

Recruitment & preliminary outcomes of a school based traumatic brain injury interventional research program for student athletes - lessons learned

Abstract

Participant recruitment and retention are considered to be the most difficult aspects of the research process. This article reports on strategies utilized in the implementation of a school district-wide interventional cohort study of traumatic brain injury in student athletes, and illustrates the obstacles to reaching planned participation goals. The purpose of this article is to:

- Identify and explain socio-behavioral barriers to recruitment for studies focused on student athletes;
- Underscore the critical need to identify and develop appropriate advocates and school-based policies to protect student athletes;

Increase awareness about the possible long-term and life-long physiological and psychosocial effects of repeated brain injury in order to underline the importance of conducting further research and establishing objective Return to Play Guidelines.

Keywords: concussion, head trauma, return to play, student athletes

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Background

Traumatic brain injury (TBI) is a graded sequence of injuries, which are clinically defined, based on subjective symptoms observed by clinicians and/or those reported by patients. Milder forms of TBI (mTBI) are often the result of concussions-defined as altered neurologic status due to an impact or acceleration/deceleration of the head.¹ The high visibility of returning military veterans with debilitating and life-altering head injuries, coupled with the lure of celebrity, particularly professional athletes, has kept much of the focus-in the media, medicine, and research-on traumatic brain injury (TBI) on the adult population. However, children and young teenagers are at the greatest risk of TBI and resultant complications, due to the fact that the pediatric brain is in a developmental and thus more vulnerable stage.² While the entire brain is vulnerable, the frontal and pre-frontal cortex, the locus of judgment, decision making, attention, and impulse longer to recover from concussions than adults.³ Sports activities cause an estimated 20% of all 33 control-are at greatest risk due their proximity to the skull, and again this is more troubling for children, since the frontal lobes don't reach maximum density until ages 25-30; contributing to the reason why it takes children TBIs among youth and young adults.⁴ In a response to the mounting epidemic, beginning in 2011, 35US states and Washington DC, have passed legislation to reduce the overall impact of TBI among young athletes, bringing the total number of states who have done so, since 2009 to 44.⁵ Among the laws in placed by the state of California, are requirements that athletes suspected or have sustained actual TBIs are removed from play, and not allowed to resume activities until they have received a clinical clearance. Also, parents, athletes, and coaches are required to be educated about the risks and consequences of TBI yearly.

Continued involvement in sports across the lifespan, increases the likelihood that youth athletes may sustain repetitive brain trauma

(RBT), which may result in neurodegenerative changes, which can resemble catastrophic brain maladies, such as Alzheimer's disease; and psychological deficits long term. The mechanisms that cause these changes are not greatly understood, and some may argue are unknown. Additionally, there are no clear methods for early and objective diagnosis of neither TBI, nor therapeutics and other treatments to effectively treat TBIs and prevent repetitive brain trauma; especially in the pediatric population. Collectively these deficits of understanding may be referred to as the "Great Unknown", and they underline the need for translational research that will fill in this gap in knowledge and assist in developing precise public health prevention initiatives, as well as improve clinical diagnosis, treatment, and follow up care; positively impact health outcomes.

Objective

The overarching goal of the interventional research study was the implementation and conduct of a mTBI screening program of youth athletes, would help to identify and objectively define mTBI using biomarkers and impact monitoring software, in order to establish personalized return to play guidelines, help to reduce the likelihood of long term injury, and allow for the longitudinal study of outcomes that would look at the relationship between TBI and other factors, and explore the potential for treatment. Other study aims included:

- Develop methods that will allow for the early identification of TBI in youth athletes.
- Monitor recovery and complications experienced by athletes who sustain a TBI, in order to improve recognition of post-concussion syndrome, which can persist for weeks, months, or even years.
- Provide needed information that will help to set medically objective return to Play guidelines that move beyond the current practice of depending upon subjective self-reporting; which does not identify those who have sustained trauma, but are asymptomatic.

- d) Assist in raising awareness about the risk of concussion and TBI through community outreach and health education efforts.
- e) Gather data that will help to provide a way to enumerate the incidents and track the problem of TBI in the Pasadena area. (Currently no state has comprehensive tracking of TBI data [by state, by age, by sport, by gender] which makes estimates about the scope of the problem difficult. The proposed local approach may serve as a statewide model.

Program description

The interventional research study was established as a city-wide TBI monitoring program, which ran in conjunction with a congenital heart disease screening study. The two arms of the program were carried out “add-ons” or more robust extension to annual physical exams that student athletes are required to have. It was established as an interdisciplinary collation, which included biomedical researchers, clinicians, community partners, the local school district’s Health Programs department, as well as the local department of public health. The program provides free imaging scans to all student athletes within the school district (which is comprised of 28 schools), as well as student athletes attending private schools within the city’s jurisdiction. Students had to be between the ages of 10-18 at the time of enrollment. This prevention-oriented research program is of particular importance to the students of a local school district, who are largely underserved with 67% of students identified as low-income, and thus likely to have minimal access to sufficient health care, including specialized procedures such as magnetic resonance imaging. The City of Pasadena and adjacent Altadena (where students were also eligible to enroll) also have a disproportionately high number of group homes, orphans, and fostered children than other cities in Los Angeles County. Thus, the program carries out health equity and social justice function, when considering the vast number of underrepresented minorities and low income adolescents who are frequently placed into athletic pipelines at a young age, and who are often without access to health resources that can monitor and safeguard their health, wellbeing, and quality of life.

Methodology

Study design

This is a prospective cohort study that is interventional in nature, and utilizes biomedical-consisting of neuroimaging and cognitive testing exams, and epidemiological approaches to assessing study participants. There is a singular study site which is centrally located and adjacent to the City’s major hospital and trauma center.

Participants in the study are enrolled for an initial period of 4years, to allow for longitudinal monitoring of health outcomes. The study’s eligibility criteria are as follows:

- a) Student athletes--participating in competitive sports,
- b) Between the ages of 10-18 at the time of enrollment,
- c) Living within the jurisdiction of the school district,
- d) Do not have metal implants-including dental braces,
- e) And are not pregnant--due to the unknown effects of magnetic resonance imaging on the fetus; female subjects were required to undergo a pregnancy test prior to each scan. At the onset of the study, it was estimated that 1500 students within the school district were eligible.

Recruitment & retention

Recruitment efforts began with a plan that targeted coaches, athletic trainers, teachers, as well as school nurses; in order to enlist them as advocates for the program. Study staff held individual meetings with these stakeholders on various school campuses. The school district’s Health Officer often arranged and attended these meetings. The stakeholders were informed about the commencement of the program, given health education materials and announcements that they could share with their students, and provided with an opportunity to ask questions and share concerns. School nurses, often tasked with reporting school-based trauma, were given “TBI Screening packets”. Study staff also accepted invitations to do classroom visits; primarily to courses being taught on health and/or life sciences. In the classroom setting, the staff conducted brief lectures about concussions and TBI, providing information about how they occur, signs and symptoms, the dangers of repeated brain trauma, and why removal from play is critical. During these visits students were directly provided with information about the program. Study staff also obtained booths and attended open houses on various campuses, and attended other school-related activities that would provide them with an opportunity to speak with students and parents. In addition, the local newspaper published an article that announced the program and spoke of its merits.

Informed consent

Informed consent was obtained by through two separate means in order to make the process more convenient for program participants (Table 1).

Study procedures

Table 2.

Table 1 Mechanisms for obtaining informed consent

Informed consent mechanism I	Informed consent mechanism II
The subject’s parent/guardian/assigned case workers were asked to review the consent forms. Subjects of reading age were asked to review the study assent form. The study coordinator and other assigned study personnel meet with the subject to review the Consent and Assent forms, to confirm the participants and their parents/guardians understanding of the study, and to answer any questions that they may have. Once the subject and (parent, guardian, assigned case worker) demonstrated understanding of the consent and assent forms and agreed to participate in the study, both forms were signed in the presence of study coordinator or assigned study staff.	TBI Screening Packet was made available to subjects via the school nurse, or directly by the Study site. These packets contained a general announcement about the program, a consent form, an assent form, and medical history, and social-behavioral questionnaires. Participants were given the option to have the forms signed and completed prior to their scheduled appointment, or review them at home and meet with the Study Coordinator prior to their initial visit to discuss any questions that may have arisen.

Table 2 Overview of study procedures

Baseline	Follow up	Concussions	Linkages
<p>Subjects enrolling in the Study were asked to do so at the beginning of the school year, where a baseline evaluation could be completed as an extension of their annual physical examinations. During these baseline evaluations students undergo the following: a quantitative neuroimaging exam that includes the following tests: Magnetic Resonance Spectroscopy (MRS) and Diffusion Tensor Imaging (DTI). Students also underwent balance testing, as well as brief cognitive test batteries, which included the SCAT-3 and Defense Automated Neurobehavioral Assessment (DANA) exam which has series of test, such as Buschke Selective Reasoning (SRT) and Symbol Digits Modality (SDMT), which assess verbal learning and memory, as well as processing speed and concentration.</p>	<p>All participants are given a follow up screening at the close of the school year. This additional visit was included to detect any notable changes from baseline that may be the result of unidentified or non-reported concussions or other forms of head trauma sustained during the season. Students are enrolled in the study for a period of 4 years.</p>	<p>Those who sustained a concussion were brought into the program immediately, regardless of whether they had a baseline scan. They underwent the same test procedures. However, they were given (2) additional follow up scans- 14 days and 30 days post-injury. These visits were to monitor the subject's recovery and progress; as well as the effects of any treatment that they may have undergone.</p>	<p>Subjects identified as having severe trauma that required immediate attention and follow up care were brought in with their (parent or guardian) to meet with Study staff, review their case, and be provided with neuroimages, a clinical report, and referral to a clinician. Those who did not have a PCP or adequate health insurance were referred to a local community partner, who has a network of pediatricians and neurologist who provided follow up care and medical services for free, or for a nominal cost.</p> <p>Participants referred for further medical care remain enrolled in the program, and pertinent records are shared with their treating clinicians. They also receive any necessary follow up scans at HMRI; and their progress is monitored.</p>

Table 3 Overview of California state concussion laws

Bill	Effective date	Mandate
AB-1451	1-Jan-13	<p>Mandates concussion training for all high school coaches, paid or unpaid, every 2 years that reviews recognizing the signs & symptoms of concussions. The new law mandates that any coach who is required to renew their CPR/BLS training must also complete a short course on concussion signs & symptoms. Student athletes suspected of sustaining a concussion/head injury shall be removed for the remainder of the day.</p>
AB-2127	1-Jan-15	<p>All athletes and their parents receive and acknowledge educational information regarding concussions. On a yearly basis, a concussion and head injury information sheet shall be signed and returned by the athlete and the athlete's parent or guardian before the athlete initiates practice or competition. An athlete who is suspected of sustaining a concussion or head injury in an athletic activity shall be immediately removed from the athletic activity for the remainder of the day, and shall not be permitted to return to the athletic activity until he or she is evaluated by a licensed health care provider. The athlete shall not be permitted to return to the athletic activity until he or she receives written clearance to return to the athletic activity from a licensed health care provider. If the licensed health care provider determines that the athlete sustained a concussion or a head injury, the athlete shall also complete a graduated return-to-play protocol of no less than seven days in duration under the supervision of a licensed health care provider.</p>

Outcomes

Preliminary outcomes were disheartening. While 1500 students within the school district were identified as being eligible for the program, 36 students initially enrolled in the TBI program, while 3 were dis-enrolled or excluded for various reasons, and 2 only opted to enroll in a parallel sudden cardiac death study. Enrollment numbers were low at approximately 3% of the eligible population; while the enrollment goal at study onset was 8-10% (approximately 120-150 students). Of those enrolled 72.2% were males and 27.8% were females, and this pattern correlates to what is seen in other studies. A 2006 survey of reporting of TBI visits to emergency being eligible for the program. 36 students initially enrolled in the TBI program, while 3 were dis-enrolled or excluded for various reasons, and 2 only opted to enroll in a parallel sudden cardiac death study. Enrollment numbers were low at approximately 3% of the eligible population; while the enrollment goal at study onset was 8-10% (approximately 120-150 students). Of those enrolled 72.2% were males and 27.8% were females, and departments found that in every age group, TBI rates are higher for males than for females.⁶ 86.1% of those who enrolled began the study with baseline scans. 11% of subjects entered the Study post-concussion as acute TBI subjects, and did not receive baseline scans. 0%, or none of these students who entered the Study after sustaining an injury, were made aware of the program prior to their TBI. 50% of these students also had previously sustained head injuries. 36.1% of all participants had sustained a prior concussion or head trauma. Of these participants 76.9% were males and 15.4% were females. Those reporting a prior concussion fell within the following age groups: 7.7% 10-12years, 38.5% 13-15years, 46.2% 15-18years. Despite our initial efforts that targeted coaches, athletic trainers, teachers, and other school officials 91.7% of the students enrolled in the study stated that they did not receive information about the program from those officials, nor was the topic of traumatic brain injury or concussion discussed with them by their coaches, athletic trainers, or physical education teachers. Our health education materials were simply not shared with the students.

Lessons learned

The number of enrollments was significantly less than expected for the pilot program. Although available funding was an issue, program evaluations and student athlete feedback revealed that we may have initially targeted the wrong advocates for the program; despite the fact that there are a number of recommendations, such as one made in *Neurology Now*, published by the American Academy of Neurology, to enlist the help of athletic trainers in concussion studies, because they are believed to “know how to block out environmental distractions during games to assess an injury properly-and they’re trained to be objective when evaluating athletes”⁷-we found that they were not the best stakeholders to engage. Despite holding a number of meetings with athletic trainers, our findings showed that the information shared with them was not passed on to student athletes, nor did the students receive any extensive training about concussion prevention, as required by the State of California (Table 3).⁵

Upon further investigation, we learned that many of the athletic trainers in the District, worked on a part-time or per diem basis, and did not always have a sports medicine, physical education, or similar background; and often the positions were not staffed. This correlates with findings from the American Society for Sports Medicine, which states that only 37% of high schools across the country have full time athletic trainers on staff.³ While another study conducted in 2015,

which also found that most (63%) high schools in the U.S. did not provide full-time Athletic Trainer services and only 31% had part-time Athletic Trainer coverage.⁷ Having 36.1% of those enrolled in the Study reveal that they had previous concussion(s) had led us to realize that a number of these “baseline” scans are truly not baseline, and that we were looking at evidence of repeated brain trauma; which for the most part has not been previously reported and/or documented. Further, considering that we were assessing a fraction of the larger pool of eligible students in the district, there is the possibility that there is a much higher rate of repeated brain trauma-amounting to what may be a silent epidemic. Coaches also seemed unwilling to engage us and lend support to the program-by sharing information about it with their athletes, and we related these attitudes and behaviors to the pervasiveness of what is referred to as the “Culture of Sport”, which involves a number of socio-economic factors that causes athletes, coaches, and even the parents of student athletes to not be forthcoming and disclose when an injury has occurred; instead they insist that the athlete continues to play despite the injury.⁸⁻¹²

Having one of the participants in the study quit his high school football team, after sustaining a concussion from a head-on collision; underscores coaches concerns for the recruitment and retention of players, especially “star” players. While school nurses proved to be supportive of the program, providing concussed students with the materials that we developed, and directly referring students into the program. However, their effectiveness as partners was limited by a number of key factors:

- a) The aforementioned “culture of sport” that made students unwilling to report injury or discomfort,
- b) The fact that many of these injuries occurred during games that are held on the evening and over the weekend, and were thus not always reported to school nurses or many days had passed since the initial injury,
- c) The lack of a district wide injury response plan (which is not uncommon, according to the American Medical Society for Sports Medicine, only 22% of states meet the recommendation that every school or organization that sponsors athletics develop an emergency) [Amr Med Assoc]13,
- d) As well as the lack of assistance in recruiting students for baseline scans that would have proved the most beneficial in terms of monitoring them post-injury.

For students who required and/or accessed clinical care, tracking of reporting and outcomes also proved challenging, and this has much to do with coding limitations on classifying sports and recreational injuries. The article *Sports and Recreational Injuries* provides a more detailed explanation of the problem, “In cases where victims undergo medical treatment, the manner in which their injuries are classified is limited by which codes are available from the International Classification of Diseases (ICD) manuals. ICD-10 fails to capture most sports and recreational activities and this lack of codes is a limiting factor in accurately determining the number of sports and recreational injuries associated with specific activities.¹

Next steps/strategic recommendations

The Study is ongoing and a number of strategies are being put forth to work towards its expansion and success:

- a) Revisiting discussions with our partners to jointly apply for and acquire funding support for the study.

- b) Report initial findings, which include noted physiological and cognitive impacts to the public health department, in order to re-start discussions on collaborating.
- c) Utilize acquired funding to obtain sensors that can be used to readily identify athletes that have sustained trauma.
- d) Utilize acquired funding to support a program assistant, who can maintain more of a presence on school campuses and host more frequent meetings with coaches, athletic trainers, and school nurses; as well as oversee outreach to the large volume of group homes, etc. in the District.
- e) Approach the many private schools in the District to obtain approval for the study, due to the recognition of the challenges of recruiting from public schools in the District.
- f) Continue direct mailing efforts targeting parents and guardians, as they proved to be more successful in getting out information about the program.
- g) Continue attending school open houses and advisor group meetings, but trying to host more health education events that will allow parents who are not able to make these campus-based events (due to the time of day that they are scheduled), an opportunity to attend.
- h) Updating all communications regarding the program to state that screening services are open to undocumented immigrants, due to the feedback that we have received regarding concerns over access.

Working with the public health department and school district to implement health education training programs and policies for all coaches, athletic trainers, and physical education instructors in the district. Training would include topics, such as: recognizing the signs and symptoms of concussions, and overview of state laws regarding the reporting of concussions, a briefing on the possible long term effects of repeated brain trauma and why it is critical to protect young athletes, basic lifesaving skills, developing emergency action plans, record-keeping and maintaining accurate records of injuries, treatment, and outcomes. Much of these skills and duties are listed as requirements for Athletic Trainers per the National Association of Athletic Trainers website.⁷⁻¹⁴

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Conflict of interest

Author declares that there is no conflict of interest

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