



Adolescent concussions

When to return to play

Abstract: Increased awareness of adolescent sport concussions has led to legislation requiring a medical professional's permission to return to play. These patient-specific and evidence-based recommendations for nurse practitioners will ensure safe return to play decisions.

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Current recommendations for a sports concussion evaluation and management are designed for adult athletes. Recently, legislation has been amended in several states requiring that a licensed medical professional assess any adolescent athlete who has a suspected concussion prior to making any decisions regarding return to play. The majority of the remaining states are expected to follow with similar legislation. Over the last 10 years, the CDC's "Heads Up" campaign has increased concussion awareness among coaches, parents, sports organizations, and medical professionals. Now, there is a growing concern over the effects of concussion injuries on adolescent athletes. Adolescents are more vulnerable to the effects of a concussion and have a longer recovery period, with a greater potential for more serious sequelae, when compared to adults. The complex nature of concussion injuries in adolescents requires individualized care as well as a more conservative approach to management, particularly when nurse practitioners (NPs) are making decisions regarding return-to-play. The following recommendations utilized by NPs are based on current

research and evaluation methods to ensure the final decision is patient-specific and evidence-informed. The purpose of this article is to review sports-related concussion injuries among adolescents as well as to propose recommendations for current practice that will assist NPs in making decisions regarding safe return-to-play.

■ Definition

A concussion is a direct blow to the body—particularly the head, face, or neck—that transmits enough force to cause the brain to move rapidly back and forth inside the skull.^{1,2} This blow can result in functional changes in the brain, manifested as neurologic impairment that has a rapid onset and resolves spontaneously, typically over a period of 7 to 10 days.²

There are two types of concussions: simple, which lasts 7 to 10 days, and complex, which lasts more than 10 days. The effects of a concussion are variable and may include deficits in attention, concentration, processing, reaction time, and memory.

Keywords: adolescent, assessment, concussion, management of sports-related concussion, neurologic impairment

■ Background

Approximately 30 to 45 million children and adolescents participate in organized sports outside of school.³ The CDC estimates 1.7 million children and adults sustain a concussion each year with one-quarter of those injuries being related to participation in organized sports.¹ In recent years, an estimated 500,000 preadolescents and adolescents were diagnosed with a concussion after visiting a hospital ED due to head injury, and approximately one-half were sport-related.^{1,3} An estimated 300,000 head injuries, the majority of which are concussions, occur annually among high school athletes.⁴ Individuals who participate in organized contact sports (such as American football) tend to have the highest rates of concussion followed by those participating in soccer, wrestling, and basketball.⁵ The rates of concussion are even higher among adolescents who participate in these sports when compared to college athletes.⁶

Concussion statistics are generated from ED reports or physician visits and rely on the ability of parents and coaches to accurately identify and respond to the symptoms of concussion. Since members of the general public have limited knowledge of the specific signs and symptoms of concussion, many athletes do not realize they have suffered a concussion even though they have experienced the symptoms.³ Moreover, the majority of athletes evaluated in the ED for a head injury are discharged without a proper diagnosis of concussion or proper instructions for follow-up, demonstrating a lack of recognition of concussions even by medical professionals.⁷ Adolescents are more susceptible and have a unique physiologic response to concussion, making them particularly vulnerable to the effects of this type of brain injury. It is imperative that NPs are knowledgeable about the mechanism of concussion and its symptoms to make safe return to play recommendations for adolescents.

■ Mechanism of concussion

The physical impacts of a concussion occur in two parts: primary injury and secondary inflammatory response. The primary injury to the brain marks the start of a complex metabolic process. This initial insult causes the release of excitatory amino acid neurotransmitters, which damage cell wall integrity, increase cellular permeability, and alter cellular pH.⁸ As these cells incur further damage and die off, they release cytokines, which initiate an inflammatory response.⁸ In addition, the metabolic needs of the damaged cells increase, leading to a heightened demand for glucose.^{8,9} In order to provide the requisite glucose to restore the intracellular ion balance, cerebral circulation must increase. However, in the presence of cellular inflammation within the brain, cerebral blood flow is restricted; thus, there is insufficient glucose for cellular metabolism.^{8,9} In order to maintain low demand for glucose and ensure glucose supplies remain adequate, cognitive and physical rest are required.²

When compared to adults, adolescents have an immature central nervous system, a larger head-to-body ratio, thinner cranial bones, a larger subarachnoid space in which the brain can move more freely, and differences in cerebral blood volume—all of which make them more vulnerable to the effects of concussion.³ Moreover, the underdeveloped neck and shoulder muscles of adolescents mean that energy received from an impact cannot efficiently dissipate throughout the rest of the body.³ In addition, adolescents have a higher risk for shear injury due to incomplete myelination of the brain.³ Furthermore, adolescents have a higher sensitivity to the cellular damage caused by the amino acids released once the complex metabolic process has been initiated.³ These pathophysiologic factors among adolescents collectively contribute to a greater sensitivity to the effects of concussion and a longer recovery time when compared to adults.

■ Diagnosis

A concussion is diagnosed using a symptom-based approach incorporating physical actions, behaviors, balance abilities, sleep patterns, cognitive domains, and a detailed history.⁹ The variable presentations of symptoms may not be evident until several hours after the initial injury, contributing to difficulties in diagnosing.⁹ Parents, coaches, and health professionals may have difficulty recognizing a concussion because the clinical presentation is similar to that of other health conditions.¹⁰ Headaches occur in the majority of athletes as well as other common symptoms, such as dizziness, confusion, disorientation, blurred vision, and amnesia.¹¹ (See *Symptoms of concussion*.) Ominous signs of concussion can include amnesia of recent events, mental foginess, and loss of consciousness (LOC). Symptom

Symptoms of concussion^{2,33}

<p>Physical</p> <ul style="list-style-type: none"> • Headache • Nausea and vomiting • Poor balance • Blurred vision • Loss of consciousness • Amnesia <p>Cognitive</p> <ul style="list-style-type: none"> • Poor concentration • Poor short-term memory • Feeling “foggy” • Slowed reaction time 	<p>Emotional</p> <ul style="list-style-type: none"> • Irritability • Sadness • Lability <p>Sensory</p> <ul style="list-style-type: none"> • Poor sleep • Excessive sleep • Fatigue • Drowsiness
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Graduated return to play^{1,2}

Stage	Activity	Goal
Rest	Complete cognitive/physical rest	Recovery
Light aerobic exercise	Walking, swimming, or stationary bike, low intensity	Increase heart rate
Sport-specific exercise	Nonimpact, such as, running in soccer	Add movement
Noncontact training drills	Throwing in football, and may start resistance training	Exercise and conditioning
Full-contact "controlled" practice	Resume normal sporting activity following medical clearance	Conditioning, build confidence, and assess skill
Return to Play	Resume normal game play	

Gradual return to play occurs with close symptom monitoring. Stepwise progression may proceed every 24 hours if the athlete remains asymptomatic. If symptoms reoccur at any stage, the athlete regresses to the previous stage until asymptomatic.

severity can only be determined retrospectively—especially in children—and LOC/amnesia do not correlate with severity of the concussion.^{2,11,12} A detailed history that is positive for a recent impact that could have led to concussion can help differentiate this type of brain injury from other preexisting conditions.

■ Assessment

Concussions are considered a functional rather than a structural injury. Initial evaluation with symptom-based questionnaires and neurologic testing are needed to formally diagnose a concussion. Abnormalities on CT or MRI scans are rarely revealed when there are no risk factors for skull fracture or hemorrhage.¹³ Imaging should be ordered only in the presence of progressive neurologic decline, focal neurologic findings, and/or a high-risk mechanism of injury that could have caused skull fracture or intracranial hemorrhage.^{10,14}

There are several tools recommended by the CDC's "Heads Up" program that can be utilized by coaches, parents, and other nonprofessionals in order to recognize a concussion, access timely assessment, and manage the injury. It is important that an appropriate sideline assessment tool be used to identify concussion early to ensure appropriate follow-up and management by a medical professional. If an athlete has sustained a significant impact to the head or body, but is not suspected to have a cervical spine injury and remains conscious, bystanders (coaches, parents, and the like) can remove the athlete from play and monitor them on the sideline prior to follow-up with a medical professional.^{15,16}

The Maddock's questions should be recommended by NPs for use on the sideline to determine symptoms, mechanisms of injury, neurologic function, and cognition.^{2,15,16}

An appropriate tool for use in the clinical setting to evaluate and manage a concussion is The Sports Concussion Assessment Tool 2 (SCAT 2) currently recommended for use among all athletes older than 10 years of age.² The SCAT 2 scoring system has not been validated in adolescents, and significant variability was noted in the areas of age, gender, previous injury, balance, and concentration.^{17,18} Until a reliable assessment tool can be developed for adolescents, a preseason baseline assessment with comparative measures post-concussion is more accurate.^{19,20} The NP can recommend that all adolescent athletes in their practice undergo SCAT 2 assessment and scoring prior to the beginning of a sports season.

■ Management

Concussion management in adolescents requires a conservative approach with an individualized care plan. The goal of concussion management is to remain symptom-free while progressing through a stepwise increase in activity.^{2,10} (See *Graduated return to play*.) The physical and cognitive rest required can be difficult for adolescents to comply with, making this a challenging condition for NPs to manage. Cognitive rest involves refraining from using all media devices, including cell phones, computers, video games, and TVs as well as being absent from school or utilizing modified lesson plans. Affected individuals may also need to avoid group conversations, outings, and playing or listening to

music. Physical rest requires that the individual avoid exercise, recreational sports, organized sports, practices, and games. Adolescents are able to resume light activities as long as they do not exacerbate their symptoms. If symptoms return, they must resume their previous level of activity for a 24-hour period before attempting the next activity level again.²

Daily evaluation of concussion is necessary to ensure recovery is taking place at an acceptable pace, one at which the athlete is not overexerted and symptoms not exacerbated. The need for ongoing evaluation is complicated by a lack of adequate assessment tools as well as the absence of a preseason assessment. Moreover, there are conflicting recommendations as to when stepwise management should

or to an athlete's return to play.^{22,24} The NP must consider whether or not it is prudent to limit athletes' return to play based solely on the presence of headaches (in the absence of all other symptoms), especially in cases where athletes have a preconcussion history of headaches.²²

Complaints of sleep disturbances are also common following a concussion. It is known that concussion symptoms are exacerbated when affected individuals are unable to get adequate rest.²² Although insomnia is the most serious post-concussion sleep disturbance among adolescents, excessive sleepiness is the most common disturbance.²² Sleep disturbances can be managed through typical interventions, including proper sleep hygiene, melatonin supplements, and

bright light therapy, which helps adjust circadian rhythms in cases where insomnia is the primary issue.²² Since sleep is required for physical restoration after a concussion, sleep maintenance must be a priority of care during the recovery period. If an athlete experiences excessive sleepiness postcon-

fusion, the NP can recommend that adjustments be made to his or her daily schedule, such as a later start time for school classes, to accommodate for increased sleep needs.

In addition, athletes may experience emotional disturbances, including irritability, sadness, and emotional lability, particularly among athletes with a known preconcussion depressive disorder.^{22,25} At 1 month postconcussion, over half of young athletes were more emotional and irritable than normal; this was decreased to one quarter after several weeks.²⁶ Disturbances in mental health among affected athletes may be due to their inability to participate in regular peer activities, such as school and sports. Additionally, NPs must consider that the physiologic changes in the brain caused by a concussion may be the cause of the depressive symptoms.²⁷ There is no evidence to support the initiation of antidepressant medications for adolescents with prolonged depressive symptoms, and the NP must consider a referral to a mental health specialist with expertise in this area.²⁸

When athletes suffer from other comorbidities, it can be difficult to differentiate these health conditions from prolonged postconcussion symptoms. Any athletes who have existing health conditions should undergo a preseason assessment so that healthcare providers are better prepared to manage a concussion if one should occur.²⁵ Athletes who suffer from comorbidities and prolonged concussion symptoms may not return to play as quickly as those without preexisting conditions and, thus, these athletes will likely require additional support. A referral to an appropriate professional should be considered for any athlete who has prolonged postconcussion symptoms.^{22,25}



Athletes who have suffered a previous concussion may experience difficulties in making decisions regarding safe return-to-play.

be initiated. The general consensus is that there must be at least a 24-hour rest period prior to initiating stepwise management²; however, some experts argue that this rest period should last several days.²¹ The NP may choose to recommend that stepwise management be initiated after a longer duration following the results of a comprehensive assessment. A daily evaluation of the athlete's symptoms and their severity is encouraged during the stepwise management process to ensure a safe progression to the goal of returning to play.

NPs must pay particular attention to any symptoms that may be related to an athlete's existing health conditions in order to distinguish a preexisting condition from a concussion with prolonged symptoms.

■ Postconcussion symptoms

Athletes who have suffered a previous concussion may experience prolonged symptoms, leading to difficulties in making decisions regarding safe return-to-play. These post-concussion decisions are dependent upon the severity of the affected athlete's symptoms when compared to baseline assessment. Common postconcussion symptoms include headache, emotional disturbances, and sleep difficulties.²² Children are more likely than adults to present with these symptoms more than 1 month after a concussion.²³ Headaches can persist even when the athlete remains otherwise asymptomatic after completing the required rest period. The recommended treatment for headaches lasting greater than 1 month postconcussion is the same as that provided for primary headaches. In addition, low-impact aerobic activities can provide symptomatic relief if performed pri-

■ Return-to-play decisions

Once athletes have completed the recommended stepwise increase in physical activity and remain asymptomatic, primary care providers can begin to make decisions related to return-to-play. Affected athletes must obtain medical clearance from their primary care provider before their sports organization will permit them to resume playing.²⁹ It is crucial that primary care providers understand that adolescent athletes require a longer recovery period when compared with adults.²

If adolescent athletes return to play in the presence of concussion symptoms, they may be at an increased risk for sustaining a second concussion. Second Impact Syndrome (SIS) can occur within minutes and is accompanied by severe cerebral edema, rapid deterioration in neurologic status, and even death.³⁰ Although SIS is rare, it is more common in athletes who are under the age of 18 compared with adults.³⁰ The adolescent's brain has limited ability to regulate complex metabolic processes, and reinjury of the brain may lead to delays in neuronal maturation.⁸ In one study, high school athletes who had suffered more than one concussion in the past also had higher rates of concussion-related symptoms, placing them at a higher risk for experiencing future complications of brain injury.³¹ Even though these complications are not fatal, they can significantly compromise the adolescent athlete's quality of life.

In the postconcussion period, academic performance is often affected by difficulties with reading comprehension, recall of learning material (new or old), and timely completion of tests or assignments.³² Modified lesson plans may be required until the affected student is able to keep up with the pace of classroom lectures and assignment/test deadlines. It is important that NPs consider athletes' abilities to cope with school work when evaluating their overall recovery and readiness to return-to-play. If the athlete continues to experience concussion symptoms with cognitive overexertion, return-to-play should be delayed even if symptoms do not accompany physical overexertion.^{30,32}

NP's must also take into account the psychological impact that prolonged activity restrictions can have on adolescents who are recovering from a concussion. Restrictions that remove adolescents from peer activities can be devastating to their identity, may exacerbate pre-existing mental health conditions, and may lead to nonadherence with the concussion recovery plan. Affected athletes may need to engage in extensive retraining prior to participating in their first postconcussion game. When designing a return-to-play plan, it is recommended that athletes reenter sports gradually, beginning with a non-contact practice and progressing to a full-contact game. If preseason assessments are conducted on a routine basis, this information can guide

NPs in determining the timing of a safe return-to-play and not prolonging it unnecessarily. In addition, it is important to provide education to those individuals who are part of the affected adolescent's life, including family members, peers, and health professionals, as support from these individuals is required to effectively modify the adolescent's lifestyle and promote optimal healing.

■ Moving forward

NPs can effectively evaluate and manage concussion injuries among adolescents. Accurate assessment of concussion is based upon an understanding of the underlying mechanisms of injury within the brain as well as a timely and thorough evaluation of concussion-related symptoms. In addition, NPs must understand the importance of placing restrictions on activity during the recovery period. By adopting a holistic approach in their patient care, NPs ensure that decisions related to safe return-to-play are individualized to each athlete and accompanied by the supports required for adequate healing. In addition, NPs remain sensitive to the unique needs of the adolescent, advocate for individualized management of concussion, and practice as part of a multidisciplinary team to effectively care for sports-related concussions. NPs are in an ideal position to educate parents, adolescents, and other healthcare providers regarding sports-related concussions in addition to increasing awareness and understanding of the impacts of this injury on young athletes. **NP**

REFERENCES

- Centers for Disease Control and Prevention. Injury Prevention and Control: Traumatic Brain Injury. Heads Up: Concussion in Youth Sports. <http://www.cdc.gov/concussion/HeadsUp/youth.html>.
- McCroly P, Meeuwisse W, Johnston K, et al. Consensus statement on concussion in sport—the 3rd International Conference on Concussion in Sport Held in Zurich, November 2008. *J Sci Med Sport*. 2009;12(3):340-351.
- Karlin AM. Concussion in the pediatric and adolescent population: different population, different concerns. *PM R*. 2011;3(10 suppl 2):S369-S379.
- Patel DR, Reddy CC. Sport-related concussion in adolescents. *Pediatr Clin North Am*. 2010;57(3):649-670.
- Gessel LM, Fields SK, Collins CL, et al. Concussions among United States high school and collegiate athletes. *J Athl Train*. 2007;42(4):495-503.
- Daneshvar DH, Nowinski CJ, McKee AC, Cantu RC. The epidemiology of sport-related concussion. *Clin Sports Med*. 2011;30(1):1-17.
- Lovell MR, Collins MW, Iverson GL, Johnston KM, Bradley JP. Grade 1 or "ding" concussions in high school athletes. *Am J Sports Med*. 2004;32(1):42-54.
- Shrey DW, Griesbach GS, Giza CC. The pathophysiology of concussions in youth. *Phys Med Rehabil Clin N Am*. 2011;22(4):577-602.
- Grady MF. Concussion in the adolescent athlete. *Curr Probl Pediatr Adolesc Health Care*. 2010;40:154-169.
- Halstead ME, Walter KD, The Council on Sports Medicine and Fitness. Sport-related concussion in children and adolescents. *Pediatrics*. 2010;126(3):597-615.
- Sabin MJ, Van Boxtel BA, Nohren MW, Broglio SP. Presence of headache does not influence sideline neurostatus of balance in high school football athletes. *Clinical Clin J Sports Med*. 2011;21(5):411-415.
- Purcell L, Carson J. Sport-related concussion in pediatric athletes. *Clin Pediatr*. 2008;47(2):106-113.

13. Pearce MS, Salotti JA, Little MP, et al. Radiation exposure from CT scans in childhood and subsequent risk of leukaemia and brain tumours: a retrospective cohort study. *Lancet*. 2012;380(9840):499-505.

14. Stiell IG, Wells GA, Vandmeheen K, et al. Canadian head CT rule for patients with minor head injury. *Lancet*. 2011;357(9266):1391-1396.

15. Maddocks DL, Dicker GD, Saling MM. The assessment of orientation following concussion in athletes. *Clin J Sport Med*. 1995;5(1):32-35.

16. Lau BC, Kontos AP, Collins MW, Mucha A, Lovell MR. Which on-field signs/symptoms predict protracted recovery from sport-related concussion among high school football players? *Am J Sports Med*. 2011;39(11):2311-2318.

17. Valovich McLeod TC, Bay C, Lam KC, Chabra A. Representative baseline values on the Sport Concussion Assessment Tool 2 (SCAT2) in adolescent athletes vary by gender, grade, and concussion history. *Am J Sports Med*. 2012;40(4):927-933.

18. Jinguji TM, Bompadre V, Harmon KG, et al. Sport Concussion Assessment Tool-2: baseline values for high school athletes. *Br J Sports Med*. 2012;46(5):365-370.

19. Whiteside JW. Management of head and neck injuries by the sideline physician. *Am Family Physician*. 2006;74(8):1357-1364.

20. Sport Concussion Library. (2011). Concussion Information for Coaches and First Responders (Trainers/Therapists). <http://www.sportconcussionlibrary.com/content/concussion-information-coaches-and-first-responders-trainertherapists>.

21. Purcell L. What are the most appropriate return-to-play guidelines for concussed child athletes? *Br J Sports Med*. 2009;43(suppl 1):i51-i55.

22. Blume K, Lucas S, Bell KR. Subacute concussion-related symptoms in youth. *Phys Med Rehabil Clin N Am*. 2011;22(4):665-681.

23. Yeates KO, Taylor HG, Rusin J, et al. Longitudinal trajectories of postconcussive symptoms in children with mild traumatic brain injuries and their relationship to acute clinical status. *Pediatrics*. 2009;123(3):735-743.

24. Gagnon I, Galli C, Friedman D, et al. Active rehabilitation for children who are slow to recover following sport-related concussion. *Brain Injury*. 2009;23(12):956-964.

25. Covassin T, Elbin RJ, Larson E, Kontos AP. Sex and age differences in depression and baseline sport-related concussion neurocognitive performance and symptoms. *Clin J Sport Med*. 2012;22(2):98-104.

26. Barlow KM, Crawford S, Stevenson A, Sandhu SS, Belanger F, Dewey D. Epidemiology of postconcussion syndrome in pediatric mild traumatic brain injury. *Pediatrics*. 2010;126(2):374-381.

27. Iverson GL. Misdiagnosis of the persistent postconcussion syndrome in patients with depression. *Arch Clin Neuropsychol*. 2006;21(4):303-310.

28. Meehan WP III. Medical therapies for concussion. *Clin Sports Med*. 2011;30(1):115-124.

29. Know Concussion. <http://knowconcussion.org/wp-content/uploads/2011/07/DISTRICT-COLUMBIA.pdf>.

30. Laker SR. Return to play decisions. *Phys Med Rehabil Clin N Am*. 2011;22(4):619-634.

31. Schatz P, Moser RS, Covassin T, Karpf R. Early indicators of enduring symptoms in high school athletes with multiple previous concussions. *Neurosurgery*. 2011;68(6):1562-1567.

32. Sady MD, Vaughan CG, Gioia GA. School and the concussed youth: recommendations for concussion education and management. *Phys Med Rehabil Clin N Am*. 2011;22(4):701-719.

33. Guskiewicz KM, Valovich McLeod TC. Pediatric sports-related concussion. *PM R*. 2011;3(4):353-364.

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