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SPECIAL COMMUNICATION

The American Congress of Rehabilitation Medicine Diagnostic Criteria for Mild Traumatic Brain Injury

Noah D. Silverberg, PhD,[a,b,c] Grant L. Iverson, PhD,[d,e,f,g,h]; ACRM Brain Injury Special Interest Group Mild TBI Task Force members: Alison Cogan, PhD, OTR/L,[i] Kristen Dams-O-Connor, PhD,[j] Richard Delmonico, PhD,[k] Min Jeong P. Graf, MD,[l,m] Mary Alexis Iaccarino, MD,[d,e,f,h,n] Maria Kajankova, PhD,[j] Joshua Kamins, MD,[o] Karen L. McCulloch, PhD,[p] Gary McKinney, DHSc,[q] Drew Nagele, PsyD,[r] William J. Panenka, MD,[s] Amanda R. Rabinowitz, PhD,[t] Nick Reed, PhD,[u] Jennifer V. Wethe, PhD,[v] Victoria Whitehair, MD,[w]; ACRM Mild TBI Diagnostic Criteria Expert Consensus Group: Vicki Anderson, PhD,[x] David B. Arciniegas, MD,[y] Mark T. Bayley, MD,[z] Jeffery J. Bazarian, MD, MPH,[aa] Kathleen R. Bell, MD,[ab] Steven P. Broglio, PhD,[ac] David Cifu, MD,[ad,ae] Gavin A. Davis, MBBS,[af] Jiri Dvorak, MD, PhD,[ag,ah] Ruben J. Echemendia, PhD,[ai] Gerard A. Gioia, PhD,[aj] Christopher C. Giza, MD,[ak] Sidney R. Hinds,II, MD,[al] Douglas I. Katz,[am] Brad G. Kurowski,[an,ao] John J. Leddy, MD,[ap] Natalie Le Sage, MD, PhD,[aq,ar] Angela Lumba-Brown, MD,[as] Andrew IR. Maas, MD,[at,au] Geoffrey T. Manley, MD, PhD,[av]

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Michael McCrea, PhD,[aw] David K. Menon, MD, PhD,[ax] Jennie Ponsford, PhD,[ay] Margot Putukian, MD,[az] Stacy J. Suskauer, MD,[ba] Joukje van der Naalt, MD, PhD,[bb] William C. Walker, MD,[bc] Keith Owen Yeates, PhD,[bd] Ross Zafonte, DO,[d,f,n,be] Nathan D. Zasler, MD,[bf] Roger Zemek, MD[bg,bh]

From the [a]Department of Psychology, University of British Columbia, Vancouver, Canada; [b]Vancouver Coastal Health Research Institute, Vancouver, Canada; [c]Djavad Mowafaghian Centre for Brain Health, Vancouver, Canada; [d]Department of Physical Medicine and Rehabilitation, Harvard Medical School, Boston, MA; [e]Sports Concussion Program, MassGeneral Hospital for Children, Boston, MA; [f]Department of Physical Medicine and Rehabilitation, Spaulding Rehabilitation Hospital, Charlestown, MA; [g]Department of Physical Medicine and Rehabilitation, Schoen Adams Research Institute at Spaulding Rehabilitation, Charlestown, MA; [h]Home Base, A Red Sox Foundation and Massachusetts General Hospital Program, Charlestown, MA; [i]Mrs. T. H. Chan Division of Occupational Science and Occupational Therapy, University of Southern California, CA; [j]Department of Rehabilitation and Human Performance, Brain Injury Research Center of Mount Sinai, Icahn School of Medicine at Mount Sinai, New York, NY; [k]Kaiser Foundation Rehabilitation Center, The Permanente Medical Group, Vallejo, CA; [l]Department of Physical Medicine and Rehabilitation, Hennepin Healthcare, Minneapolis, MN; [m]Department of Rehabilitation Medicine, University of Minnesota, Minneapolis, MN; [n]Department of Physical Medicine and Rehabilitation, Massachusetts General Hospital, Boston, MA; [o]UCLA Steve Tisch BrainSPORT Program, David Geffen School of Medicine at UCLA, Los Angeles, CA; [p]Division of Physical Therapy, Department of Health Sciences, School of Medicine, University of North Carolina at Chapel Hill, Chapel Hill, NC; [q]Traumatic Brain Injury Center of Excellence, Defense Health Agency, Silver Spring, MD; [r]School of Professional and Applied Psychology, Philadelphia College of Osteopathic Medicine, Philadelphia, PA; [s]Department of Psychiatry, University of British Columbia, Vancouver, BC, Canada; [t]Moss Rehabilitation Research Institute, Elkins Park, PA; [u]Department of Occupational Science & Occupational Therapy, University of Toronto, Toronto, Canada; [v]Mayo Clinic School of Medicine, Scottsdale, AZ; [w]MetroHealth Rehabilitation Institute and Case Western Reserve University, Cleveland, OH; [x]Murdoch Children's Research Institute, The Royal Children's Hospital, Parkville, Australia; [y]University of New Mexico School of Medicine, University of Colorado School of Medicine, Aurora, CO; [z]Toronto Rehabilitation Institute, University Health Network, University of Toronto, Toronto, Canada; [aa]University of Rochester School of Medicine and Dentistry, Rochester, NY; [ab]University of Texas Southwestern Medical Center, Dallas, TX; [ac]University of Michigan, Michigan Concussion Center, Ann Arbor, MI; [ad]Department of Physical Medicine and Rehabilitation, Virginia Commonwealth University School of Medicine, Richmond, VA; [ae]U.S. Department of Veterans Affairs, Richmond, VA; [af]Cabrini Health, Cabrini Malvern, Melbourne, Australia; [ag]Schulthess Klinic, Zurich, Switzerland; [ah]Swiss Concussion Center, Zurich, Switzerland; [ai]University Orthopedics Center, Concussion Care Clinic, University of Missouri-Kansas City, Kansas City, MO; [aj]Division of Neuropsychology/SCORE Concussion Program, Children's National Hospital, George Washington University School of Medicine, Rockville, MD; [ak]University of California at Los Angeles, Departments of Neurosurgery and Pediatrics, Steve Tisch BrainSPORT Program, Los Angeles, CA; [al]Uniformed Services University, Department of Neurology and Radiology, Bethesda, MD; [am]Department of Neurology, Boston University Chobanian & Avedisian School of Medicine, MA; [an]Division of Pediatric Rehabilitation Medicine, Cincinnati Children's Hospital Medical Center, Cincinnati, OH; [ao]Departments of Pediatrics, Neurology, and Rehabilitation Medicine, University of Cincinnati College of Medicine, Cincinnati, OH; [ap]UBMD Department of Orthopaedics and Sports Medicine, SUNY Buffalo Jacobs School of Medicine and Biomedical Sciences, Buffalo, NY; [aq]Population Health and Optimal Health Practices Axis, CHU de Québec-Université Laval Research Centre, VITAM-Centre de recherche en santé durable, Québec, Canada; [ar]Department of

shareholder in Highmark Innovations and in 360 Concussion Care, an interdisciplinary concussion clinic, and receives expert testimony fees. Dr Le Sage reports grants as a principal investigator from Canadian Institutes of Health Research (CIHR) and from Fonds de recherche du Québec en Santé (FRQ-S). She is a consultant for the Institut National d'Excellence en santé et en services sociaux (INESSS) and for the Quebec Ministry of Health and Social Services (MSSS). Dr Manley reports research funding from the Department of Defense, NIH, National Football League (NFL), Abbott Laboratories, and grateful patients. Dr Mass declares grant funding from the Framework 7 program of the European Union (Grant 602150), and consulting fees from PresSura Neuro, Integra Life Sciences, and NeuroTrauma Sciences. Dr Menon reports grants, personal fees, and non-financial support from GlaxoSmithKline; personal fees from Neurotrauma Sciences, Lantmaanen AB, Pressura, and Pfizer, outside of the submitted work. Dr McCrea reports research grants from the NIH, Department of Defense, Center for Disease Control and Prevention (CDC), Department of Veterans Affairs, Abbott Laboratories, National Football League (NFL), and National Collegiate Athletic Association (NCAA), and consultancy with the Green Bay Packers and Neurotrauma Sciences, Inc Dr Ponsford reports grants from the Victorian Transport Accident Commission and National Health and Medical Research Council and provides expert testimony for cases involving mild TBI. Dr Putukian is a paid consultant for Major League Soccer, and serves on several committees including the NFL Head, Neck & Spine Committee, the Football Association (FA) Research Task Force, the US Soccer Medical Advisory Committee and the NOCSAE Scientific Advisory Committee. She has assisted with the United Kingdom Concussion Foundation Forum, received funding for research from the NCAA-CARE-DoD 2.0 (ended 2020), and has received honoraria and reimbursement for travel for speaking and conferences attended, received royalties for the Netter's Sports Medicine textbook, and received compensation for work as an expert for cases involving concussion, team physician and other sports medicine topics. Dr Reed reports grants from the Canadian Institutes of Health Research and Special Olympics Canada, and holds a Canada Research Chair (Tier 2) in Pediatric Concussion. He is a co-investigator in a multicenter study funded by the National Football League (NFL) Scientific Advisory Board but does not receive financial support. He is an Executive Board Member for the International Pediatric Brain Injury Society. He is a minority shareholder in 360 Concussion Care, an interdisciplinary concussion clinic. Dr Silverberg reports grants from the Canadian Institutes of Health Research, Canadian Foundation for Innovation, VGH+UBC Hospital Foundation, and WorkSafeBC, and clinical consulting fees from the National Hockey League and Major League Soccer, and expert testimony fees. Dr Wethe reports a financial relationship with King-Devick technologies and a financial interest in Mayo Clinic Concussion Check. Dr Yeates is the recipient of the Ronald and Irene Ward Chair in Pediatric Brain Injury, funded by the Alberta Children's Hospital Foundation. He receives an editorial stipend from the American Psychological Association and book royalties from Guilford Press and Cambridge University Press. He is the Chair of the Canadian Concussion Network, which is funded by a grant from the Canadian Institutes of Health Research. He is a co-investigator in a multicenter study funded by the National Football League (NFL) Scientific Advisory Board but does not receive financial support. He is a member of the Scientific Advisory Committee for Brain Injury Canada and of the National Research Advisory Council for the National Pediatric Rehabilitation Resource Center. Dr Zafonte receives royalties from Springer/Demos publishing for serving as co- editor of the text Brain Injury Medicine. Dr Zafonte serves on the Scientific Advisory Board of Kisbee Nanodiagnostics, and Myomo. He also evaluates patients in the MGH Brain and Body-TRUST Program which is funded by the NFL Players Association. Dr Zafonte also serves on the Mackey White health committee. Dr Zafonte serves as PI for the Football Players Health Study at Harvard. Dr Zasler is the sole shareholder in Concussion Care Center of Virginia, LTD. He has a clinical and forensic consulting practice in brain injury medicine. Dr Zemek reports being a co-investigator in a multicenter study competitively funded by the National Football League (NFL) Scientific Advisory Board; he is a minority shareholder in 360 Concussion Care, an interdisciplinary concussion clinic. Disclaimer: Clinical practice guidelines, practice advisories, systematic reviews, case definitions, and other guidance published by the American Congress of Rehabilitation Medicine (ACRM) are assessments of current scientific and clinical information that are provided as an educational service. 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Family Medicine and Emergency Medicine, Université Laval, Québec, Canada; [as]Department of Emergency Medicine, Stanford University, Stanford, CA; [at]Antwerp University Hospital, Edegem, Belgium; [au]University of Antwerp, Edegem, Belgium; [av]Department of Neurosurgery, University of California, San Francisco, CA; [aw]Department of Neurosurgery, Medical College of Wisconsin, Milwaukee, WI; [ax]University of Cambridge, Addenbrooke's Hospital, Cambridge, United Kingdom; [ay]Monash University, Clayton, Australia; [az]Major League Soccer; Princeton, NJ; [ba]Kennedy Krieger Institute and Department of Physical Medicine & Rehabilitation, Johns Hopkins University School of Medicine, Baltimore, MD; [bb]Department of Neurology, University of Groningen, University Medical Center Groningen, Groningen, Netherlands; [bc]Virginia Commonwealth University, Richmond, VA; [bd]Department of Psychology, Alberta Children's Hospital Research Institute, and Hotchkiss Brain Institute, University of Calgary, Calgary, Canada; [be]Department of Physical Medicine and Rehabilitation, Brigham and Women's Hospital, Boston, MA; [bf]Concussion Care Centre of Virginia, Henrico, VA; [bg]Departments of Pediatrics and Emergency Medicine, University of Ottawa, Ottawa, Canada; and [bh]Children's Hospital of Eastern Ontario, Ottawa, Canada.

Abstract

Objective: To develop new diagnostic criteria for mild traumatic brain injury (TBI) that are appropriate for use across the lifespan and in sports, civilian trauma, and military settings.

Design: Rapid evidence reviews on 12 clinical questions and Delphi method for expert consensus.

Participants: The Mild Traumatic Brain Injury Task Force of the American Congress of Rehabilitation Medicine Brain Injury Special Interest Group convened a Working Group of 17 members and an external interdisciplinary expert panel of 32 clinician-scientists. Public stakeholder feedback was analyzed from 68 individuals and 23 organizations.

Results: The first 2 Delphi votes asked the expert panel to rate their agreement with both the diagnostic criteria for mild TBI and the supporting evidence statements. In the first round, 10 of 12 evidence statements reached consensus agreement. Revised evidence statements underwent a second round of expert panel voting, where consensus was achieved for all. For the diagnostic criteria, the final agreement rate, after the third vote, was 90.7%. Public stakeholder feedback was incorporated into the diagnostic criteria revision prior to the third expert panel vote. A terminology question was added to the third round of Delphi voting, where 30 of 32 (93.8%) expert panel members agreed that 'the diagnostic label 'concussion' may be used interchangeably with 'mild TBI' when neuroimaging is normal or not clinically indicated.'

Conclusions: New diagnostic criteria for mild TBI were developed through an evidence review and expert consensus process. Having unified diagnostic criteria for mild TBI can improve the quality and consistency of mild TBI research and clinical care.

Archives of Physical Medicine and Rehabilitation 2023;000:1−13

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In 1993, the Mild Traumatic Brain Injury Committee of the Head Injury Interdisciplinary Special Interest Group of the American Congress of Rehabilitation Medicine (ACRM) published a definition of mild traumatic brain injury (TBI)[1] that has been widely used since. An update of this definition was needed for several reasons. First, scientific research over the past 30 years has considerably improved our understanding of mild TBI and how to assess its acute sequelae. Second, use of the 1993 ACRM definition has exposed important limitations that definitions published since have not remedied, such as not clearly differentiating signs from symptoms. Finally, other definitions of mild TBI have been developed using weak or unclear methodologies.

Alternative mild TBI definitions that differ substantively from each other have proliferated.[2-4] One study applied 17 definitions of mild TBI to a prospectively collected dataset of 11,907 children (aged 3-16) who were evaluated in emergency departments.[5] The proportion of the sample meeting criteria for mild TBI ranged from 7% to 99%, depending on the definition applied. Consequences of diagnostic variability include uneven access to clinical care, ambiguity about who clinical practice guidelines are for, and difficulties comparing or synthesizing research findings, especially between civilian trauma, sports, and military settings.[6] Efforts to develop common data elements for the uniform collection and coding of demographic and clinical data,[7] as well as to harmonize outcome measures[8] for "big data" analytics, are being undermined by uncertainty and variability regarding who is enrolled in TBI studies.

This article presents new diagnostic criteria for mild TBI (ie, a case definition that operationalizes clinical features and specifies which are necessary or sufficient for diagnosis[9,10]) and the methodology used to develop them. Recognizing that expert consensus is needed to develop diagnostic criteria for conditions with heterogenous clinical presentations and no definitive laboratory confirmation,[7-10] we undertook a rigorous and transparent Delphi consensus process, supported by rapid evidence reviews. In an effort to create diagnostic criteria that are appropriate for use across the lifespan and in sports, civilian trauma, and military settings, we composed an expert consensus panel with broad, interdisciplinary clinical and research expertise across these subpopulations.[3] Unified diagnostic criteria for mild TBI could improve the quality and consistency of mild TBI research and clinical care.

List of abbreviations:

ACRM	**American Congress of Rehabilitation Medicine**
GCS	**Glasgow Coma Scale**
TBI	**Traumatic brain injury**

Methodology for developing the new diagnostic criteria

The Mild TBI Task Force of the ACRM Brain Injury Special Interest Group convened a Working Group in late 2018, consisting of 17 individuals from the Task Force membership. The Working Group, co-led by NDS and GLI, took several steps prior to commencing the Delphi process. First, the Working Group assembled an expert panel and surveyed their views on the diagnostic importance of various signs, symptoms, examination findings, and contextual factors. These

Activities	2019		2020		2021		2022	
Expert panel members rated the diagnostic importance of signs, symptoms, and examination findings[3].								
Working Group members conducted rapid evidence reviews to create evidence statements and associated evidence summaries.								
The Working Group drafted Version 1.0 of diagnostic criteria based on the diagnostic importance survey[3] and rapid evidence reviews.								
Delphi Round 1: Expert panel members voted on the evidence statements and Version 1.0 of the diagnostic criteria.								
The Working Group revised the diagnostic criteria (Version 1.0) to incorporate qualitative feedback from expert panel members.								
Delphi Round 2: Expert panel members voted on revised evidence statements and Version 2.0 of the diagnostic criteria.								
The Working Group revised the diagnostic criteria (Version 2.0) to incorporate qualitative feedback from expert panel members.								
ACRM elicited stakeholder feedback on the diagnostic criteria (Version 2.1) and terminology.								
The Working Group incorporated qualitative feedback from the stakeholder survey in a minor revision of the diagnostic criteria.								
Delphi Round 3: Expert panel members voted on Version 2.2 of the diagnostic criteria and the terminology question.								

Fig 1 Gantt Chart of Major Activities and Timelines. Abbreviation: ACRM, American Congress of Rehabilitation Medicine.

processes and results were published online first in the summer of 2020.[3] These survey results were intended to characterize expert opinion on the diagnostic importance of specific elements of the future diagnostic criteria, in anticipation that published empirical evidence for diagnostic accuracy would be insufficient for at least some elements. Second, the Working Group conducted rapid evidence reviews[11] to identify and synthesize research relevant to adding, removing, or modifying elements of 1993 ACRM definition[1] (see *Evidence Statements* below). Finally, the Working Group combined this evidence with expert opinion from the initial survey[3] to generate Version 1.0 of the updated ACRM diagnostic criteria for mild TBI. An overview of these preliminary steps and the Delphi expert consensus process is shown in Figure 1.

Evidence statements

Based on the initial survey of the expert panel,[3] the Working Group identified 12 topics that required evidence-checking, with each topic associated with major revisions under consideration (online supplemental material; available online only at http://www.archives-pmr.org/). Using rapid review methodology,[11] members of the Working Group searched MEDLINE between October 2019 and January 2020, using a fixed term set for mild TBI ([exp 'Craniocerebral Trauma' MeSH term] or [*concuss*] or [(mild or minor) and (head or brain) and (injur* or trauma*)]) in combination with key words and variations specific to each topic that was approved by the project lead (NDS). Searches were limited to articles published in English from 1993-present. The Working Group member leading each topic screened abstracts and extracted data for their topic. Studies related to diagnostic accuracy were graded as Class I (low risk of bias) to Class IV (high risk of bias) by a single rater based on the American Academy of Neurology Clinical Practice Guideline Process Manual.[12] Data extraction and risk of bias ratings were verified by a second Working Group member and discrepancies were resolved by the project lead (NDS). The 12 brief evidence statements were presented to the expert panel along with evidence summaries (descriptions of relevant studies with risk of bias ratings and supporting citations) (see the online supplemental material, available online only at http://www.archives-pmr.org/). In addition to rating their agreement with each statement, expert panel members were invited to explain their reasons for disagreement and suggest revisions, as well as to identify additional important articles that were not included by the Working Group's systematic evidence search.

Delphi process

The Delphi method is a widely used semi-standardized process for pursuing expert consensus.[13,14] The identification, invitation, and characteristics of the expert panel members were described in the previously published article.[3] In brief, all have expertise in mild TBI, from a variety of disciplines (eg, physiatry, neurology, neuropsychology, neurosurgery, emergency medicine, and sports medicine). Since the initial convening of the expert panel, 2 new members were added to increase the international representation and gender diversity of the panel (prior to the first Delphi round) and one member resigned for reasons unrelated to this study (after the second Delphi round). The Delphi process was conducted entirely online. In each round, expert panel members were invited to complete an online survey (hosted by Qualtrics) in which they were presented with diagnostic criteria and asked to rate their agreement on a 4-point scale (agree without reservations, agree with minor reservations, agree with major reservations, or disagree) and enter comments to explain any reasons for reservations or disagreement. After each round, the expert panel received quantitative (agreement rating frequencies) and qualitative (de-identified aggregated comments) feedback from

the previous round. Individual responses remained confidential.

Prior to commencing the Delphi process, the Working Group defined 'consensus' as at least 80% of the expert panel indicating agreement without reservations or with minor reservations. Three rounds of Delphi voting were conducted (see online supplemental material, available online only at http://www.archives-pmr.org/). Prior to the third round of Delphi voting, the expert panel received a summary of the results of the stakeholder survey (described below) and corresponding reasons for further revisions to diagnostic criteria Versions 2.0 and 2.1 (see the online supplemental material, available online only at http://www.archives-pmr.org/). In the third round of Delphi voting, expert panel members were not only asked to rate their agreement with the revised diagnostic criteria (Version 2.2), but also their agreement with the statement 'The diagnostic label 'concussion' may be used interchangeably with 'mild TBI' when neuroimaging is normal or not clinically indicated' with a yes or no response. Expert panel members who responded 'no' were prompted to share their (alternative) opinion about the relationship between the terms 'concussion' and 'mild TBI.'

Stakeholder feedback

After the second round of Delphi voting, the Working Group addressed qualitative feedback from the expert panel on Version 2.0 of the ACRM diagnostic criteria, resulting in Version 2.1, and created a stakeholder feedback survey that contained 2 items. Version 2.1 of the ACRM diagnostic criteria for mild TBI was made available for download and respondents were prompted to provide narrative comments. To solicit their opinion on terminology, respondents were then presented with "'Concussion' may be used interchangeably with 'mild TBI'. . ." and given 5 response options (see online supplemental material, available online only at http://www.archives-pmr.org/). The survey (hosted by SurveyMonkey) was disseminated in 2 ways, (1) through ACRM's email distribution lists and social media channels; and (2) by direct email invitation to organizations identified by the Working Group as having a mandate relevant to TBI (see online supplemental material, available online only at http://www.archives-pmr.org/). The survey launched on December 18, 2021 and remained open to individuals until January 18, 2022 and to stakeholder organizations until March 15, 2022.

The number and source of submissions from members of the public and stakeholder organizations are summarized in the online supplemental material (available online only at http://www.archives-pmr.org/). We analyzed responses from 68 individuals and 23 stakeholder organizations. The Working Group extracted themes from the narrative comments (see online supplemental material, available online only at http://www.archives-pmr.org/) and attempted to address them in a minor revision of the diagnostic criteria (from Version 2.1 to 2.2).

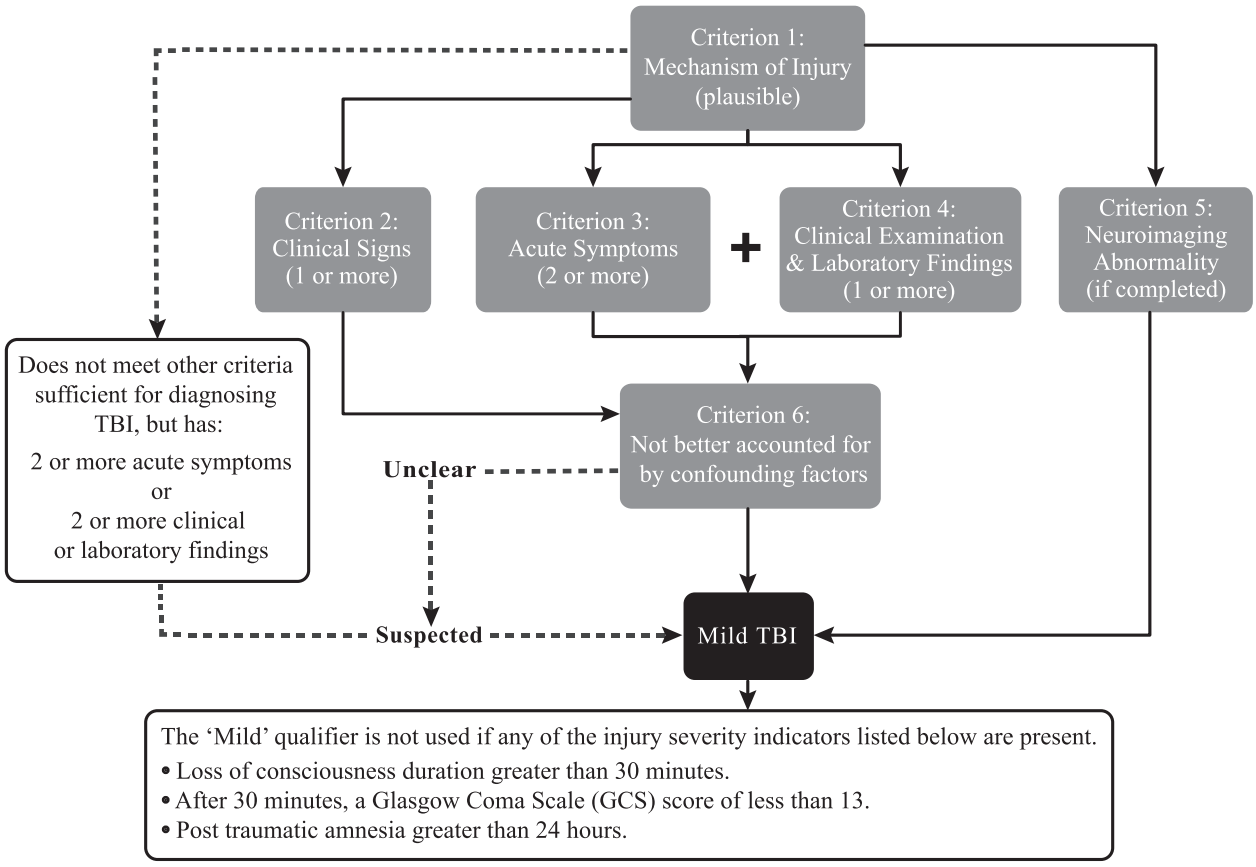


Fig 2 Visual Representation of the American Congress of Rehabilitation Medicine Diagnostic Criteria for Mild Traumatic Brain Injury. See Box 1 for the diagnostic criteria and Box 2 for the definitions and explanatory notes. The qualifier mild TBI 'with neuroimaging evidence of structural intracranial injury' may be used when computed tomography or magnetic resonance imaging reveals a trauma-related intracranial abnormality. A suspected mild TBI is represented by the dashed lines.

Results from the Delphi voting

The first 2 rounds of Delphi voting included votes relating to both the evidence statements and the diagnostic criteria for mild TBI. In the first round of expert panel voting (October-December of 2020), 10 of 12 evidence statements reached consensus agreement and others exceeded this threshold but were modestly revised to address expert panel member concerns. In total, 9 of 12 evidence statements were revised. The revised evidence statements underwent a second round of expert panel voting (June-July of 2021), where consensus was achieved for all. The final evidence statements and their agreement ratings are presented in the online supplemental material (available online only at http://www.archives-pmr.org/).

The results through 3 rounds of Delphi voting on the diagnostic criteria for mild TBI are presented in the online supplemental material (available online only at http://www.archives-pmr.org/). The response rate amongst the expert panel was 100% in all 3 rounds of voting. The first round of voting yielded an agreement rate of 75.8%. Both the second and third rounds of voting exceeded the agreement necessary for consensus (80%). The final consensus criteria (Version 2.2) had a 90.7% agreement rate (without reservations or with minor reservations). Specific reservations with the final diagnostic criteria in the third round of Delphi voting, paraphrased to preserve anonymity, are reported in the online supplemental material (available online only at http://www.archives-pmr.org/). For the terminology question in the third round of Delphi voting, 30 of 32 (93.8%) expert panel members agreed that "the diagnostic label 'concussion' may be used interchangeably with 'mild TBI' when neuroimaging is normal or not clinically indicated."

ACRM diagnostic criteria for mild traumatic brain injury

The new ACRM diagnostic criteria for mild TBI are presented in Box 1. Definitions and explanatory notes for the diagnostic criteria are presented in Box 2. The diagnostic criteria are illustrated visually in Figure 2. Examples of applying the criteria to patients with various patterns of signs, symptoms, and/or examination findings are illustrated in the online supplemental material (available online only at http://www.archives-pmr.org/).

Discussion

The Working Group of the ACRM Mild TBI Task Force developed new diagnostic criteria for mild TBI that are appropriate for use across the lifespan and in sports, civilian trauma, and military settings. The diagnostic criteria elements are explained below, highlighting similarities and differences with prior definitions of mild TBI.

Mechanism of injury (criterion 1)

A plausible mechanism of injury resulting in an external force inducing a physiological disruption of brain function is necessary for diagnosis, as in prior definitions.[1,10,15,16] The ACRM diagnostic criteria broaden the possible mechanisms of injury listed in the 1993 ACRM definition to include 'forces generated from a blast or explosion' (see the evidence summary for Evidence Statement #1, online supplemental material, available online only at http://www.archives-pmr.org/), in alignment with more recent definitions of mild TBI.[15,17] Criterion 1 may be met by the patient's

Box 1 American Congress of Rehabilitation Medicine Diagnostic Criteria for Mild Traumatic Brain Injury.

Mild traumatic brain injury (TBI) is diagnosed when, following a biomechanically plausible mechanism of injury (Criterion 1) *one or more* of the criteria (i-iii) listed below are met.
i. One or more clinical signs (Criterion 2) attributable to brain injury.
ii. At least 2 acute symptoms (Criterion 3) and at least one clinical or laboratory finding (Criterion 4) attributable to brain injury.
iii. Neuroimaging evidence of TBI, such as unambiguous trauma-related intracranial abnormalities on computed tomography or structural magnetic resonance imaging (Criterion 5).

Confounding factors do not fully account for the clinical signs (Criterion 2), acute symptoms (Criterion 3), and clinical examination and laboratory findings (Criterion 4) that are necessary for the diagnosis (Criterion 6).

Mild Qualifier: The 'mild' qualifier is not used if any of the injury severity indicators listed below are present. Instead, traumatic brain injury (TBI) is diagnosed (without the 'mild' qualifier).
i. Loss of consciousness duration greater than 30 minutes.
ii. After 30 minutes, a Glasgow Coma Scale (GCS) of less than 13.
iii. Post-traumatic amnesia greater than 24 hours.

Neuroimaging Qualifier: If neuroimaging is abnormal (Criterion 5), the qualifier mild TBI 'with neuroimaging evidence of structural intracranial injury' may be used. When neuroimaging is completed and found to be normal, the qualifier mild TBI 'without neuroimaging evidence of structural intracranial injury' may be used. If neuroimaging is not completed, no qualifier is used.

Concussion: The diagnostic label 'concussion' may be used interchangeably with 'mild TBI' when neuroimaging is normal or not clinically indicated.

Suspected Mild TBI: A mild TBI is suspected when, following a biomechanically plausible mechanism of injury (Criterion 1), one or more of the 3 criteria listed below are met.
i. At least 2 acute symptoms (Criterion 3) and the person does not meet other criteria sufficient for diagnosing mild TBI.
ii. At least 2 clinical examination or laboratory findings (Criterion 4) but the person does not meet other criteria for diagnosing mild TBI.
iii. It is unclear whether signs (Criterion 2), acute symptoms (Criterion 3), and available clinical or laboratory findings (Criterion 4) are accounted for by confounding factors (ie, it is unclear if Criterion 6 is met).

See Box 2 for definitions and explanatory notes.

Box 2 Definitions, Explanatory Notes, and Qualifiers for the American Congress of Rehabilitation Medicine Diagnostic Criteria for Mild Traumatic Brain Injury.

Criterion 1: Mechanism of Injury

Traumatic brain injury (TBI) results from a transfer of mechanical energy to the brain from external forces resulting from the (1) head being struck with an object; (2) head striking a hard object or surface; (3) brain undergoing an acceleration/deceleration movement without direct contact between the head and an object or surface; and/or (4) forces generated from a blast or explosion.

Notes: Criterion 1 can be met by direct observation (in person or video review) or collateral (witness) report of the injury event, review of acute care records, or the person's recount of the injury event during an interview.

Criterion 2: Clinical Signs

The injury event causes an acute physiological disruption of brain function, as manifested by *one or more* of the clinical signs listed below.

i. Loss of consciousness immediately following injury (eg, no protective action taken on falling after impact or lying motionless and unresponsive).

ii. Alteration of mental status immediately following the injury (or upon regaining consciousness), evidenced by reduced responsiveness or inappropriate responses to external stimuli; slowness to respond to questions or instructions; agitated behavior; inability to follow two-part commands; or disorientation to time, place, or situation.

iii. Complete or partial amnesia for events immediately following the injury (or after regaining consciousness). If post-traumatic amnesia cannot be reliably assessed (eg, due to polytrauma or sedating analgesics), retrograde amnesia (ie, a gap in memory for events immediately preceding the injury) can be used as a replacement for this criterion.

iv. Other acute neurologic sign(s) (eg, observed motor incoordination upon standing, seizure, or tonic posturing immediately following injury).

Notes: Criterion 2 can be met by direct observation (in person or video review), collateral (witness) report, review of acute care records, or when none of these are available, the person's recount of the injury event.

Criterion 3: Acute Symptoms

The physiological disruption of brain function is manifested by 2 *or more* new or worsened symptoms from the list below.

i. Acute subjective alteration in mental status: feeling confused, feeling disoriented, and/or feeling dazed.

ii. Physical symptoms: headache, nausea, dizziness, balance problems, vision problems, sensitivity to light, and/or sensitivity to noise.

iii. Cognitive symptoms: feeling slowed down, "mental fog," difficulty concentrating, and/or memory problems.

iv. Emotional symptoms: uncharacteristic emotional lability and/or irritability.

The symptoms may be from one or more categories (ie, experiencing 2 symptoms within a single category is sufficient). Other symptoms may be present, but they should not be counted toward Criterion 3. The onset of acute subjective alteration in mental status occurs immediately following the impact or after regaining consciousness. The onset of other symptoms (physical, cognitive, and emotional) may be delayed by a few hours, but they nearly always appear less than 72 hours from injury.

Notes: Criterion 3 can be met by (1) review of acute care documentation of the injured person's acute symptoms, (2) interviewing the injured person about the first few days following injury; (3) having the injured person complete a self-report rating scale documenting symptoms during the first few days following injury; or (4) collateral observation for an individual who cannot accurately report symptoms due to developmental stage (eg, children under 5 years old) or pre-injury disability.

Criterion 4: Clinical Examination and Laboratory Findings

The assessment findings listed below can also provide supportive evidence of brain injury.

i. Cognitive impairment on acute clinical examination.

ii. Balance impairment on acute clinical examination.

iii. Oculomotor impairment or symptom provocation in response to vestibular-oculomotor challenge on acute clinical examination.

iv. Elevated blood biomarker(s) indicative of intracranial injury.

Notes: Clinical and laboratory tests that meet standards of reliability and diagnostic accuracy should be considered for Criterion 4. Impairment in Criterion 4i-iii is defined as a clinically meaningful discrepancy between post-injury test performance and age-appropriate normative reference data, or where available, pre-injury test performance. The diagnostic sensitivity of most clinical and laboratory tests decreases over the first 72 hours following injury and the rate of sensitivity decline differs between specific tests.

Criterion 5: Neuroimaging

Trauma-related intracranial abnormalities on computed tomography or structural magnetic resonance imaging.

Notes: Neuroimaging is not necessary to diagnose mild TBI. Its primary clinical role is to rule out head and brain injuries that might require neurosurgical or other medical intervention in an acute care setting. When obtained, neuroimaging may reveal intracranial abnormalities indicative of TBI such as contusion(s) or intracranial hemorrhage.

Criterion 6: Not better accounted for by confounding factors

Confounding factors, including pre-existing and co-occurring health conditions, have been considered and determined to not fully account for the clinical signs, acute symptoms, and clinical examination and laboratory findings that are necessary for the diagnosis.

Notes: A clinical sign only qualifies for Criterion 2 when it is not better accounted for by acute musculoskeletal pain, psychological trauma, alcohol or substance intoxication, pulmonary or circulatory disruption, syncope prior to fall, or other confounding factors. Symptoms should only be counted toward Criterion 3 when they are not better accounted for by drug, alcohol, or medication use; co-occurring physical injuries (eg, musculoskeletal injury involving the neck or peripheral vestibular dysfunction) or psychological conditions (eg, an acute stress reaction to trauma); pre-existing health conditions; or symptom exaggeration. Criterion 4 findings must not be better accounted for by drug, alcohol, or medication use; co-occurring physical injuries or psychological conditions; pre-existing health conditions; or factors influencing the validity of the symptom reporting or test results.

General Notes: Consideration should be given to cultural and linguistic differences in symptom reporting and test performance. Caution is warranted when applying the diagnostic criteria for mild TBI to young children and individuals with pre-injury cognitive and/or communication impairments. Due to developmental stage (eg, children under 5 years old) or pre-injury disability, an individual may not be able to accurately report symptoms in Criterion 3; thus, this criterion could be met based on proxy report or observation of related behaviors (eg, changes in appetite or behaving out of character). An injured person's behavior should also be interpreted in the context of their developmental stage and pre-injury functioning. Clinical and laboratory test interpretation requires age-appropriate scales and/or cut-off scores.

own description of the injury event (if they remember it adequately), witness observations, or by inference (eg, a person is extracted from a high-speed motor vehicle collision with facial lacerations). Criterion 1 avoids referring to the injury event as an 'accident,' considering that intentional assault, including intimate partner violence, is a recognized cause of TBI. The Working Group considered more precisely defining the parameters of impact, as some prior definitions have done,[18] but found insufficient expert panel support for the diagnostic importance of variables such as whether the head made direct contact with a surface or the material of the surface.[3] Penetrating brain injury or 'other force yet to be defined'[15] fall outside of the scope of the ACRM diagnostic criteria for mild TBI. Not all head trauma events result in TBI. A diagnosis of mild TBI requires a plausible mechanism (Criterion 1) and clinical evidence of an acute physiological disruption of brain function.

Clinical signs (criterion 2)

One or more clinical signs (Criterion 2) attributed to a plausible mechanism of injury (Criterion 1) is sufficient for diagnosing mild TBI. The specific clinical signs listed in the ACRM diagnostic criteria (loss of consciousness, alteration in mental status, amnesia, other acute neurologic signs) are similar to those in prior definitions[1,10,15,16] but, importantly, are given detailed operational definitions and are distinguished from symptoms. Data from video review studies of sport-related concussion (Evidence Statement #5, online supplemental material, available online only at http://www.archives-pmr.org/) helped to identify specific observable behaviors indicative of mild TBI. For example, 'no protective action taken on falling after impact' is included in the definition of loss of consciousness (Criterion 2i).

Clinical signs can be observed (eg, patients repeatedly asking 'what happened' to cause their injury) or elicited (eg, assessing orientation in a mental status examination). In contrast, symptoms (Criterion 3) are subjective feelings of a change in health. The distinction between signs and symptoms is perhaps clearest with altered mental status (Criterion 2ii). Prior definitions of mild TBI include some version of altered mental status as a manifestation of disrupted brain function. Characterizations of altered mental status across prior definitions range from relatively narrow ('confusion or disorientation')[19] to broader, including for example 'feeling dazed'[1] or 'difficulty thinking clearly'[17] or 'slowed thinking'.[15] Prior definitions do not clearly differentiate symptoms (eg, 'feeling confused') from signs (eg, difficulty answering orientation questions). The ACRM diagnostic criteria attempt to reconcile these variations and provide a clear operational definition of observable behaviors indicative of altered mental status (Criterion 2ii). Subjectively experienced symptoms of altered mental status appear in Criterion 3. The distinction between signs and symptoms can be less clear when the first medical evaluation occurs after the acute stage and the clinician asks the patient about altered mental status (Criterion 2ii) and post-traumatic amnesia (Criterion 2iii) immediately after the injury, that is, retrospectively. If the patient did not interact with others immediately after the injury (therefore acute clinical signs were not *observed*), the clinician may need to pose a hypothetical scenario to determine if the signs were *observable* (eg, would you have been able to answer questions about where you were and what happened immediately after the injury?). In this circumstance, observable behaviors elicited through self-report can be counted as signs.

In most prior definitions of mild TBI, 'a loss of memory for events immediately before or after' the injury is sufficient for diagnosis.[1,15,17] In exception, the World Health Organization Neurotrauma Task Force definition includes post-traumatic amnesia only.[19] Based on evidence that retrograde amnesia rarely occurs without post-traumatic amnesia (see the evidence summary for Evidence Statement #2, online supplemental material, available online only at http://www.archives-pmr.org/) and isolated retrograde amnesia may be more in keeping with a non-TBI mechanism (eg, syncope or psychological trauma), the ACRM diagnostic criteria recommend considering retrograde amnesia only when assessment of post-traumatic amnesia is precluded (Criterion 2iii).

In the 1993 ACRM definition, 'focal neurologic deficit(s)' could rule in TBI. They were not clearly defined. The World Health Organization Neurotrauma Task Force definition[19] provided further clarification: 'transient neurologic abnormalities such as focal signs, seizure, and intracranial lesion not requiring surgery' (pg. 140). The Demographics and Clinical Assessment Working Group of the International and Interagency Initiative toward Common Data Elements for Research on Traumatic Brain Injury and Psychological Health definition[15] provided a non-exhaustive list of neurologic deficits that included seizure, sensory loss, and weakness/paralysis. Our Working Group considered that *focal* neurologic deficits have not been well defined. The ACRM diagnostic criteria include 'other acute neurologic sign(s)' (note removal of the word 'focal') as a clinical sign of TBI (Criterion 2iv) and lists examples as observed motor incoordination upon standing, seizure, or tonic posturing immediately after injury, in part motivated by the emerging literature on video analysis of sport-related concussions (see the evidence summary for Evidence Statement #5, online supplemental material, available online only at http://www.archives-pmr.org/).

The World Health Organization Neurotrauma Task Force definition[19] introduced the requirement that clinical signs must not be attributable to confounding factors such as acute pain, psychological trauma, and alcohol intoxication. Subsequent definitions[15,16] and the ACRM diagnostic criteria have similar requirements (Criterion 6).

Acute symptoms (criterion 3)

The new ACRM diagnostic criteria allow for diagnosis of mild TBI when there is not clear evidence of a clinical sign. Specifically, having 2 *or more* symptoms (Criterion 3) *and* one or more abnormal clinical examination or laboratory findings (Criterion 4) attributable to brain injury, is sufficient for diagnosis. It is also possible to have a 'suspected' mild TBI when the only evidence suggestive of brain injury is self-reported symptoms (Criterion 3), including symptoms that become evident only upon attempted exertion.[20] These changes should improve sensitivity over the 1993 ACRM definition. Specificity should be preserved by not counting symptoms with known poor specificity such as fatigue and nervousness toward Criterion 3 (see the evidence summary for Evidence Statements #4a-c, online supplemental material, available online only at http://www.archives-pmr.org/) and the requirement that new or worsened symptoms must have an acute onset (<72 hours) and not be better accounted for by confounding factors (Criterion 6). Note that the 72 hour time period for headache to be counted toward a diagnosis of mild TBI is shorter than the 7-day time period allowed for the classification of post-traumatic headache diagnosis.[21]

Whether 'post-concussion' symptoms, in the absence of clinical signs, can[16,22] or cannot[1,19] rule in mild TBI has been a major source of discrepancy between prior definitions. Available

research evidence does not provide a clear answer as to which approach is correct (see the evidence summary for Evidence Statements #3 and #4a-c, online supplemental material, available online only at http://www.archives-pmr.org/). Our expert panel rated symptoms has having variable and generally lower diagnostic importance than observable clinical signs.[3]

Our expert panel reached consensus but not unanimity that our approach to incorporating acute symptoms in the ACRM diagnostic criteria would balance over- and under-diagnosis. Similarly, feedback during the stakeholder engagement phase suggested that some respondents viewed the diagnostic criteria as too lenient and others as too stringent. Although imperfect and in need of empirical validation, the handling of the sensitivity/specificity balance in the ACRM diagnostic criteria may be an improvement over prior definitions of mild TBI. The 1993 ACRM definition ambiguously recommended that when evidence of clinical signs is not available, 'it is appropriate to consider symptomatology' to 'suggest the existence' of mild TBI (pg. 86).[1] The Demographics and Clinical Assessment Working Group of the International and Interagency Initiative toward Common Data Elements for Research on Traumatic Brain Injury and Psychological Health recommend to 'consider TBI as a potential cause' on the basis of symptoms after TBI when clear evidence is not available to establish a diagnosis of TBI.[15] The Concussion in Sport Group's definition[16,23] has been criticized as having an unacceptably high false positive rate because the presence of any symptom (eg, headache) may be interpreted as sufficient for diagnosis.[24]

Clinical examination and laboratory findings (criterion 4)

The ACRM diagnostic criteria incorporate clinical examination and laboratory findings for the first time, based on expert ratings of their diagnostic importance[3] and the Working Group's rapid evidence reviews (see the evidence summary for Evidence Statements #6, 7, 8, and 9, online supplemental material, available online only at http://www.archives-pmr.org/). These examination findings include objectively measured cognitive impairment, balance impairment, oculomotor impairment, or symptom provocation in response to vestibular-oculomotor challenge on acute clinical examination. Elevated blood biomarkers indicative of intracranial injury are included based on emerging evidence that they not only may help triage for head computed tomography use, but might also help identify individuals with mild TBI regardless of whether computed tomography is performed.

The ACRM diagnostic criteria do not name specific tests, neuroimaging sequences, or blood-based biomarkers to avoid the criteria becoming obsolete with emerging research evidence or advances in technology. This approach has been used in diagnostic criteria for other health conditions.[25] We found some limited evidence for the blood-based biomarker glial fibrillary acidic protein (see Evidence Statement #9, online supplemental material, available online only at http://www.archives-pmr.org/), but optimal cut-off scores and timing of blood collection have not yet been established.

Available clinical examination and laboratory findings have imperfect sensitivity and specificity. So, in the ACRM diagnostic criteria, they cannot definitively rule in mild TBI but can raise diagnostic certainty for mild TBI in the context of a plausible mechanism of injury (Criterion 1) and acute symptoms (Criterion 3). Algorithms that combine symptoms with laboratory and clinical examination findings may optimize diagnostic accuracy.[26] In patients who do not report acute symptoms, the presence of 2 or more clinical examination/laboratory findings (Criterion 4) should raise suspicion for mild TBI (see Figure 2).

Neuroimaging (criterion 5)

Neuroimaging is not required to diagnose mild TBI using the ACRM diagnostic criteria. However, when computed tomography or structural magnetic resonance imaging is completed and reveals a trauma-related intracranial abnormality, it is sufficient to diagnose TBI. This aligns with some prior definitions.[15,19] Most people with mild TBI will have negative neuroimaging.[27,28] Magnetic resonance imaging is more sensitive than computed tomography in mild TBI.[29] The ACRM diagnostic criteria suggest using the qualifier 'with neuroimaging evidence of structural intracranial injury' when computed tomography or structural magnetic resonance imaging is performed and is positive. Historically, mild TBI 'with neuroimaging evidence of structural intracranial injury" has been referred to as 'complicated' mild TBI.[30,31]

Upper threshold for "mild" TBI

Traditional clinical indicators of severity such as the duration of loss of consciousness to differentiate between mild and moderate-severe TBI were retained from prior definitions of mild TBI.[1,10,15,16] Although this upper threshold for 'mild' TBI was identified as problematic, it was not targeted for revision because efforts to replace it with a more granular severity grading system based on multidimensional biomarkers are currently underway[32,33] but not yet available. We hope and expect that these efforts will eventually produce a replacement for the traditional mild-moderate-severe TBI severity classification scheme, and the ACRM diagnostic criteria can endure as diagnostic criteria for the lower threshold of TBI, without the 'mild' qualifier. Some diagnostic criteria, such as the Veterans Administration/Department of Defense criteria,[17] reclassify an otherwise 'mild' TBI as moderate or severe TBI when there are positive findings on conventional neuroimaging. In contrast, the ACRM diagnostic criteria recommend adding a qualifier (see previous section) but retaining the mild TBI classification. This approach recognizes heterogeneity within the mild TBI diagnostic group,[34] is in keeping with the largest mild TBI cohort studies over the past 5 years,[35,36] and will enable consistent diagnostic classification as technological advancements continue to enhance the sensitivity of magnetic resonance imaging.

"Concussion" vs "mild TBI" terminology

The ACRM diagnostic criteria consider a concussion to be a mild TBI. There has been longstanding debate over the appropriate terminology for injuries at the milder end of the TBI spectrum.[4,37-39] This debate has largely centered on whether concussion is a subset of mild TBI or whether concussion and mild TBI are synonyms for the same entity. Contemporary definitions of concussion have specifically excluded macrostructural lesions visible on computed topography.[16,40]

For the terminology question in the third round of Delphi voting, 30 of 32 (93.8%) expert panel members agreed that "the diagnostic label 'concussion' may be used interchangeably with 'mild TBI' when neuroimaging is normal or not clinically indicated." Individuals and organizations completing the stakeholder survey also favored this statement (see online supplemental material,

available online only at http://www.archives-pmr.org/). This is in keeping with the historical use of the term 'concussion' to refer to a physiological disruption of brain function (*commotio cerebri*) with the possibility of microstructural brain injury.[39]

Suspected mild TBI and implications for research and clinical practice

The ACRM diagnostic criteria operationalize criteria for 'suspected' mild TBI when brain injury is considered a possible or probable explanation for signs and/or symptoms after a plausible mechanism of TBI, but diagnostic certainty is lowered by the subtlety of the clinical presentation, missing information, or prominent confounding factors. The diagnosis of mild TBI often rests on subtle and transient clinical signs and symptoms in the presence of potentially confounding factors (eg, acute traumatic stress or cervical injury) and without the opportunity for acute medical evaluation. In other cases, in-hospital evaluation for mild TBI with polytrauma may be complicated by sedation for pain or mechanical ventilation. Diagnostic uncertainty, in some cases, is simply a reality of clinical practice. When a patient meets criteria for suspected mild TBI, determination of whether mild TBI is possible vs probable requires clinical judgment and consideration of all the available evidence. The expert panel endorsed this probabilistic framework to address the continuum of diagnostic certainty for mild TBI,[3,41-43] such as diagnostic criteria for other health conditions where laboratory confirmation is not possible or feasible.[44]

A suspected mild TBI identified in the first few days after injury, according to the ACRM diagnostic criteria, means that mild TBI can be considered to have occurred, and so should be clinically managed as such. In other words, a person with suspected mild TBI usually should be treated as if they had a mild TBI.[41] For example, an athlete or military service member with suspected mild TBI should be immediately removed from play or training and required to complete a progressive return to activity protocol.[16,45] This approach mitigates potential consequences of a false negative diagnosis (eg, experiencing another mild TBI during the period of clinical recovery). In this way, the new ACRM diagnostic criteria are consistent with the 'when in doubt, sit them out' mantra.

After an initial suspected mild TBI, additional information or examination findings (eg, impaired cognitive testing in a clinic visit the day after injury; Criterion 4) could increase the certainty of a mild TBI diagnosis but would not necessarily change the clinical management plan (because the person would already be in the process of being managed as having sustained a mild TBI). Alternatively, new evidence (eg, an athlete's symptom onset and resolution better coincide with their hydration status[41,46] or a cervical strain) may suggest that mild TBI is less likely and clinical management for this condition unnecessary.

Researchers can maximize generalizability by including participants with suspected mild TBI. Natural history or epidemiologic surveillance studies, for example, would be well suited to this inclusive approach. On the other hand, certain research endeavors, such as biomarker discovery, may prioritize internal validity by excluding participants with suspected mild TBI or examining them separately from a group with definite mild TBI, to avoid underestimating biomarker performance because of false positives in the mild TBI group. In this way, the ACRM diagnostic criteria could strengthen scientific rigor in mild TBI research.

Diagnostic evaluations conducted after the acute stage

Applying the ACRM diagnostic criteria will be most straightforward in an acute medical evaluation. Commonly, however, the clinician or researcher is conducting a post-acute evaluation without details about the injury event and without acute signs and symptoms documented in acute care medical records. Criteria 1, 2, and 3 can be established retrospectively, such as through a detailed history taking of the remote injury event, considering possible recall bias,[47,48] response bias,[49,50] and confounding factors[2] (Criterion 6). Because most currently available cognitive, balance, oculomotor tests, and blood-based biomarkers lose their diagnostic accuracy by 72 hours after injury, Criterion 4 usually cannot be established in a post-acute assessment. Moreover, most patients with mild TBI presenting for post-acute clinical care will not require structural neuroimaging (Criterion 5)—and if performed it will likely be normal[28] and therefore be diagnostically unhelpful. Therefore, diagnosing mild TBI in a post-acute evaluation relies heavily on the accuracy of a person's retrospective recollection about the injury event and their experience of acute signs and symptoms. As such, there is a risk for both false positive and false negative diagnoses depending upon how accurately the diagnostic criteria can be applied.

Diagnosis vs clinical outcome

These criteria are intended for diagnosis in clinical practice and case identification in research. The criteria do not address clinical outcome. A person who sustains a mild TBI might recover, from a clinical perspective, on the day of injury, within days or weeks, or have symptoms that persist for a prolonged period of time. Delays in seeking medical attention and receiving a diagnosis of mild TBI might be associated with prolonged recovery.[51]

Future directions

Poor agreement between assessors on the diagnosis of mild TBI[52,53] is probably not only due to assessors using different case definitions (if any) but also to variability in how they apply the same definition. A structured interview with scripted questions and standardized response coding for the ACRM diagnostic criteria could optimize inter-rater reliability. Structured interviews for diagnosing mild TBI have been successfully developed[54-56] and may only require minor modifications to align with the new ACRM diagnostic criteria before validation studies. Study of the inter-rater reliability of the ACRM diagnostic criteria to identify mild TBI cases from medical records (ie, no direct interaction with the patient) also will be important. Additional recommendations about how to optimize the definition for case ascertainment from medical records may be beneficial.[10,43] Finally, research is needed to assess the validity of the distinction between diagnosed vs suspected mild TBIs.

Ongoing communication with professional organizations involved in mild TBI clinical practice guideline and care pathway development can support widespread uptake of the ACRM diagnostic criteria. Our collaboration with the Concussion in Sport

Group[57] has been one such example. Additional targeted knowledge translation efforts will likely also be necessary. Processes and activities used to facilitate uptake will be guided by knowledge translation goals, identification of the audience, and leveraging strategies, expertise, and resources described below.[58] The goals of knowledge translation are to promote awareness of the new ACRM diagnostic criteria, promote changes in clinical practice, inform changes in policy and health system practices (eg, referral criteria, admission criteria, funding and insurance criteria, etc), and improve future research. The target audience for this work are health care professionals who diagnose mild TBI, health care administrators who make decisions on how mild TBI care is delivered and to whom, and researchers in the field of TBI.

We will pursue our knowledge translation goals through a combination of diffusion, dissemination, and application strategies.[59] Diffusion strategies will include peer-reviewed publications, presentations at scientific conferences, and professional magazines targeting health care professionals.[60] Dissemination strategies will include the development of tailored written education materials and targeted social media posts. Finally, application strategies will focus on monitoring of knowledge use amongst health care professionals (eg, with surveys) and researchers (eg, new studies using the ACRM diagnostic criteria as an inclusion criterion). Both the Mild TBI Task Force of the ACRM Brain Injury Special Interest Group and the international, interdisciplinary expert panel engaged in the present initiative will contribute expertise to this knowledge translation plan. Resources for planned knowledge translation activities will be sought from the ACRM and external funding agencies, charitable organizations, and professional associations.

Study limitations

The new ACRM diagnostic criteria are evidence-based in that they incorporate the best available research evidence. However, high quality evidence to guide certain Working Group decisions was limited. For example, most studies examining the diagnostic validity of individual symptoms and examination procedures compared people with mild TBI to uninjured controls rather than people being evaluated for possible mild TBI, which is required of Class I studies.[12] The Delphi method addressed such uncertainties with expert consensus. Another limitation of the evidence base related to diagnosis of mild TBI is that much of it was conducted at level 1 trauma centers. These emergency departments likely see higher rates of more severe injuries and polytrauma. Extrapolation to other clinical settings (eg, primary care) may be misleading. When generating evidence summaries for the expert panel to consider, we followed best practices for rapid reviews[11] with one exception – abstracts were screened by a single rater. To reduce the risk of missing important studies, we invited expert panel members to identify additional relevant studies. The focus on this initiative to update the 1993 ACRM definition was on the lower threshold for diagnosis, because 90% of all TBIs are 'mild' and there is usually little diagnostic ambiguity in moderate-severe TBI.[61] Multidimensional biomarkers are poised to redefine TBI severity across a continuum.[32] The expert panel members had less than optimal diversity. Several medical and clinical specialties were represented (physical medicine and rehabilitation, neurology, neurosurgery, neuropsychology, emergency medicine, sports medicine, etc), but not primary care providers, who are a common point of health care system entry for people with mild TBI.[62] The majority of the Working Group members self-identified as women but only one in 4 expert panel members self-identified as women and one-third of expert panel members were from outside of the United States.

Updating the ACRM diagnostic criteria was intended to improve both their sensitivity and specificity. With no independent method for establishing mild TBI, the true risk for misdiagnosis cannot be determined. Clinicians are encouraged to use all information available to them and their clinical judgment to identify and medically manage a case that does not clearly fit the criteria. For example, a witnessed hard blow to the head creates a high 'pre-test' odds for TBI which in a Bayesian-informed clinical decision making framework[63] should lower the strength of evidence necessary to overcome the threshold of suspected TBI. Alternatively, the presence of atypical clinical features may lower diagnostic certainty even if criteria are technically met. Finally, we recognize that applying all aspects of the ACRM diagnostic criteria will not be feasible in all clinical settings. For example, administering a formal cognitive test such as the Standardized Assessment of Concussion may be impractical in a primary care visit, blood-based biomarker tests are not yet accessible in most emergency departments, and video review evidence of not taking protective action on falling after impact will not be available outside of elite sport settings. Having data on all components of the ACRM diagnostic criteria is not necessary to diagnose mild TBI.

Conclusions

Through an iterative Delphi process, new diagnostic criteria for mild TBI achieved consensus from an international, interdisciplinary expert panel. These diagnostic criteria are designed for use across the lifespan and in civilian trauma, sports, and military settings. As such, they could standardize detection of mild TBI in any context, improving equitable access to clinical care and harmonizing research. As science continues to improve our understanding of mild TBI pathophysiology, clinical presentation, and diagnostic test performance, the diagnostic criteria will need to undergo review and updating.

Keywords

Brain injury; Concussion; Consensus; Craniocerebral trauma; Diagnostic; Rehabilitation; Occupational therapy

Corresponding author

Noah Silverberg, PhD, Department of Psycology, University of British Columbia, Vancouver Coastal Health Research Institute, Diavad Mowafaghain Centre for Brain Health, 2136 West Mall, Vancouver BC V6t IZ4, Canada. *E-mail address:* noah.silverberg@ubc.ca.

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