NOCSAE.

The National Operating Committee on Standards for Athletic Equipment

Statement of

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Concussions in sports for male and female athletes and the marketing of sports equipment as "anti-concussion" or "concussion reducing."

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"Commissioning research and establishing standards for athletic equipment, where feasible, and encouraging dissemination of research findings on athletic equipment and sports injuries." Parents, athletes, and coaches, are becoming more aware and informed regarding concussion prevention, diagnosis, treatment, and the importance of following recognized return-to-play criteria. This increased awareness and public discussion is vitally important to advancing athlete safety, but it also creates a demand for quick solutions. Unfortunately, there are quick solutions offered for sale which have neither scientific nor medical support, and which carry the potential for creating a false sense of security and reliance on a level of protection that does not exist.

The neurobiology and biomechanics of sports concussions present complex and rapidly evolving areas of expertise both as to cause and prevention. Through its grant research funding program, NOCSAE has been one of the international leaders in helping to advance the scientific and medical knowledge relating to concussions. Despite the dedication of more than \$5,000,000 in research grants since 1994, directed specifically towards the issue of understanding and preventing sports concussions and to developing protective equipment performance standards that could eliminate concussions or reduce their frequency and severity, scientific support for such standard does not yet exist.

NOCSAE, the National Operating Committee on Standards for Athletic Equipment, is an independent and nonprofit standard-setting body with the primary mission to enhance athlete safety through scientific research, education, and where feasible, the creation of performance standards for protective equipment. NOCSAE efforts include the development of helmet performance and test standards for football, baseball and softball, ice hockey, and lacrosse, as well as faceguards and face protectors used in connection with these helmets. NOCSAE bylaws provide that the Board is comprised of representatives selected by national organizations representing a broad base of interested parties and expertise. Broken into three general categories, NOCSAE directors representing end-user or direct athlete involvement include two new members from the National Athletic Trainers Association (NATA), the Athletic Equipment Managers Association (AEMA), and the American Football Coaches Association (AFCA). NOCSAE directors representing sports medicine and related scientific research include representatives from the American College of Sports Medicine (ACSM), the American College Health Association (ACHA), American Orthopedic Society for Sports Medicine (AOSSM), the American Academy of Pediatrics (AAP), and the American Medical Society for Sports Medicine (AMSSM). NOCSAE directors representing product and manufacturing interests are selected by the Sporting Goods Manufacturers Association (SGMA) and the National Athletic Equipment Reconditioners Association (NAERA). In order to maintain balance between the interests represented and to preclude dominance or control by any group or interest, some organizations have one seat, while others have two. Currently there are 18 voting directors, five of which represent manufacturing and retail interests, 7 represent the athlete and end user interests, and 6 representing medical and scientific interests. NOCSAE also has two non-voting directors, one representing the National Federation of State High School Associations (NFHS) and one representing the National Collegiate Athletic Association (NCAA).

In support of its mission, the NOCSAE board utilizes a Scientific Advisory Committee consisting of independent leading experts in the areas of neurology, neurosurgery, orthopedics, biomechanics, and epidemiology. This committee meets as needed, and provides support, guidance, and advice in the areas of standards development as well as identifying areas for directed or targeted research.

NOCSAE also maintains an ongoing independent contract with an A2LA accredited and ISO 17025 certified testing laboratory, and a contract with Fred Mueller PhD who, as the Director of Research, oversees and administers the NOCSAE research grant application and funding program.

History of NOCSAE

NOCSAE was created in 1968 through the combined efforts of the NCAA, the American College Health Association, the NFHS, and the Sporting Goods Manufacturers Association to develop a football helmet standard that would be effective in reducing or eliminating fatalities from head injuries such as skull fractures and subdural bleeding that were occurring in organized football.

The standard which resulted from the efforts of the original NOCSAE directors and scientists mandated that football helmets meet a specific injury threshold criteria, commonly referred to as the Gadd Severity Index, Severity Index, or simply SI. The SI threshold in the NOCSAE standard works by limiting the magnitude of linear head accelerations that result when the helmet is hit. The first NOCSAE football helmet standard was originally published in 1973 and new helmets began to appear on the market certified to this new standard shortly afterwards. Eventually a requirement of compliance with the NOCSAE standard was incorporated into the rules of play by the NCAA and the NFHS in 1978 and 1980 respectively, and within a few years, helmets certified to the NOCSAE standards became required in all rules of play for governing bodies controlling football, even extending to the United States Military through the Department of Defense-Education Activity (DoDEA).

To be certified as meeting the NOCSAE standard, helmets must score less than 1200 SI on each of 16 impacts at 12 mph including two at high temperatures and two randomly selected locations, plus 4 additional impacts at two different lower speeds which have lower SI threshold requirements. Although not concussion specific, the NOCSAE standard directly addresses linear forces that are involved in most concussive events, and a helmet that passes the NOCSAE standard does provide some protection against those concussions caused by induced linear accelerations.

What the NOCSAE standard cannot yet address, and which is not addressed by any other helmet standard in the world, is how to establish and incorporate a threshold for rotational accelerations of the head that result from impact forces that are not directed through the center of gravity of the head. These rotational accelerations are directly involved in causing a significant number of concussions, and these types of accelerations can occur even without a blow to the head. Even less is known scientifically about concussion threshold values when the blow to the head results in a combination of linear and rotational accelerations occurring at different points in the same impact and with different magnitudes.

There is no helmet standard available today from any source that specifically addresses concussion prevention, and the development of a concussion specific standard for any protective equipment requires substantial scientific support that compliance with such a standard will in fact further eliminate or reduce the severity of concussions without increasing the risk of injury and other areas.

Protecting Against Concussions

While helmets certified to NOCSAE standards play an incredibly important role in protecting athletes in the field of play, improved protective equipment is not the only solution to providing better protection against concussion. Prevention, diagnosis, treatment, and management decisions about when athletes

should return to play are equally important, and prevention can be enhanced by enforcing the rules of play in a particular sport.

- Teaching and enforcing proper tackling techniques, which include not using the head as a weapon or primary contact point. These types of changes can make an immediate and likely measurable impact on the number and severity of concussions.
- Teaching athletes and active children at all ages that the signs and symptoms of a potential concussion should not be ignored, and should be followed up with an evaluation by someone properly trained and skilled in evaluating concussions.
- Adopting and enforcing return to play criteria that will prevent an athlete from returning to play until a complete and objective evaluation is completed.
- Helping parents, coaches, and players understand that although helmets provide a substantial level of protection, no helmet can prevent all head injuries, including concussions.

The Centers for Disease Control (CDC) estimates approximately 1.6 to 3.8 million sports- and recreationrelated concussions occur each year in the United States, and children and teens are at highest risk. Parents, coaches and trainers must exercise caution in deciding when athletes can and should return to play. The Center for Injury Research and Policy at Nationwide Children's Hospital, funded in part by grants from NOCSAE, found that in 2008, more than 40 percent of high school athletes were allowed prematurely to return to play after suffering concussions. And, of those players, 16 percent of concussed football players were actually allowed to return to play in the same game after losing consciousness.

NOCSAE ongoing efforts to address concussions

As stated earlier, there are currently no helmet standards published in the world which contain performance thresholds specific to concussions. Helmet standards which limit linear accelerations do provide a level of protection for those concussions where linear acceleration may be the primary cause, but a concussion specific helmet standard to be effective must incorporate not only limitations to linear accelerations, but also reflect and incorporate an understanding of injury thresholds associated with rotational accelerations and strong scientific support for the concussion injury thresholds utilized. For many years, NOCSAE has dedicated its resources to answering those questions NOCSAE's first concussion research grant award of \$49,000 was given in 1996 to Dr. Kevin Guskiewicz at the University of North Carolina to study the "Effect of Mild Head Injury on Cognition and Postural Stability" in evaluating potential concussion diagnostic modalities. In the past 10 months, NOCSAE has funded specific targeted concussion research grants totaling \$2,319,000 to scientists and biomechanical researchers at Dartmouth Medical School, Dartmouth Department of Engineering, Wayne State University School of Engineering, Ottawa University Bioengineering Laboratory, and the Southern Impact Research Center. From that first concussion grant in 1996 through today's date, NOCSAE has dedicated over \$5,000,000 to the study of sports related concussions to advance medicine and science in that area to the point that concussion specific changes to the NOCSAE standards can be adopted. These concussion specific grants are in addition to other NOCSAE funded research in the areas of sports medicine and science, including research that eventually identified the biomechanics and physiology of

commotio cordis, a sudden cardiac death in youth sports resulting from an impact to the chest, and which may be preventable through the use of an appropriately tested chest protector that meets an impact standard currently being developed by NOCSAE.

As early as 2002 and 2003, NOCSAE was becoming aware through its sponsored research and from the research of others that any performance standard that might effectively address injury thresholds from rotational accelerations would require a new testing methodology in addition to the drop test which is utilized by all existing helmet performance standards. To that end, NOCSAE advanced funding for the fabrication of five prototype horizontal ram impactor devices, sometimes referred to as a linear impactor. This impactor is designed in such a way as to permit a testing apparatus to induce rotational accelerations into a helmet and headform in unlimited magnitudes, direction, and orientation, which no existing helmet impact drop tests are able to accomplish. NOCSAE decided in 2004 that the validation of such a testing component was necessary so that there would be no delay in incorporating rotational acceleration thresholds and testing in the NOCSAE standards once those thresholds were identified. A proposed revision to the NOCSAE standard incorporating this new testing protocol was published in 2004, and work has continued to this day in validating and refining the linear at five different laboratory locations around the country.

Public Education programs

In addition to regular public speaking engagements, daily interaction with the public to telephone calls and e-mails, and providing and disseminating research and educational information through the internet, NOCSAE has entered into a partnership with the CDC National Center for Injury Prevention and Control to develop and disseminate a concussion awareness and educational campaign called "Heads up to Parents". This national campaign utilizes multiple informational outlets, including social media, to present parents and athletes with concussion information, building on the CDC's already-successful "Heads Up" initiative, featuring free tools that provide important information on preventing, recognizing and responding to a concussion. Materials can be found on the CDC's website, <u>www.cdc.gov/concussion/sports/</u>. These tools are an invaluable resource for parents as their athletes take the field, and NOCSAE is proud to be a partner with the CDC Foundation to provide financial and substantive support for the program.

Changes to the NOCSAE helmet standards

The NOCSAE helmet standard, unique among all existing helmet standards for the use of a biofidelic headform, the use of a pass fail criteria which incorporates both impact force and time duration (SI), and the requirement of low-speed and high-speed certification impacts, has undergone significant and substantial revisions and improvements since it was first adopted and published in 1973.

 In 1992, NOCSAE undertook a multi-factor revision to its testing protocol, which included implementation of a scientifically proven calibration method of the NOCSAE headform using a specially designed impact surface, added a requirement that headform calibration be performed before all certification testing, the headform and helmet carriage assembly was made more rigid, and the air craft cable guide wires were replaced with smoother music wire. This decreased friction in the drop system and increased stability of the carriage assembly throughout the drop impact. The test impact pad was hardened from a 36 Shore A hardness natural rubber surface to a 43 Shore A hardness urethane to produce a more consistent impact surface. These changes resulted in significantly higher impact velocities and increased impact energies to the helmet, a more demanding test than in the previous standard. The increased impact energies now required in the testing were so significant that the impacts began to break expensive head forms and attachment assemblies, which required a redesign of those components.

- In 1996, NOCSAE amended its helmet standards by toughening pass fail criteria for helmets. The original SI value of 1500 was reduced to 1200, making it is 20% more demanding, and bringing the pass fail threshold in line with Federal Motor Vehicle Safety Standards.
- In 1999 an anthropometrically correct size medium testing headform was introduced along with other design changes to allow the headforms to withstand the new impact energies that resulted from the changes in 1992 and 1996.
- In 2003, a proprietary data acquisition system and standardization of data collection was developed by NOCSAE and implemented with all licensees, requiring that the pretest and posttest system checks be performed correctly or all helmet test data performed between these system checks becomes invalid. A temperature sensor incorporated in the software automatically invalidates all test data generated when the temperature of the test lab is outside the specified range. Additionally, the results of all impact certification tests are stored in encrypted files and available to NOCSAE by direct download or electronic exchange.
- In 2011, the football helmet standard was revised to add low level pass/fail thresholds for drop impacts at 7 miles per hour This low speed impact threshold is in addition to the 1200 SI pass/fail for drops of 12 mph.

NOCSAE enforcement of its standards

The NOCSAE name, and the various sport specific logos, phrases, and designs that are incorporated into the NOCSAE standards are registered and trademarked properties, and NOCSAE controls the use of those properties through a license agreement. Any manufacturer which intends to certify equipment to the NOCSAE standards must first sign a license agreement to do so. This agreement obligates the manufacturer to not only comply with the specific requirements of the standards, but also requires that each licensee provide certification testing data, quality assurance and quality control program documentation, and annual reports from third party independent testing laboratories certified compliant with ISO 17025 requirements proving compliance with the NOCSAE standards for every piece of equipment certified by that licensee in the previous 12 months. In exchange for permitting the manufacturer to use the intellectual property of NOCSAE, a license fee is also charged. This license fee is non-negotiable, and is assessed on a per unit basis. The fees per unit are extremely small, but generate

the revenue used by NOCSAE to fund the scientific research grant program which supports the content of standards.

The license agreement also obligates each licensee to obtain prior approval of proposed advertising which uses the NOCSAE name or references NOCSAE as part of its advertising.

Although NOCSAE is not a certifying body, we do engage in market surveillance of certified equipment, and we independently investigate certified equipment performance through mandatory annual third party laboratory validation testing, and direct product testing through our own contracted and A2LA accredited testing laboratory.

Recertification of reconditioned equipment

In addition to the standards that apply to the certification of new athletic equipment, NOCSAE has also published standards that permit previously certified equipment to be recertified as part of a formal reconditioning process. NOCSAE standards for the recertification of previously certified athletic equipment provide schools, clubs, universities, and even professional teams with a way to economically maintain the performance and integrity of their certified helmets, and provide NOCSAE with the opportunity to reevaluate helmet performance even after they have been in use for one or more seasons. The recertification standards require that reconditioners test a statistically significant number of helmets submitted for reconditioning and recertification. These helmets must be tested first in the condition they are in "as received from the field" before any repair or reconditioning is undertaken. Following completion of the reconditioning process which includes a thorough and complete inspection of every individual helmet for cracks and defects, and the replacement of worn or damaged padding and fitting components, these same randomly selected helmets are retested utilizing a proprietary data acquisition software program developed for NOCSAE by engineers at the University of Tennessee. The test results of the nearly 50,000 helmets from both pre-and post reconditioning tests are collected and evaluated every year.

Conclusion

Concussions are complex events both biomechanically and physiologically, and scientists are working hard to understand these issues so that improvements can be made in protection, prevention, and treatment. Any device or supplement promoted as being able to prevent, diagnose, or cure a concussion must be supported by scientific data and peer reviewed research. The same is true with regard to standards for protective equipment. Without solid scientific support for a concussion specific change to an existing helmet standard, any changes made to address concussions becomes nothing more than a hopeful experiment, turning players into involuntary test subjects.