

CDC Guideline for the Diagnosis and Management of Mild Pediatric Traumatic Brain Injury

Summary of CDC Response to Public Comments

OVERVIEW

The Centers for Disease Control and Prevention (CDC) published a notice in the *Federal Register* ([82 FR 45588](#)) to announce the public comment opportunity on a draft guideline and systematic review on pediatric mild traumatic brain injury (mTBI). The guideline (*CDC Guideline on the Diagnosis and Management of Mild Traumatic Brain Injury Among Children*) and systematic review (Diagnosis and Management of Mild Traumatic Brain Injury Among Children: A Systematic Review) were posted on Regulations.gov (docket number CDC-2017-0089) for a 60-day period between September 29, 2017 through November 28, 2017. CDC received 10 comments from the public during this time period, including from: clinicians, researchers, individuals with traumatic brain injury, and health and medical organizations. CDC subject-matter experts carefully reviewed each comment individually and considered modifications to the guideline and systematic review. The complete set of public comments may be viewed on Regulations.gov at <https://www.regulations.gov/docket?D=CDC-2017-0089>.

The summary below provides an overview of the more substantial changes CDC made to the guideline and systematic review in response to the feedback received through this process. The areas summarized are not inclusive of all the edits made. CDC thanks all those who submitted comments through the public comment opportunity. Based on the feedback, CDC was able to strengthen and improve the quality of the guideline and systematic review.

RESPONSE TO COMMENTS ABOUT THE SYSTEMATIC REVIEW:

General Comments:

- Some commenters suggested inclusion of evidence that was not part of the systematic review; this evidence was not added to the systematic review given its inconsistency with the inclusion/exclusion criteria or time frame for the review.
- A few comments were received regarding grading of the evidence, the limited number of studies that use randomized control methodologies, or concerns about the generalizability of some studies to a large population. To grade the evidence CDC followed a National Academy of Science compliant process for evidence-based reviews. As part of this, CDC took into account generalizability and applicability for use in clinical practice as some of the factors for grading the evidence. Details on the methodology used was included in the systematic review.
- One comment expressed concern about the conclusions outlined in the systematic review and how it relates to clinical practice. To address this comment, language was added to highlight that the purpose of the systematic review, as a stand-alone document, is to summarize existing literature and should not be interpreted as clinical recommendations for healthcare providers. Interpretation of the systematic review by the expert Workgroup, and incorporation of evidence into recommendations, is detailed in the guideline.
- There was a comment requesting the listing of biographies for each of the Workgroup members. Due to word limit requirements, CDC was not able to add in this information. However, additional language was added to specify the clinical specialties that were included on the Workgroup and that a patient representative was a member of the Workgroup. Bolded text was added to this

sentence “*Members of the Workgroup were nominated by CDC and approved by the BSC based on TBI expertise, representation across professional settings (e.g., clinical, research, sports, education, patient representative), and credentials in a wide range of clinical specialties (e.g., neurology, neuropsychology, athletic training, emergency medicine).*”

Comments Specific to Clinical Questions:

Question 2, Conclusion:

- Multiple comments were received regarding the content in the systematic review on the use of CT imaging. Commenters explained that current evidence that provides the basis for CT imaging focus on ruling out clinical-important traumatic brain injury (ciTBI) among pediatric patients presenting with a TBI. To address this CDC revised the conclusion section of Question 2 regarding use of CT scans to specify that the recommendations are for children presenting with mTBI versus TBI of all severity levels in the acute care setting. The conclusion statement was revised to state:
 - *“Specific imaging modalities were assigned a likelihood of identifying important outcomes among children presenting to an acute care setting with mTBI. The following is not a reflection of sensitivity or specificity of the imaging modality, but rather the likelihood of identifying intracranial pathologies in children with presumed mTBI who underwent neuroimaging:*
 - *7.1% (95% CI, 4.0%-10.3%) of children with mTBI may possibly have a skull fracture identified via skull X-ray. (low confidence).*
 - *18.2% (95% CI, 11.5%-24.9%) of children with mTBI may possibly have isolated skull fractures identified via head CT (low confidence).*
 - *7.5% (95% CI, 6.0%-9.1%) of children with mTBI may possibly have intracranial injury identified via head CT. (low confidence).*
 - *1.9% (95% CI, 1.3-2.5) of children with mTBI may possibly have intracranial injuries associated with clinically important outcomes (list important outcomes) identified via head CT. (low confidence).*
 - *0.8% (95% CI, 0.5%-1.2%) of children with mTBI may possibly have intracranial injuries requiring neurosurgical intervention identified via head CT (low confidence). ”*

Question 3, Conclusion:

- Commenters requested further clarification on risk factors for important intracranial injury (iICI). The conclusion now includes more information related to the risk of independent factors in relation to iICI. Specifically, the text in bold was added to the following paragraph:

“A substantial body of research has established statistically significant associations between a range of individual risk factors and iICI, however these independent associations cannot be applied clinically in most cases. Aside from GCS score and the presence of skull fracture, the effect size of these risk factors in relation to iICI suggests that they are not clinically meaningful predictors when considered in isolation (i.e., not confounded with other risk factors). In contrast, validated prediction rules and algorithms that combine multiple risk factors are able to predict the absence of iICI with substantial accuracy (i.e., >95% negative predictive power).

RESPONSE TO COMMENTS ABOUT THE GUIDELINE:

General Comments:

- Some commenters suggested inclusion of evidence that was not part of the guideline; this evidence was not added to the guideline given its inconsistency with the inclusion/exclusion criteria or time frame for the review.
- A few commenters expressed concern regarding recommendations not being applicable in the emergency care setting. As the clinical recommendations in the guideline were created for both the acute care and primary care setting, language was added to emphasize that the recommendations were drafted to be relevant for both settings. Specifically, the following bolded text was added to this sentence in the Conclusion: ***"This guideline identifies best practices based on current evidence for healthcare providers in the primary care, outpatient specialty, inpatient, and emergency care settings."***

Two commenters noted that CDC used a broad definition of mTBI and that the field lacks a standard definition for this injury. Additional language to describe the rationale for the use of a broad definition of mTBI and was added: ***"A wide clinical and functional definition of pediatric mTBI was employed for this Guideline in order to be cognizant of the heterogeneity of presentations and outcomes of children with mTBI and to prevent the exclusion of children representing the more severe end of the mTBI spectrum."***

Comments Specific to Clinical Recommendations

Recommendation Sets 1-6

- As in the systematic review, multiple comments were received regarding the use of CT imaging. Commenters explained that current evidence that provides the basis for CT imaging focus on ruling out clinical-important traumatic brain injury (ciTBI) among pediatric patients presenting with a TBI. To further clarify that the recommendations regarding the use of diagnostic tools, such as head imaging, are specific to children presenting with mTBI versus TBI of all severity levels, the text that describes the purpose of the diagnosis recommendations (recommendation sets 1-6) was revised. The text now reads: ***"This section contains recommendations regarding the diagnostic utility of head imaging, use of symptom scales, cognitive testing, and serum biomarkers in pediatric mTBI."***

Recommendation Set 1

- Comments were received regarding the content in the guideline on “isolated findings” as risk factors and the importance of GCS and the suspicions of skull fracture. CDC updated the rationale for Recommendation Set 1, to state: ***"Generally, risk factors are not sufficiently predictive in isolation to guide clinical care (excluding GCS and clinical suspicion for skull fracture)."***

Recommendation Set 10

- Some comments focused on limited evidence for use of assessment tools as outlined in Recommendation Set 10, requested inclusion of other assessment tools not noted in the guideline, or questioned the use of certain tools in the acute care setting. CDC does not state that assessment tools should be used in isolation. Instead, the guideline states that tools are “a component of the diagnostic evaluation”. As the guideline is focused on healthcare providers in the primary care, outpatient specialty, inpatient, and emergency care settings, CDC did not include recommendations specific to assessment tools used for different environments (i.e., only in the acute care setting or on-field or athletic environments).

Recommendation Set 13

- One comment noted that Recommendation set 13 on “cognitive/physical rest and aerobic treatment” is vague about the extent (“more restrictive”) and duration (“several days”) of rest. Recommendation set 13 is supported by evidence and consensus recommendations and related evidence. Due to limitations in the current literature, CDC was unable to update this recommendation with the level of granularity requested.

Recommendation set 17

- One commenter noted the importance of vision health following an mTBI. To address this, within the rationale for Recommendation set 17, the text explicitly identifying *“vestibu-ocular and cervico-vestibular physical therapy”* was added.

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