



cine in Winston-Salem, NC, said the passage of the Food and Drug Administration Amendments Act of 2007 should have given the agency more regulatory ammunition to push companies to comply with conducting post-marketing studies. “The problem prior to the act’s passage was that some of the commitments to complete postmarketing studies had no deadlines, so it was

hard to claim they were delinquent. And clearly there have been no consequences and no one at the FDA paid attention to this problem,” Furberg said. “The changes in the regulations should help, but when I look at the list of studies on the accelerated approval list, some have been conducted and some are pending, and to me it is hard to say the situation has improved.”

Nissen remains frustrated with the inaction by FDA leadership to improve the accelerated approval process. “The people at the FDA approving drugs are very pharma friendly; they view pharmaceutical manufacturers as their principal clients. So we see this lack of enforcement over and over,” Nissen said. “I do not think we need tough laws; we need tougher regulators.” □

Reports of Concussions From Youth Sports Rise Along With Awareness of the Problem

Mike Mitka

A NEW STUDY HAS DOCUMENTED a growing number of emergency department visits by children and adolescents with sports-related concussion, but it is unknown whether the increase reflects a true rise in the number of incidents or better reporting due to greater awareness.

The study, by researchers from Brown University in Providence, RI, found that from 1997 to 2007, US emergency department visits for concussions occurring in organized team sports had almost doubled (from 3946 to 7791) in children aged 8 to 13 years and more than tripled (from 7276 to 23 239) among youths aged 14 to 19 years (Bakhos LL et al. *Pediatrics*. doi:10.1542/peds.2009-3101 [published online August 30, 2010]). In addition, the researchers found that from 2001 to 2005, children and adolescents aged 8 to 19 years had an estimated 502 000 emergency department visits for concussion, with about 35% involving 8- to 13-year-olds and half of the total visits related to a sports incident.

The Brown researchers, using data from the National Sporting Goods Association, found that for 2001 to 2005, the concussion rate was highest for ice hockey, at 10 per 10 000 participants for 7- to 11-year-olds and 29 per 10 000 participants for 12- to 17-year-olds. Foot-

ball accounted for the second highest concussion rate, at 8 and 27 per 10 000 for the 2 age groups, respectively.

Lisa L. Bakhos, MD, lead author and now a pediatric emergency physician at Jersey Shore Medical Center in Neptune, NJ, said a major part of their retrospective review of data from the National Electronic Injury Surveillance System was to provide solid concussion data for the pre-high-school population. She said the reason for the high numbers of emergency department visits for concussion is unclear. “We do not know if it is an actual increase; we hope it is increased awareness and reporting,” Bakhos said. “We do speculate that youth sports are getting extremely competitive, and kids, in general, are getting bigger; so you end up with

8-year-olds in 13-year-old bodies but with the maturity still of 8-year-olds.”

Michael A. McCrea, PhD, executive director of the ProHealth Care Neuroscience Center and Research Institute in Waukesha, Wis, speculated that most of the increase in reported concussions could be tied to greater awareness of the problem by parents, coaches, and trainers, but he added that some percentage of the increase should be attributed simply to more concussions. “It feels evolutionary and seems natural to me that if we saw great speed, strength, and mass—all the requirements for a collision—at the professional level, we naturally saw it trickle down to the collegiate level, and now it is trickling down to the youth sports level.



James Boulette/iStockphoto.com

A new report reminds those involved in organized team sports that even the youngest participants are at risk for concussion.



Bakhos and colleagues also found that during the time period when reported concussions increased, participation in organized team sports decreased. The researchers estimated that about 385 000 children aged 7 to 17 participated in the top 5 organized teams posts in 1997, with the number falling to just over 330 000 participants by 2007.

McCrea does not have hard data, but he speculated that the increasing number of concussions during a time of apparent declining participation in sports may be the result of how those children remaining in a sport train and compete. "Participation in sports has become a year-around commitment; you used to play football for 2 months and then move onto basketball and then maybe track and field," McCrea said. "So maybe participation is down, but for those playing, say football, the num-

ber of exposures seems to be certainly higher than seen a decade ago."

In August, the American Academy of Pediatrics issued its first clinical report offering guidance in the treatment and management of sports-related concussion in children and adolescents (Halstead ME, Walter KD; the Council on Sports Medicine and Fitness. *Pediatrics*. 2010;126[3]:597-615). Mark E. Halstead, MD, a coauthor of the clinical report and assistant professor of orthopedics and pediatrics at Washington University in St Louis, said their guidance lays out parameters to be used in assessing when an athlete can return to competition following a concussion. "Rather than telling a player to sit out for a set period of time, we gradually increase the athlete's activities over a 5-day period to

make sure the athlete does not demonstrate symptoms," Halstead said.

Deciding when an athlete is well enough to return to competition remains a bit of a mystery, McCrea said, because there is little rigorous evidence to show what works best. He said the decision to return is especially difficult to make for those who have had repeated concussions and that such a determination is probably best made by the treating physician.

"No adult signs his or her own return-to-work slip after they have had a stroke, but return-to-play for concussion for decades has been managed by the injured athlete or nonmedical professionals" such as parents, coaches, or trainers, McCrea said. "But there has been some positive movement in creating policy requiring medical clearance before one can return to an activity." □

National Children's Study Expands

Bridget M. Kuehn

WITH NEARLY 40 OF THE planned 105 sites across the United States recruiting, the pilot phase of the National Children's Study is well under way, after years of uncertainty.

The study will follow up more than 100 000 infants and their mothers from before conception through the child's 21st birthday and may provide critical information about how environmental and genetic factors contribute to disease. Unprecedented in its scope and length, the study has faced both logistic and funding challenges since it was authorized by Congress as part of the Children's Health Act of 2000.

Although the initial estimate of the study's cost was \$2.7 billion over 25 years, subsequent media reports have suggested it could cost more than twice as much. It is being led by a consortium of federal agencies; including the Eunice Kennedy Shriver National Institute of Child Health and Human Development,

the National Institute of Environmental Health Sciences, the US Centers for Disease Control and Prevention, and the US Environmental Protection Agency. The planning for the project began in 2000 and included input from the National Academy of Sciences. However, funding fell short of target amounts during the planning phase, leading to concern about the viability of the study. But funding levels have increased substantially since 2007, when the implementation phase began, and \$414.3 million has been secured to date.

The payoff of such a massive investment, in terms of unique insights on how the interaction between genes and the environment lead to both childhood and adult disease, is expected to be enormous. "We are embarking upon one of the richest data-collection efforts ever conducted, and the wealth of information we hope to amass could have a major impact on the health of future generations," said Steven Hirschfeld, MD, PhD, the study's acting director, in a statement.

The endeavor also may provide insights into the best ways to conduct such a massive research effort. During the study's pilot phase, each participating site will use 1 of 3 strategies for recruiting women to participate: referral of patients by practitioners; outreach efforts to contact women at home (via advertisements) and at community events; and the mailing of a questionnaire to women to complete and then selection of a group to participate further. Insights from this phase will be used to determine the most efficient and cost-effective strategies for recruitment for use during the rest of the study. Currently, the sites are recruiting women who are pregnant or who may soon become pregnant for the study's pilot phase.

Initial results from this phase of the study should be available later this year or in early 2011, Hirschfeld said. Early findings from the study may begin to filter in sometime in 2013.

More information on the project is available online at <http://www.nationalchildrensstudy.gov>. □