

Patient, hospital and regional characteristics associated with undertriage of injured children in California (2005–2015): a retrospective cohort study

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ABSTRACT

Background/objective Trauma centers save lives, but they are scarce and concentrated in urban settings. The population of severely injured children in California who do not receive trauma center care (undertriage) is not well understood.

Methods Retrospective observational study of all children (0–17 years) hospitalized for severe trauma in California (2005–2015). We used the California Office of Statewide Health Planning and Development linked Emergency Department and Inpatient Discharge data sets. Logistic regression models were created to analyze characteristics associated with undertriage. The model was clustered on differential distance between distance from residence to primary triage hospital and distance from residence to nearest trauma center. We controlled for body part injured, injury type, intent and year. The *a priori* hypothesis was that uninsured and publicly insured children and hospitals and regions with limited resources would be associated with undertriage.

Results Twelve percent (1866/15 656) of children with severe injury experienced undertriage. Children aged >14 years compared with 0–13 years had more than 2.5 times the odds of undertriage (OR 2.58; 95% CI 2.1 to 3.16). Children with private Health Maintenance Organization (HMO) insurance compared with public insurance had 13 times the odds of undertriage (OR 12.62; 95% CI 8.95 to 17.79). Hospitals with >400 compared with <200 beds had more than three times the odds of undertriage (OR 3.64; 95% CI 2.6 to 5.11). Urban versus suburban residence had 1.3 times increased odds of undertriage (OR 1.31; 95% CI 1.02 to 1.67). Undertriage volume was largest in urban areas.

Conclusion Undertriage is associated with private HMO insurance, primary triage to large hospitals and urban residence. Understanding the characteristics associated with undertriage can help improve trauma systems.

Level of evidence Level III (non-experimental retrospective observational study).

BACKGROUND

Although pediatric and adult trauma centers have been demonstrated to save lives,^{1–3} trauma is still the number one cause of morbidity and mortality for children and young adults. Trauma centers are hospitals which have demonstrated a commitment to 24/7 trauma care with required facilities, resources, staff and systems. Trauma center levels (I, II, III and IV) indicate resources available and

volume. Although all trauma centers should be able to stabilize a child with severe trauma, pediatric trauma centers have special services (eg, pediatric intensive care; subspecialty expertise, equipment) and experience to care for children <14 years. In 2005, California had 46 level I and II, 8 level III/IV trauma centers and 11 pediatric trauma centers.

A trauma system attempts to organize and coordinate the complex process of trauma care. A trauma system (1) receives a trauma call, (2) dispatches Emergency Medical Services (EMS) personnel to the field who (3) use protocols to resuscitate and stabilize patients and (4) triage and transport patients to the appropriate facility to get 'the right patient to the right place at the right time'. However, California does not have a fully coordinated statewide trauma system. Instead, 33 local EMS agencies administer trauma services for 58 counties with guidance from the California Emergency Medical Services Authority (EMSA). Patients with severe trauma would ideally experience primary triage (triage from location of injury to the initial hospital of care) to a trauma center. However many factors, including the fact that trauma centers are relatively scarce and concentrated in urban areas, can result in severely injured patients experiencing primary triage to a non-trauma hospital. Once a patient is triaged to a non-trauma hospital, although they can be transferred, this transfer occurs at the discretion of the provider and is generally outside of the auspices of the trauma system. Thus, a significant minority of children with severe traumatic injury may be 'undertriaged' or never cared for in a pediatric or even adult trauma center. The objective of this analysis was to calculate the prevalence of pediatric trauma undertriage, as well as patient, hospital and regional characteristics associated with undertriage. The *a priori* hypothesis was that uninsured and publicly insured children, and hospitals and regions with limited resources, for example, small hospitals and rural residence, would be associated with increased probability of undertriage.

METHODS

We conducted a retrospective analysis of characteristics associated with pediatric undertriage by using emergency department (ED) and inpatient linked records during the study period. We adhered to the Strengthening the Reporting of Observational Studies in Epidemiology reporting guideline in the reporting of our results and the discussion.⁴

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Data and population

We used California Office of Statewide Health Planning and Development (OSHPD) ED and Inpatient Discharge linked data sets to conduct a retrospective observational study of all children (0–17 years) hospitalized for severe trauma with International Classification of Disease, Ninth Revision (ICD-9) codes (800–904.9, 910–929.0, and 950–959.9) from 2005 to Q3 of 2015 (ICD-10 diagnosis coding was adopted in Q4 of 2015). There is no EMS data available in this data set. Likewise, specific trauma data such as ‘mode of transport’ and ‘trauma activation level’ found in trauma databases curated by registrars at trauma centers are not available.

As an indicator of injury severity, we used the Injury Severity Score (ISS), an anatomic, consensus-based measure of injury severity, which is widely used in trauma research and quality assurance. ISS was derived from ICD-9 codes using validated methods.^{5 6} ISS >15 was designated as severe injury per the American College of Surgeons.⁷ Children with burns, injuries associated with pregnancy and perinatal conditions, late effects of injury, non-California residents and scheduled admissions were excluded per our usual methods,⁸ resulting in a total of 15 656 severely injured children during the study period. For the purposes of this study, we then focused our analysis on the population of children with primary triage to an adult non-trauma hospital (n=3405). Transfers were identified per the methods of Staudenmayer *et al*⁹ allowing 2 days for either ED or hospital transfer due to the inexact timestamp of OSHPD, as well as the fact that transfers processes could take longer than 24 hours in rural areas. Zip code of patient residence was used as a proxy for injury location per usual practice as validated by Myers *et al*.¹⁰ Distance from patient residence to the hospital was calculated using direct line distance between centroid of patient residence zip code to the actual location of the hospital according to our usual methods, as validated by Phibbs *et al*¹¹ and Bliss *et al*.¹²

We chose to identify trauma centers according to county EMS agency ‘designation,’ (as opposed to American College of Surgeons verification) since the local EMS agency has ultimate jurisdiction over county trauma triage protocols, including where patients with severe injuries are transported. Given the relatively long, 11-year study period, all hospitals’ status as adult and pediatric level I/II trauma centers, adult III/IV trauma centers and pediatric and adult non-trauma hospitals were identified from the California EMSA website¹³ and verified for each study year. Pediatric non-trauma centers were defined as hospitals not designated as a trauma center, but which belonged to the Children’s Hospital Association. Because adult level III/IV trauma centers are established in areas with scarce resources with the aim of functioning in collaboration with level I/II trauma centers and pediatric non-trauma centers serve as de facto specialty centers; the few patients receiving care at level III/IV and pediatric non-trauma centers (n=282/15656 (1.8%) and n=593/15656 (3.8%), respectively) were not considered undertriaged. We defined the primary outcome as a severely injured child (ISS>15) who never received trauma center care after primary triage to an adult non-trauma hospital (undertriage).

Independent variables

We stratified patient age according to standard developmental stages: 0–364 days, 1–3, 4–13, 14–17 years of age.³ Race and ethnicity were categorized as a single variable with the following categories: white non-Hispanic, black non-Hispanic, Hispanic, Asian/Pacific Islander and other. Insurance status was categorized as: public or government, private non-HMO, private HMO

insurance, no insurance or self-pay and other. Urban, suburban and rural status was designated by the metropolitan statistical area (MSA) of the county of patient residence.¹⁴

Statistical analysis

We tabulated frequencies and proportions of demographic and injury, hospital and regional characteristics grouped by trauma specialty status of the hospitals where initial and definitive care was received. We examined the subgroup of children with primary triage to an adult non-trauma hospital for the primary outcome of odds of undertriage using multiple logistic regression. The initial model consisted of patient (age categories, sex, race/ethnicity, payer status), injury (body part injured, mechanism, intent), hospital (size, teaching and profit status) and regional characteristics (trauma center within the county, trauma center within the local EMS agency and county rurality). We developed different clustering models to account for the differential trauma center access influenced by the variability of resources based on geography. We ultimately used a model that was clustered on differential distance between distance from residence to primary triage hospital and distance from residence to nearest trauma center ((distance from residence to location of primary triage) – (distance from residence to nearest trauma center)). No common interaction effects (race/ethnicity, payer, poverty and MSA) were identified as significant; thus, none were included in the model. We controlled for body part injured, injury type, intent and year. Records with missing data comprised less than 5% of records and were not included in the model. All variables were checked to confirm a normal distribution, linearity of continuous variables and additivity of effects. Model assumptions were verified, including functional form, random distribution of residuals and outliers. P values <0.05 were a priori designated as statistically significant.

Due to the fact that older adolescents are often treated as adults and cared for in adult trauma centers, a sensitivity analysis was performed with patient age less than 14 years repeating the same methods. Analysis was performed using SAS V.9.4 and STATA V.14 for Windows.

RESULTS

During the study period, 3405 of the 15 656 (21.7%) children (0–17 years) hospitalized with severe trauma (ISS>15) experienced primary triage to an adult non-trauma hospital. Of these patients, 1866 of the 3405 (54.8%) children were not transferred to trauma center care, resulting in a statewide undertriage rate of 1866 of 15 656 (11.9%) (table 1). The median age of children experiencing primary triage to a non-trauma hospital and of those children ultimately undertriaged was 13.0 years (IQR 4.0–16.2) and 14.6 years (IQR 7.0–16.7), respectively.

Children aged >14 years comprised the majority of children with primary triage to an adult trauma center (1513 of 3405 children, 44.4%). Of these children, 38.5%, 34.3% and 23.0% had public, private non-HMO and private HMO insurance, respectively; 39.8% and 45.5% of children experienced primary triage to a hospital with less than 200 beds and 200–399 beds, respectively. Interestingly, although 40.2% of children from rural counties experienced primary triage to an adult non-trauma hospital, they comprised only 4.5% of the population with primary triage to a non-trauma hospital. For children with primary triage to an adult non-trauma center, the median distance of the patient resident zip code to the nearest trauma center was more than double the distance to the primary triage hospital 12.4 (IQR 5.9–25.8) versus 5.5 (IQR 2.5–12) miles.

Table 1 Characteristics of severely injured (ISS>15) children with primary triage to an adult non-trauma center, and those subsequently undertriaged in California from 2005 to 2015 (N=15 656)

Characteristic	Grand total	Trauma center	Adult non-trauma center	Undertriage*
N	15 656	12 251 (78.3%)	3405 (21.7%)	1866 (11.9%)
Age category				
Age median (IQR)	12.8 (4.1–16.2)	12.8 (4.1–16.3)	13.0 (4.0–16.2)	14.6 (7.0–16.7)
0–364 days	2027 (12.9%)	1551 (12.7%)	476 (14.0%)	207 (11.1%)
1–3 years	1287 (8.2%)	1022 (8.3%)	265 (7.8%)	104 (5.6%)
4–13 years	5441 (34.8%)	4290 (35.0%)	1151 (33.8%)	536 (28.7%)
14–<18 years	6901 (44.1%)	5388 (44.0%)	1513 (44.4%)	1019 (54.6%)
Gender				
Female	4662 (29.8%)	3719 (30.4%)	943 (27.7%)	489 (26.2%)
Male	10 991 (70.2%)	8529 (69.6%)	2462 (72.3%)	1377 (73.8%)
Race/ethnicity				
White non-Hispanic	5228 (33.4%)	3770 (30.8%)	1458 (42.8%)	755 (40.5%)
Black non-Hispanic	1233 (7.9%)	989 (8.1%)	244 (7.2%)	143 (7.7%)
Hispanic	6769 (43.2%)	5498 (44.9%)	1271 (37.3%)	722 (38.7%)
Asian, Pacific Islander	802 (5.1%)	592 (4.8%)	210 (6.2%)	113 (6.1%)
Other	837 (5.3%)	725 (5.9%)	112 (3.3%)	57 (3.1%)
Missing	787 (5.0%)	677 (5.5%)	110 (3.2%)	76 (4.1%)
Payer status				
Public	8481 (54.2%)	7170 (58.5%)	1311 (38.5%)	491 (26.3%)
Private	4835 (30.9%)	3668 (29.9%)	1167 (34.3%)	646 (34.6%)
Private HMO	1710 (10.9%)	926 (7.6%)	784 (23.0%)	643 (34.5%)
Self	522 (3.3%)	394 (3.2%)	128 (3.8%)	78 (4.2%)
Length of stay				
Days, median (IQR)	4 (2–9)	4 (2–10)	3 (2–6)	3 (1–6)
Mortality				
Died	915 (5.8%)	774 (6.3%)	141 (4.1%)	87 (4.7%)
Died <48 hours.	566 (3.6%)	475 (3.9%)	91 (2.7%)	60 (3.2%)
Trauma center in LEMSA of residence	14 762 (94.3%)	12 110 (98.8%)	2652 (77.9%)	1514 (81.1%)
Patient county MSA designation				
Urban (large central metro)	9177 (58.6%)	7445 (60.8%)	1732 (50.9%)	1163 (62.3%)
Suburban (large fringe, medium and small metro)	6096 (38.9%)	4577 (37.4%)	1519 (44.6%)	661 (35.4%)
Rural (micropolitan/non-core)	383 (2.4%)	229 (1.9%)	154 (4.5%)	42 (2.3%)
Distance to hospital in miles, median (IQR)				
From zip code of residence to trauma center	7.4 (3.6–18.4)	6.5 (3.4–15.1)	12.4 (5.9–25.8)	10.3 (5.1–22.7)
From zip code of residence to Primary Triage Hospital	9.5 (4–22.5)	10.5 (5–26)	5.5 (2.5–12)	7.5 (3–15.5)
Hospital size				
<200 beds	2316 (14.8%)	962 (7.9%)	1354 (39.8%)	457 (24.5%)
200–399 beds	6813 (43.5%)	5264 (43.0%)	1549 (45.5%)	1033 (55.4%)
>400 beds	6477 (41.4%)	6012 (49.1%)	465 (13.7%)	361 (19.3%)
LOS in days, median (IQR)	4 (2–9)	4 (2–10)	3 (2–6)	3 (1–6)

Undertriage is a subset of those triaged to an adult non-trauma center and are not part of grand total

HMO, Health Maintenance Organization; ISS, Injury Severity Score; LEMSA, Local Emergency Medical Services Agency; LOS, length of stay; MSA, Metropolitan Statistical Area.

Regression analysis demonstrated that children aged >14 years compared with children aged 0–13 years had more than twice the odds of undertriage (OR 2.58; 95% CI 2.1 to 3.16) (table 2). Children with private HMO insurance compared with children with public insurance had 13 times the odds of undertriage (OR 12.62; 95% CI 8.95 to 17.79); those without insurance and those with private non-HMO insurance had approximately double the odds of undertriage compared with those with public insurance (OR 2.43; 95% CI 1.53 to 3.87; OR 1.93; 95% CI 1.55 to 2.4, respectively). Hospitals with >400 beds compared with <200 beds had more than three times increased odds of undertriage (OR 3.64; 95% CI 2.6 to 5.11). Non-rural hospitals compared with rural hospitals had more than 1.5 times the odds of undertriage (OR 1.56; 95% CI 1.08 to 2.27). Residence in an

urban versus suburban area had greater odds of undertriage (OR 1.31; 95% CI 1.02 to 1.67), whereas rural residence was not associated with undertriage (table 2). Although similar proportions of children were undertriaged across urban, suburban and rural residences, the absolute number of children undertriaged in urban settings was 27 times greater than in rural settings (figure 1).

Because in some areas, children >14 years are not considered part of the pediatric trauma system, we conducted a sensitivity analysis of all severely injured children <14 years (n=8775), of which 1892 (21.6%) experienced primary triage to an adult non-trauma center. After allowing for transfer, 847 remained in a non-trauma center, resulting in an undertriage rate of 847 of 8755 (9.7%) (data available on request). Children 4–13 years

**Table 2** Characteristics associated with undertriage of severely injured (ISS>15) children of all ages using multiple logistic regression analysis clustered on differential distance between distance from residence to primary triage hospital and distance from residence to nearest trauma center

Characteristic	Multiple Logistic Regression Model, Outcome of Under-triage			
	All ages		Ages 0–13	
	Odds Ratio (95% CL)	P-value	Odds Ratio (95% CL)	P-value
Age, years				
0–13	reference			
0–364 days	NA		0.86 (0.61–1.21)	0.387
1–3	NA		0.92 (0.62–1.37)	0.685
4–13	NA		reference	
14–<18	2.58 (2.1–3.16)	<0.0001		
Male sex	0.9 (0.73–1.11)	0.324	0.93 (0.71–1.23)	0.615
Race/Ethnicity				
White Non-Hispanic	reference		reference	
Black Non-Hispanic	1.27 (0.87–1.84)	0.218	1.1 (0.64–1.91)	0.727
Hispanic	1.37 (1.1–1.72)	0.006	1.54 (1.12–2.1)	0.008
Asian, Pacific Islander	0.92 (0.62–1.36)	0.671	0.75 (0.45–1.24)	0.254
Other or Missing	1.02 (0.61–1.7)	0.948	1.17 (0.61–2.22)	0.643
Payer				
Public	reference		reference	
Private	1.93 (1.55–2.4)	<0.0001	1.6 (1.17–2.2)	0.003
Private HMO*	12.62 (8.95–17.79)	<0.0001	17.8 (11.1–28.7)	<0.0001
Self-Insured	2.43 (1.53–3.87)	0.001	4.2 (2.1–8.42)	<0.0001
Patient County MSA† designation				
Urban (Large central metro)	1.31 (1.02–1.67)	0.031	1.47 (1.05–2.05)	0.026
Suburban (Large fringe, Medium and Small metro)	reference		reference	
Rural Micropolitan/Noncore	0.8 (0.48–1.33)	0.379	1.1 (0.48–2.53)	0.829
Trauma Center in County of Residence	0.94 (0.74–1.2)	0.628	0.74 (0.53–1.03)	0.077
Hospital size				
<200 beds	reference		reference	
200–399 beds	3.76 (3.01–4.69)	<0.0001	6.05 (4.31–8.49)	<0.0001
>400 beds	3.64 (2.6–5.11)	<0.0001	5.42 (3.37–8.73)	<0.0001
Nonrural Hospital	1.56 (1.08–2.27)	0.019	1.01 (0.55–1.88)	0.965
Model Information				
c-statistic	0.82		0.85	

P values <0.05 were a priori designated as statistically significant. Model adjusted for year, body part injured, injury type and mechanism. designated as statistically significant. model adjusted for year, body part injured, injury type and mechanism.

*LEMSA: Local Emergency Medical Services Agency

†MSAMetropolitan Statistical Area

of age comprised 60.8% of those with primary triage to a non-trauma center. Of these children, 44.3, 29.4% and 22.6% had public, private non-HMO and private HMO insurance, respectively; 38.0% and 46.6% of children experienced primary triage to a hospital with less than 200 beds and 200–399 beds, respectively. Although 39.5% of children <14 years from rural counties experienced primary triage to an adult non-trauma hospital; they comprised only 4.3% of the population with primary triage to an adult non-trauma hospital.

Regression modeling of children <14 years demonstrated that age was not associated with undertriage (table 2) (). Hispanic children had increased odds of undertriage (OR 1.54; 95% CI 1.1 to 2.1). Children with private HMO insurance compared with public insurance had almost 18 times the odds of undertriage (OR 17.8; 95% CI 11.1 to 28.7); those private non-HMO and without insurance had 1.5 and four times odds of undertriage compared with those with public insurance (OR 1.6; 95% CI 1.17 to 2.2 and OR 4.2; 95% CI 2.1 to 8.42, respectively).

Hospitals with 200–399 and >400 beds compared with hospitals with <200 beds had more than five times increased

odds of undertriage (6.05 OR 95% CI 4.31 to 8.49; 5.42 OR 95% CI 3.37 to 8.73 respectively). Although non-rural hospitals compared with rural hospitals did not have significantly increased undertriage, residence in an urban versus suburban area had greater odds of undertriage (OR 1.47; 95% CI 1.05 to 2.05).

DISCUSSION

In California, a large, diverse state that is home to 1 of 8 US children,¹⁵ 11.9% of severely injured children 0–17 years of age and 9.7% of those 0–13 years of age are undertriaged, approximately twice the American College of Surgeons Committee on Trauma's recommended undertriage benchmark of 5%.⁷ Once a child experiences primary triage to an adult non-trauma hospital, a significant minority are never transferred to a trauma center and experience undertriage. Contrary to our hypothesis, private HMO insurance, primary triage to urban hospitals, hospitals with >200 beds, and urban county of residence were associated with undertriage for all children, as well as for those <14 years.

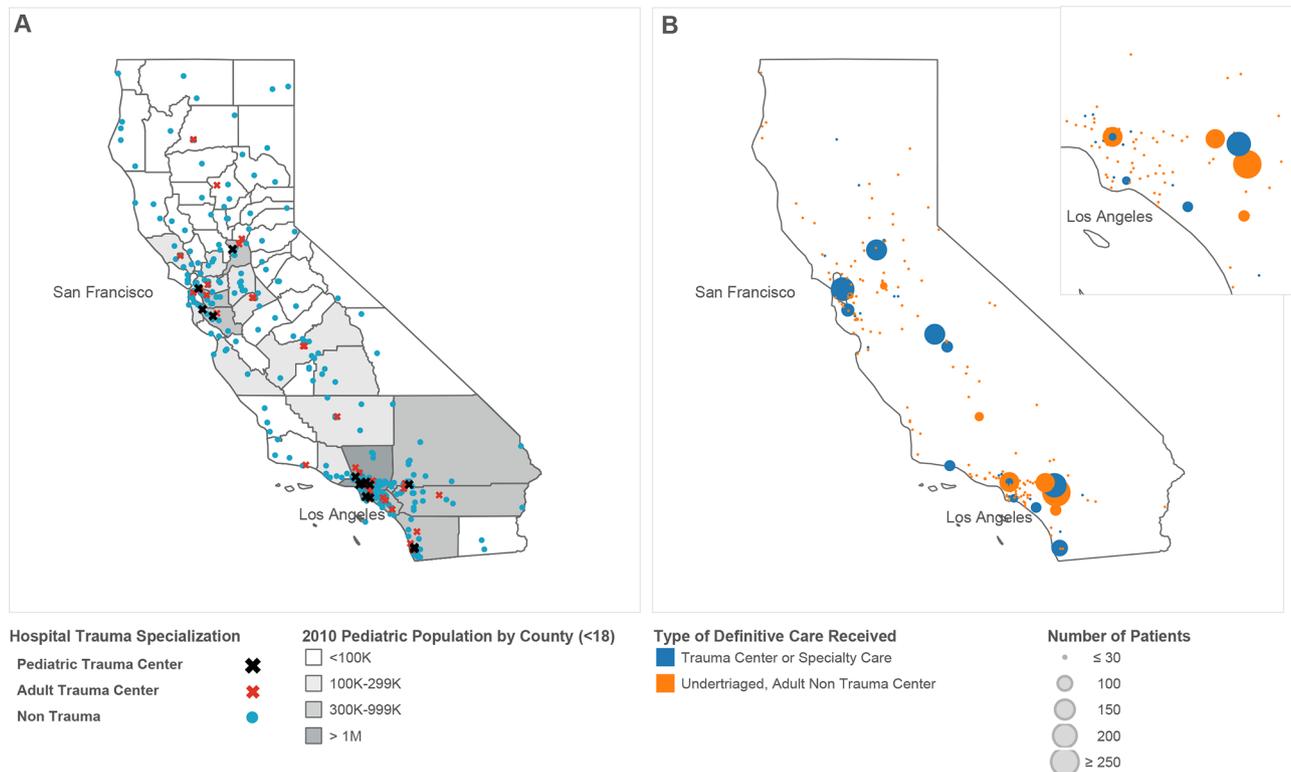


Figure 1 Map of (A) California hospital types by trauma specialization and 2010 pediatric populations and (B) Location of definitive care received by severely injured children (ISS > 15) with primary triage to...

Our analyses are the only ones, of which we are aware, that examine the most severely injured children (ISS > 15), differentiate between private HMO and private non-HMO insurance and are able to consider regional characteristics. These distinctions are important. Although there may be controversy regarding the appropriateness of requiring trauma center care in the setting of scarce resources, it is generally accepted that the most critically injured children (ISS > 15) should receive specialty trauma care.⁷

Our findings, and others,⁹ demonstrate that the location of primary triage is critical because it often becomes the location of definitive care. Although a severely injured patient can be triaged from the field to a non-trauma hospital for many reasons including lack of local resources juxtaposed with need for acute stabilization, local EMS agency protocol, EMS personnel error and patient request, many are never subsequently transferred to a trauma center. Interfacility transfer of a trauma patient can be difficult due to lack of a system and guidelines. It can also be logistically difficult for a busy ED practitioner to coordinate calling the appropriate trauma center to obtain acceptance of a severely injured trauma patient while caring for an ED full of patients as well as resuscitating and stabilizing the trauma patient.

Other studies have demonstrated that private insurance and lack of insurance have been associated with undertriage.^{16 17} We add nuance with our analyses in considering private HMO and private non-HMO insurances separately. HMO systems educate their patients to go to an HMO hospital and actively repatriate patients as soon as they are stable. HMO insurance is often affiliated with large hospitals within a hospital system with potentially more resources than private non-HMO affiliated hospitals; thus, HMO systems can possibly provide a level of care not available in single private hospitals. These hospital systems may not transfer patients because they are larger, more

resourced and may have the expertise to care for severely injured children (eg, pediatric neurosurgeon); however, if these HMO/hospital systems have not made the commitment to become verified trauma centers within the county, the actual resources available, the quality of care and the outcomes of these children are not known. However, with the knowledge provided by our findings, potentially trauma systems could work with HMOs to explicitly identify severely injured pediatric patients who should be transferred to the trauma center, to educate/collaborate with providers or at least to share trauma data for quality and outcome analyses.

We analyzed the contribution of regional characteristics to undertriage with some degree of detail. We had hypothesized that undertriage would occur in rural areas due to lack of resources and potentially long travel times with severely injured patients. However, rural EMS systems appear to accomplish primary triage and transfer of severely injured children to trauma centers despite longer travel distances. Although primary triage may occur to adult non-trauma hospitals, severely injured patients are then transferred appropriately to a trauma center. Thus, even in the setting of scarce resources, undertriage is not associated with rural residence. However, we found that the largest absolute numbers of undertriaged patients are associated with larger, non-rural hospitals in metropolitan areas. Thus, given that in our study, geography and resources are not the major characteristics associated with undertriage, our findings point to the need for improved trauma system coordination for appropriate triage and monitoring in suburban and metropolitan areas. Larger hospitals and urban hospitals may believe they have resources to care for an injured child, but they have not fulfilled the requirements to become a trauma center. Likewise, they may not have the resources and expertise to provide long-term, family-centered care to a patient, for example, rehabilitation care.

Children who are undertriaged are a vulnerable population. These children are ‘invisible’ to the trauma system and there is no simple method to understand the number of undertriaged children, their characteristics, quality of care or outcomes. Although it is important to make allowances for hospital capability and regional resources and variation, it must be remembered these are the most severely injured children who have the most to benefit from trauma care.

Limitations

Our study is based on only one state; however, we believe that this population-wide analysis of a large, varied state using analysis on a patient, hospital and regional level, is applicable to the variability in trauma care access found throughout the USA. Limitations inherent with administrative data sets apply, although this is the only method to obtain a population perspective of patterns of regionalization. We use distance variables based on patient zip code according to our previous and validated methods^{3 8 12}; however, we acknowledge these distance measures are imprecise, and zip codes could have changed during the time period of our study.

CONCLUSION

We identified characteristics associated with a population of severely injured children who are undertriaged in a large and varied state. These analyses demonstrate the success that EMS and regionalization protocols have accomplished for rural areas. Identification of the association of private HMO insurance with undertriage can inform collaboration of private HMO insurance systems with trauma centers and promote sharing of data. The finding that the largest volume of undertriage occurs in suburban and urban areas with readily available resources demonstrates the need to perhaps better regulate policy and protocols in suburban and urban areas. This knowledge of patient, hospital and system contributions to undertriage of severely injured children can result in the development of targeted reporting, quality assessment and improvement of programmes. Our findings are also potentially hypothesis generating, for future clinical studies targeted towards specific populations.

Contributors NEW conceived the study, obtained research funding, designed, conducted, analysis, drafted the initial manuscript, reviewed and revised the manuscript. EP designed and conducted analysis, reviewed and revised the manuscript. CN and DS aided in the interpretation of the analyses and reviewed the manuscript for important intellectual content. All authors approved the final manuscript as submitted and agree to be accountable for all aspects of the work.

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