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Mode of Transport and Trauma Activation Status in Admitted Pediatric Trauma Patients



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ABSTRACT

Background: Injured children who arrive by self-transport to the emergency department (ED) may receive delayed or inadequate care. We studied differences in demographics, clinical characteristics, and trauma activation status for admitted pediatric trauma patients based on arrival by self-transport or Emergency Medical Services (EMS).

Materials and methods: We performed a retrospective cohort study at two level I pediatric trauma centers. Inclusion criteria: <15 y old with blunt or penetrating injury. We used univariate and multivariate logistic regression analyses to determine associations between trauma activation, ED length of stay (LOS), and hospital LOS with demographic and clinical characteristics.

Results: We identified 1161 patients: 40.1% arrived by self-transport and 59.9% by EMS. Self-transport patients were less likely to have an abnormal Glasgow Coma Scale score < 15 (2.1% versus 22.0%, $P < 0.001$) and Injury Severity Score > 15 (2.4% versus 11.7%, $P < 0.001$). Trauma activation was initiated in 52.5% of patients, occurring less often in self-transport than EMS patients (2.4% versus 86.2%, $P < 0.001$). Trauma activation rate was negatively associated with arrival by self-transport (odds ratio [OR] 0.001, 95% CI 0.00-0.003), positively associated with Glasgow Coma Scale < 15 (OR 25.9, 95% CI 6.6-101.2) and site (OR 15.4, 95% CI 6.3-37.5) but not with Injury Severity Score > 15 (OR 2.8, 95% CI 0.8-9.2). Self-transport arrival was associated with longer ED LOS (estimated regression slope 0.47, 95% CI 0.13-0.82).

Conclusions: Almost half of admitted pediatric trauma patients arrived by self-transport; however, trauma team activation rarely occurs for these patients. Trauma team activation may be underutilized in self-transport patients with injuries resulting in hospital admission.

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Introduction

Nonfatal injuries resulted in 7.9 million pediatric emergency department (ED) visits in the United States in 2016.¹ The rapid identification, evaluation, and resuscitation of patients with serious injury are essential because of evidence that the time to definitive care after injury is directly linked to patient outcomes, including mortality.²⁻⁴ The creation and organization of a trauma response team for pediatric patients has been associated with decreased time to head computerized tomography, time to operating room, ED length of stay (LOS), and mortality.⁵

Optimal team performance during trauma resuscitations requires timely coordination of care by providers from multiple specialties. Prior studies at pediatric trauma centers have found that the primary and secondary surveys are often incompletely performed.⁶ Trauma team activation before patient arrival provides time for team assembly and preparation, leading to a shared mental model and a coordinated, organized response. At the trauma system level, pre-arrival notification has been associated with lower risk-adjusted odds of death in trauma patients.⁴ In contrast, a lack of pre-arrival notification can result in disorganized resuscitations, including decreased adherence to the Advanced Trauma Life Support primary survey protocol and presence of fewer team members.⁶⁻⁸ However, certain subsets of patients who arrive by self-transport (and thus lack pre-arrival notification) have improved outcomes, including a decreased mortality rate in adult patients who sustained penetrating injury.⁹

The American College of Surgeons Committee on Trauma recommends an undertriage goal of <5% and overtriage goal of 25%-35% in trauma team activation.¹⁰ Undertriage of patients may result in the lack of timely presence of the trauma resuscitation team and negatively impact outcomes, whereas overtriage may result in overutilization of limited resources including staff and supplies that are required elsewhere in the hospital. The ultimate goal is to initiate trauma activations accurately to ensure rapid, effective intervention and appropriate utilization of resources.¹¹

Injured children who arrive to the ED without emergency medical services (EMS) transport and pre-arrival notification present unique challenges to clinicians. We hypothesized that injured children who arrive without EMS transport are less likely to initiate trauma activations and have worse outcomes compared with those who arrive by EMS. Characterization of the outcomes of this population is needed to identify those patients most at risk for undertriage and to optimize their initial trauma care. Our objective was to describe differences in patient characteristics and trauma activation practices for admitted pediatric trauma patients based on mode of arrival.

Materials and methods

Study design and selection of participants

We performed a retrospective cohort study with data from trauma registries at two American College of Surgeons accredited level I pediatric trauma centers. We employed two

study sites to increase generalizability of findings. The institutional review boards at both institutions approved the study and granted waivers of informed consent. We identified all patients present in the trauma registries from July 1, 2014, to June 30, 2016. We included patients who were less than 15 y old (as patients ≥ 15 y old are directed to an adult trauma center per EMS trauma protocols in this region), sustained blunt or penetrating injury, required hospital admission, and arrived directly to the ED by self-transport or EMS. Transfers from outside facilities were excluded to reduce confounding variables, as these patients received initial facility stabilization elsewhere.

Study variables

We evaluated the demographics, injury characteristics, and hospital course of patients arriving by self-transport or EMS. For race, ethnicity, and insurance status, we included an "other/unknown" category for known classifications with small numbers and missing data. Injury severity was determined using the Glasgow Coma Scale (GCS), Injury Severity Score (ISS), and Abbreviated Injury Scale (AIS). Severity was defined as GCS < 15, ISS > 15, and maximum AIS > 2. We used Google Maps to calculate the distance from injury site to the hospital in miles using the ZIP codes of the injury site recorded in the trauma registry and of the hospital. Patients were grouped into daytime versus nighttime arrival, with daytime arrival defined to be 07:00-18:59. Weekend presentation was considered to be all Saturdays and Sundays from 00:00 to 23:59. The primary outcome measures included trauma activation, ED LOS, and hospital LOS.

Trauma activation criteria for each center are based on the American College of Surgeons–Committee on Trauma guidelines. For site A, the highest level trauma team activation includes evidence of shock, respiratory distress, and GCS < 9, as well as specific serious injuries that are clearly outlined in the protocol. For site A, the lowest level trauma activation criteria include GCS 9-14, specific moderate injuries, and moderate mechanism of injury. Site A also has pediatric ED trauma activation criteria for injuries that do not meet trauma criteria or physician discretion. For site B, the highest level criteria include serious or worsening respiratory failure, requirement for cardiopulmonary resuscitation, hemodynamic instability, GCS ≤ 8 , requirement for serious procedural intervention, and specific serious injuries that are clearly outlined in the protocol. For site B, lower level activation criteria includes GCS 9-14, requirement for intubation at an outside facility, specific moderate injuries or symptoms associated with moderate injuries, moderate mechanism of injury, or physician discretion.

Primary data analysis

We compared patient characteristics by arrival mode (self-transport versus EMS) using Student's *t*-test and χ^2 tests for continuous and categorical variables, respectively. We performed multivariate logistic regression analysis to determine the association between patient characteristics (including mode of arrival, age, sex, race, ethnicity, insurance, injury

type, GCS, ISS, AIS injury severity > 2, arrival d/time) and trauma activation. Linear regression with bootstrapped standard errors was used to assess the association between ED/hospital LOS and covariates, while accounting for non-normal distribution of the outcome. Data were analyzed using SPSS Statistics 23.0 (SPSS Inc, Chicago, IL). All tests were performed at 0.05 level of significance.

Results

We identified 1161 patients who met study criteria, including 466 (40.1%) who arrived by self-transport and 695 (59.9%) by EMS (Table 1). We observed a difference in the distribution in arrival mode by site, with 15.5% of patients arriving by self-transport at site A and 84.5% at site B ($P < 0.001$). Self-transport patients were younger (5.8 ± 3.6 versus 7.8 ± 4.4 y, $P < 0.001$) and more likely to be female (42.7% versus 32.5%, $P < 0.001$) and Hispanic/Latino (21.9% versus 10.5%, $P < 0.001$) compared with EMS patients. A lower proportion of patients who were identified as white (27.9% versus 34.1%, $P < 0.001$) and black (38.2% self-transport versus 48.8% EMS, $P < 0.05$) arrived by self-transport compared with EMS. Aggregated "other" patient race included Pacific Islander 0.1%, Asian 1.6%, other 21.8%, and unknown 0.3%. Patients arriving by self-transport were more likely to have private or government insurance than those arriving by EMS (40.8% versus 25.6%, $P < 0.001$). Aggregated "other" patient insurance included self 2.1%, none 2.2%, other 3.9%, and unknown 13.4%. Public insurance (including Medicaid and Medicare) was the most frequent insurance in both groups (49.4% self-transport and 44.5% EMS, $P > 0.05$).

The self-transport group was less likely to arrive from the scene of injury (45.3% versus 98.3%, $P < 0.001$) and traveled a shorter distance from the injury site than EMS patients (15.6 ± 17.6 versus 20.8 ± 21.8 miles, $P < 0.001$). Blunt injury was the most common injury type in both groups. Self-transport patients were less likely to have sustained penetrating trauma (3.6% versus 7.6%, $P < 0.001$), have a GCS <15 (2.1% versus 22.0%, $P < 0.001$), or an ISS >15 (2.4% versus 11.7%, $P < 0.001$). Of note, patients from site B had a slightly but significantly lower ISS (4.0) compared with site A (5.0, $P = 0.0012$). A lower proportion of self-transport patients had an AIS >2 compared with EMS patients in all body regions with documented injury (head/neck: 8.6% versus 23.0%, $P < 0.001$; chest: 1.1% versus 6.9%, $P < 0.001$; abdomen/pelvis: 0.6% versus 5.2%, $P < 0.001$; extremities: 10.5% versus 16.1%, $P = 0.007$).

No difference was observed in trauma activation status based on arrival time or day. Trauma activation occurred in 610 (52.5%) of patients, including 2.4% of self-transport versus 86.2% of EMS patients ($P < 0.001$). Patients arriving by self-transport had a longer ED LOS (5.9 ± 2.6 versus 4.8 ± 2.9 h, $P < 0.001$) and a shorter hospital LOS (1.5 ± 1.8 versus 3.9 ± 7.2 d, $P < 0.001$) compared with those arriving by EMS in initial analyses. Self-transport patients were more frequently admitted to the floor (84.8% versus 61.7%, $P < 0.001$) and less frequently admitted to the intensive care unit (ICU) from the ED (6.0% versus 25.8%, $P < 0.001$). A similar percentage of self-transport and EMS patients was admitted to the operating

room from the ED (9.2% versus 12.5% of EMS, $P > 0.05$). Among self-transport patients requiring immediate operating room care, no patients (0/43) had trauma activations compared with 74.7% of EMS patients (65/87). Among self-transport patients requiring ICU care, only 7.1% (2/28) had trauma activation compared with 91.0% (162/178) of EMS patients. Self-transport patients requiring ICU admission had a similar length of hospital day ($4.6 \text{ d} \pm 5.6$ versus $7.9 \text{ d} \pm 11.7$, $P = 0.14$) but a longer ED LOS ($5.57 \text{ h} \pm 2.74$ versus EMS $3.05 \text{ h} \pm 2.20$, $P < 0.001$) compared with EMS patients.

Most patients were ultimately discharged home from the hospital, but fewer self-transport patients were transferred to inpatient rehabilitation or skilled nursing facility compared with EMS patients (0.9% versus 5.9%, $P < 0.001$). Whereas no patient in the self-transport group died, 1.2% of EMS patients did not survive to hospital discharge ($P < 0.001$).

In multivariate analyses, we observed that trauma activation was associated with self-transport (odds ratio [OR] 0.001, 95% CI 0.00-0.003, Figure), arrival from the scene of injury (OR 0.10, 95% CI 0.03-0.31), and site B (OR 15.4, 95% CI 6.3-37.5). Trauma activation was also statistically significantly associated with GCS <15 (OR 25.9, 95% CI 6.6-101.2) but not with ISS >15 (OR 2.8, 95% CI 0.8-9.2). Trauma activation status was not significantly associated with age, sex, race, ethnicity, insurance, injury type, or daytime or weekend presentation in multivariate logistic regression analysis.

Multivariate linear regression analysis showed that a longer ED LOS was associated with site B (estimated regression slope 0.40, 95% CI 0.07-0.74, $P = 0.01$), public insurance (0.46, 95% CI 0.08-0.86, $P = 0.02$), blunt mechanism of injury (1.26, 95% CI 0.59-1.91, $P < 0.001$), daytime presentation (0.67, 95% CI 0.37-0.99, $P < 0.001$), and arrival by self-transport (0.47, 95% CI 0.13-0.82, $P = 0.01$). A shorter ED LOS was associated with GCS <15 (estimated regression slope -1.74 , 95% CI -2.18 to -1.32 , $P < 0.001$) and ISS >15 (-1.70 , 95% CI -2.16 to -1.24 , $P < 0.001$).

Multivariate linear regression analysis showed that a longer hospital LOS was associated with patients who identified as black (estimated regression slope 0.78, 95% CI 0.08-1.45, $P = 0.02$), GCS <15 (3.52, 95% CI 2.20-5.01, $P < 0.001$), and ISS >15 (8.35, 95% CI 5.74-11.25, $P < 0.001$). A shorter hospital LOS was associated with site B (estimated regression slope -0.77 , 95% CI -1.50 to -0.001 , $P = 0.048$). Hospital LOS was not associated with arrival mode.

Discussion

This study assesses trauma activation utilization in the unique population of admitted pediatric trauma patients who arrive by self-transport. Admitted patients arriving by self-transport have a lower acuity (as measured by GCS, ISS, and hospital LOS) and lower rate of admission directly from the ED to the ICU and operating room than EMS patients, and we would expect to see a lower trauma team activation rate in this population compared with EMS patients. However, although self-transport patients were overall less severely injured in comparison with EMS patients, nearly 1 in 6 self-transport patients (15%) required immediate operating room or ICU care. Moreover, self-transport patients comprised

Table 1 – Characteristics of admitted pediatric trauma patients by arrival mode of transport.

| | Self-transport (n = 466) | EMS(n = 695) | P value |
|--|--------------------------|-----------------------|---------|
| Demographics | | | |
| Site | | | |
| A (n = 499) | 72/466 (15.5%) | 427/695 (61.4%) | <0.001 |
| B (n = 662) | 394/466 (84.5%) | 268/695 (38.6%) | |
| Mean age (y) | 5.8 ± 3.6 | 7.8 ± 4.4 | <0.001 |
| Male sex | 267/466 (57.3%) | 469/695 (67.5%) | <0.001 |
| Race | | | |
| White | 130/466 (27.9%)* | 237/695 (34.1%)* | <0.001 |
| Black | 178/466 (38.2%)* | 339/695 (48.8%)* | |
| Other/unknown | 158/466 (33.9%)* | 119/695 (17.1%)* | |
| Ethnicity | | | |
| Not Hispanic/Latino | 358/466 (76.8%)* | 610/695 (87.8%)* | <0.001 |
| Hispanic/Latino | 102/466 (21.9%)* | 73/695 (10.5%)* | |
| Other/unknown | 6/466 (1.3%) | 12/695 (1.7%) | |
| Insurance | | | |
| Private/government | 190/466 (40.8%)* | 178/695 (25.6%)* | <0.001 |
| Public (Medicaid, Medicare) | 230/466 (49.4%) | 310/695 (44.6%) | |
| Other/unknown | 46/466 (9.9%)* | 207/695 (29.8%)* | |
| Injury characteristics | | | |
| Origin | | | |
| Scene of injury | 211/466 (45.3%) | 683/695 (98.3%) | <0.001 |
| Other | 255/466 (54.7%) | 12/695 (1.7%) | |
| Distance from injury site (mean miles) | 15.6 ± 17.6 (n = 348) | 20.8 ± 21.8 (n = 661) | <0.001 |
| Injury type | | | |
| Penetrating | 17/466 (3.6%) | 53/695 (7.6%) | 0.005 |
| Blunt | 449/466 (96.4%) | 642/695 (92.4%) | |
| Glasgow Coma Scale < 15 | 9/438 (2.1%) | 153/694 (22.0%) | <0.001 |
| Injury Severity Score > 15 | 11/466 (2.4%) | 81/694 (11.7%) | <0.001 |
| Abbreviated Injury Scale severity >2 | | | |
| Head/neck | 40/466 (8.6%) | 160/695 (23.0%) | <0.001 |
| Face | 0/466 (0%) | 0/695 (0%) | N/A |
| Chest | 5/466 (1.1%) | 48/695 (6.9%) | <0.001 |
| Abdomen/pelvic contents | 3/466 (0.6%) | 36/695 (5.2%) | <0.001 |
| Extremities | 49/466 (10.5%) | 112/695 (16.1%) | 0.007 |
| External | 0/466 (0%) | 0/695 (0%) | N/A |
| Hospital course | | | |
| Daytime presentation | 256/465 (55.1%) | 414/695 (59.6%) | 0.13 |
| Weekend presentation | 134/466 (28.8%) | 232/695 (33.4%) | 0.10 |
| Trauma activation | 11/466 (2.4%) | 599/695 (86.2%) | <0.001 |
| ED LOS (h) | 5.9 ± 2.6 | 4.8 ± 2.9 | <0.001 |
| Hospital LOS (d) | 1.5 ± 1.8 | 3.9 ± 7.2 | <0.001 |
| ED disposition | | | |
| Floor | 395/466 (84.8%)* | 429/695 (61.7%)* | <0.001 |
| Intensive care unit | 28/466 (6.0%)* | 179/695 (25.8%)* | |
| Operating room | 43/466 (9.2%) | 87/695 (12.5%) | |
| Final disposition | | | |
| Home | 451/466 (96.8%)* | 632/695 (90.9%)* | <0.001 |
| Foster care | 9/466 (1.9%) | 7/695 (1.0%) | |

(continued)

Table 1 – (continued)

| | Self-transport (n = 466) | EMS(n = 695) | P value |
|---------------------------------|--------------------------|----------------|---------|
| Inpatient rehab/skilled nursing | 4/466 (0.9%)* | 41/695 (5.9%)* | |
| Death | 0/466 (0%)* | 8/695 (1.2%)* | |
| Other | 2/466 (0.4%) | 7/695 (1.0%) | |

Final disposition “other” includes acute care hospital, residential facility, psychiatric hospital, jail, and specialty referral center.

*P < 0.05 for post hoc pairwise comparison of columns for each variable subcategory for self-transport versus EMS groups.

nearly half of the study population, yet this group represented only 1.8% of all trauma activations, and trauma team activation was associated with EMS arrival in multivariate analyses. Our data suggest that trauma team activation may be underutilized in some self-transport patients, particularly in patients who require immediate operating room or ICU-level care. The difference in the frequency of trauma activation between these groups of hospitalized trauma patients is larger than expected and should be a focus of quality improvement efforts.

The cost of trauma team underutilization (i.e., inappropriately low activation rates) may include delay to definitive care, delay in subspecialty consultation, unnecessary testing, and worse outcomes.¹² Both the underutilization and overutilization of the trauma team has implications for the individual patient and hospital system when the primary aim is to deliver efficient, high-quality care for all patients.

The Cribari calculation has been used as a method to evaluate undertriage and overtriage rates, but we were unable to calculate this metric because of the lack of access to some necessary variables in this retrospective study.¹⁰ This metric is based on ISS, which interestingly was not associated with

trauma activation in our multivariate analysis. Prior studies have evaluated trauma team activation and worked to move undertriage and overtriage rates into the goal range as determined by the American College of Surgeons.^{11,13} One group found that the creation of an updated, standardized trauma team activation criteria led to improvements in undertriage and overtriage.¹¹ Using the Cribari metric in future studies will help to address our concern of possibly high undertriage rates in self-transport patients.

Trauma team activation was associated with GCS <15 but not with ISS >15. Because GCS is used as trauma activation criteria, the frequency of trauma activation is influenced by abnormal GCS. Although ISS is associated with mortality,¹⁴ the limitations of using ISS as a predictor of mortality are well known. ISS is an anatomical scoring system based on body region that may underestimate injury severity especially when more than one severe injury occurs in a given body region.¹⁵ These factors may explain the lack of association between ISS and trauma team activation.

We found demographic differences between patients arriving by self-transport and EMS, including differences in age, sex, race, and ethnicity. Self-transport patients were

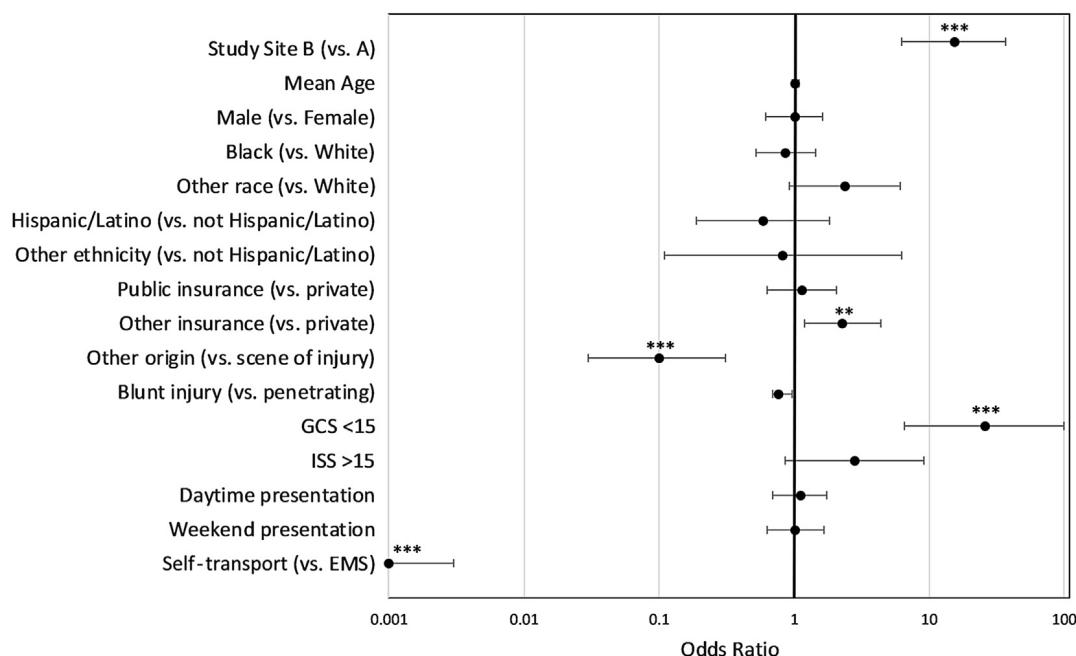


Fig – Multivariate logistic regression showing estimated odds ratios of trauma activation for admitted pediatric trauma patients. Likelihood of trauma activation was associated with site B, origin, GCS <15, and self-transport. Trauma activation was not significantly associated with age, sex, race, ethnicity, private versus public insurance, injury type, ISS >15, and daytime or weekend presentation. Error bars represent 95% confidence interval. *P < 0.05, **P ≤ 0.01, ***P ≤ 0.001.

younger and more likely to be female and Hispanic/Latino compared with EMS patients. Consistent with our findings, prior studies have found lower rates of EMS use for Hispanic/Latino patients compared with white or black patients of all ages.^{16,17} Reasons for this increased use of self-transport in the Hispanic population may include possible bias of or by EMS use, proximity to a level 1 trauma center, or cultural factors. The identification of this population as more likely to use self-transport for serious injury may help to target future public health interventions.

Similar to previous studies, we found a larger than expected proportion of pediatric patients arriving by self-transport with injuries severe enough to require hospital admission.^{18,19} A study in Singapore of pediatric patients with ISS >8 found even higher rates of self-transport compared with our study. Differences between our findings may be due to access to EMS, distance to trauma center, injury severity cutoff, or other cultural differences.²⁰

Several confounding variables may have influenced patient disposition and arrival mode. The number of EMS and their differing criteria for transport (*versus* a recommendation for self-transport) may have influenced the proportion of patients arriving as self-transport. Given the large number of EMS and variability in the decisions of individual providers to recommend self-transport, it is not possible to measure this source of variability. Another consideration is whether payor status may have influenced patient disposition; however, insurance status is often not known when injured children are treated in the ED at each site. In addition, because both sites are designated pediatric trauma centers, transfer to other facilities rarely occurs at these sites, so insurance status is less likely to influence outcomes.

We found significant variability in patient characteristics and outcomes between sites in initial analyses, including arrival mode and proportion of trauma activation; however, study site was adjusted for in our regression analyses. Differences between sites may reflect differences in private vehicle ownership, proximity of the served population to the trauma center, institutional practices for trauma management, patient population, and actual rates of and public perception of ambulance use. In addition, variability may occur in data entry into pediatric trauma registries. Trauma registries may not capture all trauma patients discharged from the ER and may be biased to include patients who require hospital admission or trauma team activation.

Study site B had a higher proportion of self-transport patients, a lower median ISS, a longer ED and shorter hospital LOS, and high association with trauma activation compared with site A. Both are large urban academic medical centers located about 40 miles apart within cities of population size of about 600,000. Site A is embedded in a populous underserved residential neighborhood. This center is physically located at the same site of adult inpatient and outpatient medical care. Within this city, there are also multiple surrounding community hospitals that serve the local communities. Site B is located in a less residential area and is more difficult to access by walking and public transportation. This center is a free-standing children's hospital and only provides care for children and adolescents. At site B, 24.0% of patients identified as Hispanic/Latino, a group who has previously been shown to

have a higher rate of self-transport arrival, compared with site A that had only 3.2% of patients identifying as Hispanic/Latino. These differences between the location of these sites, their position within the medical community, and the populations that each serve may explain the observed differences in modes of transport. Differences in institutional practice such as criteria for admission may also account for differences observed between each site. Given the diversity of injuries and their associated management, it is not feasible within this study to account for institutional differences. Our findings highlight the need for consensus approaches for treating injured children who arrive by self-transport.

This study has several limitations. First, this study was based on retrospective data manually entered into each site's trauma registry. Second, although two sites were included in the study, the use of sites in relative geographical proximity to each other may limit generalizability of the results. Third, institutional practices for the evaluation and management of injured patients and entry into the trauma registry may vary among the sites. One way that we minimized variability due to potential site differences was to include only more seriously injured patients with injuries resulting in hospital admission. Fourth, data were rarely absent in the trauma registries, including the distance traveled from injury site. The estimation of travel from injury site was calculated using injury ZIP code, which may have overestimated or underestimated actual distance traveled. Factors such as traffic or method of self-transport (e.g., via car, public transportation, bike, or ambulation) may also affect time, route, and distance traveled.

Conclusions

Our findings provide perspective that can be used to optimize the care of trauma patients arriving by self-transport, including addressing factors such as the longer ED LOS and the low proportion of trauma activation. Assessing the triage, nursing, and physician workflow for injured patients who arrive by self-transport is needed to ensure prompt recognition and management of injuries, including trauma team activation as appropriate. In summary, these data show that a significant proportion of pediatric trauma patients who require hospital admission arrive by self-transport, yet they constitute a low proportion of trauma team activation even when controlling for demographic and clinical confounders. Trauma team activation may be underutilized in self-transport patients who require hospital admission, especially in those who require immediate operating room or ICU level care. Further evaluation of the triage and trauma team activation process for injured children arriving by self-transport is needed to ensure appropriate utilization of resources.

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Authors' contributions: L.M.R., J.H.R., and R.S.B. conceived study and designed the trial. D.S. and R.S.B. supervised the

conduct of the trial and data collection. O.Z.A., R.S.B., and D.S. undertook recruitment of participating centers and patients and managed the data, including quality control. G.Y. provided statistical advice on study design, and J.H.R., L.M.R., and R.S.B. analyzed the data; L.M.R. chaired the data oversight committee. J.H.R. drafted the manuscript, and all authors contributed substantially to its revision.

Disclosure

The authors have no conflicts of interest to disclose.

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