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# **Research Article**





# Racial and Socioeconomic Disparities on Childhood Helmet and Restraint Use at a Trauma Center in Boston

# Carol Pineda<sup>1</sup>, Leslie Rideout<sup>2</sup>, Megan Sweeney<sup>2</sup>, Aashka Shah<sup>2</sup>, Janis L Breeze<sup>3</sup>, Walter J Chwals<sup>2</sup>, Carl-Christian A Jackson<sup>2</sup>, Zenab Mansoor<sup>1</sup>

<sup>1</sup>Tufts Children's Hospital, Department of Pediatrics, Division of Critical Care, Boston, MA, USA

<sup>2</sup> Tufts Children's Hospital, Department of Pediatric Surgery, Boston, MA, USA

<sup>3</sup>Tufts Clinical and Translational Science Institute, Tufts University and Institute for Clinical Research and Health Policy Studies, Tufts Medical Center, Boston MA, USA

\*Corresponding Author: Carol Pineda, Baystate Children's Hospital, 759 Chestnut Street, Springfield MA, USA

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## Abstract

**Background:** Disparities in the usage of childhood protective devices exist despite current efforts. We investigated the influence of racial and socioeconomic factors on the use of protective devices.

**Methods:** A retrospective review of the pediatric trauma inpatient registry (0-17 years of age) for the Kiwanis Pediatric Trauma Unit at Tufts Medical Center in Boston between 2001 and 2014 was performed. Protective devices (helmets or child passenger restraints) use at the time of injury in motor vehicle crashes (MVC) and sport-related injuries were included. Descriptive and inferential statistics were used to analyze socioeconomic characteristics and the use of protective devices.

**Results:** Out of 470 children (2 months to 17 years old) included, only 209 (45%) used a protective device, with 73% suffering sports-related injuries and 27% MVC. Only 24% of bicycle injuries and 50% of MVCs used a protective device. Unhelmeted children were more likely to be non-white (38% *vs* 17%, p < 0.001), female (25% *vs* 15%, p = 0.03), live in low-income neighborhoods (55% *vs* 29%, p < 0.0001), be publicly insured (p < 0.001) and have more severe head injuries (Acute Injury Score > 3, 12% *vs* 3%, p = 0.002). Unrestrained children involved in MVCs were older (14 v. 8.5 years, p = 0.04) and experienced greater injury severity scores (5 *vs* 2, p = 0.008).

**Conclusion:** Only 45% of injured children used a protective device when involved in sports-related injuries and MVCs. Non-white children (African-American and Hispanics), patients living in low-income neighborhoods, and those publicly insured were at higher risk of not using a protective device.

**Keywords:** Children; Trauma; Helmets; Seat Belts; Injury Prevention

**Abbreviations:** MVCs: Motor Vehicle Crashes; ISS: Injury Severity Score; GCS: Glasgow coma score; AIS: Abbreviated Injury Score; LOS: Length of Stay; ED: Emergency Department; EMS: Emergency Medical Services

#### Introduction

Unintentional injuries remain the leading cause of morbidity and mortality among children and adolescents in the United States [1]. In addition to acutely influencing the health of children and their families, unintentional injuries can also induce both short and long-term disability and high medical costs [2,3]. Motor vehicle crashes (MVCs) remain the leading cause of childhood death in

the United States, while bicycle-related injuries account for 2.2 million of all pediatric emergency department visits annually [4,5].

Although child restraints (e.g., car seats, seatbelts) and helmets have proven to reduce fatalities and severity of injuries, the use of these continues to be unacceptably low. Pediatric mortality rates from a motor vehicle crashes in the United States are over double the rates of 22 high-income European countries combined [6,7]. The vulnerability of the pediatric population requires attention from policymakers to implement effective interventions that lessen the occurrence of injuries.

One hundred million Americans ride bicycles every year, but only 43% self-reported wearing bicycle helmets regularly [8]. Any cyclist who does not wear a bicycle helmet is at increased risk of head injury and worse outcomes [7]. Twenty-one states including Massachusetts have enacted bicycle helmet legislation that require children to wear a helmet while operating a bike [9]. Despite the shift in supportive policy, rates of helmet utilization amongst children throughout the country range from 11% to 42% [9-12].

Prior research has shown a link between demographic characteristics and the use of protective devices, demonstrating higher pediatric mortality rates resulting from unrestrained and un-helmeted deaths among marginalized populations [13-19]. To promote the development of culturally-competent injury prevention programs, we sought to determine the pattern of protective device use amongst pediatric patients throughout the greater Boston area. The objective of this exploratory study was to determine whether helmet and child restraint use is associated with ethnicity and socioeconomic status among injured pediatric patients to develop targeted community-specific injury prevention programs.

#### **Materials and Methods**

We performed a retrospective review of our pediatric trauma database, which included patients less than 17 years old admitted between January 1, 2001 and December 31, 2014 to the Kiwanis Pediatric Trauma Unit at Tufts Medical Center in Boston, a Level 1 pediatric trauma unit. This study was approved by the Tufts Institutional Review Board. Children were classified on whether a protective device (helmet or child restraint) was used and mechanism of injury – motor vehicle crash (if injured as a

passenger during an MVC) or sports-related injury while playing a sport (if they were hit by a car or fell while cycling, skating, riding a scooter or skateboard). Other injury mechanisms that did not require the use of protective devices were excluded. Injury data (including protective device status) was collected and recorded by the emergency department (ED) personnel upon arrival. Incomplete data within the Pediatric Trauma Registry "Collector" Program (Digital Innovations, Forest Hill, MD) was verified through the electronic health records to abstract primary study characteristics and outcomes.

The appropriateness of protective device use was verified according to age and Massachusetts legislation at the time of the patient's injury since these changed during the study period. Data collected included socioeconomic status, severity (using the injury severity score (ISS), the Glasgow coma score (GCS), the Abbreviated Injury Score (AIS) and outcome characteristics such as hospital length of stay (LOS), emergency department (ED) and discharge disposition, and mortality (death prior to hospital discharge). Age was classified according to the American Academy of Pediatrics whereby groups were characterized by infants and toddlers (< 3 years), preschoolers (3 - 5 years), grade-schoolers (> 5 - 12 years) and teenagers (> 12 - 17 years).

Socioeconomic status was based on: US census median household income, insurance status and race/ethnicity. Patients' residential zip codes were referenced to group children according to their median neighborhood income level per the 2010 US Census Bureau classification (low-income: < \$31,999, middle-income: \$32,000 - \$70,000 and high-income: > \$70,001). Insurance status was classified as publicly insured (Medicaid or none), private or unknown. Chi-square and Wilcoxon Rank Sum Tests were used to describe differences in socioeconomic, injury and outcome data based on the use of protective devices. Data analysis was performed using SAS v9.4 (SAS Institute, Cary, NC) with twosided t-tests and the significance level was established at p alpha < 0.05.

#### Results

Of the 1987 total pediatric patients (age, 2 months to 17 years) admitted to the pediatric trauma unit between 2001 to 2014, 1517 were excluded due to other mechanisms of injury (Figure 1).



#### Figure 1: Determination of Study Cohort.

Of the remaining 470 patients that met study criteria, 129 (27%) sustained injuries from MVCs and 341 (73%) were from sports. The median age at the time of patients' hospital admissions was 12 years, and the majority were male (73%). Only 210 (45%) children included in this analysis used a protective device (helmet or child restraint). Children that used a protective device were more likely to be male (77% *vs* 69%, p = 0.04) and white (78% *vs* 61%, p = < 0.0001). Hispanic children were less likely to use a protective device when compared to others (21% *vs* 9%, p = 0.001). The majority of children were elementary school-aged (> 5 to 12 years, 45%) or teenagers (> 12 to 17 years, 43%) but no significant age difference was seen with the use of helmets or restraints. Unprotected children were more likely to be publicly insured (50% *vs* 30%, p = < 0.0001), to live in low-income neighborhoods (51% *vs* 31%, p < 0.0001), to have a higher proportion of head/neck injuries (AIS > 1: 35% *vs* 23%, p = 0.004) as well as more severe head injuries (AIS > 3: 12% *vs* 5%, p = 0.008). Most children were discharged home (94%), while 20 (5%) individuals were transferred to an inpatient rehabilitation center. Our cohort in-hospital mortality was 1% which included one unrestrained passenger during an MVC and 3 from sports-related injuries. Differences in other severity of injury scores or trauma-related outcomes did not achieve statistical significance (Table 1).

Variable	Protective device used	Protective device not used	P valuo	
	N = 210	n = 260	r - value	
Age, median (IQR)	12 (8, 14)	12 (9, 14)	0.6†	
Race/Ethnicity				
White	163 (77.6)	159 (61.2)		
African-American	15 (7.1)	28 (10.8)	0.001	
Hispanic	18 (8.6)	55 (21.1)	0.001	
Asian	12 (5.7)	14 (5.4)		
Other	2 (1.0)	4 (1.5)		

	Protective device used	Protective device not used	
Variable	N = 210	n = 260	P - value
White vs Non-White			
White	163 (77.6)	159 (61.2)	< 0.0001
Non-white	47 (22.4)	101 (38.8)	< 0.0001
Gender			
Male	162 (77.1)	179 (68.8)	0.040
Female	48 (22.8)	81 (31.2)	
Age Classification			
Infants / toddlers ( < 3 years)	6 (2.8)	13 (5.0)	
Pre-school ( $\ge 3 - \le 5$ years)	21 (10.0)	16 (6.2)	0.300
Grade-school ( $> 5 - \le 12$ years)	94 (44.8)	117 (45.0)	
Teens ( > 12 - 17 years)	89 (42.4)	114 (43.8)	
Income Group			
Low	65 (31.0)	133 (51.2)	
Middle	69 (32.8)	78 (30.0)	< 0.0001
High	76 (36.2)	49 (18.8)	
Insurance Status			
Public	62 (29.5)	130 (50.0)	. 0.0001*
Private	147 (70.0)	127 (48.8)	< 0.0001*
Unknown	1 (0.5)	3 (1.2)	
Injury Severity Score	n = 191	n = 245	0.100*
Median (IQR)	4 (1, 9)	4 (4, 9)	0.100
AIS Sevenity Classification			
Als the double (region $1 > 1$	48 (22.9)	91 (35.0)	0.004
Als Head/Neck (region 1) $> 1$	11 (5.2)	32 (12.3)	0.004
AIS Head (region 1) $> 3$			0.008
Length of Stay			
Median # of days (min-max)	1 (1 - 32)	1 (1 - 37)	0.400†
IQR	1, 3	1, 3	
ED Disposition			
PICU	92 (43.8)	145 (51.5)	0.100
Floor	118 (56.2)	126 (48.5)	

Variable	Protective device used	Protective device not used	P - value	
	N = 210	n = 260		
Discharge Disposition				
Home	201 (95.7)	245 (94.2)	0.700	
Tione	7 (3.3)	13 (5.0)	0.700	
Inpatient rehabilitation	2 (1 0)	2 (0.8)		
Death	2 (1.0)	2 (0.8)		

**Table 1:** Demographics Characteristics and Use of Protective Devices (n = 470); IQR: interquartile range; <sup>†</sup>Wilcoxon signed-rank test for continuous variables; <sup>\*</sup>Fisher's exact test

#### **Sports-Related Injuries and Helmets**

Of the total 470 patients, 341 (73%) suffered sports-related injuries. Only 146 (43%) of these children were helmeted at the time of injury. The median age for this subgroup was 12 years and the use of helmets did not differ by age (p = 0.09). Unhelmeted children were more likely to be non-white (38% *vs* 17%, p < 0.0001), female (25% *vs* 15%, p = 0.03), live in low-income neighborhoods (55% *vs* 29%, p < 0.0001) or publicly insured (51% *vs* 23%, p = 0.0001). African-American children were less likely to wear a helmet in sport-related injuries when compared to other groups (10% *vs* 4%, p = 0.03) (Table 2).

Variable	Helmets Used	No Helmets Used	Dl.
	n = 146	n = 195	r - value
Age, median (IQR)	12 (10, 14)	12 (9, 14)	0.090†
Gender			
Male	124 (85.0)	147 (75.3)	0.020
Female	22 (15.0)	48 (24.6)	0.030
White vs Non-White			
White	121 (82.8)	120 (61.5)	< 0.0001
Non-white	25 (17.1)	75 (38.5)	< 0.0001
African-American vs Other Race/Ethnicity			
African American	6 (4.1)	20 (10.3)	0.030
Non-African American	140 (95.9)	175 (89.7)	0.030
Income Group			
Low	42 (28.8)	108 (55.4)	< 0.0001
Middle	42 (28.8)	56 (28.7)	< 0.0001
High	62 (42.4)	31 (15.9)	
Insurance Status			
Public	33 (23.0)	99 (50.8)	
Private	113 (77.0)	93 (47.7)	< 0.0001*
Unknown	0 (0)	3 (1.5)	

		1	
Glasgow Coma Score			
Severe $\leq 8$	6 (4.2)	8 (4.2)	
Moderate 9 - 12	0 (0)	2 (1.0)	0.700*
Mild 13 - 15	138 (95.8)	183 (94.8)	
Acute Injury Severity Classification			
AIS Head/Neck (region 1) > 1	35 (24.0)	72 (36.9)	0.010
AIS Head (region $1$ ) > 3	4 (2.7)	24 (12.3)	0.002
Injury Severity Score	n = 134	n = 195	0.000*
Median (IQR)	4 (9, 29)	4 (9, 26)	0.900
Length of Stay			
Median (days), (min-max)	1 (1 - 18)	1 (1 - 34)	0.600†
IQR	1, 2	1, 2	0.000
Emergency Department Disposition			
Pediatric Intensive Care Unit	58 (42.8)	95 (48.7)	0.090
Floor	88 (60.3)	100 (53.2)	
Discharge Disposition			
Home	143 (98)	190 (97.4)	
Inpatient rehabilitation	2 (1.4)	3 (1.5)	0.900*
Death	1 (0.7)	2 (1.0)	

Table 2: Helmet use and outcomes of sports-related injuries (n = 341); \*Denominators adjusted due to missing data

<sup>†</sup>Wilcoxon signed-rank test for continuous variables; <sup>\*</sup>Fisher's exact test.

Of the 341 sports-related injuries, 177 (52%) were bicycle-related (bicycle *vs* MVC collisions, bicycle falls), 46 (13%) were football injuries, 41 (12%) were skateboard and scooter falls and 77 (23%) were classified as other sports-related injuries (hockey, equestrian, baseball, ski/snowboarding, lacrosse and rollerblading/ice skating). Amongst the 177 bicycle-related injuries, 127 were due to bicycle falls (72%) and 50 (28%) were bicycle-MVC collisions. Only 42 (24%) were wearing a helmet at the time of their bicycle-related injury. Children with skateboarding and scooter injuries were more likely to be unhelmeted (78% *vs* 54% in all other sports, p = 0.004). Helmet use was much higher amongst football-related injuries (91% *vs* 35%, p < 0.0001) when compared to other sports (Table 3).

Variable	Helmets used	Helmets not used	P - value
	n = 146	n = 195	I - Value
Bicycle-related Injuries (n=177)	42 (23.7)	135 (76.3)	
Bicycle falls $n = 127$	34 (26.8)	93 (73.2)	0.100
Bicycle vs. MVC collisions n = 50	8 (16.0)	42 (84.0)	

Football vs All other sports			
Football collisions $n = 46$	42 (91.3)	4 (8.7)	< 0.0001
All other sports $n = 295$	104 (35.2)	191 (64.8)	< 0.0001
Skateboard/Scooter falls vs All other sports			
Skateboard/Scooter Injuries n = 41	9 (22.0)	32 (78.0)	0.004
All other sports $n = 300$	137 (45.7)	163 (54.3)	0.004

**Table 3:** Types of sports-related injuries (n = 341).

There was a larger proportion of head/neck injuries and severe head injuries in the unhelmeted vs helmeted group (AIS > 1: 37% vs 24%, p = 0.01); (AIS > 3, 12% vs 3%, p = 0.0015), respectively. We found no difference in disposition, LOS, GCS and injury severity score (ISS) in relation to helmet use (Table 2). Three sports-related injury deaths resulted from a bicycle fall, a bicycle vs MVC collision and a skateboard/scooter fall.

#### **MVCs and Child Passenger Restraints**

Of the total 470 patients, 129 (28%) were involved in MVCs, only 64 (50%) used a child restraint out of which 47 (74%) were ageappropriate. The median age for the MVC-related injury subgroup was 10 years old. Fourteen (11%) children had moderate or severe traumatic brain injury by GCS  $\leq$  12. Unrestrained children were found to be older (median, 14 *vs* 8.5 years, p = 0.04) and had higher ISS (median, 5 *vs* 2, p = 0.008). The use of child restraints did not differ in this subgroup when comparing other severity of injury scores, socioeconomic or outcome data (Table 4).

Variable	Child restrained	Child not restrained n = 65	P - value	
	n = 64			
Age, median (IQR)	8.5 (5, 15)	14 (5, 16)	$0.040^{\dagger}$	
G e n d e r				
Male	38 (59.3)	32 (49.2)	0.200	
Female	26 (41)	33 (50.8)		
White vs Non-White				
White	42 (65.6)	39 (60)	0.500	
Non-white	22 (34.4)	26 (40)	0.500	
Income Group				
Low	23 (36)	25 (38.4)		
Middle	27 (42)	22 (33.8)	0.600	
High	14 (22)	18 (27.8)		

Insurance Status			
Dublic	20 (45.2)	21 (47.7)	
Public	29 (45.5)	51 (47.7)	
Private	34 (53.1)	34 (52.3)	0.900*
Unknown	1 (1.6)	0 (0)	
Glasgow Coma Score			
Severe < 8	5 (7.8)	8 (12.3)	
Moderate 9 - 12	0 (0)	1 (1.5)	0.500*
Mild 13 - 15	59 (92.2)	56 (86.2)	
AIS Severity Classification			
Head/Neck (region 1) > 1	13 (20.3)	19 (29.2)	0.200
Head/Neck (region 1) > 3	7 (10.9)	8 (12.3)	0.800
Face (region $2$ ) > 1	2 (1.6)	3 (4.6)	> 0.990*
Chest (region $3$ ) > 1	5 (7.8)	6 (9.2)	0.800
Abdomen/Pelvis (region 4) > 1	8 (12.5)	8 (12.3)	0.970
Extremities (region 5) > 1	10 (15.6)	18 (27.7)	0.100
Injury Severity Score	n = 57	n = 58	0.000*
Median, (IQR)	2 (1, 8)	5 (2, 10)	0.008
Length of Stay			
Median (days), (min-max)	1 (1 - 34)	2 (1 - 38)	0.400
IQR	1,4	1, 4	0.400
<b>Emergency Department Disposition</b>			
Pediatric Intensive Care Unit	34 (53.1)	39 (60.0)	0.400
Floor	30 (46.9)	26 (40.0)	
Discharge Disposition			
Home	58 (90.6)	55 (84.6)	
Inpatient rehabilitation	5 (7.8)	10 (15.4)	0.300*
Death	1 (1.6)	0 (0)	

**Table 4:** Child Passenger Restraint Use and Outcomes in Motor Vehicle Collisions (n = 129); \*Denominators adjusted due to missing data; †Wilcoxon signed-rank test for continuous variables; \*Fisher's exact test for categorical variables.

#### Discussion

Although the use of child passenger restraints and helmets has been shown to decrease disability and childhood death, it is not a consistently widespread practice. Attitudes toward and habitual usage of safety devices has previously been associated with socioeconomic disparities [13,17,18,20]. Since Massachusetts had already approved both child safety laws when this study took place, we sought to describe socioeconomic differences in relation to protective device use in a city with supportive state policies. In this single center study, we found that a significant proportion of children (45%), did not use a protective device at the time of injury. Only 24% of bicycle injuries and 50% of MVCs used a helmet or passenger restraint respectively. Non-white children (African-American and Hispanics), patients living in low-income neighborhoods, and those publicly insured were at higher risk of not using a protective device [18,19,21]. Results of this study suggest the need for improved strategies and targeted campaigns to mitigate disparities in minority and socially disadvantaged populations [22]. To our knowledge, this is the first pediatric trauma study in the Boston area focusing on socioeconomic disparities in the use of protective devices and health-related outcomes.

Despite the effectiveness of helmets in decreasing head injuries by 85%, as well as reducing severity of traumatic brain injury which our data supported, our helmet compliance rate was only 43% in sport-related injuries and 24% in bicycle injuries which is consistent with other United States studies that describe alarmingly low helmet use rates in children [6,9]. Our data is comparable to the National SAFE KIDS Campaign study in which only 41% of children 5-14 years old were observed to be wearing helmets when engaged in wheeled sports (bicycle, skateboard, scooter or skate). Helmet usage in the forgoing wheeled sports has been mandatory in Massachusetts for children younger than 16 since 2004 [10,23-25]. A Boston Bicycle report from 2013, showed that cyclists wore helmets in less than 50% of emergency medical services (EMS) incident cases, markedly lower than the citywide helmet usage rate of 72% suggesting that cyclists that use helmets are less likely to need EMS attention which is consistent with our data [26]. Likewise, skateboard/scooterrelated injuries were predominantly unhelmeted, akin to national injury data that showed that while bicycle-related ED injury visits decreased by 28% between 2005 and 2015, scooter injuries rose by 40% and that these children are less likely to routinely wear a helmet [22,27]. Therefore the use of helmets needs to be promoted and reinforced amongst all wheeled sports, not only among bicycle users. Football-related injuries were predominantly helmeted (91%) but not unanimous. Unhelmeted football injuries exclusively occurred under a recreational setting (i.e. impromptu pick-up games) demonstrating that sports played in an organized environment where helmet use is mandatory and reinforced (by either the school or a sports club), leads to a high usage compliance as opposed to when children operate independently without strong adult supervision [28].

In the MVC subgroup, unrestrained children were older, only half used a child restraint and roughly a quarter of these were inappropriately restrained, showing that further education and awareness, particularly among teenagers, is needed. As expected, children that were unrestrained had higher injury severity scores and were older, results that likely reflect how as children gain independence, parental supervision/involvement declines [29-31]. We found no association between socioeconomic status and the use of child restraints. This finding could be explained by a disparity neutral primary child seat safety law that enables law enforcement to stop a vehicle exclusively based on child seat violations along with stricter enforcement of that law and accompanying public safety initiatives. On the contrary, Massachusetts law specifically excludes penalties for violations of the helmet law which may negatively influence the use of helmets in populations that are already at risk of not using one and subsequently increasing socioeconomic gaps.

White males had an overall higher protective device use compliance rate, a result likely driven by their higher participation in organized sports, where the use of helmets is highly enforced. We found that unhelmeted children were more likely to be nonwhite (specifically African-American), to live in lower income neighborhoods and/or to be publicly insured which is consistent with prior studies that correlate lower helmet use among Hispanics, African-Americans, Asians and low income status children [18]. Likewise, several national reports indicate African-American and Hispanic children have the highest MVC occupant death rates compared to Whites, as well as higher proportions of unrestrained death [32]. Our low protective device usage, was likely driven by a large percentage of patients (approximately 40%) belonging to these same minority groups which have had a lower helmet and seatbelt usage rate. Legislative action increases the use of childhood protective devices however, there are many other complex factors that may contribute to unacceptably low compliance and that are influenced by the socioeconomic and racial/ethnic background of each child such as family dynamics, lack of education, misinformed perceptions concerning supervision and parental modeling behavior [21,22,33-36]. Therefore, public education about injury prevention is imperative and demonstrably effective in increasing protective device use, decreasing injury and mortality, as well as eliminating disparity gaps [5,33,34]. Our findings support creating targeted injury prevention programs focused on these low income and minority groups, with special emphasis on reinforcement of protective device use and the importance of parental supervision.

The present study is subject to several limitations. First, its retrospective single-centered nature and small sample size challenged our ability to analyze different mechanisms of

injury with heterogenous protective device type (helmets and child restraints) while controlling for socioeconomic status. A multicenter study in the greater Boston area is needed, in order to expand our preliminary findings and perform conclusive statistical modeling. Second, our data is now 6 years old and therefore local interventions which we are unaware of, may have occurred to diminish these disparities. Including organized sports, likely overestimated our true prevalence of helmet use since helmets are heavily enforced in these sports. Lastly, this study only includes data from hospitalized patients, likely skewing the true incidence of protective device usage which is presumed to be lower in injured children requiring in-hospital admission compared to those that were discharged home from the ED, those that did not require transfer to a level 1 trauma center, or those that were only seen in an outpatient setting.

As a result of our findings, two initiatives are underway at our center in the general pediatric clinic including a pilot study where parents are given a 5-min face-to-face presentation about protective device use (including educational brochures) in parallel with a survey to obtain each participants' family socioeconomic status, level of knowledge, and safety practices to be used for future studies. These surveys and brochures will be available in Spanish, Portuguese and Cantonese, in line with the demographics of our neighborhood and hospital population. Telephone interpreters are available to help with the face-to-face education. We are also developing short audio and video public service announcements promoting helmet and child restraint use in the aforementioned languages to be played on radio and television stations popular with our target population. Additionally, the Kiwanis Pediatric Trauma Program distributes free helmets and car seats for financially stressed families across Massachusetts, which have reportedly increased the use of these devices [37].

#### Conclusion

Children that required hospital admission in a major American city were predominantly unhelmeted and unbuckled at the time of injury. Non-white children (African-American and Hispanics), patients living in low-income neighborhoods, and those publicly insured were at higher risk of not using a protective device. Our findings emphasize the need for close adult supervision in the use of protective devices and increasing awareness of these inequalities in order to implement injury prevention programs that are targeted towards low income and minority groups.

## **Conflict of Interest**

The authors have no financial relationships relevant to this article to disclose. The Kiwanis Pediatric Trauma Institute and the Tufts Clinical and Translational Science Institute, NIH CTSA grant: UL1TR001064 supported this study.

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