice
Keywords:	TRAUMA MANAGEMENT, Protocols & guidelines < HEALTH SERVICES ADMINISTRATION & MANAGEMENT, Implementation, systematic review

What is the quality of reporting on guideline, protocol or algorithm implementation in adult trauma centers: Protocol for a systematic review

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ABSTRACT

Introduction: Quality improvement (QI) is mandatory in trauma centers but no prescription for doing successful QI exists. Considerable variation in implementation strategies and inconsistent use of evidence-based protocols therefore exist across centers. The quality of reporting on these strategies may limit the transferability of successful initiatives across centers. This systematic review will assess the quality of reporting on guideline, protocol or algorithm implementation within a trauma center in terms of the Revised Standards for Quality Improvement Reporting Excellence (SQUIRE 2.0).

Methods and analysis: We will search for English language articles published after 2010 in EMBASE, MEDLINE, CINAHL electronic databases, and the Cochrane Central Register of Controlled Trials. The database search will be supplemented by searching trial registries and grey literature online. Included studies will evaluate the effectiveness of guideline implementation in terms of change in clinical practice or improvement in patient outcomes.. The primary outcome will be a global score reporting the proportion of studies respecting at least 80% of the SQUIRE 2.0 criteria and will be obtained based on the18-items identified in the SQUIRE 2.0 guidelines.. Secondary outcome will be the risk of bias assessed with the Risk Of Bias In Non-randomised Studies - of Interventions (ROBINS-I) tool for observational cohort studies and with the Cochrane Collaboration tool for randomized controlled trials. Meta-analyses will be conducted in randomized controlled trials to estimate the effectiveness of guideline implementation if studies are not heterogeneous. If meta-analyses are conducted, we will combine studies according to the risk of bias (low, moderate, or high/unclear) in subgroup analyses. All study titles, abstracts and full-text screening will be completed independently and

in duplicate by the review team members. Data extraction and risk of bias assessment will also be done independently and in duplicate.

Ethics and dissemination: Results will be disseminated through scientific publication and conferences.

Systematic review registration: PROSPERO registration number CRD42018084273

Strengths and limitations of this study:

- The research team is comprised of methodological and content experts in the fields of knowledge synthesis, trauma and quality improvement.
- A rigorous literature search and systematic review methodology will be used to identify relevant guideline implementation studies in the trauma care context.
- Indexing of quality improvement studies in the electronic databases is poor and inconsistent which may result in some studies not being captured in this review.

INTRODUCTION

Trauma centers are state or regionally designated hospitals that are resourced to provide specialized care for severely injured patients. In addition to being designated as such, trauma centers may also go through the process of accreditation or verification by an external body; the verification process utilizes standard criteria to ensure that trauma centers are suitably equipped to provide the highest quality trauma care.[1] Center verification criteria include engagement in quality improvement (QI) activity as part of a Performance Improvement and Patient Safety (PIPS) program.[1] A PIPS program is designed to monitor center performance and outcomes over time, with continuous improvement as the ultimate objective.

Despite the mandated existence of PIPS programs, patient outcomes across accredited trauma centers continue to be highly variable.[2-4] Differences in structures and processes of care across centers are hypothesized to contribute to these persistent variations in outcomes.[5] Trauma centers also report inconsistent use of evidence-based protocols, which may contribute to differences in quality of care across institutions.[6-8,] Finally, implementation of PIPS programs and QI strategies has varied considerably across centers; inadequacy of a center's PIPS program is the most frequent reason for failing verification review.[9] Identifying ways to support trauma centers in developing and implementing successful QI strategies is therefore critical.

One mechanism to support QI in trauma centers is the American College of Surgeons' Trauma Quality Improvement Program (TQIP).[10] Launched in 2010, TQIP provides performance data reports to enrolled trauma centers on their processes of care and patient outcomes relative to their peers using risk-adjusted benchmarking, as well as evidence-based guidelines. TQIP has also developed best practice guidelines in the areas of geriatric trauma management, massive transfusion in trauma, traumatic brain injury management, management of orthopedic trauma

and palliative care.[11] Each year, more than 1000 representatives of TQIP enrolled trauma centers meet to share successes and challenges in their QI efforts. Some centers have also published these successes in peer reviewed journals, for example reporting on reduction in rates of venous thromboembolism (VTE) and urinary tract infection (UTI).[12,13]

While successful QI strategies are increasingly published in the scholarly and grey literatures, the quality of that reporting may be playing an important role in the observed variation in the success of QI initiatives across centers. At this time we do not know if QI reporting in trauma is of sufficient detail or of high enough quality to enable replication or transferability to other centers. Even successful QI strategies, if inadequately reported, may result in failed initiatives at other centers wishing to implement them. The Revised Standards for Quality Improvement Reporting Excellence (SQUIRE 2.0) guidelines were developed to ensure the utility and quality of QI reporting in health care and to establish a common ground to share QI outcomes in the scholarly literature.[14] SQUIRE 2.0 is a checklist that guides reporting on QI methods and interventions. (Appendix I) The objective of our study is to assess the quality of reporting on trauma QI studies with reference to SQUIRE 2.0. Our research question is: In trauma centers, what is the quality of reporting on guideline, protocol or algorithm implementation within a hospital setting in terms of the Revised Standards for Quality Improvement Reporting Excellence (SQUIRE 2.0)?

METHODS AND ANALYSIS

This protocol was drafted using Preferred Reporting Items for Systematic Reviews and Meta-analysis Protocols (PRISMA-P) 2015.[15] (See Appendix II). Registration of this protocol was completed in the International Prospective Register of Systematic Reviews (PROSPERO) on

January 15, 2018, registration number CRD42018084273. If protocol amendments are made, we will date and elaborate upon the rationale and details of such amendments in the final report

Eligibility criteria

Studies

We will include quantitative studies such as experimental studies (randomized clinical trials (RCTs), quasi-RCTs, non-RCTs); quasi-experimental studies (controlled before and after studies, interrupted time series); and, observational studies (cohort, case-control, registry studies). Only studies evaluating effectiveness of guideline implementation in terms of change in clinical practice (e.g., adherence to guideline) or improvement in patient outcomes (e.g., mortality, morbidity, resource utilization). Studies will be excluded if they describe a guideline, protocol or algorithm implementation without6 evaluating its effects in a trauma setting. Qualitative studies, conference abstracts, proceedings, editorials and commentaries will be excluded.

Participants

Articles will be included in the review if the reported QI study is exclusively oriented to the care of injured adults (>18yrs) and focused on change involving health care practitioners within a hospital setting (i.e. trauma center).

Health care practitioners include the following:

- Surgeon (trauma, orthopedic, neurosurgery, plastics, vascular, urology)
- Physician (emergency medicine, anesthesiologist, radiologist, transfusion medicine, geriatrician, intensive care)

- Housestaff or trainee in any of the previously listed medical or surgical specialties
- Nurse or nurse practitioner
- Health professional student
- Physiotherapist
- Occupational therapist
- Speech therapist
- Pharmacist or pharmacy technician
- Social worker

Intervention: Guideline, protocol or algorithm

Using the American College of Surgeons' Resources for Optimal Care of the Injured (2014) as a guide, we have defined a guideline, protocol or algorithm as any effort to reduce unnecessary variation in care through the development of a standardized tool and/or statement derived from evidence-based validated sources or best available literature and clinical experience.[1] Guidelines and protocols may be systematically developed consensus statements that are designed to assist in clinical decision-making within an institution, and consist of a step-by-step explanation of procedures for problem-solving or achieving a desired outcome.[16] Protocols are often displayed in an algorithm format and implemented as clinical pathways using provider education and/or computerized clinical decision support tools in the form of order sets or standardized consultation requests.

Outcomes

The primary outcome will be a global score reporting the proportion of studies respecting at least 80% of the SQUIRE 2.0 criteria and will be obtained based on the18-items identified in the SQUIRE 2.0 guidelines. Secondary outcome will be the risk of bias in each study assessed with the Risk Of Bias In Non-randomised Studies - of Interventions (ROBINS-I) tool for observational cohort studies[17] and with the Cochrane Collaboration tool for randomized controlled trials[18]. Meta-analyses will be conducted in randomized controlled trials to estimate the effectiveness of guideline implementation if studies are not heterogeneous. If meta-analyses are conducted, we will combine studies according to the risk of bias (low, moderate, or high/unclear) in subgroup analyses.

Setting

We will include reports of QI studies undertaken in any adult trauma center (Level I, II, or III). Clinical areas may include but are not limited to the trauma ward, trauma bay, emergency department, operating room, intensive care unit and angioembolization suite.

Information Sources – search strategy

The databases searched will include EMBASE, MEDLINE, CINAHL, and the Cochrane Central Register of Controlled Trials from 2010. The year 2010 was selected to coincide with the launch of TQIP which has made evidence-based guidelines widely available to trauma centers. The database search will be supplemented by searching trial registries (e.g., clinicaltrials.gov) and grey literature online (e.g., American College of Surgeons Trauma Quality Improvement Program (ACS TQIP); Victorian State Trauma Outcomes Registry Monitoring Group (VSTORM); the Trauma Audit and Research Network (TARN); Agency for Healthcare

Research and Quality (AHRQ). Only English articles will be considered due to limited language resources. There are no restrictions by country of study. If necessary we will contact study authors for data clarification and to identify additional studies. Lastly, we will hand search publications known for publishing QI in trauma namely the Journal of Trauma and Acute Care Surgery and Journal of Trauma Nursing. We will also hand search the references of included studies. An information specialist (LP) with expertise developing searches for QI systematic reviews will develop and implement the search (Appendix III – Search strategy).

To verify the sensitivity of our search strategy we identified three articles that would be included in the review. We subsequently ran our search strategy to ensure these articles were captured. We assessed the specificity of the search which resulted in 2259 articles in MEDLINE which we determined to be feasible for review.

Data management

A web-based software such as Covidence (https://www.covidence.org/) will be used for data management.

Study selection

A pilot test of 75 randomly selected citations will be conducted by all authors to verify the inclusion/exclusion criteria. Subsequently, all study titles and abstracts will be reviewed by two reviewers independently (Level I screening). Full texts of studies considered appropriate or uncertain for inclusion will be retrieved. Full-text articles will be reviewed by two reviewers independently (Level II screening). All discrepancies will be resolved by discussion or a third reviewer. Study selection process and reasons for exclusion will be reported.

Data collection

Data from included studies will be abstracted independently by two reviewers using a standardized data collection form to address the primary and secondary outcomes. Data to address the primary outcome will be obtained based on the18-items identified in the SQUIRE 2.0 guidelines (Appendix II – SQUIRE 2.0 guideline data collection form). Additional data will be collected to address the secondary outcomes, and will include information on study design, guideline-type, population, control, outcomes and other necessary information for assessment of risk of bias or meta-analyses, such as effect estimates on guideline implementation outcomes. The data collection form will be pilot tested on a randomly selected 10% sample of included studies to ensure high inter-rater agreement between reviewers. Discrepancies will be resolved by discussion or with a third reviewer.

Data synthesis

The flow of the screening process will be presented in a PRISMA flow diagram. A table in PICO format will present the characteristics of the included studies. Other important information will be included in the tables as needed. The primary outcome, i.e., the proportion of studies respecting at least 80% of the SQUIRE 2.0 criteria, will be presented descriptively by narrative summaries and as percentage scores for each guideline item across included studies. These data will be extracted by way of their absence or presence in the QI report (i.e., yes, no or unclear). Narrative summaries of sub-groups will also be provided for example of guideline-type, targeted deficiencies or providers (e.g. physicians, nurses, etc).

Risk of bias assessment will be performed independently in duplicate for each included study. Any disagreement will be resolved through discussion and consensus. For RCTs, we will use the Cochrane Collaboration's tool[18], which assesses bias in domains of sequence generation,

allocation concealment, blinding of outcomes, incomplete outcome data, selective outcome reporting, and baseline imbalances. For cohort studies, risk of bias will be evaluated on the selection of the exposed and non-exposed cohorts, the comparability of the cohorts, the assessment of outcomes, and the adequacy of follow-up, using the ROBINS-I tool [17].

The outcomes of each intervention (the effects of the guideline implementation on processes and/or patients) will be synthesized in a table. Studies will be combined in meta-analyses if sufficient clinical, methodological, and statistical homogeneity is found. Clinical and methodological heterogeneity across the studies will be assessed by examining the details of the subjects, the baseline data, the interventions and the outcomes to determine whether the studies are sufficiently similar or not. Statistical heterogeneity will be determined using the I^2 statistic and the chi-square test. Pooling of overall estimates of effect will be performed using generic inverse variance weighting methods. Using these methods, each study estimate of the relative treatment will be given a weight that is equal to the inverse of the variance of the effect estimate (i.e., one divided by the standard error squared).

We will use computer software (RevMan 5.3, The Nordic Cochrane Centre, The Cochrane Collaboration, 2015 or similar) to carry out a quantitative analysis. If performed, meta-analyses will be conducted using a mixed-effect model if heterogeneity is high. Reporting bias will be assessed with a funnel plot of the studies included in the review.

Patient and Public Involvement

No patients or public were involved in the design of the protocol.

ETHICS AND DISSEMINATION

QI is required in trauma centers but needs to be effectively designed and implemented in order to achieve improvements in targeted outcomes. Trauma centers have variable success with QI that may be modifiable by enhancing the quality of QI reporting and thus the transferability of findings. It is therefore timely to review the quality of reporting by trauma centers that are implementing guidelines and protocols with a view to describe current gaps and opportunities. There are no ethical or safety concerns with this study. We will disseminate the results of this review through scientific publication and conferences. We expect our results to have important implications for trauma center leaders and practitioners when planning future guideline implementations.

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Contributions of protocol authors: LGC is the guarantor, conceived of the study and drafted the protocol. ABN, BH, AW and LDL provided expertise on trauma. LP developed the search strategy. LP and LDL provided expertise on systematic review methods. LGC, ABN, LP, BH, AW, DDP, AZ, LDL contributed to development of the selection criteria. LGC, ABN, LP, BH, AW, DDP, AZ, LDL provided critical revisions and approved the final version of the manuscript.

Competing interests statement: The authors declare no competing interests.

APPENDIX I – Data collection form based on SQUIRE 2.0

Revised Standards for Quality Improvement Reporting Excellence (SQUIRE 2.0)		
Data collection form		**Yes/No/Unclear**
TITLE AND ABSTRACT		
1. Title	Indicate that the manuscript concerns an initiative to improve healthcare (broadly defined to include the quality, safety, effectiveness, patient-centeredness, timeliness, cost, efficiency and equity of healthcare).	
2. Abstract	a. Provide adequate information to aid in searching and indexing. b. Summarise all key information from various sections of the text using the abstract format of the intended publication or a structured summary as background, local problem, methods, interventions, results, conclusions.	
INTRODUCTION	*WHY DID YOU START?*	
3. Problem description	Nature and significance of the local problem.	
4. Available knowledge	Summary of what is currently known about the problem, including relevant previous studies.	
5. Rationale	Informal or formal frameworks, models, concepts and/or theories used to explain the problem, any reasons or assumptions that were used to develop the intervention(s) and reasons why the intervention(s) was expected to work.	
6. Specific aims	Purpose of the project and of this report.	
METHODS	*WHAT DID YOU DO?*	
7. Context	Contextual elements considered important at the outset of introducing the intervention(s)	
8. Intervention(s)	a. Description of the intervention(s) in sufficient detail that other(s) could reproduce it. b. Specifics of the team involved in the work.	
9. Study of the intervention(s)	a. Approach chosen for assessing the impact of the intervention(s). b. Approach used to establish whether the observed outcomes were due to the intervention(s).	
10. Measures	a. Measures chosen for studying processes and outcomes of the intervention(s), including rationale for choosing them, their operational definitions and their validity and reliability b. Description of the approach to the ongoing assessment of contextual elements that contributed to the success, failure, efficiency and cost. c. Methods employed for assessing completeness and accuracy of data.	

11. Analysis	a. Qualitative and quantitative methods used to draw inferences from the data. b. Methods for understanding variation within the data, including the effects of time as a variable.
12. Ethical considerations	Ethical aspects of implementing and studying the intervention(s) and how they were addressed, including but not limited to formal ethics review and potential conflicts of interest.
RESULTS	*WHAT DID YOU FIND?*
13. Results	a. Initial steps of the intervention(s) and their evolution over time (e.g., time-line diagram, flow chart or table), including modifications made to the intervention during the project. b. Details of the process measures and outcomes. c. Contextual elements that interacted with the intervention(s). d. Observed associations between outcomes, interventions and relevant contextual elements. e. Unintended consequences such as unexpected benefits, problems, failures or costs associated with the intervention(s). f. Details about missing data.
DISCUSSION	*WHAT DOES IT MEAN?*
14. Summary	a. Key findings, including relevance to the rationale and specific aims. b. Particular strengths of the project.
15. Interpretation	a. Nature of the association between the intervention(s) and the outcomes. b. Comparison of results with findings from other publications. c. Impact of the project on people and systems. d. Reasons for any differences between observed and anticipated outcomes, including the influence of context. e. Costs and strategic trade-offs, including opportunity costs.
16. Limitations	a. Limits to the generalisability of the work. b. Factors that might have limited internal validity such as confounding, bias or imprecision in the design, methods, measurement or analysis. c. Efforts made to minimise and adjust for limitations.
17. Conclusions	a. Usefulness of the work.

	b. Sustainability. c. Potential for spread to other contexts. d. Implications for practice and for further study in the field. e. Suggested next steps.
OTHER INFORMATION	
18. Funding	Sources of funding that supported this work. Role, if any, of the funding organisation in the design, implementation, interpretation and reporting.

APPENDIX II – PRISMA-P checklist

PRISMA-P (Preferred Reporting Items for Systematic review and Meta-Analysis Protocols) 2015 checklist: recommended items to address in a systematic review protocol*

Section and topic	Item No	Checklist item	Information reported		Page number(s)
			Yes	No	
ADMINISTRATIVE INFORMATION					
Title: Identification	1a	Identify the report as a protocol of a systematic review	√		01
Update	1b	If the protocol is for an update of a previous systematic review, identify as such			N/A
Registration	2	If registered, provide the name of the registry (such as PROSPERO) and registration number	√		03
Authors: Contact	3a	Provide name, institutional affiliation, e-mail address of all protocol authors; provide physical mailing address of corresponding author	√		01
Contributions	3b	Describe contributions of protocol authors and identify the guarantor of the review	√		14
Amendments	4	If the protocol represents an amendment of a previously completed or published protocol, identify as such and list changes; otherwise, state plan for documenting important protocol amendments			N/A
Support: Sources	5a	Indicate sources of financial or other support for the review	√		14
Sponsor	5b	Provide name for the review funder and/or sponsor	√		14
Role of sponsor or funder	5c	Describe roles of funder(s), sponsor(s), and/or institution(s), if any, in developing the protocol	√		14
INTRODUCTION					
Rationale	6	Describe the rationale for the review in the context of what is already known	√		04-05
Objectives	7	Provide an explicit statement of the question(s) the review will address with reference to participants, interventions, comparators, and outcomes (PICO)	√		05
METHODS					
Eligibility criteria	8	Specify the study characteristics (such as PICO, study design, setting, time frame) and report characteristics (such as years considered, language, publication status) to be used as criteria for eligibility for the review	√		05-09
Information sources	9	Describe all intended information sources (such as electronic databases, contact with study authors, trial registers or other grey literature sources) with planned dates of coverage	√		08
Search strategy	10	Present draft of search strategy to be used for at least one electronic database, including planned limits, such that it could be repeated	√		Appendix III

Study records: Data management	11a	Describe the mechanism(s) that will be used to manage records and data throughout the review	√		08
Selection process	11b	State the process that will be used for selecting studies (such as two independent reviewers) through each phase of the review (that is, screening, eligibility and inclusion in meta-analysis)	√		08-09
Data collection process	11c	Describe planned method of extracting data from reports (such as piloting forms, done independently, in duplicate), any processes for obtaining and confirming data from investigators	√		09
Data items	12	List and define all variables for which data will be sought (such as PICO items, funding sources), any pre-planned data assumptions and simplifications	√		09-11
Outcomes and prioritization	13	List and define all outcomes for which data will be sought, including prioritization of main and additional outcomes, with rationale	√		09-10
Risk of bias in individual studies	14	Describe anticipated methods for assessing risk of bias of individual studies, including whether this will be done at the outcome or study level, or both; state how this information will be used in data synthesis	√		10
Data synthesis	15a	Describe criteria under which study data will be quantitatively synthesised	√		10-11
	15b	If data are appropriate for quantitative synthesis, describe planned summary measures, methods of handling data and methods of combining data from studies, including any planned exploration of consistency (such as I^2, Kendall's τ)	√		11
	15c	Describe any proposed additional analyses (such as sensitivity or subgroup analyses, meta-regression)	√		11
	15d	If quantitative synthesis is not appropriate, describe the type of summary planned			N/A
Meta-bias(es)	16	Specify any planned assessment of meta-bias(es) (such as publication bias across studies, selective reporting within studies)			N/A
Confidence in cumulative evidence	17	Describe how the strength of the body of evidence will be assessed (such as GRADE)			N/A

APPENDIX III - Search Strategy

Database: Ovid MEDLINE: Epub Ahead of Print, In-Process & Other Non-Indexed Citations, Ovid MEDLINE® Daily and Ovid MEDLINE® <1946-Present>

Search Strategy:

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1 trauma$.mp.
2 exp "Wounds and Injuries"/
3 injur$.tw.
4 or/1-3
5 Practice Guidelines as Topic/ [Guidelines]
6 Guidelines as Topic/
7 Guideline Adherence/
8 Critical Pathways/
9 Clinical Protocols/
10 Algorithms/
11 (practice adj guideline?).tw.
12 (clinical adj guideline?).tw.
13 (treatment adj guideline?).tw.
14 (diagnos$ adj guideline?).tw.
15 (management adj guideline?).tw.
16 (clinical adj algorithm?).tw.
17 (treatment adj algorithm?).tw.
18 (diagnos$ adj algorithm?).tw.
19 (management adj algorithm?).tw.
20 (clinical adj protocol?).tw.
21 (treatment adj protocol?).tw.
22 (diagnos$ adj protocol?).tw.
23 (management adj protocol?).tw.
24 (critical adj pathway?).tw.
25 (clinical adj pathway?).tw.
26 (treatment adj pathway?).tw.
27 (diagnos$ adj pathway?).tw.
28 (management adj pathway?).tw.
29 or/5-28
30 ((study adj12 protocol?) or (trial adj12 protocol?)).ti.
31 29 not 30
32 exp Hospitals/
33 Emergency Service, Hospital/
34 Trauma Centers/
35 Academic Medical Centers/
36 Intensive Care Units/
37 hospital$.tw.
38 (emergenc$ adj care).tw.
39 (emergenc$ adj department?).tw.

40 (emergenc$ adj unit?).tw.
41 (emergenc$ adj room?).tw.
42 (emergenc$ adj service?).tw.
43 "accident and emergency".tw.
44 "accident & emergency".tw.
45 (trauma adj center?).tw.
46 (trauma adj centre?).tw.
47 (trauma adj unit?).tw.
48 (trauma adj department?).tw.
49 "academic medical centre?".tw.
50 "academic medical center?".tw.
51 ICU?.tw.
52 (intensive adj care).tw.
53 or/32-52
54 randomized controlled trial.pt. [RCT fitler - validated]
55 randomized.mp.
56 placebo.mp.
57 Controlled Clinical Trial/ [quasi-expt-observ study filter]
58 Observational Study/
59 (descriptive adj3 stud$).tw.
60 (descriptive adj3 design).tw.
61 (descriptive adj3 analys?s).tw.
62 nonrandom$.tw.
63 non-random$.tw.
64 non-experiment$.tw.
65 nonexperiment$.tw.
66 (natural adj experiment?).tw.
67 (observational$ adj3 stud$).tw.
68 (observational$ adj3 design).tw.
69 (observational$ adj3 analys?s).tw.
70 quasirandom$.tw.
71 quasi-random$.tw.
72 quasiexperimental.tw.
73 quasi-experimental.tw.
74 exp Cohort Studies/
75 Registries/
76 Epidemiologic Methods/
77 limit 76 to yr=1971-1988
78 cohort$.tw.
79 (follow-up adj stud$).tw.
80 (followup adj stud$).tw.
81 (follow-up adj design).tw.
82 (followup adj design).tw.
83 (follow-up adj analys?s).tw.
84 (followup adj analys?s).tw.
85 (follow-up and base-line).tw.

86 (followup and baseline).tw.
87 longitudinal.tw.
88 ("long term" adj stud$).tw.
89 (longterm adj stud$).tw.
90 ("long term" adj design).tw.
91 (longterm adj design).tw.
92 ("long term" adj analys?s).tw.
93 (longterm adj analys?s).tw.
94 (population adj stud$).tw.
95 (population adj analys?s).tw.
96 prospective.tw.
97 retrospective.tw.
98 registry.tw.
99 registries.tw.
100 Cross-Sectional Studies/
101 (cross adj sectional).tw.
102 (incidence adj stud$).tw.
103 (prevalence adj stud$).tw.
104 (transversal adj stud$).tw.
105 exp Case-Control Studies/
106 Control Groups/
107 Matched-Pair Analysis/
108 (case$ adj3 control$).tw.
109 (case adj3 comparison$).tw.
110 (case$ and series).tw.
111 case-referent.tw.
112 (control$ adj3 stud$).tw.
113 (control adj group$).tw.
114 before-after.tw.
115 "before and after".tw.
116 (before adj after).tw.
117 (time adj series).tw.
118 Evaluation Studies/
119 Comparative Study/
120 Multicenter Study/
121 Pilot Projects/
122 Program Evaluation/
123 Validation Studies/
124 (comparative adj stud$).tw.
125 (comparison adj stud$).tw.
126 (evaluation adj stud$).tw.
127 effectiveness.tw.
128 intervention.tw.
129 (multicenter adj stud$).tw.
130 (multi-center adj stud$).tw.
131 (multicenter adj stud$).tw.

(multi-center adj stud$).tw.
(multidimensional adj stud$).tw.
(multi-dimensional adj stud$).tw.
(pre- adj5 post-).tw.
(pretest adj5 posttest).tw.
(program$ adj6 evaluat$).tw.
or/54-75,77-137
4 and 31 and 53 and 138
exp Animals/ not (exp Animals/ and Humans/)
139 not 140
limit 141 to yr="2010 -Current"
limit 142 to english language

APPENDIX II – PRISMA-P checklist

PRISMA-P (Preferred Reporting Items for Systematic review and Meta-Analysis Protocols) 2015 checklist: recommended items to address in a systematic review protocol*

Section and topic	Item No	Checklist item	Information reported		Page number(s)
			Yes	No	
ADMINISTRATIVE INFORMATION					
Title: Identification	1a	Identify the report as a protocol of a systematic review	√		01
Update	1b	If the protocol is for an update of a previous systematic review, identify as such			N/A
Registration	2	If registered, provide the name of the registry (such as PROSPERO) and registration number	√		03
Authors: Contact	3a	Provide name, institutional affiliation, e-mail address of all protocol authors; provide physical mailing address of corresponding author	√		01
Contributions	3b	Describe contributions of protocol authors and identify the guarantor of the review	√		14
Amendments	4	If the protocol represents an amendment of a previously completed or published protocol, identify as such and list changes; otherwise, state plan for documenting important protocol amendments			N/A
Support: Sources	5a	Indicate sources of financial or other support for the review	√		14
Sponsor	5b	Provide name for the review funder and/or sponsor	√		14
Role of sponsor or funder	5c	Describe roles of funder(s), sponsor(s), and/or institution(s), if any, in developing the protocol	√		14
INTRODUCTION					
Rationale	6	Describe the rationale for the review in the context of what is already known	√		04-05
Objectives	7	Provide an explicit statement of the question(s) the review will address with reference to participants, interventions, comparators, and outcomes (PICO)	√		05
METHODS					
Eligibility criteria	8	Specify the study characteristics (such as PICO, study design, setting, time frame) and report characteristics (such as years considered, language, publication status) to be used as criteria for eligibility for the review	√		05-09
Information sources	9	Describe all intended information sources (such as electronic databases, contact with study authors, trial registers or other grey literature sources) with planned dates of coverage	√		08
Search strategy	10	Present draft of search strategy to be used for at least one electronic database, including planned limits, such that it could be repeated	√		Appendix III

Study records: Data management	11a	Describe the mechanism(s) that will be used to manage records and data throughout the review	√		08
Selection process	11b	State the process that will be used for selecting studies (such as two independent reviewers) through each phase of the review (that is, screening, eligibility and inclusion in meta-analysis)	√		08-09
Data collection process	11c	Describe planned method of extracting data from reports (such as piloting forms, done independently, in duplicate), any processes for obtaining and confirming data from investigators	√		09
Data items	12	List and define all variables for which data will be sought (such as PICO items, funding sources), any pre-planned data assumptions and simplifications	√		09-11
Outcomes and prioritization	13	List and define all outcomes for which data will be sought, including prioritization of main and additional outcomes, with rationale	√		09-10
Risk of bias in individual studies	14	Describe anticipated methods for assessing risk of bias of individual studies, including whether this will be done at the outcome or study level, or both; state how this information will be used in data synthesis	√		10
Data synthesis	15a	Describe criteria under which study data will be quantitatively synthesised	√		10-11
	15b	If data are appropriate for quantitative synthesis, describe planned summary measures, methods of handling data and methods of combining data from studies, including any planned exploration of consistency (such as I^2, Kendall's τ)	√		11
	15c	Describe any proposed additional analyses (such as sensitivity or subgroup analyses, meta-regression)	√		11
	15d	If quantitative synthesis is not appropriate, describe the type of summary planned			N/A
Meta-bias(es)	16	Specify any planned assessment of meta-bias(es) (such as publication bias across studies, selective reporting within studies)			N/A
Confidence in cumulative evidence	17	Describe how the strength of the body of evidence will be assessed (such as GRADE)			N/A