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Toward Complete, Candid, and Unbiased International Consensus Statements on Concussion in Sport

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Abstract

Five international consensus statements on concussion in sports have been published. This commentary argues that there is a strong need for a new approach to them that foregrounds public health expertise and patient-centered guidance. Doing so will help players, parents, and practitioners keep perspective about these potentially life-altering injuries especially when they recur.

Keywords

Concussion; Consensus Statements; Disclosure; Sports Medicine; Informed Consent

Introduction

Over the last two decades, five international consensus statements on concussion in sports have been published. Reviewing these studies, our primary finding is that the process creating these documents has been narrow, compromised, and flawed. A careful reading of these studies suggests that the authors have adhered to a libertarian framing of causality, risk, and intervention, rather than considering a precautionary, public health and patient-centered point of view.

This commentary evaluates the creation of the prior consensus statements using the structural competency frameworks utilized in public health, medical sociology, the history of medicine, bioethics, medical ethics, economics, and healthcare policy and law.¹ It also explores how incorporating patient and caregiver perspectives could result in consensus recommendations that would bolster trust in future statements.

We suggest that greater attention to inclusion, sequestration, stronger forms of peer review, and procedural transparency would result in practice protocols and medical guidelines that would keep the patient firmly in view, procure better informed consent, and lead to an approach to concussion management informed by bioethical and public health standards.²

There is a strong need for a new approach to consensus statements on concussions in sports that foregrounds public health expertise and patient-centered guidance. Doing so will help players, parents, and practitioners keep perspective about these potentially life-altering injuries, especially when they recur.

Background of the Signatories

We are researchers, clinicians, humanists, advocates, and caregivers calling for a public health paradigm to inform new consensus guidelines on the causes, effects, and consequences of brain injury on society and individuals.

The upcoming 6th International Conference on Concussion in Sport will promise to assemble many of the world’s concussion leaders together and charge them with producing an updated guideline. The process will be exclusionary, but this guideline will be tailored for all medical and allied health providers caring for the spectrum of athletes representing ages pediatric to geriatric, with skills from novice to professional.

We wish to foreground what might be termed a public health and patient-centered view of these efforts by drawing attention to evident limitations in both the consensus process and the substance of past versions of recommendations. We hope our efforts will aid in creating a representative consensus that reflects the current state of knowledge and uses patient well-being as the lodestar to guide policy recommendations. We propose that the following changes be included in a new consensus statement.

We Propose Broader Inclusion

Over the last twenty years the consensus statements that emerged from these conferences have been dominated by individuals with close relationships to professional and amateur sports organizations.³ The documents have promoted sports-friendly viewpoints that could be construed to pronounce concussions and repeated subconcussive impacts more benign, recoverable, transient, and reversible injuries than we consider reasonable. In so doing, the guidelines have arguably compromised informed consent.⁴ We would suggest, too, that these guidelines have almost certainly avoided the candor required for informed consent to be complete and frank.

Consider one outcome: the statements have been biased towards the experiences of exceptional, elite athletes at the professional, club, or collegiate levels. There is only modest contemplation of whether the recommendations make sense on a precautionary basis for the overwhelming majority of athletes whose participation in sports is exclusively recreational.⁵ For such individuals, continued exposure to repeated traumatic brain injury increases risks well beyond any foreseeable financial payoff — and there is much risk.⁶ The trade-offs, and the risks and benefits, are different across these groups and the international consensus has made little effort to address this clear imbalance.

Equally of concern, the consensus statements have consistently failed to include experts with the diversity of training, experience, cultural competence, and affiliations it would be reasonable to expect for so common and ubiquitous an injury — a concern about consensus processes that has been voiced since the 1980s.⁷ Experts in social medicine, bioethics, medical and sport anthropology, and clinicians with a range of experiences, including work with historically marginalized populations or in economically impoverished areas of the world, should all be included to provide deeper awareness about the lack of uniformity in the provision of and access to healthcare across cultures, geographies, and economic divides.

Since the 1970s, medicine has aspired to place medical evidence and consensus⁸ in parallel conversation to the voice of the patient and caregiver.⁹ It is noteworthy that parents who have lost a child, caregivers who have lost a spouse or parent, and indeed the voices of patients living with a tentative diagnosis of traumatic encephalopathy syndrome (TES) or persistent post-concussion symptoms are conspicuously absent among signatories on these statements. Including into the consensus process voices of individuals who have paid, or are paying, the high price that repeated exposure to concussion in sports can exact would provide a fuller, more balanced picture, especially since so many of the intended subjects have ended up as objects of sports research.¹⁰

Past statements have also included signatories who have consistently downplayed the risks of concussion injury and sought to emphasize all that we do not yet know rather than all that we do know, a pattern that was first established in concussion research for sports by the NFL MTBI Committee.¹¹ Such statements have ignored the precautionary principle, whose grounding in the concept of social responsibility requires scientists and researchers to act to protect the public from potential harm long before absolute metaphysical certainty has been achieved.¹² Indeed, the evidence linking collision sports to brain injury well exceeds

the level at which this principle should inform policy.¹³ Further, we find it noteworthy that Dr. Ann McKee has never signed a consensus statement, although she has arguably done more than most researchers in the last twenty years to advance our understanding of what all athletes risk playing collision sports.¹⁴ The numbers of reports on chronic traumatic encephalopathy by McKee alone far exceed the number of reports authored by the typical author of past consensus statements. Nor has, as far as we can tell, any expert on molecular neurodegeneration been sought to shape these documents.

Finally, there are other notable disciplines one would expect to find among a truly representative consensus statement. Where are frontline trauma surgeons, physical medicine and rehabilitation specialists, general practitioners, and experts in education and learning, public health, quantitative risk assessment, epidemiology, bioethics, and the sociology of medicine? The exclusion of all such experts restricts the generalizability of the consensus statements.¹⁵

We Propose Significant Additional Disclosure

Most signatories submit some form of disclosure. Many disclosures that we and investigative journalists have evaluated are far from complete.¹⁶ This is concerning because of the significant history of influence that the sports industry has exerted upon brain injury research.¹⁷ In light of a history of undue influence by industry in concussion research, the journals publishing these statements should conduct more than cursory due diligence to confirm the veracity and thoroughness of submissions. Further, each signatory should describe the amount of grants and their funders, including the source and amount of any funding provided directly to the journal to pay for open access. This is because advocates may have an interest in expanding readership for articles they favor, and because a funder's direct relationship to a journal may be a back door to getting rights of review after the article is out of the hands of the authors. Since industry funding contracts sometimes include provisions that limit disclosure and restrict publishing subject to funder approval, a blanket statement that indicates the existence of such non-disclosure agreements and details their various restrictions should also be entered in the record, including whether any contract (or even oral understanding exists) that gives consensus funders right of review prior to submission. With journals having the capacity to provide supplementary files online, it should be no onerous task for journals to achieve this full and complete disclosure and it would help to dispel or at least diminish concerns that these consensus statements serve as works of agnotology.¹⁸

We Propose Additional Vetting

It is beyond question that sports industries are or should be duty bound to get the best information possible, and it makes sense that such authorities might wish for this reason to be involved in a consensus process. At the same time, such involvement creates inevitable conflicts and risks. These phenomena have been well-recognized by scholars.¹⁹

Whether real or mere appearance, these conflicts call into question the integrity of the documents and their suitability for generalization to all sports populations. Clinicians

focused on professional athletes may have limited appreciation for the ministrations suited for children at play or those who engage in club sport on weekends. Clinicians with experiences of college and amateur sports, meanwhile, may not appreciate the legal requirements such a broad, international consensus statement may be seeking to fulfill for those who serve industry.

A more acceptable consensus statement might not exclude those with industry experiences, but it would identify them with fulsome transparency and would identify those with industry ties (past or present). *It would be even better, however, if the consensus conveners were sequestered and only fully unconflicted experts authored the end product.* We would suggest, either way, that the signatory in the masthead line explicitly indicate with an asterisk all experts with potential conflicts. However it is achieved, there should be a real effort to transparently explain any conflicts, which would help all readers and experts evaluate the generalizability of the document and suitability of its application to individual patients.

We Propose Rigorous Peer Review

Our impression is that these Consensus Statements have not been externally peer-reviewed, except in the sense that they have been vetted by those involved in the consensus process. The most important thing that the signatories of these consensus statements can do is seek peer review substantially and substantively outside the consensus process. In addition to peers, athletes, patients, and caregivers might well be solicited for review as yet an additional safeguard. Such thorough peer review protects everyone.

We therefore also suggest that editors of the journals that publish these statements include open reviews of them by leading, sequestered experts in neurosurgery, trauma surgery, general medicine, public health, bioethics, and equipment standards. We also call on them to give patients or caregivers a public voice.

We think that a consensus statement like this should spell out to readers the mainstream view among clinicians who are in favor of doing absolutely everything feasible to avert any brain injury whatsoever. Everyone should recognize that there are sports that minimize the risks of brain injury while yielding the benefits of physical activity.

We Propose Procedural Transparency

We would suggest that each section and sub-section of these future consensus statements indicate who among the signatories agreed and who did not. This effort can be done easily by a tally of votes placed in italics beneath the title of the section and subsection — there is no reason that the vote should be anonymous. It is essential, we think, that each section then offer a broader enumeration of the evidence and counter evidence so readers may understand the nature of the controversy. Obviously, those sections where there was agreement would be important to identify. Those sections where agreement is divided need to be more transparent about the reason for those divided opinions. Doing so would help readers understand all stakeholder perspectives and decide for themselves whether a more precautionary or a more libertarian approach makes sense.

Conclusions

Improving the process of creating Consensus Statements will result in less biased content within the documents. For example, the section of the 2016 Statement discussing chronic traumatic encephalopathy (CTE) states perfunctorily that “the literature on neurobehavioral sequelae and long-term consequences of exposure to recurrent head trauma is inconsistent.” A more responsible summary, we believe, might have instead read “the literature on neurobehavioral sequelae and long-term consequences of exposure to recurrent head trauma suggests reason for serious concern, although much remains to be clarified.” Similarly, the statement that “A cause-and-effect relationship has not yet been established between CTE and sports-related concussions or exposure to contact sports” is incomplete: a more honest summary might have read “The strong statistical associations found between CTE and SRCs or exposure to contact sports may not represent a true cause-and-effect relationship, but at present attempts to attribute these associations to confounding, bias, or artifacts have not been persuasive”.²⁰ We also note that prospective longitudinal studies of a well-characterized cohort, the claimed sine qua non of the establishment of a causal link between repetitive head trauma and later-in-life neurodegenerative diseases, are not only impractical but also unethical in light of the significant probability of patient harm. As many as seven decades might separate a particular individual’s exposure and the emergence of neurological signs and symptoms. Waiting for results and conclusions from studies that require many decades is unethical in light of the significant probability of harm to at least some nonzero proportion of any collision sport cohort.²¹

We have offered several remedies that can help all stakeholders resolve the challenge of concussions in sports through the bulwark of science. For well over a century the consequences of concussions have given rise to public controversy.²² The nature of these injuries is that they create adversarial points of view. Sports are deeply ingrained in our cultures. As a rule, most people do not like to contemplate their risks.²³ No harm can be done by telling readers there are reasons for interpreting and implementing guidelines in a more precautionary way than the center of gravity of a consensus process unduly weighted by industries with a vested economic interest in the outcome might prefer.

Competing Interests

Corresponding author STC discloses that he is retained in concussion litigation by firms representing plaintiffs against leading sports organizations worldwide. DCo previously advised the Morey Objectors on economic and health matters in the National Football League Players’ Concussion Injury Litigation, Case No. 12-md-02323-AB, U.S. District Court for the Eastern District of Pennsylvania between August 2013 and April 2015. AJP currently receives partial research salary funding from Sports Health Check charity. AJP has previously received partial research funding from the Australian Football League, Impact Technologies Inc., and Samsung Corporation. AF served as a consultant to the Football Players Health Study (Harvard University) in 2015 and 2016. RT and JG have been caregivers for retired professional athletes. In the past, SG has served as a consultant to Roche and has held grants from Pfizer, Baxter, and Polyphenolics/Constellation Wines. None of these relationships is currently active. SG is a founder of Recuerdo Pharmaceuticals, also currently inactive. SG’s research on TBI and CTE was funded by the Alzheimer’s Drug Discovery Foundation. PET ligands for these studies were donated to SG by Avid and Lilly. The Mount Sinai Center for Cognitive Health and NFL Neurological Care is one of five centers designated to receive referrals from the NFL Neurological Care Program Player Care Plan <http://www.nfl.com/news/story/0ap1000000228352/article/neurological-care-program>.

Dr. Buckland is the director of the Australian Sports Brain Bank, part of the Concussion Legacy Foundation Global Brain Bank initiative. Dr. Casper reports personal fees from Shrader and Associates, personal fees from Zimmer Reed, other from Langfit and Gardner, and other from Rylands, outside the submitted work. Dr. Pearce reports

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