

New and Recurrent Concussions in High-School Athletes Before and After Traumatic Brain Injury Laws, 2005–2016

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Objectives. To examine the trends of new and recurrent sports-related concussions in high-school athletes before and after youth sports traumatic brain injury laws.

Methods. We used an interrupted time-series design and analyzed the concussion data (2005–2016) from High School Reporting Injury Online. We examined the trends of new or recurrent concussion rates among US representative high-school athletes participating in 9 sports across prelaw, immediate-postlaw, and postlaw periods by using general linear models. We defined 1 athlete exposure as attending 1 competition or practice.

Results. We included a total of 8043 reported concussions (88.7% new, 11.3% recurrent). The average annual concussion rate was 39.8 per 100 000 athlete exposures. We observed significantly increased trends of reported new and recurrent concussions from the prelaw, through immediate-postlaw, into the postlaw period. However, the recurrent concussion rate showed a significant decline 2.6 years after the laws went into effect. Football exhibited different trends compared with other boys' sports and girls' sports.

Conclusions. Observed trends of increased concussion rates are likely attributable to increased identification and reporting. Additional research is needed to evaluate intended long-term impact of traumatic brain injury laws. (*Am J Public Health.* 2017;107:1916–1922. doi:10.2105/AJPH.2017.304056)

Each year in the United States, an estimated 1.1 to 1.9 million sports- and recreation-related concussions occur among children aged 18 years and younger.^{1–3} Potential long-lasting effects of concussions on developing brains include decreased physical, cognitive, emotional, and sleep health.^{4–6} Untreated or improperly managed concussions can increase risk of repeated concussions, resulting in increased potential for severe health consequences, such as chronic neurocognitive impairment and chronic traumatic encephalopathy.^{6–9}

The first public health law intervention to address concussions in youth sports was the Zackery Lystedt Law, enacted in 2009 in Washington State. The Lystedt Law was designed to mitigate the consequences of concussions in youth sports through education, information, and medical intervention following an initial concussion.^{10,11} By 2014, all 50 states and the District of Columbia had

enacted 1 or more traumatic brain injury (TBI) laws, with most including 3 tenets of the Lystedt Law: athletes' mandatory removal from play following actual or suspected concussions, requirements to receive clearance to return to play from a licensed health professional, and annual education of coaches, parents, and athletes regarding concussion signs and symptoms.^{11,12}

Because of the rapid uptake in youth sports TBI laws, recent research efforts have attempted to evaluate the actual and potential impact of these laws.^{13–20} However, most existing studies have focused primarily on the content, goals, structure, and implementation of the laws,^{11,13–17} with few directly measuring the impact of the laws on the incidence of concussions. Existing studies are also limited in scope to either a few^{13,17} or single^{14,18} states, or have only included injuries requiring hospital visits.^{19,20} The paucity of national-level studies have largely been attributable to the lack of national injury surveillance data and the relatively recent time in which all states enacted such laws (2014).^{18–20} Furthermore, the use of hospital visits or insurance claims²⁰ rather than TBI reporting in sport activities may prevent a more accurate estimation of the impact of TBI laws on injury risk because of lack of athletic exposure details. Finally, although secondary prevention (e.g., management of a concussion after it occurs) is a key feature in TBI laws,^{11,12} evaluations of such laws have not explicitly differentiated between new and recurrent concussions while measuring the law's impact.

Given these limitations of previous studies, more research across a larger number of states, with rigorous outcome measures, is needed to

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evaluate impact of the TBI laws, as revisions to such laws remain ongoing.^{15,21} The aim of this study was to use data from a large, national sports-injury surveillance system to determine the effect of state-level TBI laws on trends of new and recurrent concussion rates among US representative high-school athletes while participating in sports across a period from pre- to postlaw enactment. We hypothesized that, immediately after the state's TBI laws (the first year after the laws went into effect), increased rates of new and recurrent concussions would be observed among high-school athletes and then, during the postlaw period, a declining rate of recurrent concussions would follow.

METHODS

We used an interrupted time-series research design. We merged state-level concussion law data from 2009 to 2014 obtained from LawAtlas²² with concussion data collected from the 2005–2006 through 2015–2016 academic years among athletes in a nationally representative sample of high schools (100 schools per academic year) that participated in High School Reporting Injury Online (RIO; described in the next paragraph).^{23,24} Athletes included were those who participated in at least 1 of 9 common high-school sports (boys' football, basketball, soccer, baseball, and wrestling; and girls' basketball, soccer, softball, and volleyball).

Concussion Data and Traumatic Brain Injury Law Data

Concussion data were obtained from High School RIO, a prospective, longitudinal Internet-based surveillance system that collects sport-related injuries and exposures among athletes from a nationally representative sample of US high schools.²⁴ Each year, 100 high schools are randomly selected from all eligible schools (i.e., school has a certified athletic trainer who is willing to serve as a reporter) based on stratification of US Census geographic location (Northeast, Midwest, South, and West) and high-school size (enrollment < 1000 or ≥ 1000 students). All athletes who participated in at least 1 of the 9 sports in the selected schools were included. National estimates could be generated by

applying a weighting algorithm designed by High School RIO based on the inverse probability of a school being selected.²⁴ Athletic trainers from each respective school are responsible for reporting both injury (including concussion) and exposure data weekly throughout the academic year via the High School RIO Web site. Detailed descriptions about High School RIO methodology are reported elsewhere.^{3,23–25}

This study analyzed the following: each reported sport-related concussion (new or recurrent), date of sustained concussion, sport in which the concussion occurred, gender of the injured athlete, and athletic exposure data (e.g., game or practice, which enables calculation of concussion rates).

We obtained state-level, youth-sport TBI law data from LawAtlas, a publicly available, comprehensive online portal that collects, assesses, and presents law data in a textual and quantitative form.²² LawAtlas uses advanced data coding of state public health law language to provide data on common and unique features of each state's TBI laws, along with a codebook.¹¹ We used the effective date for a state's TBI law to define periods relative to the law enactment.¹³

Measures

We defined concussion as one that (1) occurred in a school-sanctioned sport competition or practice, (2) required medical attention by an athletic trainer or a physician, and (3) was recorded in High School RIO. Before the 2007–2008 academic year, High School RIO only captured concussions that resulted in restriction of the athlete's participation for 1 or more days. However, starting with the 2007–2008 academic year, the definition of injury was expanded to capture all concussions, even if there was no time lost from sports participation.³ In the High School RIO online injury report form, a drop-down menu, which includes concussion, facilitates athletic trainers in indicating injury diagnoses for each case. Although clinical practices regarding use of various diagnostic tools varied across clinical teams, each concussion reported to this surveillance system had at least 1 concussion symptom and the vast majority of cases involved multiple health care professionals (i.e., athletic trainers and physicians)

in diagnosis, management, and return-to-play decisions.^{3,25} The report form captures date of concussion, and whether the injury is new (i.e., athlete sustained a sport-related concussion for the first time) or recurrent (i.e., athlete sustained a second or other subsequent sport-related concussion following an initial concussion during the same sport's season or before the same sport's season).

We measured rate of new (or recurrent) concussions as the number of new (or recurrent) concussions sustained in organized school sports during a specified time (academic year and standardized year, respectively), divided by the total number of athlete exposures in the same period, multiplied by 100 000.^{3,25} Athlete exposure is defined as 1 athlete attending 1 competition or practice.^{3,25}

We classified law enactment period as prelaw (before the law went into effect), immediate-postlaw (the first year after the law went into effect), or postlaw (the second year after the law became effective until the end of the study period).²²

We then categorized all new and recurrent concussions occurring during the study as occurring during the prelaw, immediate-postlaw, or postlaw period according to the date and year of injury. Because the concussion law effect date varied by state, categorization of concussion data relative to law-effective date for each school varied accordingly.

Statistical Analysis

We reported the number of new and recurrent concussions occurring during the study by academic year along with national estimates by incorporating sampling weights. We calculated annual concussion rates by gender, sports, type of exposure (competition or practice), and type of concussion (new or recurrent) by using Poisson regression models. We then estimated average annual concussion rates and corresponding 95% confidence intervals (CIs) by using the non-parametric bootstrap technique, in which the 50th percentile, 2.5th percentile, and 97.5th percentile were calculated from the empirical distribution of annual concussion rates (resampling number = 1000).

To adjust for variation in time of law enactment across states, we scaled the time of

academic year to the standardized year measured as every 52 weeks when evaluating the effect of state-level TBI laws on the trends of concussion rates. We categorized the concussions occurring during the week of the relevant state law effective date as “0,” the concussions occurring within 1 standardized year (i.e., 52 weeks) prelaw as “-1” with 1 unit of subtraction for each additional standardized year (i.e., 52 weeks) before, and concussions occurring within 1 standardized year after the law as “+1” with 1 unit of addition for each additional standardized year after. We then calculated average rates of new and recurrent concussions for each standardized year by using Poisson regression models, and adjusted for sport and state in which a high school was located. We used general linear models to evaluate the impact of state-level TBI laws on the trends of concussion rates, along with 95% CIs, across prelaw, immediate-postlaw, and postlaw periods for new and recurrent concussions, and for concussions incurred in boys’ and girls’ sports, respectively. We set statistical significance level as .05. We conducted all analyses in SAS version 9.4 (SAS Institute Inc, Cary, NC).

RESULTS

Athletic trainers reported 8043 concussions to High School RIO during the 11-year study period. The weighted estimates represented 2 693 245 total reported concussions, or 671 concussions per day, among US high-school athletes participating in at least 1 of the 9 study sports during the study period. Of the 8043 reported concussions, 7134 (88.7%) were new and 909 (11.3%) were recurrent (Table 1). Concussions were more frequent among male athletes ($n = 5984$; 74.4%), in football ($n = 4280$; 53.2%), and during competitions ($n = 5193$; 64.6%).

Athlete exposures totaled 20 240 570 during the study period (5 526 635 competition exposures and 14 713 935 practice exposures; Table 1). The average annual concussion rate was 39.8 per 100 000 athlete exposures—35.3 per 100 000 athlete exposures (95% CI = 34.6, 36.3) for new and 4.5 per 100 000 athlete exposures (95% CI = 4.2, 4.8) for recurrent concussions. Average annual concussion rates were significantly

higher in competition than practice ($P < .001$). Football had the highest average annual rate (78.4 per 100 000 athlete exposures; 95% CI = 76.1, 80.7), followed by girls’ soccer and boys’ wrestling (Table 1). Boys had a higher average annual concussion rate than girls ($P < .001$). However, when we compared the rates in gender-comparable sports (basketball, soccer, baseball/softball), girls had almost double the annual rate of concussions as boys ($P < .001$).

Trends of New and Recurrent Concussions

The rate of new concussions significantly increased from the prelaw to immediate-postlaw period (Figure 1). Specifically, the rate was increasing even 2 standardized years before the law-effective date ($P < .001$; adjusted $R^2 = 0.94$; Figure 1). The increase persisted during the postlaw period before declining 3.8 standardized years after the law. Although rates of recurrent concussions were consistently lower than new concussions, trends from the prelaw to immediate-postlaw period were similar ($P = .003$; adjusted $R^2 = 0.89$; Figure 2). However, during the postlaw period, rate of recurrent concussions showed significant decline from 2.6 years after the laws went into effect (Figure 2).

Sport and Gender Differences

When we compared overall concussion rates in football with other boys’ sports and girls’ sports (Figure 3), the trend mimicked that of the recurrent concussion rate. Rate increases were noted prelaw through the postlaw periods and began to decline at standardized year 2.8 and beyond ($P < .001$; adjusted $R^2 = 0.92$; Figure 3). The trends of overall concussion rate for girls’ sports and boys’ sports excluding football were similar from the prelaw to the immediate-postlaw period. Differences were apparent only during the postlaw period when the trend for girls’ sports slightly increased ($P < .001$; adjusted $R^2 = 0.93$) whereas the trend for boys’ sports (excluding football) showed a slight decline from 3.2 years after the laws went into effect ($P = .002$; adjusted $R^2 = 0.91$; Figure 3).

When we compared trends of overall concussion rates in gender-comparable sports, girls’ sports exhibited a continued increase from the prelaw, through immediate-

postlaw, to postlaw period ($P < .001$; adjusted $R^2 = 0.91$) and boys’ sports exhibited an increase from the prelaw to immediate-postlaw period and remained similar during the postlaw period. Girls’ sports also exhibited consistently higher concussion rates than boys’ sports over time ($P < .001$), and a greater increase during immediate-postlaw and postlaw periods.

DISCUSSION

This study was the first to our knowledge to use data from a large, national high-school sports injury surveillance system to analyze associations between enactment of state-level TBI laws and trends in sports-related concussion rates. More specifically, we evaluated trends across the period from before to after the law’s enactment. The main findings showed significantly increased trends in reporting new and recurrent concussion rates; increases were observed from the prelaw period, through the immediate-postlaw period, and into to the postlaw period. However, by approximately 2 and a half years after the laws went into effect, the recurrent concussion rate showed a significant decline. These findings provide empirical data and support our hypotheses partially. These findings also have implications for evidence-based effective legislative interventions in protecting the health and safety of youth sport participants.²¹

The observed significant increase in overall, new, and recurrent concussions shortly after the law went into effect is consistent with previous state-specific studies and those studies that used emergency department visit data.^{19,20,26} The increase may be attributable to greater recognition and reporting of concussions by athletic trainers or athletes following the implementation of concussion education requirements of these laws, rather than increased number of injuries.^{27,28} As concussion diagnosis relies heavily on observed and athlete-reported signs and symptoms, lack of knowledge about concussion signs and symptoms may have resulted in underreporting of concussions during the prelaw period. Mandatory education about concussion signs and symptoms, 1 of the 3 core elements of state TBI laws, is expected to have improved coaches’, athletic

TABLE 1—Number and Rate of New and Recurrent Concussions Among US High School Students: United States, Academic Years 2005–2006 Through 2015–2016

Variable	Concussions				AEs, No.	Average Annual Concussion Rate ^b (95% CI)
	All, No.	National Estimate, No.	New, No. ^a (%)	Recurrent, No. ^a (%)		
Total	8 043	2 693 245	7 134 (88.7)	909 (11.3)	20 240 570	39.8 (38.9, 40.5)
School year						
2005–2006	393	134 963	337 (85.8)	56 (14.2)	1 729 774	22.8 (20.9, 24.7)
2006–2007	415	123 865	365 (88.0)	50 (12.0)	1 820 367	22.9 (20.6, 25.0)
2007–2008	502	137 804	441 (87.8)	61 (12.2)	2 077 780	24.2 (22.2, 26.2)
2008–2009	539	149 696	477 (88.5)	62 (11.5)	2 112 479	25.5 (23.6, 27.1)
2009–2010	568	192 051	489 (86.1)	79 (13.9)	1 763 241	32.2 (29.9, 34.6)
2010–2011	721	249 653	630 (87.4)	91 (12.6)	1 762 485	40.9 (38.2, 43.7)
2011–2012	882	331 406	797 (90.4)	85 (9.6)	1 733 895	50.9 (47.8, 53.9)
2012–2013	1 026	348 565	922 (89.9)	104 (10.1)	1 874 256	54.8 (51.4, 57.6)
2013–2014	993	342 394	856 (86.2)	137 (13.8)	1 873 729	52.9 (49.8, 56.1)
2014–2015	970	315 543	861 (88.8)	109 (11.2)	1 719 036	56.5 (53.2, 59.8)
2015–2016	1 034	367 306	959 (92.7)	75 (7.3)	1 773 528	58.3 (55.2, 61.5)
Gender						
Male	5 984	1 842 897	5 329 (89.1)	655 (10.9)	13 410 066	45.1 (44.0, 46.1)
Female	2 059	850 348	1 805 (87.7)	254 (12.3)	6 830 503	30.5 (29.4, 31.6)
Sport						
Boys' football	4 280	1 234 988	3 802 (88.8)	478 (11.2)	5 497 599	78.4 (76.1, 80.7)
Boys' soccer	581	319 627	523 (90.0)	58 (10.0)	1 917 524	30.9 (28.9, 33.1)
Girls' soccer	911	510 448	792 (86.9)	119 (13.1)	1 692 697	54.9 (52.0, 58.0)
Girls' volleyball	273	78 193	241 (88.3)	32 (11.7)	1 794 928	15.1 (13.6, 16.6)
Boys' basketball	382	95 602	353 (92.4)	29 (7.6)	2 401 514	16.0 (14.6, 17.3)
Girls' basketball	653	171 775	560 (85.8)	93 (14.2)	1 925 104	34.6 (32.5, 36.6)
Boys' wrestling	590	145 182	513 (86.9)	77 (13.1)	1 688 334	36.4 (34.0, 38.8)
Boys' baseball	151	47 498	138 (91.4)	13 (8.6)	1 905 095	8.0 (7.0, 9.1)
Girls' softball	222	89 932	212 (95.5)	10 (4.5)	1 417 775	15.9 (14.1, 17.6)
Activity						
Competition	5 193	1 829 490	4 592 (88.4)	601 (11.6)	5 526 635	94.7 (92.4, 96.9)
Practice	2 850	863 755	2 542 (89.2)	308 (10.8)	14 713 935	19.6 (18.9, 20.3)
Gender-comparable sports						
Boys' sports	1 114	462 727	1 014 (91.0)	100 (9.0)	6 224 133	18.1 (17.2, 18.9)
Girls' sports	1 786	772 155	1 564 (87.6)	222 (12.4)	5 035 576	36.1 (34.8, 37.5)

Note. AE = athlete exposure, with attending 1 competition or practice defined as 1 AE; CI = confidence interval.

^aThe number of new or recurrent concussions and the percentage of new or recurrent concussions among all concussions.

^bOne per 100 000 AEs. Annual concussion rates were calculated as the number of concussions sustained during an academic year divided by total number of AEs during that year. Average annual injury rates and corresponding 95% CIs were calculated by using nonparametric bootstrap technique, in which the 50th percentile, 2.5th percentile, and 97.5th percentile were calculated from the empirical distribution of annual concussion rates (resampling number = 1000).

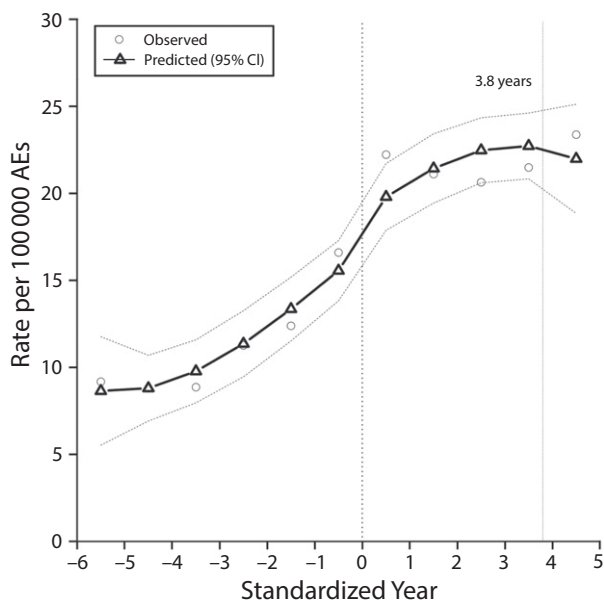
trainers', parents', and students' knowledge of concussion signs and symptoms, and dangers of undiagnosed and untreated concussion, thus leading to an increase in concussion recognition and reporting.^{18,27,28}

Although education about concussion signs and symptoms is important for concussion recognition and reporting after an injury, most state TBI laws do not generally apply proscriptive measures designed to

reduce the risk of initial concussions.^{11,12} Our results, along with those of others, can be used as evidence for more public health efforts that focus on preventing concussions in the first place, such as preventing or reducing initial head or body impact.^{11,21}

Although most state TBI laws primarily focus on reducing the secondary effects of concussions rather than preventing the likelihood of initial exposure,^{11,12} existing studies

have not examined differential outcomes of new or recurrent concussions specific to youth sports. Our results showed that recurrent concussions showed a significant decline after 2.6 years following the law-effective dates as a function of prolonged implementation of the state TBI laws. One core function of these laws is to reduce the immediate risk of health detriments caused by premature return to play that could lead to

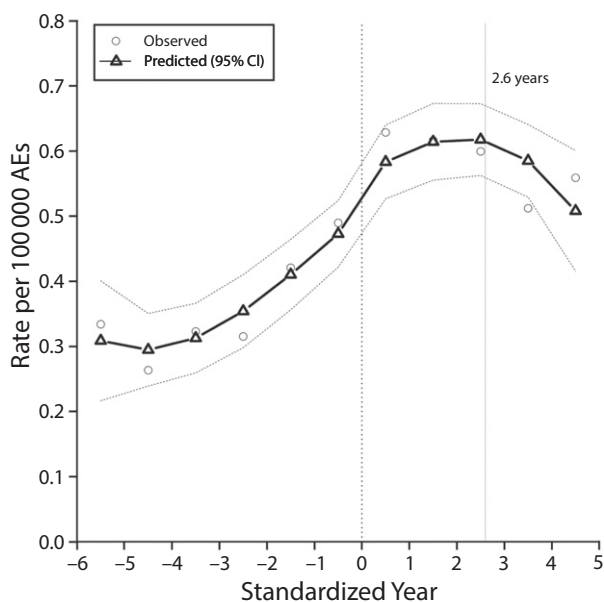


Note. AE = athlete exposure with attending 1 competition or practice defined as 1 AE; CI = confidence interval.

FIGURE 1—Trend of New Concussion Rates Among US High-School Athletes Across a Period From Pre- to Postlaw: United States, Academic Years 2005–2006 Through 2015–2016

additional head impact while recovering from the previous injury.^{11,29} The observed decline in recurrent concussion rates might be the effects of mandatory removal from play or

permission requirements to return to play.^{15,25} Further research evaluating the impact of TBI laws should consider using a longitudinal prospective design to



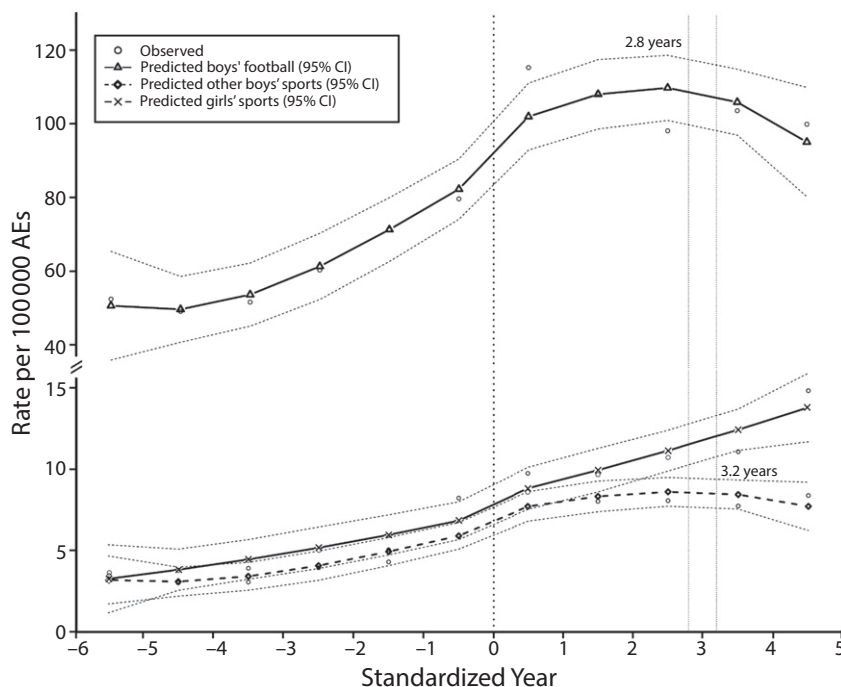
Note. AE = athlete exposure with attending 1 competition or practice defined as 1 AE; CI = confidence interval.

FIGURE 2—Trend of Recurrent Concussion Rates Among US High-School Athletes Across a Period From Pre- to Postlaw: United States, Academic Years 2005–2006 Through 2015–2016

determine long-term effects, and effects of specific elements of the laws on both new and recurrent concussion rates.²¹

Consistent with the findings from previous studies, our trend analysis identified increases in new and recurrent concussion rates before state-level TBI laws went into effect. For example, a study using insurance claims data found concussion-related office-visit rates increased by 20% per school year even before the Lystedt Law, and that all concussion-related office visits increased by 60% for states without legislation during the study period.²⁰ The increase in reported concussion rates observed in this study could be attributable to the change in the definition of injury that expanded to capture all concussions,³ along with a combination of increased awareness, more accurate assessment, an absolute rise in incidences, or other unmeasured factors.^{11,16,21} Nationally heightened media awareness on sports-related concussions in general, on educational interventions such as the Centers for Disease Control and Prevention’s HEADS UP program,³⁰ and on TBI laws from early adopting states²⁰ may have contributed to the observed initial increase in reporting of concussions. Given that all high schools participating in High School RIO have at least 1 athletic trainer who is responsible for collecting and reporting injury data, the athletic trainers in these schools would be expected to report a concussion, regardless of their specific state’s law requirements.³¹

Our findings also confirm the results of other nonsurveillance studies indicating that trends of concussions differ between male and female youth athletes.^{32,33} In addition, our results indicate that concussions from playing football exhibited a different trend compared with other boys’ and girls’ sports. These findings may add additional evidence that the state-level TBI laws have affected football concussion rates more because of the large number of concussions occurring in football and more public concerns about safety of youth football.^{3,12} However, current state concussion laws take a “one-size-fits-all” approach, without considering factors such as gender, age, or type of sports that may alter risk or outcomes of concussions.^{11,34} As laws continue to be updated and revised, more finely tailored laws, particularly those that include sex-specific reduction methods, are



Note. AE = athlete exposure with attending 1 competition or practice defined as 1 AE; CI = confidence interval.

FIGURE 3—Trend of Concussion Rates Among US High-School Athletes by Gender Across a Period From Pre- to Postlaw: United States, Academic Years 2005–2006 Through 2015–2016

needed to ensure the effectiveness of the laws across all populations.³⁴

Limitations

This study had several limitations. First, this study only examined the effects of the presence or absence of a state's TBI law on the trends of concussion rates. Our observed increase in concussion rates after TBI laws may not reflect the true impact of the law. To better measure the law's impact, future studies should account for variations in the language; type and number of legal or regulatory interventions; state, district, school, and provider interpretation; and the implementation of such laws, as well as other methods that can be developed to evaluate as-yet-unmeasured factors such as widespread educational programs, enhanced media attention, improved diagnostic tools or clinic practices, change in sports rules, or liability and legal implications of the law itself.

Second, the schools participating in this surveillance study were likely to be most compliant with state concussion law requirements and associated best practices

regarding concussion prevention and management because, to be eligible to participate in High School RIO, schools must have a certified athletic trainer providing care to their student athletes. Thus, they might not be representative of schools in their states without athletic trainers. The rates of concussions reported in this study might also be higher than schools without athletic trainers because of likely increased recognition of concussions and compliance with interaction with health care professionals when these sports medicine clinicians are present.

Third, athletes in this study may have had a previous undiagnosed or unreported concussion(s). Thus, some concussions recorded as new in this surveillance data set might not truly be first concussions.

Fourth, all new and recurrent concussions included in this study were measured within scholastic sports per athlete, without capturing concussions outside sports for that athlete. The exposure information used for calculating the rate of new and recurrent concussion was the same, which could have led to the overestimation of the new concussion rate

and underestimation of the recurrent concussion rate.

Fifth, the concussion rate for football accounted for roughly half of all reported concussions during the study period. Further analysis of non-football-related concussions is needed to determine whether the observed trends remain.

Finally, because the last 3 states passed their TBI laws in 2014,²⁰ the postlaw period concussion data were limited for these states.

Conclusions

We observed increases in new concussion rates during prelaw, immediate-postlaw, and postlaw periods (Figure 1), which is consistent with the findings from previous studies and may be caused by a range of factors including increased awareness and identification of concussions. Reduced recurrent concussion rates after law implementation (Figure 2) could be ascribed to removal and return-to-play requirements, indicating that TBI laws may have an effect on reducing negative public health outcomes, as intended. Future studies evaluating the impact of state-level TBI laws should include a longer postlaw period with a broader age range of youth athletes, and should account for potential contributing factors (e.g., strength of law, evidence-based policymaking approaches, the effect of media awareness, and the role of school compliance) on observed concussion rates. Finally, additional legislative reinforcement and refinement, which include primary prevention measures with sex-tailored law elements, are needed to effectively prevent new and recurrent concussions among youth sports participants. *AJPH*

CONTRIBUTORS

J. Yang designed and conceptualized the study and drafted the initial article. R. D. Comstock collaborated with J. Yang on study design and conceptualization and obtained concussion data. H. Yi conducted data analysis. H. H. Harvey collaborated with J. Yang on study design and conceptualization and aided in drafting and traumatic brain injury law data analysis. P. Xun aided in data analysis. All authors critically reviewed and revised the article and approved the final article as submitted.

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Note. The views expressed here do not necessarily reflect the views of the Robert Wood Johnson Foundation.

HUMAN PARTICIPANT PROTECTION

This study was approved by the institutional review board of the Nationwide Children's Hospital, the Ohio State University, and Colorado School of Public Health, University of Colorado Anschutz.

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