This is a repository copy of *Low-value clinical practices in adult traumatic brain injury: an umbrella review protocol*.

White Rose Research Online URL for this paper: http://eprints.whiterose.ac.uk/152624/

Version: Published Version

**Article:**
Tardif, P.A., Moore, L., Lauzier, F. et al. (11 more authors) (2019) Low-value clinical practices in adult traumatic brain injury: an umbrella review protocol. BMJ Open, 9 (10). 031747.

https://doi.org/10.1136/bmjopen-2019-031747

**Reuse**
This article is distributed under the terms of the Creative Commons Attribution-NonCommercial (CC BY-NC) licence. This licence allows you to remix, tweak, and build upon this work non-commercially, and any new works must also acknowledge the authors and be non-commercial. You don't have to license any derivative works on the same terms. More information and the full terms of the licence here: https://creativecommons.org/licenses/

**Takedown**
If you consider content in White Rose Research Online to be in breach of UK law, please notify us by emailing eprints@whiterose.ac.uk including the URL of the record and the reason for the withdrawal request.
ABSTRACT

Introduction Traumatic brain injury (TBI) leads to 50 000 deaths, 85 000 disabilities and costs $60 billion each year in the USA. Despite numerous interventions and treatment options, the outcomes of TBI have improved little over the last three decades. In a previous scoping review and expert consultation survey, we identified 13 potentially low-value clinical practices in acute TBI. The objective of this umbrella review is to synthesise the evidence on potentially low-value clinical practices in the care of acute TBI.

Methods and analysis Using umbrella review methodology, we will search Cochrane Central Register of Controlled Trials, Embase, Epistemonikos, International Prospective Register of Systematic Reviews (PROSPERO) and PubMed to identify systematic reviews evaluating the effect of potential intrahospital low-value practices using tailored population, intervention, comparator, outcome and study design questions based on the results of a previous scoping review. We will present data on the methodological quality of these reviews (Assessing the Methodological Quality of Systematic Reviews-2), reported effect sizes and strength of evidence (Grading of Recommendations, Assessment, Development and Evaluation).

Ethics and dissemination Ethics approval is not required as original data will not be collected. Knowledge users from five healthcare quality organisations and clinical associations are involved in the design and conduct of the study. Results will be disseminated in a peer-reviewed journal, at international scientific meetings and to clinical, healthcare quality and patient-partner associations. This work will support the development of metrics to measure the use of low-value practices, inform policy makers on potential targets for deimplementation and in the long term reduce the use of low-value clinical practices in acute TBI care.

PROSPERO registration number CRD42019132428.

INTRODUCTION

Traumatic brain injury (TBI) is the main cause of mortality from injury in people under 45 years of age, and it leads to approximately US$60 and €33 billion in total medical costs in the USA and Europe each year, respectively. Moreover, outcomes following TBI have not improved significantly in the last four decades.

Intervention and treatment options for TBI are multiple, but many lack robust evidence of their effectiveness.

Low-value clinical practices, defined as a test or procedure that is not supported by evidence and/or could expose patients to unnecessary harm or consume up to 30% of healthcare budgets. In the past decade, the medical community has turned towards the deimplementation of low-value practices as a promising means to reduce the strain on healthcare budgets, free-up resources and reduce harm to patients.

Physicians report using low-value practices because of a lack of alternative treatment options, fear of legal consequences but also because of lack of guidelines on low-value care. The Brain Trauma Foundation, among others, publish guidelines on TBI care. However, emphasis is on practices that should be adhered to rather than practices that should be avoided. Choosing Wisely publish recommendations specifically targeting low-value practices but few pertain to TBI care and many are based uniquely on expert consensus.
scoping review and expert consultation survey identified 13 potentially low-value clinical practices in acute TBI care. These practices represent potential targets for guidelines, overuse metrics and deimplementation interventions. However, before recommendations can be made, we need to synthesise the evidence base for these practices.

Interventions and treatment options for acute TBI have been the subject of multiple systematic reviews. Given this large body of available evidence, evidence maps have previously been used to summarise evidence from systematic reviews on acute TBI interventions. However, these evidence maps were not designed to target low-value practices and focused on moderate to severe TBI when the mild TBI population represent great potential for reducing low-value care. In addition, previous reviews have not provided a synthesis of effect sizes or strength of evidence. The objective of the present study is to synthesise the evidence on potentially low-value intrahospital clinical practices in acute adult TBI.

METHODS AND ANALYSIS
Given the multitude of systematic reviews available for the clinical practices identified as potentially low-value (over 60 were identified in our scoping review), we opted to conduct an umbrella review (a systematic review of systematic reviews). While the former aimed to fill a knowledge gap on medical overuse for acute injury care by identifying all potential low-value clinical practices, the latter will synthesise the evidence on the low-value practices pertaining to TBI. The review will be conducted according to published guidelines. In the absence of reporting guidelines for umbrella reviews, we will use the applicable Preferred Reporting Items for Systematic Reviews and Meta-Analysis (PRISMA) Protocols.

Eligibility criteria
The project steering committee comprising clinicians (two emergency physicians, seven critical care physicians, one neurosurgeon), methodologists (four) and health system managers (three) used the population, intervention, comparator, outcome and study design (PICOS) framework to develop specific research questions for each potentially low-value clinical practice (table 1). We will consider systematic reviews of original studies evaluating the effectiveness of predetermined clinical practices in acute TBI in adults (≥16 years old) without restriction on location of publication but limited to studies published in English since 1990.

We will use the Cochrane definition to identify systematic reviews. We will consider a review to be systematic if it clearly stated a set of objectives and reported explicit eligibility criteria, an extensive search strategy (a refined search strategy ran on Medline or Cochrane Library

### Table 1 PICOS for each clinical practice

| # | Clinical practice |
|---|------------------|
| 1 | Population: adults with acute mild traumatic brain injury<br>Intervention: validated clinical decision rule (eg, CCHR, CHIP, NEXUS II, NOC)<br>Comparator: none<br>Primary outcome: false negative rate (intracranial injury, neurosurgical intervention)<br>Secondary outcomes: sensitivity, specificity<br>Study design: systematic review |
| 2 | Population: adults with acute mild complicated traumatic brain injury<br>Intervention: routine repeat head CT in absence of neurological deterioration<br>Comparator: none or no repeat head CT in absence of neurological deterioration<br>Primary outcome: progression of intracranial injury<br>Secondary outcomes: neurosurgical intervention, mortality, change in management, hospital length of stay<br>Study design: systematic review |
| 3 | Population: adults with acute mild traumatic brain injury and on anticoagulant and/or antiplatelet therapy<br>Intervention: routine repeat head CT in absence of neurological deterioration<br>Comparator: none or no repeat head CT in absence of neurological deterioration<br>Primary outcome: progression of intracranial injury<br>Secondary outcomes: neurosurgical intervention, mortality, change in management, hospital length of stay<br>Study design: systematic review |
| 4 | Population: adults with acute mild traumatic brain injury who are negative on head CT<br>Intervention: neurological consultation<br>Comparator: none or no neurological consultation<br>Primary outcome: hospital admission<br>Secondary outcomes: neurosurgical intervention, mortality, ICU admission, repeat head CT, hospital length of stay<br>Study design: systematic review |
| 5 | Population: adults with acute mild complicated traumatic brain injury who are not on irreversible anticoagulation<br>Intervention: intensive care unit admission<br>Comparator: admission to regular ward or step-down unit<br>Primary outcome: neurological/medical decline, neurosurgical intervention<br>Secondary outcomes: medical interventions, mortality, adverse events, hospital length of stay, discharge destination<br>Study design: systematic review |

**Continued**
Table 1  Continued

| # | Clinical practice |
|---|---|
| 6 | Population: adults with acute traumatic brain injury on antithrombotic therapy  
Intervention: platelet transfusion  
Comparator: no platelet transfusion  
Primary outcome: GOS or GOS-E  
Secondary outcomes: mortality, adverse events, hospital and ICU length of stay  
Study design: systematic review |
| 7 | Population: adults with basal skull fractures without evidence of cerebrospinal fluid leakage  
Intervention: antibiotic prophylaxis  
Comparator: no antibiotic prophylaxis  
Primary outcome: meningitis (confirmed by lumbar puncture)  
Secondary outcomes: GOS or GOS-E, mortality, surgical correction in patients with CSF leakage, non-CNS infection, hospital and ICU length of stay  
Study design: systematic review |
| 8 | Population: adults with acute traumatic brain injury and no refractory intracranial hypertension  
Intervention: therapeutic hypothermia  
Comparator: no therapeutic hypothermia  
Primary outcome: intracranial pressure, mortality, adverse events, hospital and ICU length of stay  
Study design: systematic review |
| 9 | Population: adults with acute traumatic brain injury and no refractory intracranial hypertension  
Intervention: antibiotic prophylaxis for external ventricular drain placement  
Comparator: no antibiotic prophylaxis  
Primary outcome: ventriculostomy-related infection  
Secondary outcomes: GOS, mortality, hospital and ICU length of stay  
Study design: systematic review |
| 10 | Population: adults with acute traumatic brain injury and no refractory intracranial hypertension  
Intervention: neuromuscular blocking agents  
Comparator: no neuromuscular blocking agents  
Primary outcome: GOS or GOS-E  
Secondary outcomes: intracranial pressure, mortality, adverse events, hospital and ICU length of stay  
Study design: systematic review |
| 11 | Population: adults with acute traumatic brain injury  
Intervention: plasma transfusion  
Comparator: no plasma transfusion  
Primary outcome: GOS or GOS-E  
Secondary outcomes: mortality, adverse events, hospital and ICU length of stay  
Study design: systematic review |

Continued
practice, two sets of 100 citations will independently be evaluated and then discussed by the reviewers. Pairs of reviewers (PAT, LM, IF, KMB) will then independently screen all identified records using titles, abstracts and full texts, consecutively. Any disagreement will be resolved through discussion between reviewers and, if necessary, consultation with a senior author (AFT). Potentially eligible studies excluded using full texts will be described through discussion between reviewers and, if necessary, consultation with a senior author (AFT). When information is unclear or unavailable, we will contact study authors (up to three email attempts) or experts to obtain additional information.

### Data items and abstraction process

Using a standardised data abstraction form piloted on a representative sample of five studies, pairs of experienced reviewers (PAT, LM, IF, KMB) will independently extract the following data: first author, title, year of publication, databases used and date of the last search; population(s), intervention(s), comparator(s), outcome(s) and study designs included; measures of association and their respective measure of heterogeneity; tools used to assess the quality (risk of bias) of original studies and overall rating from the authors. Any disagreement will be resolved through discussion between reviewers and, if necessary, consultation with a senior author (AFT). When information is available in figures only, we will abstract graphical data using computer-assisted software. Furthermore, we will contact study authors (up to three email attempts) when information is unclear or unavailable.

### Methodological quality assessment

Two reviewers (PAT, LM) will independently critically appraise the quality of systematic reviews using the Assessing the Methodological Quality of Systematic Reviews (AMSTAR-2) tool.

### Synthesis

Results will be presented according to current recommendations for umbrella reviews. For each low-value practice, we will present the number of studies, study designs and patients included, the quality of the reviews (AMSTAR-2), effect sizes for primary and secondary outcomes (forest plots) and strength of recommendations (Grading of Recommendations, Assessment, Development and Evaluation).

### Potential limitations

To ensure the feasibility of the review, we will restrict our search to low-value practices identified in the scoping review and expert consultation study, which may lead us to miss some low-value practices. However, given the robust search strategy used in our scoping review and the fact that experts were asked to add any other practices they considered low value, it is unlikely that important low-value practices have been missed. By targeting systematic reviews rather than original studies, we may miss some
evidence. However, given the availability of high-quality, up-to-date reviews in TBI care suggested by our scoping review, we think it unlikely that we will miss a large body of evidence. For certain clinical practices, we may not identify any high-quality, up-to-date reviews. These practices will be the subject of systematic reviews in subsequent phases of the research programme. Finally, for feasibility reasons, we limited this umbrella review to reviews published in English since 1990 as per recommendations for umbrella reviews.25 26 These limitations should have negligible impact on results since few systematic reviews were published prior to 1990 and most published reviews are likely to be written in English.25 26

Potential impact
This review is part of the Canadian Program on Monitoring Low-Value Clinical Practices in Injury Care (Canadian Institutes of Health Research #113664), aiming to evaluate the effectiveness of an audit-feedback module targeting low-value clinical practices in acute injury care. The results of this review will be used to inform the development of quality indicators to be integrated in the audit-feedback module.

We will use state-of-the-art methods to optimise the sensitivity of our search strategy and the robustness of results. Results will be synthesised graphically. Ultimately, this research will inform the development of metrics, guidelines and deimplementation interventions, all targeting low-value injury care. The reduction of low-value clinical practices in acute TBI care has the potential to reduce pressure on strained healthcare budgets, free up resources, reduce adverse events and improve patient outcomes.

Ethics and dissemination
Ethics approval is not required as original data will not be collected. This study will be disseminated in a peer-reviewed journal, international scientific meetings, to knowledge users through clinical and healthcare quality associations (Choosing Wisely Canada, Trauma Association of Canada, American College of Surgeons—Committee on Trauma, International Federation of Emergency Medicine, Institut national d’excellence en santé et en services sociaux du Québec, Brain Injury Canada) and to patient partners associations (Brain Injury Canada).

Patient and public involvement
No patient or public representatives will be involved in this study.

Author affiliations
1Population Health and Optimal Health Practices Unit, Trauma—Emergency—Critical Care Medicine, Centre de Recherche du CHU de Québec—Université Laval (Hôpital de l’Enfant–Jésus), Université Laval, Montreal, Quebec, Canada
2Department of Social and Preventative Medicine, Université Laval, Montreal, Quebec, Canada
3Department of Critical Care Medicine, Department of Anesthesiology and Critical Care Medicine, Université Laval, Quebec City, Quebec, Canada
4Département de médecine familiale et médecine d’urgence, Université Laval, Quebec, QC, Canada
5Department of Medicine, Université de Sherbrooke, Sherbrooke, Quebec, Canada
6Department of Medicine, Université de Montréal, Montreal, Quebec, Canada
7Departments of Critical Care Medicine, Medicine and Community Health Sciences, O’Brien Institute for Public Health, University of Calgary, Calgary, Alberta, Canada
8Monash University School of Public Health and Preventive Medicine, Melbourne, Victoria, Australia
9Farr Institute, Swansea University Medical School, Swansea University, Swansea, UK
10School of Health and Related Research, The University of Sheffield, Sheffield, UK
11Department of Surgery, University of Calgary, Calgary, Alberta, Canada
12Department of Surgery, Division of Neurosurgery, Université Laval, Quebec City, Quebec, Canada
13Institut national d’excellence en santé et en services sociaux du Québec, Quebec City, Quebec, Canada

Contributors P-AT contributed to the elaboration of keywords, developed and tested the search strategy, drafted the manuscript and approved the final version of the manuscript. LM led the development of the protocol and drafted the manuscript with the first author. She acts as guarantor for the review. Flau contributed to developing keywords, validated the search strategy and the data extraction form, revised the manuscript and approved the final version. IF contributed to the elaboration of keywords, the search strategy and the data extraction form, critically revised and approved the final version of the manuscript. PA contributed to working definitions, developed keywords, revised the manuscript and approved the final version. MC validated the search strategy and the data extraction form, revised the manuscript and approved the final version. HTS contributed to the development of research objectives, inclusion criteria, the search strategy and the extraction form, developed keywords, revised the manuscript and approved the final version. BJJ elaborated inclusion and exclusion criteria and keywords, revised the manuscript and approved the final version. FL contributed to developing keywords, validated the search strategy and the data extraction form, revised the manuscript and approved the final version. FL elaborated inclusion and exclusion criteria and keywords, revised the manuscript and approved the final version. J-BC contributed to the development of research objectives, study definitions, inclusion criteria and the extraction form, developed keywords, revised the manuscript and approved the final version. PL-B contributed to the development of research objectives and inclusion criteria, elaborated keywords, validated the data extraction form, critically revised the manuscript and approved the final version. CT elaborated inclusion and exclusion criteria and keywords, contribution to the development of the conceptual framework and concept definitions, revised the manuscript and approved the final version. AFT elaborated inclusion criteria and clinically significant outcomes, validated the search strategy, elaborated keywords, revised the manuscript and approved the final version.

Funding This research was supported by the Canadian Institutes of Health Research (Foundation grant, #353374 and Embedded Clinician Researcher (PA)). LM, FLau, Flam and MC are recipients of a research salary award from the Fonds de Recherche du Québec—Santé (FRQS). AFT is the Canada Research Chair in Critical Care Neurology and Trauma. The funders had no role in developing this protocol.

Competing interests None declared.

Patient consent for publication Not required.

Provenance and peer review Not commissioned; externally peer reviewed.

Open access This is an open access article distributed in accordance with the Creative Commons Attribution Non Commercial (CC BY-NC 4.0) license, which permits others to distribute, remix, adapt, build upon this work non-commercially, and license their derivative works on different terms, provided the original work is properly cited, appropriate credit is given, any changes made indicated, and the use is non-commercial. See: http://creativecommons.org/licenses/by-nc/4.0/.

ORCID iDs
Pier-Alexandre Tardif http://orcid.org/0000-0003-3003-2399
Alexis F Turgeon http://orcid.org/0000-0001-5675-8791

REFERENCES
1. The American Association for the Surgery of Trauma (AAST). Traumatic brain injury in the United States: a report to Congress, CDC, 1999. Available: http://www.aast.org/trama-facts [Accessed 19 Nov 2018].
2. Coronado VG, Haileyesus T, Cheng TA, et al. Trends in Sports- and Recreation-Related traumatic brain injuries treated in US emergency departments: the National electronic injury surveillance System-All injury program (NEISS-AIP) 2001-2012. *J Head Trauma Rehabil* 2015;30:185–97.

3. Olesen J, Gustavsson A, Svensson M, et al. The economic cost of brain disorders in Europe. *Eur J Neurol* 2012;19:155–62.

4. Rosenfeld JV, Totten AM, O’Reilly C, et al. Early management of severe traumatic brain injury. *The Lancet* 2012;380:1088–98.

5. Maas AIR, Menon DK, Adelson PD, et al. Traumatic brain injury: integrated approaches to improve prevention, clinical care, and research. *Lancet Neurol* 2017;16:987–1048.

6. Maas AIR, Roozenbeek B, Manley GT. Clinical trials in traumatic brain injury: past experience and current developments. *Neurotherapeutics* 2016;33:1461–78.

7. Bragge P, Synnot A, Maas AI, et al. A State-of-the-Science overview of randomized controlled trials evaluating acute management of moderate-to-severe traumatic brain injury. *J Neurotrauma* 2016;33:2418–50.

8. Boat TF, Chao SM, O’Neill PH. From waste to value in health care. *JAMA* 2009;299:568–71.

9. Reilly BM, Evans AT. Much ado about (doing) nothing. *Ann Intern Med* 2008;149:191–4.

10. Berwick DM, Hackeborn AD. Eliminating waste in US health care. *JAMA* 2012;307:1513–6.

11. Choosing Wisely Canada. 2015. Available: https://choosingwiselycanada.org/ [Accessed 19 Nov 2018].

12. Morgan DJ, Druva SS, Wright SM, et al. 2016 update on medical overuse—a systematic review. *JAMA Intern Med* 2016;176:1887–92.

13. Berwick DM. Avoiding overuse—the next quality frontier. *The Lancet* 2017;390:102–4.

14. Brownelee S, Chalkidou K, Doust J, et al. Evidence for overuse of medical services around the world. *Lancet* 2017;390:156–88.

15. Brownelee S, Chalkidou K, Doust J, et al. Evidence for underuse around the world. *The Lancet* 2017;390:105–7.

16. Fisher ES, Wennberg DE, Stukel TA, et al. The implications of regional variations in Medicare spending. Part 2: health outcomes and satisfaction with care. *Ann Intern Med* 2003;138:288–98.

17. Niven DJ, Mklias KJ, Holodinsky JK, et al. Towards understanding the de-adoption of low-value clinical practices: a scoping review. *BMC Med* 2015;13:255.

18. Emanuel EJ, Fuchs VR. The perfect storm of overutilization. *JAMA* 2008;299:2789–91.

19. Torner JC, Elshagui AG, et al. Addressing overuse and underuse around the world. *Lancet* 2017;390:105–7.

20. Fisher ES, Wennberg DE, Stukel TA, et al. The implications of regional variations in Medicare spending. Part 2: health outcomes and satisfaction with care. *Ann Intern Med* 2003;138:288–98.

21. Niven DJ, Mklias KJ, Holodinsky JK, et al. Towards understanding the de-adoption of low-value clinical practices: a scoping review. *BMC Med* 2015;13:255.

22. Emanuel EJ, Fuchs VR. The perfect storm of overutilization. *JAMA* 2008;299:2789–91.

23. Shepperd S, Grant A, Tenebaum AJ, et al. Systematic reviews in health care: a scoping review and expert consultation survey. *J Med Libr Assoc* 2016;104:240–3.

24. Moher D, Shamseer L, Clarke M, et al. Preferred reporting items for systematic review and meta-analysis protocols (PRISMA-P) 2015 statement. *Syst Rev* 2015;4:1.

25. Moher D, Shamseer L, Clarke M, et al. Preferred reporting items for systematic review and meta-analysis protocols (PRISMA-P) 2015 statement. *Syst Rev* 2015;4:1.

26. The Joanna Briggs Institute. Joanna Briggs Institute Reviewers’ Manual: 2016 edition / Supplement. The Joanna Briggs Institute, 2014.

27. Moher D, Shamseer L, Clarke M, et al. Preferred reporting items for systematic review and meta-analysis protocols (PRISMA-P) 2015 statement. *Syst Rev* 2015;4:1.

28. Stone PW. Popping the (PICO) question in research and evidence-based practice. *Appl Nurs Res* 2002;15:197–8.

29. Marshall IJ, Marshall R, Wallace BC, et al. Rapid reviews may produce different results to systematic reviews: a meta-epidemiological study. *J Clin Epidemiol* 2019;109:30–41.

30. Kassam A, Siddiqui A, Stiell IG, et al. Summary of the evidence for the diagnosis and management of mild traumatic brain injury in children and adults. *Can Med Assoc J* 2007;177:793–804.

31. Kassam A, Siddiqui A, Stiell IG, et al. Summary of the evidence for the diagnosis and management of mild traumatic brain injury in children and adults. *Can Med Assoc J* 2007;177:793–804.

32. Centre for Reviews and Dissemination. Prospero. Available: https://www.crd.york.ac.uk/PROSPERO/ [Accessed 19 Nov 2018].

33. Horton L, Rhodes J, Wilson L. Randomized controlled trials in adult traumatic brain injury: a review of compliance to consort statement. *J Neurol Neurosurg Psychiatry* 2010;81:115–26.

34. Horton L, Rhodes J, Wilson L. Randomized controlled trials in adult traumatic brain injury: a review of compliance to consort statement. *J Neurol Neurosurg Psychiatry* 2010;81:115–26.

35. Horton L, Rhodes J, Wilson L. Randomized controlled trials in adult traumatic brain injury: a review of compliance to consort statement. *J Neurol Neurosurg Psychiatry* 2010;81:115–26.

36. Horton L, Rhodes J, Wilson L. Randomized controlled trials in adult traumatic brain injury: a review of compliance to consort statement. *J Neurol Neurosurg Psychiatry* 2010;81:115–26.

37. Horton L, Rhodes J, Wilson L. Randomized controlled trials in adult traumatic brain injury: a review of compliance to consort statement. *J Neurol Neurosurg Psychiatry* 2010;81:115–26.

38. Horton L, Rhodes J, Wilson L. Randomized controlled trials in adult traumatic brain injury: a review of compliance to consort statement. *J Neurol Neurosurg Psychiatry* 2010;81:115–26.

39. Horton L, Rhodes J, Wilson L. Randomized controlled trials in adult traumatic brain injury: a review of compliance to consort statement. *J Neurol Neurosurg Psychiatry* 2010;81:115–26.

40. Horton L, Rhodes J, Wilson L. Randomized controlled trials in adult traumatic brain injury: a review of compliance to consort statement. *J Neurol Neurosurg Psychiatry* 2010;81:115–26.

41. Horton L, Rhodes J, Wilson L. Randomized controlled trials in adult traumatic brain injury: a review of compliance to consort statement. *J Neurol Neurosurg Psychiatry* 2010;81:115–26.

42. Horton L, Rhodes J, Wilson L. Randomized controlled trials in adult traumatic brain injury: a review of compliance to consort statement. *J Neurol Neurosurg Psychiatry* 2010;81:115–26.