

EVMS JC: Critical Appraisal Worksheet: Systematic Review/Meta-analysis

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Citations:

Lumba-Brown A, et al., CDC for Disease Control and Prevention Guideline on the Diagnosis and Management of Mild Traumatic Brain Injury Among Children. JAMA Pediatr. 2018 Nov 1;172(11):1104.

Lumba-Brown A, et al, Diagnosis and Management of Mild Traumatic Brain Injury in Children: A Systematic Review. JAMA Pediatr. 2018 Nov 1;172(11)

Guide	
1. Did the review explicitly address a sensible question?	<p>Yes. To provide a guideline based on a previous systematic review of the literature to obtain and assess evidence toward developing clinical recommendations for health care professionals related to the diagnosis, prognosis, and management/treatment of pediatric mTBI.</p> <p>The workgroup began with a total of 119 "candidate questions" and after 3 rounds of voting selected 6 clinical questions to address in the systematic review and guideline.</p>
2. Was the search for relevant studies details and exhaustive?	<p>Yes. Search terms (in supplement) were exhaustive. Two consecutive searches were conducted on PubMed, Embase, ERIC, CINAHL, and SportDiscus. The first included the dates January 1, 1990, to November 30, 2012, and an updated search included December 1, 2012, to July 31, 2015.</p>
<p>3. Were the primary studies of high methodological quality?</p> <p>Question 1 "For children (18 years of age and younger) with suspected mTBI, do specific tools, compared with a reference standard, assist in accurately diagnosing mTBI?"</p> <p>Question 2 "For children (18 years of age and younger) presenting to the emergency department (or other acute care setting) with mTBI, how often does routine head imaging identify important intracranial injury?"</p> <p>Question 3 "For children (18 years of age and younger) presenting to the emergency department (or other acute care setting) with mTBI, which features identify patients at risk for intracranial injury?"</p> <p>Question 4 "For children (18 years of age and younger) with mTBI, what factors identify patients at increased risk for ongoing impairment, more severe symptoms, or delayed recovery (<1 year postinjury)?"</p> <p>Question 5 "For children (18 years of age and younger) with mTBI, which factors identify patients at increased risk of long-term sequelae?"</p> <p>Question 6 "For children (18 years of age and younger) with mTBI (with ongoing symptoms), which treatments improve mTBI-associated outcomes?"</p>	<p>Depended on the question addressed:</p> <p>Questions 3, 4 and 5 were based on ANA Class I and II higher quality studies Questions 1,2 and 6 were based upon Class II and III studies</p> <p>Authors used The American Academy of Neurology Classification of Evidence Scheme to assign the risk of bias and assign a class for each study:</p> <ul style="list-style-type: none"> • Class I (high-quality [RCTs]) • Class II (RCTs with significant limitations) • Class III ("other controlled studies") • Class IV (studies with no measures of effectiveness or statistical precision).
4. Were the criteria for study inclusion pre-determined and clearly stated?	<p>Yes. Studies were included:</p> <ul style="list-style-type: none"> • with participants through 18 years of age were allowed for applicability of results to older high school populations that are commonly

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	<p>cared for in pediatric practices.</p> <ul style="list-style-type: none"> Each of the 6 primary questions had clearly defined inclusion criteria <p>Studies did not meet the inclusion criteria if they</p> <ul style="list-style-type: none"> included patients older than age 18 years without presenting the results in the subgroup of patients 18 years or younger included children with moderate or severe TBI without presenting results in the mTBI subgroup. were comments, editorials, biographies or case reports
<p>5. Did the authors adequately assess the quality of the included studies?</p>	<p>Yes. The risk of bias in each study was determined using the American Academy of Neurology Classification of Evidence Scheme as well as the GRADE criteria for development of a systematic review.</p> <p>Authors worked in pairs to abstract study characteristics and a third author adjudicated any disagreements.</p> <p>In, addition, Levels of recommendations (left margin) were not based solely upon the Class of Evidence but workgroup members assessments which included expert opinion regarding:</p> <ul style="list-style-type: none"> the importance of the outcome benefit relative to harm expected variation in patient preferences financial burden relative to benefit expected and the feasibility of the intervention (eg, the availability).
CLINICAL IMPORTANCE	
<p>6. What were the overall results of the review?</p> <ul style="list-style-type: none"> Level A: The recommendation almost always should be followed. Level B: The recommendation usually should be followed. Level C: The recommendation may sometimes be followed. Level U: There is insufficient evidence to make a recommendation. Level R: The intervention generally should not be done outside of a research setting (applicable only to recommendations related to interventions). 	<p>The following are a selection of the most applicable recommendations in the ED environment. Please refer to supplement for all recommendations.</p> <p>Do not routinely obtain head computed tomography (CT) for diagnostic purposes in children with mTBI (moderate “level B”).</p> <p>Use validated clinical decision rules to identify children with mTBI at low risk for ICI in whom head CT is not indicated, as well as children who may be at higher risk for clinically important ICI (moderate “level B”).</p> <p>Discuss the risks of pediatric head CT in the context of risk factors for ICI with the patient and his/her family (moderate; level B).</p> <p>Do not routinely use magnetic resonance imaging (MRI) in the acute evaluation of suspected or diagnosed mTBI (moderate; level B).</p> <p>Do not use skull radiographs in the diagnosis of pediatric mTBI (high; level B).</p> <p>Do not use the Standardized Assessment of Concussion in distinguishing those children with mTBI from those without mTBI</p> <p>Do not use biomarkers outside of a research setting for the diagnosis of children with mTBI.</p> <p>Counsel patients and families that most (70-80%) of children with mTBI do not show significant difficulties that last more than 1-3 months after injury.</p> <p>Counsel patients and their families that recovery from mTBI might be delayed in those with histories of prior mTBI, lower cognitive ability,</p>

	<p>neurological or psychiatric disorders, learning difficulties, family and social stressors, children of lower socioeconomic status, those with more severe presenting symptoms (moderate; level B).</p> <p>Include the following at discharge:</p> <ul style="list-style-type: none"> • Warning signs of more serious injury • Description of injury and expected course of symptoms and recovery • Instructions on how to monitor postconcussive symptoms • Prevention of further injury • Management of cognitive and physical activity/rest • Instructions regarding return to play/recreation and school • Clear clinician follow-up instructions (high; level A). <p>Counsel patients to observe more restrictive physical and cognitive activity during the first several days after mTBI in children (moderate; level B).</p> <p>Counsel patients and families to resume a gradual schedule of activity that does not exacerbate symptoms, with close monitoring of symptom expression (number and severity) (moderate; level B).</p> <p>Post-concussion symptoms and academic progress in school should be monitored collaboratively by the student, family, health care professional(s), and school teams, who jointly determine what modifications or accommodations are needed to maintain an academic workload without significantly exacerbating symptoms (high; level B).</p> <p>Health care professionals in the ED should clinically observe and consider obtaining a head CT in children seen with severe headache, especially when associated with other risk factors and worsening headache after mTBI (high; level B).</p> <p>The CDC has great resources for providers and families. www.cdc.gov/HEADSUP</p>
8. Were the results similar from study to study?	Uncertain. The systematic review that the guidelines are based upon did not report on heterogeneity (clinical, methodological or statistical) between the articles they included to address each of their questions. This can be a major source of bias.
APPLICABILITY	
9. How can I best interpret the results to apply them to the care of my patients?	For ED providers, I think an emphasis on patient education, expectations, and appropriate follow up is vital. Many times, we do not complete a mTBI screening but I think this could be helpful to guide further patient management and compare patients progress. The SCAT is a commonly used assessment in the outpatient sports medicine setting. The CDC provides an assessment form for ED providers. https://www.cdc.gov/headsup/pdfs/providers/ace_ed-a.pdf
10. Were all patient important outcomes considered?	Yes. The authors appear to have addressed a majority of clinically relevant issues in mTBI
11. Are the benefits worth the costs and potential risks?	<p>The benefits of diagnosing mTBI and providing appropriate pt education can make a difference in patients' quality of life and prevent reinjury/prolonged duration of symptoms. For example, pt with an appropriate diagnosis can access formal education planning incorporating protections under formal statues.</p> <p>However, I think the major costs in providing additional concussive screening/patient education is time. Filling out forms is time consuming and likely does not change patient's disposition. With high patient volumes and limited nursing resources, this presents a challenge. Difficult to</p>

	implement without a streamlined process. Finding a robust resource to "hand off" these ED patients for timely post-concussive assessments would be a major benefit in advancing clinical management.
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Limitations:

Limited number of studies for some of the systemic review questions.
 No reporting of heterogeneity between studies
 Expert opinion likely played a significant role because of limitations in quality of evidence.
 Because the guidelines were developed by a "workgroup" the results are limited to the biases of the group. The background of the workgroup members was not disclosed (ie pediatricians, neurologists, PhDs, etc). Limited to studies between 1990-2016.
 Limited to papers printed in English.

My Clinical Bottom Line: Make the STOP and educate patients and their families on expectations and initial management of mTBI. Patients will need consistent follow up for return to activity.

Deleted: good

Discharge instructions are imperative (references 77, 78,79,102)

1. Cognitive and physical rest in the first three days (B)
2. After first few days, patients should resume a gradual schedule of activity that does not exacerbate symptoms (B)
3. After resumption of regular activity, patient can slowly resume noncontact aerobic activity that does not exacerbate symptoms (B)
4. Return to school should be customized and medical and school-based teams should counsel pt and families. It's a team effort (B)
5. Patients with worsening headache/symptoms should undergo emergent neuroimaging (B)
6. Pain can be treated with ibuprofen/Tylenol but patients and families should be counseled on risk of rebound headache
7. Chronic headache after mTBI should be referred for multidisciplinary evaluation and treatment (B)
8. Vestibular rehabilitation (C)
9. Patients should be given guidance on sleep hygiene (B)

Supplement

eTable. CDC Pediatric mTBI Guideline Recommendations

DIAGNOSTIC RECOMMENDATIONS	
Risk factors for Intracranial Injury and Computed Tomography (CT), Recommendation #1	
1a.	Health care providers <i>should not routinely obtain head CT for diagnostic purposes in children with mTBI</i> .
1b.	Health care providers <i>should use validated clinical decision rules to identify children with mTBI at low risk for intracranial injury (ICI), in whom head CT is not indicated, as well as children who may be at higher risk for clinically important ICI, and therefore may warrant head CT.</i> Existing decision rules, such as the Pediatric Emergency Care Applied Research Network (PECARN) decision rules, combine a variety of factors that, when assessed together, may increase the risk for more serious injury. Such risk factors include the following: <ul style="list-style-type: none"> • Age < 2 years old • Vomiting • Loss of consciousness • Severe mechanism of injury • Severe or worsening headache • Amnesia • Non-frontal scalp hematoma • Glasgow Coma Score < 15 • Clinical suspicion for skull fracture.
1c.	For children diagnosed with mTBI, health care providers <i>should discuss the risks of pediatric head CT in the context of risk factors for ICI with the patient and his/her family.</i>
Brain Magnetic Resonance Imaging (MRI), Recommendation #2	
2.	Health care providers <i>should not routinely use MRI in the acute evaluation of suspected or diagnosed mTBI.</i>
Single Photon Emission Computed Tomography (SPECT), Recommendation #3	
3.	Health care providers <i>should not use SPECT in the acute evaluation of suspected or diagnosed mTBI.</i>
Skull X-ray, Recommendation #4	
4a.	Skull X-rays <i>should not be used in the diagnosis of pediatric mTBI.</i>
4b.	Skull X-rays <i>should not be used in the screening for ICI.</i>
Neuropsychological Tools, Including Symptom Scales, Computerized Cognitive Testing, and Standardized Assessment of Concussion, Recommendation #5	
5a.	Health care providers <i>should use an age-appropriate, validated, symptom rating scale as a component of the diagnostic evaluation in children seen with acute mTBI.</i>
5b.	Health care providers <i>may use validated, age-appropriate computerized cognitive testing in the acute period of injury as a component of the diagnosis of mTBI.</i>
5c.	The Standardized Assessment of Concussion (SAC) <i>should not be exclusively used to diagnose mTBI in children 6-18 years.</i>
Serum Markers, Recommendation #6	
6.	Health care providers <i>should not use biomarkers outside of a research setting for the diagnosis of children with mTBI.</i>
PROGNOSTIC RECOMMENDATIONS	
General Health care Provider Counseling of Prognosis, Recommendation #7	
7a.	Health care providers <i>should counsel patients and families that most (70-80%) of children with mTBI do not show significant difficulties that last more than 1-3 months after injury.</i>
7b.	Health care providers <i>should counsel patients and families that, although some factors predict an increased or decreased risk for prolonged symptoms, each child's recovery from mTBI is unique and will follow its own trajectory.</i>
Prognosis Related to Premorbid Conditions, Recommendation #8	

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13a.	Health care providers should counsel patients to observe more restrictive physical and cognitive activity during the first several days following mTBI in children.
13b.	Following these first several days, health care providers should counsel patients and families to resume a gradual schedule of activity that does not exacerbate symptoms, with close monitoring of symptom expression (number, severity).
13c.	Following the successful resumption of a gradual schedule of activity (see 13b), health care providers should offer an active rehabilitation program of progressive re-introduction of non-contact aerobic activity that does not exacerbate symptoms, with close monitoring of symptom expression (number, severity).
13d.	Health care providers should counsel patients to return to full activity when they return to pre-morbid performance if they have remained symptom-free at rest and with increasing levels of physical exertion.
Psychosocial/Emotional Support, Recommendation #14	
14.	Health care providers may assess the extent and types of social support (i.e., emotional, informational, instrumental, appraisal) available to children with mTBI and emphasize social support as a key element in the education of caregivers and educators.
Return to School, Recommendation #15	
15a.	To assist children returning to school following mTBI, medical and school-based teams should counsel the student and family regarding the process of gradually increasing the duration and intensity of academic activities as tolerated, with the goal of increasing participation without significantly exacerbating symptoms.
15b.	Return-to-school protocols should be customized based on the severity of postconcussion symptoms in children with mTBI as determined jointly by medical and school-based teams.
15c.	For any student with prolonged symptoms that interfere with academic performance, school-based teams should assess the educational needs of that student and determine the student's need for additional educational supports, including those described under pertinent federal statutes (e.g., Section 504, IDEA).
15d.	Postconcussion symptoms and academic progress in school should be monitored collaboratively by the student, family, health care provider(s), and school teams, who jointly determine what modifications or accommodations are needed to maintain an academic workload without significantly exacerbating symptoms.
15e.	The provision of educational supports should be monitored and adjusted on an ongoing basis by the school-based team until the student's academic performance has returned to pre-injury levels.
15f.	For students who demonstrate prolonged symptoms and academic difficulties despite an active treatment approach, health care providers should refer the child for a formal evaluation by a specialist in pediatric mTBI.
Posttraumatic Headache Management/Treatment, Recommendation #16	
16a.	Health care providers in the ED should clinically observe and consider obtaining a head CT in children presenting with severe headache, especially when associated with other risk factors and worsening headache following mTBI, to evaluate for ICI requiring further management in accord with validated clinical decision-making rules.
16b.	Children undergoing observation periods for headache with acutely worsening symptoms should undergo emergent neuroimaging.
16c.	Health care providers and caregivers should offer non-opioid analgesia (i.e., ibuprofen or acetaminophen) to children with painful headache following acute mTBI but also provide counseling to the family regarding the risks of analgesic overuse, including rebound headache.
16d.	Health care providers should not administer 3% hypertonic saline to children with mTBI for treatment of acute headache outside of a research setting at this time.
16e.	Chronic headache following mTBI is likely to be multifactorial; therefore, health care providers should refer children with chronic headache after mTBI for multidisciplinary evaluation and treatment, with consideration of analgesic overuse as a contributory factor.
Vestibulo-Oculomotor Dysfunction Management/Treatment, Recommendation #17	

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17.	Health care providers may refer children with subjective or objective evidence of persistent vestibulo-oculomotor dysfunction following mTBI to a program of vestibular rehabilitation.
Sleep Management/Treatment, Recommendation #18	
18a.	Health care providers should provide guidance on proper sleep hygiene methods to facilitate recovery from pediatric mTBI.
18b.	If sleep problems emerge or continue despite appropriate sleep hygiene measures, health care providers may refer children with mTBI to a sleep disorder specialist for further assessment.
Cognitive Impairment Management/Treatment, Recommendation #19	
19a.	Health care providers should attempt to determine the etiology of cognitive dysfunction within the context of other mTBI symptoms.
19b.	Health care providers should recommend treatment for cognitive dysfunction that reflects its presumed etiology.
19c.	Health care providers may refer children with persisting problems related to cognitive function for a formal neuropsychological evaluation to assist in determining etiology and recommending targeted treatment.