Patient Safety Events in Out-of-Hospital Pediatric Airway Management: A Medical Record Review by the CSI-EMS

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Patient Safety Events in Out-of-Hospital Pediatric Airway Management: A Medical Record Review by the CSI-EMS

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ABSTRACT

Objective

To describe the frequency and characterize the nature of patient safety events in pediatric out-of-hospital airway management.

Methods

We conducted a retrospective medical record review of all “lights and sirens” Emergency Medicine Services (EMS) transports over 4 years in patients less than 18 years of age in a large metropolitan area. A chart review tool was adapted from landmark patient safety studies and revised after pilot testing. Expert panels of physicians and paramedics performed blinded reviews of each chart, identified safety events, and described their nature. The primary outcomes were presence and severity of patient safety events related to airway management including oxygen administration, bag-valve-mask ventilation (BVM), airway adjuncts, and endotracheal intubation (ETI).

Results

From a total of 11,328 pediatric transports, we identified 497 “lights and sirens” (code 3) transports (4.4%). Seven were excluded due to missing data. Overall, 329 patients had airway management procedures: 61.6% were treated with oxygen, 15.3% with BVM, 8.6% with ETI, and 2% with airway adjuncts. The frequency of errors was: 21% (71/338) related to oxygen use, 9.8% (33/338) related to BVM, 9.5% (32/338) related to intubation, and 0.9% (3/338) related to airway adjunct use. Fifty-eight percent of intubations required 3 or more attempts or failed
altogether. Cardiac arrest was independently associated with higher odds of a severe error (OR 74.09, 95% CI 1.09 – 15.3).

Conclusions

Errors in pediatric out-of-hospital airway management are common, especially in the context of intubations and during cardiac arrest.

Strengths and Limitations of the Study:

Strengths:

This study provides an in depth look at pediatric out-of-hospital airway management from a patient safety perspective. It uses a rigorously developed chart review process. It provides a more detailed description of the types of errors that take place and thus gives providers specific targets for quality improvement. This paper looks at airway management from a broad perspective rather than focusing on an individual procedure.

Limitations:

This study was conducted in a large urban area in the United States with many paramedics and short response times and may not apply to other geographical areas. This is a retrospective study.
INTRODUCTION

The US National Quality Forum defines “Patient Safety” as: the prevention and mitigation of harm caused by errors of omission or commission that are associated with healthcare...[1] The patient safety movement in medicine, triggered by retrospective studies of clinical care, started two decades ago and has triggered massive efforts to improve care in hospital based medicine.[2,3] Out-of-hospital care, in particular pediatric care, has little published literature regarding patient safety and the nature of safety events is largely unknown, limiting our ability to improve care on a system-based level.

Airway management is a critical component of resuscitation during many pediatric emergencies and includes a set of technical procedures that are potentially high risk for errors. The skillset required for pediatric out-of-hospital airway management includes oxygen administration, bag-valve-mask ventilation (BVM), oral and nasal airway insertion, supraglottic device insertion, and endotracheal intubation (ETI). ETI has long been considered “definitive” airway management for patients of any age and is practiced by many EMS agencies throughout the world.[4] Pediatric ETI is taught in paramedic training programs and is part of the US National Registry of Emergency Medical Technicians (NREMT) practical examination.[5]

Although pediatric ETI is considered an essential skill for paramedics, the single existing controlled trial found no benefit compared to BVM, and reported harm in some subgroups.[6] Other studies have demonstrated low success rates for pediatric out-of-hospital ETI and increased complications compared to in-hospital ETI.[7–10] In addition, paramedics perform pediatric ETI infrequently, perhaps only once every 5 years, and rapidly lose skills after training.[11][12,13] As a result of these factors, ETI for children in the out-of-hospital setting is
controversial. There are little data on other aspects of out-of-hospital pediatric airway management such as airway adjuncts and supraglottic devices. Several existing pediatric studies have been conducted in patient simulators and found high success rates, however an adult study on the laryngeal mask airway demonstrated high success in patients simulators (100%) with substantially lower success in practice (64%). [14–17] A national Delphi study recently found that pediatric airway management is a critical unmet educational need for paramedics and that airway management is the most high risk scenario for errors in pediatric out-of-hospital care.[18,19] Another recent study performed in a large national database found that intubation remains the most commonly used pediatric advanced airway technique out-of-hospital with lower success rates than in adults, with the lowest success being among patients less than 1 year of age.[20] Though this study addressed success rates it did not include detailed review of the charts and was thus unable to identify the rates of specific types of errors in airway management such as tube depth, tube size, and the potential harm associated with the errors.

The objective of this study is to describe the rates and nature of patient safety events related to pediatric out-of-hospital airway management in a cohort of critically ill pediatric transports from a large metropolitan area.

METHODS

Study Design and Setting:

This study represents one portion of the CSI-EMS using a chart review designed to capture a broad range of potential and manifest safety events. The Children’s Safety Initiative-EMS (CSI-EMS) is a National Institutes of Health (NICHD R01HD062478) funded mixed-methods study. The goal of the CSI-EMS is to identify, describe and classify the occurrence of safety events in
out-of-hospital pediatric emergency care.[21] We sub classified safety events as: unintended injury or consequences, near misses, suboptimal actions, errors, and management complications.

In this report, we present a retrospective medical record review of individual EMS transports in the Portland, Oregon (USA) metropolitan area. This metro area has a “dual advanced life support (ALS)” system where separate ALS fire and transport agencies respond to all calls. The transport and fire agencies in this study serve a population of over 700,000 residents. Airway management procedures in scope of practice in this system include oxygen administration, BVM, oral and nasal airways, supraglottic airways (King LT), and ETI including rapid sequence intubation (RSI). The cardiac arrest survival in Portland, OR is among the highest in the US, with EMS treated cardiac arrest survival of 10.4% reported in a 2008 study using the Resuscitation Outcomes Consortium sites. These high survival rates likely result from rapid response times and an effective (or ‘high-functioning’) EMS system.[22]

The transport agency units respond with 2 paramedics in each ambulance. Fire units include 4-5 person teams with at least 1 paramedic per team. Though fire units respond to each call, the transporting units can elect to dismiss them. If the fire department responders do not intervene, they do not complete a chart. In this system, fire units respond to 90% of calls in less than 7 minutes and transport units respond to 90% of calls in less than 8 minutes. Fire department crews work in 24-hour shifts. All transport paramedics work rotating shifts and experienced paramedics are equally distributed during all times of day.

Paramedics in this system are all required to participate in annual airway management training using simulation with adult, pediatric, and infant mannequins. In addition to this training, they are all required to maintain Pediatric Advanced Life Support certification. There were no specific
protocols designating which paramedic among those responding would perform the intubation. The protocol for pediatric intubation at the time of the study called for using BVM or a rescue device if 2 attempts at intubation failed. However, at the time of the study, the King LT was the rescue device being used and it was not available in sizes suitable for most children under the age of 8. Providers did have access to oral and nasal airways in all pediatric sizes.

**Selection of Participants:**

We reviewed records for transports from 2008-2011 for all patients less than 18 years of age which were transported “code 3” (lights and sirens) indicating a critical transport. This transport priority is used at the discretion of the treating providers for patients felt to have a life or limb threatening condition. Reviews included charts from the transporting agency, and when applicable, the fire response unit. This group was chosen to identify a subset of patients more likely to need and receive interventions.

**Chart Review Tool Development**

Our chart review tool and review methods were based on forms from the Harvard Medical Practice Study and the Utah and Colorado Medical Practice Study that were the foundation for the Institute of Medicine Report on patient safety in medicine.[23] In turn, the chart review tool was adjusted to the out-of-hospital setting based on results from our EMS focus group study.[21][2,3] The tool was iteratively revised and finalized in several rounds of testing which included “talk aloud” sessions and pilot reviews using 30 sample EMS charts.

Given the lack of data defining patient safety events in pediatric EMS, the presence or absence of a safety event was based on judgment of the expert chart reviewers. Given the somewhat subjective nature of judging certain potential safety events each chart was reviewed in tandem by
both a paramedic and Emergency Physician using a standardized review tool. A Pediatric Emergency Physician with expertise in pediatric EMS performed a third review to arbitrate differences between the initial reviews. Chart reviewers could not be blinded to the study objectives since the review tool specifically focused on safety events. However, reviewers were blinded to results of all interim analysis and study hypotheses. All chart reviewers received a 2-hour training session on the chart review tool, completed test cases before and after the session, and were provided feedback on their test reviews. Based on results of test reviews and questions during feedback sessions a guidebook was created and provided to all reviewers as a resource to ensure consistency and quality. Reviews were completed online via SurveyMonkey™. The expert chart review panel consisted of 13 paramedics and 7 physicians who were not affiliated with the agencies submitting charts for review. Paramedic reviewers were recruited by word of mouth in the local EMS community, and physician reviewers included Emergency Physicians who work in the pediatric ED of the metro area’s academic medical/trauma center and provide online medical control and one pediatrician.

As a final quality control measure, all charts were arbitrated by one of two pediatric emergency physician investigators with experience in EMS. Inter-rater reliability was established between the two pediatric emergency physician investigators prior to arbitration. A kappa statistic of 0.615 was achieved between the two arbiters on the presence of safety events in the various domains. Following the initial blinded review to establish inter-rater reliability, the arbiters met and discussed all discrepancies in the reviews to achieve consensus.

The review tool was designed to identify errors in the following domains: resuscitation; assessment, impression/diagnosis, and clinical decision making; airway/breathing; fluids and medication; procedures; equipment; environment; and system. Where available, data was
abstracted from the chart electronically (scene time, transport time, time of day). Through a
series of checkboxes, Likert-type questions, and open-ended responses, the reviewers manually
abstracted chart data not available electronically including age, sex, weight, scene location, and
transport priority. The reviewers then identified details of care including the dispatch complaint,
clinical impression, all procedures performed including airway management procedures, whether
or not an error occurred with any of the procedures or in other specific domains, details about the
nature and cause of the error, and the degree of potential harm to the patient. The degrees of
harm were assessed by the chart review tool using the following question: Using your best
clinical judgement, to what degree could the (specific domain inserted eg. airway management)
issue have harmed the patient. The following were the potential responses: 1) no harm likely or a
near miss, 2) mild or temporary harm, including additional treatment, and 3) permanent or severe
harm including death.

Analysis

First, we identified the cohort of patients who had airway management procedures including
oxygen administration, BVM, airway adjuncts (oral, nasal, supraglottic airways), and
endotracheal intubation out of the complete study population of critical transports as indicated by
the chart reviewers. Next, we performed a descriptive analysis of the age, sex, scene location,
and dispatch complaint of all patients who had airway management interventions. We then
described the clinical impression of the paramedics documented in the electronic patient care
report in cases where airway management procedures were performed. We then identified all
patients who had an error in airway management indicated by the reviewers. The reviewers also
described the potential severity of harm caused by each error using three categories including
“no harm,” “mild or temporary harm,” and “permanent or severe harm including death” using
their best judgment based on the information available in the EMS patient care report. The reviewers described the nature of the error using a free text field where problems such as “tube too deep” could be entered. The list of independent variables included in the initial analysis is in the left sided column of Table 2. This list of variables was created based on a priori hypotheses developed by the study team of factors we felt could be associated with errors based on the experience of EMS professionals on the team as well as previous studies. We used univariate logistic regression to calculate odds ratios, 95% confidence intervals, and p-values using the Wald F statistic for each independent variable and the outcome of an error judged to have the potential for severe harm. Independent variables found to be moderately associated with severe harm errors (p<0.2) in the univariate analysis were used to form a multiple logistic regression model to control for potential confounding. This multivariate logistic regression model was used to estimate adjusted odds ratios, 95% confidence intervals, and p-values for the regression coefficients.

The study team reviewed the free text responses regarding the specific nature of the airway management errors (eg. tube too deep) and then divided them into specific categories. In addition, one study team member reviewed each cardiac arrest chart and abstracted the airway intervention and medication administration times from the event log in the patient care report to perform an analysis of the time to first epinephrine administration in patients who had advanced airway attempts vs. those who did not as well as total time spent prior to securing the airway (defined as the interval between time of first patient contact and documented success of ETI). The Institutional Review Board from Oregon Health & Science University approved all study components (IRB Number 00006942). Analysis was conducted using SAS software version 9.4 (SAS Institute Inc., Cary, NC, USA).
RESULTS

From a total of 11,328 pediatric transports during the study period, we identified 497 “code 3” transports (4.4%). We eliminated 2 transports due to missing data and 5 transports because we were unable to obtain the associated fire department chart, leaving a total of 490 charts for review. Table 1 presents the characteristics of the 490 pediatric patients and details for those who received specific airway interventions. Approximately two-thirds of patients transported code 3 had an airway management intervention of some kind (329/490, 67%). Of those transported code 3, 61.6% (302/490) were treated with oxygen, 15.3% (75/490) with BVM, 8.6% with ETI (42/490), and 2.0% (10/490) with airway adjuncts. Half of all intubations (21/42) were performed in children less than 12 months of age. The most common reason for dispatch among patients with airway management procedures was cardiopulmonary arrest followed by trauma. In contrast, the most common reason for dispatch in the entire study population was trauma, followed by nearly equal proportions of interfaculty transports and seizures/altered level of consciousness.
Table 1. Characteristics of patients who had airway management procedures

<table>
<thead>
<tr>
<th>Age</th>
<th>All Patients</th>
<th>Any Airway Management</th>
<th>Oxygen</th>
<th>BVM(^a)</th>
<th>Airway Adjuncts</th>
<th>Intubation</th>
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<tbody>
<tr>
<td></td>
<td>N = 490</td>
<td>N = 329</td>
<td>N = 302</td>
<td>N = 75</td>
<td>N = 10</td>
<td>N = 42</td>
</tr>
<tr>
<td></td>
<td>n (%)</td>
<td>n (%)</td>
<td>n (%)</td>
<td>n (%)</td>
<td>n (%)</td>
<td>n (%)</td>
</tr>
<tr>
<td>0-28 days</td>
<td>23 (4.7)</td>
<td>18 (5.5)</td>
<td>12 (4.0)</td>
<td>7 (9.3)</td>
<td>0 (0.0)</td>
<td>6 (14.3)</td>
</tr>
<tr>
<td>29 days – 11 months</td>
<td>61 (12.5)</td>
<td>50 (15.2)</td>
<td>41 (13.6)</td>
<td>22 (29.3)</td>
<td>3 (30.0)</td>
<td>15 (35.7)</td>
</tr>
<tr>
<td>12 months – 5 years</td>
<td>169 (34.5)</td>
<td>117 (35.6)</td>
<td>110 (36.4)</td>
<td>19 (25.3)</td>
<td>0 (0.0)</td>
<td>6 (14.3)</td>
</tr>
<tr>
<td>6-11 years</td>
<td>84 (17.1)</td>
<td>56 (17.0)</td>
<td>55 (18.2)</td>
<td>7 (9.3)</td>
<td>1 (10.0)</td>
<td>2 (4.8)</td>
</tr>
<tr>
<td>12 – 17 years</td>
<td>153 (31.2)</td>
<td>88 (26.8)</td>
<td>84 (27.8)</td>
<td>20 (26.7)</td>
<td>6 (60.0)</td>
<td>13 (31.0)</td>
</tr>
<tr>
<td>Female</td>
<td>195 (39.8)</td>
<td>134 (40.7)</td>
<td>120 (39.7)</td>
<td>33 (44.0)</td>
<td>3 (30.0)</td>
<td>20 (47.6)</td>
</tr>
<tr>
<td>Scene Location</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
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<tr>
<td>Home</td>
<td>219 (44.7)</td>
<td>174 (52.9)</td>
<td>154 (51.0)</td>
<td>51 (68.0)</td>
<td>6 (60.0)</td>
<td>31 (73.8)</td>
</tr>
<tr>
<td>School</td>
<td>25 (5.1)</td>
<td>9 (2.7)</td>
<td>9 (3.0)</td>
<td>3 (4.0)</td>
<td>1 (10.0)</td>
<td>1 (2.4)</td>
</tr>
<tr>
<td>Street/Highway</td>
<td>117 (23.9)</td>
<td>64 (19.5)</td>
<td>63 (20.9)</td>
<td>10 (13.3)</td>
<td>1 (10.0)</td>
<td>7 (16.7)</td>
</tr>
<tr>
<td>Hospital/Clinic</td>
<td>110 (22.5)</td>
<td>69 (21.0)</td>
<td>63 (20.9)</td>
<td>9 (12.0)</td>
<td>0 (0.0)</td>
<td>2 (4.8)</td>
</tr>
<tr>
<td>Recreation/Sport</td>
<td>14 (2.9)</td>
<td>10 (3.0)</td>
<td>10 (3.3)</td>
<td>2 (2.7)</td>
<td>2 (20.0)</td>
<td>1 (2.4)</td>
</tr>
<tr>
<td>Other</td>
<td>5 (1.0)</td>
<td>3 (0.9)</td>
<td>3 (1.0)</td>
<td>0 (0.0)</td>
<td>0 (0.0)</td>
<td>0 (0.0)</td>
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<td>First Responder</td>
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<td></td>
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<tr>
<td>Ambulance</td>
<td>183 (37.4)</td>
<td>129 (39.2)</td>
<td>119 (39.4)</td>
<td>33 (44.0)</td>
<td>3 (30.0)</td>
<td>18 (42.9)</td>
</tr>
<tr>
<td>Fire</td>
<td>181 (36.9)</td>
<td>129 (39.2)</td>
<td>119 (39.4)</td>
<td>33 (44.0)</td>
<td>3 (30.0)</td>
<td>18 (42.9)</td>
</tr>
<tr>
<td>Police</td>
<td>14 (2.9)</td>
<td>6 (1.8)</td>
<td>6 (2.0)</td>
<td>0 (0.0)</td>
<td>0 (0.0)</td>
<td>1 (2.4)</td>
</tr>
<tr>
<td>Unknown</td>
<td>112 (22.9)</td>
<td>73 (22.2)</td>
<td>65 (21.5)</td>
<td>22 (29.3)</td>
<td>2 (20.0)</td>
<td>10 (23.8)</td>
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<tr>
<td>Reason for Dispatch</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Cardiopulmonary Arrest</td>
<td>35 (7.1)</td>
<td>35 (10.6)</td>
<td>19 (6.3)</td>
<td>33 (44.0)</td>
<td>5 (50.0)</td>
<td>26 (61.9)</td>
</tr>
<tr>
<td>Trauma</td>
<td>203 (41.4)</td>
<td>94 (28.6)</td>
<td>91 (30.1)</td>
<td>11 (14.7)</td>
<td>2 (20.0)</td>
<td>10 (23.8)</td>
</tr>
<tr>
<td>Seizure or ALOC(^b)</td>
<td>107 (21.8)</td>
<td>95 (28.9)</td>
<td>93 (30.8)</td>
<td>17 (22.7)</td>
<td>1 (10.0)</td>
<td>2 (4.8)</td>
</tr>
<tr>
<td>Ingestion/Poisoning/Intoxication</td>
<td>29 (5.9)</td>
<td>15 (4.6)</td>
<td>15 (5.0)</td>
<td>4 (5.3)</td>
<td>2 (20.0)</td>
<td>2 (4.8)</td>
</tr>
<tr>
<td>Respiratory Distress</td>
<td>79 (16.1)</td>
<td>73 (22.2)</td>
<td>68 (22.5)</td>
<td>9 (12.0)</td>
<td>0 (0.0)</td>
<td>2 (4.8)</td>
</tr>
<tr>
<td>Allergic Reaction/Anaphylaxis</td>
<td>11 (2.2)</td>
<td>7 (2.1)</td>
<td>7 (2.3)</td>
<td>1 (1.3)</td>
<td>0 (0.0)</td>
<td>0 (0.0)</td>
</tr>
<tr>
<td>Pain (non-trauma)</td>
<td>12 (2.5)</td>
<td>5 (1.5)</td>
<td>5 (1.7)</td>
<td>0 (0.0)</td>
<td>0 (0.0)</td>
<td>0 (0.0)</td>
</tr>
<tr>
<td>Other</td>
<td>14 (2.9)</td>
<td>5 (1.5)</td>
<td>4 (1.3)</td>
<td>0 (0.0)</td>
<td>0 (0.0)</td>
<td>0 (0.0)</td>
</tr>
</tbody>
</table>

\(^a\)BVM = Bag-Valve-Mask Ventilation

\(^b\)ALOC = Altered Level of Consciousness
Overall, 27.8% of charts with airway management (94/338) were judged to have airway management errors. Errors were related to oxygen use in 21% of cases (71/338), to BVM in 9.8% (33/338), to airway adjunct use in 0.9% (3/338), and to ETI in 9.5% (32/338). Nine percent of cases had errors in more than one aspect of airway management.

Over 70% of cases in which ETI was performed contained an error of some type. The specific nature of errors relating to ETI were: ETT placed too deep in 25% of cases, incorrect ETT size used in 29% (78% of the time too small), and dislodgement of the ETT during transport in 13% of cases. Reviewers felt that 24% of the time, ETI was not indicated when performed. The most common type of error in ETI was technical difficulty with the procedure, accounting for 58% of errors, defined as failure to secure ETI or requiring three or more attempts.

The most common clinical scenario in which ETI was performed was cardiac arrest. In cardiac arrest scenarios, intubation was attempted 74% of the time. On average, in cardiac arrest cases where ETI was attempted the mean time to the first dose of epinephrine was 11 minutes. In cases where ETI was not attempted, the mean time to the first dose of epinephrine was 7 minutes. In addition, in cases where ETI was attempted, 10 minutes passed on average prior to securing an airway or abandoning further attempts. This may indicate that on average providers conclude advanced airway management prior to administration of epinephrine.

Further analysis of other types of airway management errors found that 48% of the time, oxygen was administered when it was not indicated, and 32% of the time oxygen was not administered when it was indicated. Errors related to BVM were most commonly due to lack of use when indicated or failure to attempt for a long enough period prior to performing ETI. Airway adjuncts
were infrequently used (n=10) and all errors identified were related to lack of use when indicated, rather than inappropriate use or a complication related to their use.

Figure 1 presents the distribution of errors in airway management by age. Neonates had the highest rate of severe errors followed by infants, with a trend towards decreased rate of severe errors with increasing age. Figure 2 shows the level of harm of the errors according to airway management procedures. Intubation had the highest rate of severe errors among the airway management procedures.

Errors in airway management were commonly associated with errors in other domains of care. In cases with any airway management error 64% had errors in decision making, 62% in resuscitation, and 48% in medications (p < 0.01 for all). In cases where there were errors in BVM or ETI more than 90% of cases also had an error identified in resuscitation, over 65% had errors in assessment/decision-making, and over 60% had errors in medications (p < 0.01 for all).

We performed univariate analyses to identify factors associated with severe airway management errors (Table 2). In these unadjusted analyses, an increased risk of a severe error related to airway management was strongly associated with patient age less than 28 days (OR 6.62, 95% CI 1.68 – 26.03), less than 12 months (OR = 5.73, 95% CI 1.91 – 17.20) patients in cardiopulmonary arrest (OR = 15.61, 95% CI 5.65 – 43.12), fire department involvement (fire department team and transport team both provided significant care) (OR = 2.75, 95% CI 1.30-5.82), and calls occurring between 10pm and 8am (OR=2.21, 95% CI 1.05-4.62).
Table 2. Univariate analysis of factors associated with a severe airway management error

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>Odds Ratio</th>
<th>95% CI</th>
<th>P Value</th>
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<td><strong>Patient Characteristic</strong></td>
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<tr>
<td>Age</td>
<td></td>
<td></td>
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<tr>
<td>0-28 days</td>
<td>6.62</td>
<td>1.68 – 26.03</td>
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<tr>
<td>29 days – 11 months</td>
<td>5.73</td>
<td>1.91 – 17.20</td>
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<td>1-5 years</td>
<td>1.07</td>
<td>0.33- 3.47</td>
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<tr>
<td>6 – 11 years</td>
<td>1.65</td>
<td>0.46 – 5.99</td>
<td>0.44</td>
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<tr>
<td>12–17 years (reference category)</td>
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<tr>
<td><strong>Gender</strong></td>
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<tr>
<td>Male</td>
<td>0.79</td>
<td>0.39 – 1.60</td>
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<td><strong>Call Characteristic</strong></td>
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<tr>
<td>Reason for Dispatch</td>
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<td></td>
<td></td>
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<tr>
<td>Trauma (reference category)</td>
<td>1</td>
<td>--</td>
<td>--</td>
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<tr>
<td>Seizure or ALOCc</td>
<td>0.14</td>
<td>0.02 – 1.12</td>
<td>0.06</td>
</tr>
<tr>
<td>Respiratory Distress</td>
<td>1.4</td>
<td>0.47 – 4.16</td>
<td>0.55</td>
</tr>
<tr>
<td>Cardiorespiratory Arrest</td>
<td>15.61</td>
<td>5.65 – 43.12</td>
<td>&lt;0.0001</td>
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<tr>
<td>Ingestion/Poisoning/Intoxication</td>
<td>--</td>
<td>--</td>
<td>--</td>
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<tr>
<td>Other (including Birth/Delivery)</td>
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<tr>
<td>Pain (non-trauma)</td>
<td>--</td>
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<tr>
<td>Allergic Reaction/Anaphylaxis</td>
<td>2.19</td>
<td>0.23 – 20.83</td>
<td>0.5</td>
</tr>
<tr>
<td><strong>Fire Department Involvement</strong></td>
<td></td>
<td></td>
<td></td>
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<tr>
<td>(fire chart)</td>
<td>2.75</td>
<td>1.30 – 5.82</td>
<td>0.008</td>
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<td><strong>Call During the Night</strong></td>
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<tr>
<td>(10pm-8am)</td>
<td>2.21</td>
<td>1.05 – 4.62</td>
<td>0.04</td>
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<tr>
<td><strong>Scene Time</strong></td>
<td></td>
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<tr>
<td>(per one minute increase)</td>
<td>1.03</td>
<td>0.99 – 1.07</td>
<td>0.14</td>
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<tr>
<td><strong>Transportation Time</strong></td>
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<tr>
<td>(per one minute increase)</td>
<td>0.96</td>
<td>0.91 – 1.01</td>
<td>0.10</td>
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</table>

*338 observations (338 out of 490 charts reviewed; airway error information not available for 152 charts)

b336 observations (gender not available for two charts)

cALOC= Altered Level of Consciousness

d337 observations (scene time not available for one chart)

In multivariate analyses (Table 3), age < 12 months remained statistically significant and the effect size of cardiopulmonary arrest was reduced, although it remained a strong and significant predictor of severe airway management errors (OR = 4.09, 95% CI 1.09 – 15.3). The results of the multiple regression model discussed above are displayed in Table 3. Table 3. Adjusted odds ratios from multivariate logistic regression of factors associated with a severe airway management errora,b
Table 3. Multivariate analysis of factors associated with a severe airway management error\(^a\)

<table>
<thead>
<tr>
<th>Characteristics</th>
<th>Odds Ratio</th>
<th>95% CI</th>
<th>P Value</th>
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<tr>
<td><strong>Patient Characteristic</strong></td>
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<td></td>
<td></td>
</tr>
<tr>
<td>Age</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Newborn (0-28 days) or infant (29 days through 11 months)</td>
<td>7.96</td>
<td>1.42 – 44.6</td>
<td>0.02</td>
</tr>
<tr>
<td>1-5 years</td>
<td>3.49</td>
<td>0.69 – 17.7</td>
<td>0.13</td>
</tr>
<tr>
<td>6-11 years</td>
<td>3.21</td>
<td>0.49 – 21.2</td>
<td>0.23</td>
</tr>
<tr>
<td><strong>Call Characteristic</strong></td>
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<tr>
<td>Reason for Dispatch</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Cardiorespiratory Arrest</td>
<td>4.09</td>
<td>1.09 – 15.3</td>
<td>0.04</td>
</tr>
<tr>
<td>Seizure or ALOC(^c,d)</td>
<td>--</td>
<td>--</td>
<td></td>
</tr>
<tr>
<td>Respiratory Distress</td>
<td>0.69</td>
<td>0.19 – 2.54</td>
<td>0.58</td>
</tr>
<tr>
<td>Allergic Reaction/Anaphylaxis(^d)</td>
<td>--</td>
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<td></td>
</tr>
<tr>
<td><strong>EMS Scene Care</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Fire department involvement</td>
<td>3.89</td>
<td>1.32 – 11.4</td>
<td>0.01</td>
</tr>
<tr>
<td>Night call</td>
<td>4.42</td>
<td>1.48 - 13.2</td>
<td>0.008</td>
</tr>
<tr>
<td>Scene time in minutes</td>
<td>1.05</td>
<td>0.98 - 1.12</td>
<td>0.15</td>
</tr>
</tbody>
</table>

\(^a\)203 observations (out of 490 charts, after excluding certain call reason categories in addition to the charts with missing info on airway errors, gender, and scene time); Cox and Snell R-Square = 0.22 Nagelkerke R-Square = 0.38

\(^b\)One outlier with a standardized deviance residual of 2.46 was removed from the final model.

\(^c\)ALOC= Altered Level of Consciousness

\(^d\)Only one case of severe airway error was identified in each of these categories, and therefore these categories were not included in the multivariate analysis.
DISCUSSION

In this analysis we found that airway management errors are relatively common, occurring in >25% of cases where airway management was performed, and that a high proportion of errors had the potential to cause severe patient harm. Patients less than 12 months of age and those with cardiac or respiratory arrest were at highest risk for severe airway management errors and were the patient populations who most commonly needed airway management. Of airway management procedures, ETI had the highest proportion of errors and required three or more attempts or was unsuccessful 58% of the time bringing into question the safety of this procedure. Airway adjuncts and BVM were judged to be under-utilized.

Several previous investigations have documented pediatric ETI success rates from 50 to 100%, and major complications between 1.8% and 50%.[24–27] The only controlled trial on out-of-hospital pediatric ETI found no benefit compared to BVM but has been criticized for inadequate training.[6] Our study also provides additional insight into the nature of ETI related errors by identifying incorrect tube size, incorrect tube depth, multiple attempts, failure to successfully place the tube, and unnecessary intubation as the specific types of errors.

We also found that patients with cardiac arrest had significantly increased odds of an airway management error. In these cases, EMS providers may face cognitive and emotional overload.[28] Similar to our study, an analysis of more than 10 years of data from San Diego, California found that the majority of pediatric out-of-hospital intubations are for cardiac arrest, indicating this is an important area of focus.[29]

Infants experience a disproportionate portion of airway management errors. The airway anatomy of children less than 1 year of age differs substantially from that of older children. In addition,
the small size of the patient makes performing simultaneous interventions such as airway management and CPR challenging. In cases with airway management errors, we also found high rates of errors in resuscitation, assessment/decision-making, and medication administration. This indicates that airway management errors are not likely due to one specific skill deficit, but while multiple critical decisions and interventions are being performed quickly.

One reason pediatric ETI may not benefit patients is that the potential advantages of an endotracheal tube securing the airway are mitigated by procedural complications and by detrimental effects on other aspects of resuscitation. A recent study done in the Emergency Department found that significant adverse events increase rapidly with the number of intubation attempts.[30] We found that in cases of cardiac arrest, on average, ETI was being performed prior to administration of epinephrine, which contradicts American Heart Association guidelines.[31,32] This suggests that ETI may have a negative effect on other important components of out-of-hospital pediatric resuscitation.

Our analysis adds to the literature by evaluating a broad range of airway interventions. We found that BVM and airway adjuncts were at times not used when indicated. Previous simulation studies have found technical problems with prehospital BVM which may reflect the challenging nature of this procedure in children or lack of experience in its use.[33,34] In addition, BVM in pediatric patients may be resource intensive and require two providers to achieve adequate mask seal.

Airway adjuncts such as supraglottic devices, OPAs, and NPAs appear to be used very infrequently in children, even when indicated. Simulation-based studies have shown high success rates with supraglottic devices in pediatric manikins placed by EMS providers and may be a promising solution.[16,35]
Limitations:

Our study has several limitations. First, it was conducted in a single metropolitan area. Next this is a retrospective study and limited to the data available in the medical record. Also our reliance on the written record likely underestimates errors.[36] Though a standard definition was used, assessment of harm was based on the judgment of chart reviewers and is inherently subjective, although this practice has been used in other landmark patient safety studies.[2,3] Finally, this study was conducted in a well-developed EMS system with short response times utilizing paramedics as initial responders to all calls, and with a relatively high cardiac arrest survival.[22] Our findings may not be generalizable to other EMS systems.

In conclusion, our study finds high error rates in pediatric out-of-hospital airway management. ETI was the modality associated with the highest rate of errors, and the youngest patients as well as those with cardiopulmonary arrests were at highest risk of errors. These findings raise serious concerns about the safety of advanced airway management procedures. Future directions for this work could include expanding this research to other types of EMS systems and conducting prospective trials assessing the efficacy of different airway management strategies.
Contributorship statement
MH contributed to the design of the study, and analysis of data, and writing of the manuscript. GM and WL and JMG contributed to the design of the study, development of data collection tools, collection, validation, and analysis of data, and critical review of the manuscript. CK and KD contributed to the design of the study, development of data collection tools, collection, validation, and analysis of data and provided critical review of the manuscript. JVO contributed to the analysis of data and provided critical review of the manuscript.

Competing Interests
All authors had financial support from the National Institute of Child Health and Human Development (NICHD) grant (R01HD062478) for the submitted work; no financial relationships with any organizations that might have an interest in the submitted work in the previous three years; no other relationships or activities that could appear to have influenced the submitted work.

Funding
This work is supported by the National Heart Lung and Blood Institute (NHLBI) grant number 5K12HL108974-03. This work is also supported by the National Institute of Child Health and Human Development grant: “Epidemiology of Preventable Safety Events in Pre-hospital EMS of Children,” Grant # 1R01HD062478-04. The content is solely the responsibility of the authors and does not necessarily represent the official views of the National Heart, Lung, and Blood Institute, the National Institute of Child Health and Human Development, or the National Institutes of Health. All researchers had independence from the funder with regard to design, conduct, and analysis of the study.

Data Sharing
There is no additional data available

PRISMA Guidelines
This paper follows the STROBE guidelines for observational research.
References:


17 Michael J Murray MJV. Evaluation of prehospital insertion of the laryngeal mask airway by primary care paramedics with only classroom mannequin training. CJEM 2002;4:338–43.


Figure Legends:

Figure 1. Severity of airway management errors by patient age. 02: oxygen; BVM: Bag-Valve-Mask Ventilation

Figure 2. Severity of airway management errors by type of procedure. 02=oxygen; BVM = Bag-Valve-Mask Ventilation
Figure 1. Severity of airway management errors by patient age. 02: oxygen; BVM: Bag-Valve-Mask Ventilation
Figure 2. Severity of airway management errors by type of procedure. O2 = oxygen; BVM = Bag-Valve-Mask Ventilation
STROBE Statement—checklist of items that should be included in reports of observational studies

<table>
<thead>
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<th>Item No</th>
<th>Recommendation</th>
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<tbody>
<tr>
<td><strong>Title and abstract</strong></td>
<td><em>(a) Indicate the study’s design with a commonly used term in the title or the abstract. Page 1</em></td>
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<tr>
<td></td>
<td><em>(b) Provide in the abstract an informative and balanced summary of what was done and what was found Page 2</em></td>
</tr>
<tr>
<td><strong>Introduction</strong></td>
<td><em>(a) Expect the scientific background and rationale for the investigation being reported Page 5</em></td>
</tr>
<tr>
<td><strong>Objectives</strong></td>
<td><em>(a) State specific objectives, including any prespecified hypotheses Page 5</em></td>
</tr>
<tr>
<td><strong>Methods</strong></td>
<td><em>(a) Present key elements of study design early in the paper Pages 5-6</em></td>
</tr>
<tr>
<td></td>
<td><em>(b) Describe the setting, locations, and relevant dates, including periods of recruitment, exposure, follow-up, and data collection Pages 6-7</em></td>
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<tr>
<td><strong>Participants</strong></td>
<td><em>(a) Cohort study—Give the eligibility criteria, and the sources and methods of selection of participants. Describe methods of follow-up</em></td>
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<td><em>(a) Case-control study—Give the eligibility criteria, and the sources and methods of case ascertainment and control selection. Give the rationale for the choice of cases and controls</em></td>
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<td>Cross-sectional study—Give the eligibility criteria, and the sources and methods of selection of participants Page 7</td>
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<td><em>(b) Cohort study—For matched studies, give matching criteria and number of exposed and unexposed N/A</em></td>
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<td><em>(c) Case-control study—For matched studies, give matching criteria and the number of controls per case</em></td>
</tr>
<tr>
<td><strong>Variables</strong></td>
<td><em>(a) Clearly define all outcomes, exposures, predictors, potential confounders, and effect modifiers. Give diagnostic criteria, if applicable Page 8-9</em></td>
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<tr>
<td><strong>Data sources/measurement</strong></td>
<td><em>(a) For each variable of interest, give sources of data and details of methods of assessment (measurement). Describe comparability of assessment methods if there is more than one group Page 7, page 8-9</em></td>
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<tr>
<td><strong>Bias</strong></td>
<td><em>(a) Describe any efforts to address potential sources of bias Page 9-10</em></td>
</tr>
<tr>
<td><strong>Study size</strong></td>
<td><em>(a) Explain how the study size was arrived at Page 7</em></td>
</tr>
<tr>
<td><strong>Quantitative variables</strong></td>
<td><em>(a) Explain how quantitative variables were handled in the analyses. If applicable, describe which groupings were chosen and why Pages 9-10</em></td>
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<tr>
<td><strong>Statistical methods</strong></td>
<td><em>(a) Describe all statistical methods, including those used to control for confounding Pages 9-10</em></td>
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<td><em>(b) Describe any methods used to examine subgroups and interactions N/A</em></td>
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<td><em>(c) Explain how missing data were addressed Page 11</em></td>
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<td><em>(d) Cohort study—If applicable, explain how loss to follow-up was addressed</em></td>
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<td><em>(Case-control study—If applicable, explain how matching of cases and controls was addressed</em></td>
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<td>Cross-sectional study—If applicable, describe analytical methods taking account of sampling strategy N/A</td>
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<td><em>(e) Describe any sensitivity analyses N/A</em></td>
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Continued on next page
Results

Participants 13* (a) Report numbers of individuals at each stage of study—eg numbers potentially eligible, examined for eligibility, confirmed eligible, included in the study, completing follow-up, and analysed Page 11

(b) Give reasons for non-participation at each stage Page 11

(c) Consider use of a flow diagram

Descriptive data 14* (a) Give characteristics of study participants (eg demographic, clinical, social) and information on exposures and potential confounders Table 1

(b) Indicate number of participants with missing data for each variable of interest Page 11

(c) Cohort study—Summarise follow-up time (eg, average and total amount) N/A

Outcome data 15* Cohort study—Report numbers of outcome events or summary measures over time

Case-control study—Report numbers in each exposure category, or summary measures of exposure

Cross-sectional study—Report numbers of outcome events or summary measures Table 1

Main results 16 (a) Give unadjusted estimates and, if applicable, confounder-adjusted estimates and their precision (eg, 95% confidence interval). Make clear which confounders were adjusted for and why they were included Table 2

(b) Report category boundaries when continuous variables were categorized Table 2

(c) If relevant, consider translating estimates of relative risk into absolute risk for a meaningful time period

Other analyses 17 Report other analyses done—eg analyses of subgroups and interactions, and sensitivity analyses Table 3

Discussion

Key results 18 (a) Summarise key results with reference to study objectives Page 17

Limitations 19 (a) Discuss limitations of the study, taking into account sources of potential bias or imprecision. Discuss both direction and magnitude of any potential bias Page 19

Interpretation 20 (a) Give a cautious overall interpretation of results considering objectives, limitations, multiplicity of analyses, results from similar studies, and other relevant evidence Page 17-18

Generalisability 21 (a) Discuss the generalisability (external validity) of the study results Page 19

Other information

Funding 22 (a) Give the source of funding and the role of the funders for the present study and, if applicable, for the original study on which the present article is based Page 20

*Give information separately for cases and controls in case-control studies and, if applicable, for exposed and unexposed groups in cohort and cross-sectional studies.

# Patient Safety Events in Out-of-Hospital Pediatric Airway Management: A Medical Record Review by the CSI-EMS

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<td>Complete List of Authors:</td>
<td>Hansen, Matt; Oregon Health and Science University, Emergency Medicine Meckler, Garth; University of British Columbia Lambert, William; Oregon Health and Science University Dickinson, Caitlin; Oregon Health and Science University Dickinson, Kathryn; Oregon Health and Science University Van Otterloo, Joshua; Oregon Health Authority Public Health Division Guise, Jeanne-Marie; Oregon Health and Science University</td>
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Patient Safety Events in Out-of-Hospital Pediatric Airway Management: A Medical Record Review by the CSI-EMS

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Author contributions: All of the authors have made substantial contributions in 1) the conception and design of the study, acquisition of the data, and/or analysis and interpretation of the data 2) drafting and revising the article for important content and 3) finally approving the submitted version.

Grant support: this work is supported by the National Heart Lung and Blood Institute (NHLBI) grant number 5K12HL108974-03. This work is also supported by the National Institute of Child Health and Human Development grant: “Epidemiology of Preventable Safety Events in Pre-hospital EMS of Children,” Grant # 1R01HD062478-04. The content is solely the responsibility of the authors and does not necessarily represent the official views of the National Heart, Lung, and Blood Institute, the National Institute of Child Health and Human Development, or the National Institutes of Health.

Keywords: pediatrics; airway management; intubation; pediatric cardiac arrest; out-of-hospital pediatric airway management

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Word count (excludes title page, abstract, references, tables, and figures): 4378

Aknowledgement: We would like to acknowledge Barbara Skarika for her work in re-analysis of the data for this revision.
ABSTRACT

Objective

To describe the frequency and characterize the nature of patient safety events in pediatric out-of-hospital airway management.

Methods

We conducted a retrospective cross-sectional medical record review of all “lights and sirens” Emergency Medicine Services (EMS) transports from 2008 to 2011 in patients less than 18 years of age in the Portland Oregon metropolitan area. A chart review tool (see appendix) was adapted from landmark patient safety studies and revised after pilot testing. Expert panels of physicians and paramedics performed blinded reviews of each chart, identified safety events, and described their nature. The primary outcomes were presence and severity of patient safety events related to airway management including oxygen administration, bag-valve-mask ventilation (BVM), airway adjuncts, and endotracheal intubation (ETI).

Results

From a total of 11,328 pediatric transports, we identified 497 “lights and sirens” (code 3) transports (4.4%). Seven were excluded due to missing data. Overall, 329 patients had a total of 338 airway management procedures: 61.6% were treated with oxygen, 15.3 % with BVM, 8.6% with ETI, and 2% with airway adjuncts. The frequency of errors was: 21% (71/338) related to oxygen use, 9.8% (33/338) related to BVM, 9.5% (32/338) related to intubation, and 0.9% (3/338) related to airway adjunct use. Fifty-eight percent of intubations required three or more attempts or failed altogether. Cardiac arrest was associated with higher odds of a severe error.
Conclusions

Errors in pediatric out-of-hospital airway management are common, especially in the context of intubations and during cardiac arrest.

Strengths and Limitations of the Study:

Strengths:

This study provides an in depth look at pediatric out-of-hospital airway management from a patient safety perspective. It uses a rigorously developed chart review process. It provides a more detailed description of the types of errors that take place and thus gives providers specific targets for quality improvement. This paper looks at airway management from a broad perspective rather than focusing on an individual procedure.

Limitations:

This study was conducted in a large urban area in the United States with many paramedics and short response times and may not apply to other geographical areas. This is a retrospective study.
INTRODUCTION

The US National Quality Forum defines “Patient Safety” as: the prevention and mitigation of harm caused by errors of omission or commission that are associated with healthcare.[1] The patient safety movement in medicine, triggered by retrospective studies of clinical care, started two decades ago and has triggered massive efforts to improve care in hospital based medicine.[2,3] Out-of-hospital care, in particular pediatric care, has little published literature regarding patient safety and the nature of safety events is largely unknown, limiting our ability to improve care on a system-based level.

Airway management is a critical component of resuscitation during many pediatric emergencies and includes a set of technical procedures that are potentially high risk for errors. The skillset required for pediatric out-of-hospital airway management includes oxygen administration, bag-valve-mask ventilation (BVM), oral and nasal airway insertion, supraglottic device insertion, and endotracheal intubation (ETI). ETI has long been considered “definitive” airway management for patients of any age and is practiced by many EMS agencies throughout the world.[4] Pediatric ETI is taught in paramedic training programs and is part of the US National Registry of Emergency Medical Technicians (NREMT) practical examination.[5]

Although pediatric ETI is considered an essential skill for paramedics, the single existing controlled trial found no benefit compared to BVM, and reported harm in some subgroups.[6] Other studies have demonstrated low success rates for pediatric out-of-hospital ETI and increased complications compared to in-hospital ETI.[7–10] In addition, paramedics perform pediatric ETI infrequently, perhaps only once every five years, and rapidly lose skills after training.[11][12,13] As a result of these factors, ETI for children in the out-of-hospital setting is
controversial. There are little data on other aspects of out-of-hospital pediatric airway management such as airway adjuncts and supraglottic devices. Several existing pediatric studies have been conducted in patient simulators and found high success rates, however an adult study on the laryngeal mask airway demonstrated high success in patients simulators (100%) with substantially lower success in practice (64%). [14–17] A national Delphi study recently found that airway management is the most high risk scenario for errors in pediatric out-of-hospital care.[18,19] Another recent study performed in a large national database found that intubation remains the most commonly used pediatric advanced airway technique out-of-hospital with lower success rates than in adults, with the lowest success being among patients less than 1 year of age.[20] Though this study addressed success rates, it did not include detailed review of the charts and was thus unable to identify the rates of specific types of errors in airway management such as tube depth, tube size, and the potential harm associated with the errors.

The objective of this study is to describe the rates and nature of patient safety events related to pediatric out-of-hospital airway management in a cohort of critically ill pediatric transports from a large metropolitan area.

METHODS

Study Design and Setting:

This is a retrospective cross-sectional study representing one portion of the Children’s Safety Initiative-EMS (CSI-EMS) using a chart review designed to capture a broad range of potential and manifest safety events. The CSI-EMS is a National Institutes of Health (NICHD R01HD062478) funded mixed-methods study. The goal of the CSI-EMS is to identify, describe and classify the occurrence of safety events in out-of-hospital pediatric emergency care.[21] We
sub classified safety events as: unintended injury or consequences, near misses, suboptimal actions, errors, and management complications. This classification scheme had not been previously used but was developed by patient safety experts on our research team to capture the spectrum of errors as broadly as possible.

In this report, we present a retrospective medical record review of individual EMS transports in the Portland, Oregon (USA) metropolitan area. This metro area has a “dual advanced life support (ALS)” system where separate ALS fire and transport agencies respond to all calls. The transport and fire agencies in this study serve a population of over 700,000 residents. Airway management procedures in scope of practice in this system include oxygen administration, BVM, oral and nasal airways, supraglottic airways (King LT), and ETI including rapid sequence intubation (RSI). The cardiac arrest survival in Portland, OR is among the highest in the US, with EMS treated cardiac arrest survival of 10.4% reported in a 2008 study using the Resuscitation Outcomes Consortium sites. These high survival rates likely result from rapid response times and an effective (or ‘high-functioning’) EMS system.[22]

The transport agency units respond with two paramedics in each ambulance. Fire units include four to five person teams with at least one paramedic per team. Though fire units respond to each call, the transporting units can elect to dismiss them. If the fire department responders do not intervene, they do not complete a chart. In this system, fire units respond to 90% of calls in less than seven minutes and transport units respond to 90% of calls in less than eight minutes. Fire department crews work in 24-hour shifts. All transport paramedics work rotating shifts and experienced paramedics are equally distributed during all times of day.
Paramedics in this system are all required to participate in annual airway management training using simulation with adult, pediatric, and infant mannequins. In addition to this training, they are all required to maintain Pediatric Advanced Life Support certification. There were no specific protocols designating which paramedic, among those responding, would perform the intubation.

The protocol for pediatric intubation, at the time of the study, called for using BVM or a rescue device if two attempts at intubation failed. However, at the time of the study, the King LT was the rescue device being used and it was not available in sizes suitable for most children under the age of eight. Providers did have access to oral and nasal airways in all pediatric sizes.

Selection of Participants:

We reviewed records for transports from 2008-2011 for all patients less than 18 years of age which were transported “code 3” (lights and sirens) indicating a critical transport. This transport priority is used at the discretion of the treating providers for patients felt to have a life or limb threatening condition. Reviews included charts from the transporting agency, and when applicable, the fire response unit. This group was chosen to identify a subset of patients more likely to need and receive interventions.

Chart Review Tool Development

Our chart review tool and review methods were based on forms from the Harvard Medical Practice Study and the Utah and Colorado Medical Practice Study that were the foundation for the Institute of Medicine Report on patient safety in medicine.[23] In turn, the chart review tool was adjusted to the out-of-hospital setting based on results from our EMS focus group study.[21][2,3] The tool was iteratively revised and finalized in several rounds of testing which included “talk aloud” sessions and pilot reviews using 30 sample EMS charts.
Given the lack of data defining patient safety events in pediatric EMS, the presence or absence of a safety event was based on judgment of the expert chart reviewers. Given the somewhat subjective nature of judging certain potential safety events, each chart was reviewed in tandem by both a paramedic and Emergency Physician using a standardized review tool. A Pediatric Emergency Physician, with expertise in pediatric EMS, performed a third review to arbitrate differences between the initial reviews. Chart reviewers could not be blinded to the study objectives since the review tool specifically focused on safety events. However, reviewers were blinded to results of all interim analysis and study hypotheses. All chart reviewers received a 2-hour training session on the chart review tool, completed test cases before and after the session, and were provided feedback on their test reviews. Based on results of test reviews and questions during feedback sessions, a guidebook was created and provided to all reviewers as a resource to ensure consistency and quality. Reviews were completed online via SurveyMonkey™. The expert chart review panel consisted of 13 paramedics and 7 physicians who were not affiliated with the agencies submitting charts for review. Paramedic reviewers were recruited by word of mouth in the local EMS community, and physician reviewers included one pediatrician and emergency physicians who worked in the pediatric ED of the metro area’s academic medical/trauma center and provide online medical control and one pediatrician.

As a final quality control measure, all charts were arbitrated by one of two pediatric emergency physician investigators with experience in EMS. Inter-rater reliability was established between the two pediatric emergency physician investigators prior to arbitration. A kappa statistic of 0.615 was achieved between the two arbiters on the presence or absence of safety events in the major domains described below. Following the initial blinded review to establish inter-rater reliability, the arbiters met and discussed all discrepancies in the reviews to achieve consensus.
The review tool was designed to identify errors in the following major domains: resuscitation; assessment, impression/diagnosis, and clinical decision making; airway/breathing; fluids and medication; procedures; equipment; environment; and system. Where available, data was abstracted from the chart electronically (scene time, transport time, time of day). Through a series of checkboxes, Likert-type questions, and open-ended responses, the reviewers manually abstracted chart data not available electronically including age, sex, weight, scene location, and transport priority. The reviewers then identified details of care including the dispatch complaint, clinical impression, all procedures performed including airway management procedures, whether or not an error occurred with any of the procedures or in other specific domains, details about the nature and cause of the error, and the degree of potential harm to the patient. The degrees of harm were assessed by the chart review tool using the following question: Using your best clinical judgement, to what degree could the (specific domain inserted eg. airway management) issue have harmed the patient. The following were the potential responses: 1) no harm likely or a near miss, 2) mild or temporary harm, including additional treatment, and 3) permanent or severe harm including death.

Analysis

First, we identified the cohort of patients who had airway management procedures including oxygen administration, BVM, airway adjuncts (oral, nasal, supraglottic airways), and endotracheal intubation out of the complete study population of critical transports as indicated by the chart reviewers. Next, we performed a descriptive analysis of the age, sex, scene location, and dispatch complaint of all patients who had airway management interventions. We then described the clinical impression of the paramedics documented in the electronic patient care report in cases where airway management procedures were performed. We then identified all
patients who had an error in airway management indicated by the reviewers. The reviewers also described the potential severity of harm caused by each error using three categories including “no harm,” “mild or temporary harm,” and “permanent or severe harm including death” using their best judgment based on the information available in the EMS patient care report. The reviewers described the nature of the error using a free text field where problems such as “tube too deep” could be entered. This list of variables was created based on a priori hypotheses developed by the study team of factors we felt could be associated with errors based on the experience of EMS professionals on the team as well as previous studies. Univariate analysis was performed on variables thought to be predictors of severe airway error and then used to select variables to be put in a regression model for severe airway error. Univariate analysis of continuous variables versus severe airway error was performed using logistic regression. Variables with a p value < 0.2 from univariate logistic regression were entered into the model.

Univariate analysis of categorical variables was performed using chi-square analysis. The Phi coefficient or Cramer’s V was then used to measure the strength of association between severe airway error and variables for which the Chi-square test was found to be significant. Variables with a mild association to very strong association (|Phi or Cramer’s V| greater than or equal to 0.15) were entered into the regression model. Variables with a mild to weak association that were suspected to be effect modifiers were entered into the model. One variable with a Phi or Cramer’s V greater than 0.40 but less than 0.50 was not entered into the model (reason for dispatch) because of concerns that the variable distorted the parameters of the other predictor variables, i.e., collinearity with other predictor variables.

When performing chi-square analysis on nominal variables, categories with cell counts less than five were not included in the analysis. Odds ratios and confidence intervals from 2x2 tables for
categorical variables are reported in Table 1 with the results of the univariate analysis. Estimates of odds ratios in categories with zero cell counts were reported by adding 0.5 to all cells used to calculate those odds ratios.

The study team reviewed the free text responses regarding the specific nature of the airway management errors (e.g. tube too deep) and then divided them into specific categories. In addition, one study team member reviewed each cardiac arrest chart and abstracted the airway intervention and medication administration times from the event log in the patient care report to perform an analysis of the time to first epinephrine administration in patients who had advanced airway attempts vs. those who did not as well as total time spent prior to securing the airway (defined as the interval between time of first patient contact and documented success of ETI).

The Institutional Review Board from Oregon Health & Science University approved all study components (IRB Number 00006942). Analysis was conducted using SAS software version 9.4 (SAS Institute Inc., Cary, NC, USA).

RESULTS

From a total of 11,328 pediatric transports during the study period, we identified 497 “code 3” transports (4.4%). We eliminated two transports due to missing data and five transports because we were unable to obtain the associated fire department chart, leaving a total of 490 charts for review. Table 1 presents the characteristics of the 490 pediatric patients and details for those who received specific airway interventions. Approximately two-thirds of patients transported code 3 had an airway management intervention of some kind (329/490, 67%) and 25.51% of patients had more than one airway management intervention. The median number of interventions was “1”. Of those transported code 3, 61.6% (302/490) were treated with oxygen, 15.3% (75/490)
with BVM, 8.6% with ETI (42/490), and 2.0% (10/490) with airway adjuncts. Half of all intubations (21/42) were performed in children less than 12 months of age. The most common reason for dispatch among patients with airway management procedures besides oxygen administration was cardiopulmonary arrest, the second most common seizure, and the third most common reason was trauma. In contrast, the most common reason for dispatch in the entire study population was trauma, followed by nearly equal proportions of interfaculty transports and seizures/altered level of consciousness.

Table 1. Characteristics of patients who had airway management procedures

<table>
<thead>
<tr>
<th></th>
<th>All Patients N = 490</th>
<th>Any Airway Management N = 329</th>
<th>Oxygen N = 302</th>
<th>BVM&lt;sup&gt;a&lt;/sup&gt; N = 75</th>
<th>Airway Adjuncts&lt;sup&gt;c&lt;/sup&gt; N = 10</th>
<th>Intubation N = 42</th>
</tr>
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<tbody>
<tr>
<td>Age</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>0-28 days</td>
<td>23 (4.7)</td>
<td>18 (5.5)</td>
<td>12 (4.0)</td>
<td>7 (9.3)</td>
<td>0 (0.0)</td>
<td>6 (14.3)</td>
</tr>
<tr>
<td>29 days – 11 months</td>
<td>61 (12.5)</td>
<td>50 (15.2)</td>
<td>41 (13.6)</td>
<td>22 (29.3)</td>
<td>3 (30.0)</td>
<td>15 (35.7)</td>
</tr>
<tr>
<td>12 months – 5 years</td>
<td>169 (34.5)</td>
<td>117 (35.6)</td>
<td>110 (36.4)</td>
<td>19 (25.3)</td>
<td>0 (0.0)</td>
<td>6 (14.3)</td>
</tr>
<tr>
<td>6-11 years</td>
<td>84 (17.1)</td>
<td>56 (17.0)</td>
<td>55 (18.2)</td>
<td>7 (9.3)</td>
<td>1 (10.0)</td>
<td>2 (4.8)</td>
</tr>
<tr>
<td>12 – 17 years</td>
<td>153 (31.2)</td>
<td>88 (26.8)</td>
<td>84 (27.8)</td>
<td>20 (26.7)</td>
<td>6 (60.0)</td>
<td>13 (31.0)</td>
</tr>
<tr>
<td>Female</td>
<td>195 (39.8)</td>
<td>134 (40.7)</td>
<td>120 (39.7)</td>
<td>33 (44.0)</td>
<td>3 (30.0)</td>
<td>20 (47.6)</td>
</tr>
<tr>
<td>Scene Location</td>
<td></td>
<td></td>
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<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Home</td>
<td>219 (44.7)</td>
<td>174 (52.9)</td>
<td>154 (51.0)</td>
<td>51 (68.0)</td>
<td>6 (60.0)</td>
<td>31 (73.8)</td>
</tr>
<tr>
<td>School</td>
<td>25 (5.1)</td>
<td>9 (2.7)</td>
<td>9 (3.0)</td>
<td>3 (4.0)</td>
<td>1 (10.0)</td>
<td>1 (2.4)</td>
</tr>
<tr>
<td>Street/Highway</td>
<td>117 (23.9)</td>
<td>64 (19.5)</td>
<td>63 (20.9)</td>
<td>10 (13.3)</td>
<td>1 (10.0)</td>
<td>7 (16.7)</td>
</tr>
<tr>
<td>Hospital/Clinic</td>
<td>110 (22.5)</td>
<td>69 (21.0)</td>
<td>63 (20.9)</td>
<td>9 (12.0)</td>
<td>0 (0.0)</td>
<td>2 (4.8)</td>
</tr>
<tr>
<td>Recreation/Sport</td>
<td>14 (2.9)</td>
<td>10 (3.0)</td>
<td>10 (3.3)</td>
<td>2 (2.7)</td>
<td>2 (20.0)</td>
<td>1 (2.4)</td>
</tr>
<tr>
<td>Other</td>
<td>5 (1.0)</td>
<td>3 (0.9)</td>
<td>3 (1.0)</td>
<td>0 (0.0)</td>
<td>0 (0.0)</td>
<td>0 (0.0)</td>
</tr>
<tr>
<td>First Responder</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Ambulance</td>
<td>183 (37.4)</td>
<td>121 (36.8)</td>
<td>112 (37.1)</td>
<td>20 (26.7)</td>
<td>5 (50.0)</td>
<td>13 (31.0)</td>
</tr>
<tr>
<td>Fire</td>
<td>181 (36.9)</td>
<td>129 (39.2)</td>
<td>119 (39.4)</td>
<td>33 (44.0)</td>
<td>3 (30.0)</td>
<td>18 (42.9)</td>
</tr>
<tr>
<td>Police</td>
<td>14 (2.9)</td>
<td>6 (1.8)</td>
<td>6 (2.0)</td>
<td>0 (0.0)</td>
<td>0 (0.0)</td>
<td>1 (2.4)</td>
</tr>
<tr>
<td>Unknown</td>
<td>112 (22.9)</td>
<td>73 (22.2)</td>
<td>65 (21.5)</td>
<td>22 (29.3)</td>
<td>2 (20.0)</td>
<td>10 (23.8)</td>
</tr>
<tr>
<td>Reason for Dispatch</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Cardiopulmonary Arrest</td>
<td>35 (7.1)</td>
<td>35 (10.6)</td>
<td>19 (6.3)</td>
<td>33 (44.0)</td>
<td>5 (50.0)</td>
<td>26 (61.9)</td>
</tr>
<tr>
<td>Trauma</td>
<td>203 (41.4)</td>
<td>94 (28.6)</td>
<td>91 (30.1)</td>
<td>11 (14.7)</td>
<td>2 (20.0)</td>
<td>10 (23.8)</td>
</tr>
<tr>
<td>Seizure or ALOC(^b)</td>
<td>107 (21.8)</td>
<td>95 (28.9)</td>
<td>93 (30.8)</td>
<td>17 (22.7)</td>
<td>1 (10.0)</td>
<td>2 (4.8)</td>
</tr>
<tr>
<td>------------------------</td>
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</tr>
<tr>
<td>Ingestion/Poisoning/Intoxication</td>
<td>29 (5.9)</td>
<td>15 (4.6)</td>
<td>15 (5.0)</td>
<td>4 (5.3)</td>
<td>2 (20.0)</td>
<td>2 (4.8)</td>
</tr>
<tr>
<td>Respiratory Distress</td>
<td>79 (16.1)</td>
<td>73 (22.2)</td>
<td>68 (22.5)</td>
<td>9 (12.0)</td>
<td>0 (0.0)</td>
<td>2 (4.8)</td>
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<tr>
<td>Allergic Reaction/Anaphylaxis</td>
<td>11 (2.2)</td>
<td>7 (2.1)</td>
<td>7 (2.3)</td>
<td>1 (1.3)</td>
<td>0 (0.0)</td>
<td>0 (0.0)</td>
</tr>
<tr>
<td>Pain (non-trauma)</td>
<td>12 (2.5)</td>
<td>5 (1.5)</td>
<td>5 (1.7)</td>
<td>0 (0.0)</td>
<td>0 (0.0)</td>
<td>0 (0.0)</td>
</tr>
<tr>
<td>Other</td>
<td>14 (2.9)</td>
<td>5 (1.5)</td>
<td>4 (1.3)</td>
<td>0 (0.0)</td>
<td>0 (0.0)</td>
<td>0 (0.0)</td>
</tr>
</tbody>
</table>

\(^a\)BVM = Bag-Valve-Mask Ventilation
\(^b\)ALOC = Altered Level of Consciousness
\(^c\)Airway Adjuncts: Airway adjuncts in the chart review included nasopharyngeal or oropharyngeal airways n=9 and one King LT supraglottic airway device.

Overall, 27.8% of charts with airway management (94/338) were judged to have airway management errors. Errors were related to oxygen use in 21% of cases (71/338), to BVM in 9.8% (33/338), to airway adjunct use in 0.9% (3/338), and to ETI in 9.5% (32/338). Nine percent of cases had errors in more than one aspect of airway management.

Over 70% of cases in which ETI was performed contained an error of some type. The specific nature of errors relating to ETI were: ETT placed too deep in 25% of cases, incorrect ETT size used in 29% (78% of the time too small), and dislodgement of the ETT during transport in 13% of cases. Reviewers felt that 24% of the time, ETI was not indicated when performed. The most common type of error in ETI was technical difficulty with the procedure, accounting for 58% of errors, defined as failure to secure ETI or requiring three or more attempts.

The most common clinical scenario in which ETI was performed was cardiac arrest. In cardiac arrest scenarios, intubation was attempted 74% of the time. On average, in cardiac arrest cases where ETI was attempted the mean time to the first dose of epinephrine was 11 minutes. In cases where ETI was not attempted, the mean time to the first dose of epinephrine was 7 minutes. In addition, in cases where ETI was attempted, 10 minutes passed on average prior to securing an
airway or abandoning further attempts. This may indicate that on average providers conclude advanced airway management prior to administration of epinephrine.

Further analysis of other types of airway management errors found that 48% of the time, oxygen was administered when it was not indicated, and 32% of the time oxygen was not administered when it was indicated. There was a broad range of clinical scenarios where oxygen was applied and reviewers felt it was not indicated. Errors related to BVM were most commonly due to lack of use when indicated or failure to attempt for a long enough period prior to performing ETI.

Airway adjuncts were infrequently used (n=10) and all errors identified were related to lack of use when indicated, rather than inappropriate use or a complication related to their use.

Figure 1 presents the distribution of errors in airway management by age. Neonates had the highest rate of severe errors followed by infants, with a trend towards decreased rate of severe errors with increasing age. Figure 2 shows the level of harm of the errors according to airway management procedures. Intubation had the highest rate of severe errors among the airway management procedures.

Errors in airway management were commonly associated with errors in other domains of care. In cases with any airway management error, 64% had errors in decision making, 62% in resuscitation, and 48% in medications (p < 0.01 for all). In cases where there were errors in BVM or ETI, more than 90% of cases also had an error identified in resuscitation, over 65% had errors in assessment/decision-making, and over 60% had errors in medications (p < 0.01 for all).

We performed univariate analyses to identify factors associated with severe airway management errors (Table 2). In these unadjusted analyses, an increased risk of a severe error related to airway management was strongly associated with patient age less than 28 days (OR 6.62, 95%
CI 1.68 – 26.0), less than 12 months (OR = 5.73, 95% CI 1.91 – 17.20) patients in cardiopulmonary arrest (OR = 15.61, 95% CI 5.65 – 43.12), fire department involvement (fire department team and transport team both provided significant care) (OR = 2.75, 95% CI 1.30-5.82), and calls occurring between 10pm and 8am (OR=2.21, 95% CI 1.05-4.62).

Table 2. Univariate analysis of factors associated with a severe airway management error

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>Odds Ratio</th>
<th>95% CI</th>
<th>P Value</th>
</tr>
</thead>
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<tr>
<td><strong>Patient Characteristic</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Age <strong>b</strong></td>
<td></td>
<td></td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>0-28 days</td>
<td>6.62</td>
<td>1.68 – 26.0</td>
<td></td>
</tr>
<tr>
<td>29 days – 11 months</td>
<td>5.73</td>
<td>1.91 – 17.2</td>
<td></td>
</tr>
<tr>
<td>1-5 years</td>
<td>1.07</td>
<td>0.33- 3.47</td>
<td></td>
</tr>
<tr>
<td>6 – 11 years</td>
<td>1.65</td>
<td>0.46 – 5.99</td>
<td></td>
</tr>
<tr>
<td>12–17 years (reference category)</td>
<td>1</td>
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<tr>
<td><strong>Gender</strong>&lt;sup&gt;c,d&lt;/sup&gt;</td>
<td></td>
<td></td>
<td>0.51</td>
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<tr>
<td>Male</td>
<td>0.79</td>
<td>0.39 – 1.60</td>
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<td><strong>Call Characteristic</strong></td>
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<td></td>
</tr>
<tr>
<td>Reason for Dispatch&lt;sup&gt;b,e&lt;/sup&gt;</td>
<td></td>
<td></td>
<td>&lt;.001</td>
</tr>
<tr>
<td>Trauma (reference category)</td>
<td>1</td>
<td>--</td>
<td>--</td>
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<tr>
<td>Seizure or ALOC&lt;sup&gt;f&lt;/sup&gt;</td>
<td>0.14</td>
<td>0.02 – 1.12</td>
<td></td>
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<td>Respiratory Distress</td>
<td>1.4</td>
<td>0.47 – 4.16</td>
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<td>Cardiorespiratory Arrest</td>
<td>15.61</td>
<td>5.65 – 43.1</td>
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<tr>
<td>Ingestion/Poisoning/Intoxication</td>
<td>0.40</td>
<td>0.02 – 7.32</td>
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<tr>
<td>Other (including Birth/Delivery)</td>
<td>0.95</td>
<td>0.05 – 18.5</td>
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<tr>
<td>Pain (non-trauma)</td>
<td>1.12</td>
<td>0.06 – 22.3</td>
<td></td>
</tr>
<tr>
<td>Allergic Reaction/Anaphylaxis</td>
<td>2.19</td>
<td>0.23 – 20.8</td>
<td></td>
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<tr>
<td><strong>Fire Department Involvement</strong></td>
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<td>0.006</td>
</tr>
<tr>
<td>Fire chart</td>
<td>2.75</td>
<td>1.30 – 5.82</td>
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</tr>
<tr>
<td><strong>Call During the Night</strong>&lt;sup&gt;d&lt;/sup&gt;</td>
<td></td>
<td></td>
<td>0.032</td>
</tr>
<tr>
<td>(10pm-8am)</td>
<td>2.21</td>
<td>1.05 – 4.62</td>
<td></td>
</tr>
<tr>
<td><strong>Scene Time</strong>&lt;sup&gt;g&lt;/sup&gt;</td>
<td></td>
<td></td>
<td>0.14</td>
</tr>
<tr>
<td>(per one minute increase)</td>
<td>1.03</td>
<td>0.99 – 1.07</td>
<td></td>
</tr>
<tr>
<td><strong>Transportation Time</strong></td>
<td></td>
<td></td>
<td>0.10</td>
</tr>
<tr>
<td>(per one minute increase)</td>
<td>0.96</td>
<td>0.91 – 1.01</td>
<td></td>
</tr>
</tbody>
</table>

<sup>a</sup>338 observations (338 out of 490 charts reviewed; airway error information not available for 152 charts)

<sup>b</sup>Odds ratios and confidence intervals calculated from 2x2 tables of each category against the reference category. Reported P-value from a chi-square test performed on all categories; the Cramer’s V was found to be > 0.20.
In multivariate logistic regression analyses (Table 3), 0-28 days and age < 12 months remained statistically significant with strong associations with severe errors. We noted fire department involvement was associated with increased odds of severe errors, increased transport time was mildly protective against severe errors, while increased scene time was associated with increased odds of severe errors.

Table 3. Multivariate analysis of factors associated with a severe airway management error\textsuperscript{a,b}

<table>
<thead>
<tr>
<th>Characteristics</th>
<th>Odds Ratio</th>
<th>95% CI</th>
<th>P Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Patient Characteristic</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Age</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Newborn (0-28 days)</td>
<td>7.50</td>
<td>2.11 – 26.6</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Infant (29 days through 11 months)</td>
<td>5.69</td>
<td>1.13 – 28.8</td>
<td>0.02</td>
</tr>
<tr>
<td>1-5 years</td>
<td>1.52</td>
<td>0.34 – 6.86</td>
<td>0.22</td>
</tr>
<tr>
<td>6-11 years</td>
<td>0.96</td>
<td>0.4 – 3.92</td>
<td>0.43</td>
</tr>
<tr>
<td>12–17 years (reference category)</td>
<td>1</td>
<td>--</td>
<td>--</td>
</tr>
<tr>
<td>EMS Scene Care</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Fire department involvement</td>
<td>3.91</td>
<td>1.55 – 9.85</td>
<td>0.004</td>
</tr>
<tr>
<td>Transport time in minutes</td>
<td>0.94</td>
<td>0.88 – 1.00</td>
<td>0.04</td>
</tr>
<tr>
<td>Scene time in minutes</td>
<td>1.04</td>
<td>1.00 – 1.09</td>
<td>0.03</td>
</tr>
</tbody>
</table>

\textsuperscript{a}331 observations (out of 490 charts, after excluding charts with missing info on airway errors, gender, and scene time and excluding outliers); Likelihood-based pseudo R-square = 0.12 Maxrescaled R-Square = 0.26

\textsuperscript{b}Four outliers with a standardized deviance residual of greater than 2.50 were removed from the final model.

DISCUSSION

In this analysis we found that airway management errors are relatively common, occurring in >25% of cases where airway management was performed, and that a high proportion of errors
had the potential to cause severe patient harm. Patients less than 12 months of age and those with cardiac or respiratory arrest were at highest risk for severe airway management errors and were the patient populations who most commonly needed airway management. Of airway management procedures, ETI had the highest proportion of errors and required three or more attempts or was unsuccessful 58% of the time bringing into question the safety of this procedure. Airway adjuncts and BVM were judged to be under-utilized.

Several previous investigations have documented pediatric ETI success rates from 50 to 100%, and major complications between 1.8% and 50%.[24–27] The only controlled trial on out-of-hospital pediatric ETI found no benefit compared to BVM but has been criticized for inadequate training.[6] Our study also provides additional insight into the nature of ETI related errors by identifying incorrect tube size, incorrect tube depth, multiple attempts, failure to successfully place the tube, and unnecessary intubation as the specific types of errors.

We also found that patients with cardiac arrest had significantly increased odds of an airway management error. In these cases, EMS providers may face cognitive and emotional overload.[28] Similar to our study, an analysis of more than 10 years of data from San Diego, California found that the majority of pediatric out-of-hospital intubations are for cardiac arrest, indicating this is an important area of focus.[29]

Infants experience a disproportionate portion of airway management errors. The airway anatomy of children less than one year of age differs substantially from that of older children. In addition, the small size of the patient makes performing simultaneous interventions such as airway management and CPR challenging. In cases with airway management errors, we also found high rates of errors in resuscitation, assessment/decision-making, and medication administration. This
indicates that airway management errors are not likely due to one specific skill deficit, but while multiple critical decisions and interventions are being performed quickly.

One reason pediatric ETI may not benefit patients is that the potential advantages of an endotracheal tube securing the airway are mitigated by procedural complications and by detrimental effects on other aspects of resuscitation. A recent study done in the Emergency Department found that significant adverse events increase rapidly with the number of intubation attempts.[30] We found that in cases of cardiac arrest, on average, ETI was being performed prior to administration of epinephrine, which contradicts American Heart Association guidelines.[31,32] This suggests that ETI may have a negative effect on other important components of out-of-hospital pediatric resuscitation.

Our analysis adds to the literature by evaluating a broad range of airway interventions. We found that BVM and airway adjuncts were at times not used when indicated. Previous simulation studies have found technical problems with prehospital BVM which may reflect the challenging nature of this procedure in children or lack of experience in its use.[33,34] In addition, BVM in pediatric patients may be resource intensive and require two providers to achieve adequate mask seal.

Airway adjuncts such as supraglottic devices, OPAs, and NPAs appear to be used very infrequently in children, even when indicated. Simulation-based studies have shown high success rates with supraglottic devices in pediatric manikins placed by EMS providers and may be a promising solution.[16,35]

We found that the presenting complaint of seizure/altered level of consciousness was almost protective against the presence of an error. We believe this is because these patients were likely over-triaged to code 3 transport, given the benign natural course of most pediatric seizures.
Errors were not unexpectedly associated with calls during the nighttime hours. Increased scene time was associated with increased odds of errors likely reflecting increased time at risk. Increased transport time was associated with reduced odds of errors after controlling for scene time. This could be due to more stable patients at lower risk for errors being transported longer distances due to bypassing the nearest hospital in favor of a children’s hospital a greater distance away. Finally, we found that fire department involvement had a significant association with increased odds of a severe error. This is most likely due to confounding by indication since locally the fire department only provides ongoing care to the most severely ill patients.

There are several potential mechanisms to improve the safety of pediatric airway management based on the results of this study. Each provider in our system undergoes pediatric airway simulation training, but it is clearly not adequate. Increased time in simulation training low cost models that are more realistic are potential solutions. Simulation training is resource intensive so this may not be sustainable or generalizable. Given the highest rate of errors was in the youngest patients, limiting intubation to older children may be reasonable. This study was not powered to detect differences by age group so we cannot comment on what the correct age should be. Increased use of supraglottic airways may be a promising option in children as well, though further study is needed.

**Limitations:**

Our study has several limitations. First, it was conducted in a single metropolitan area. Next this is a retrospective study and limited to the data available in the medical record. Our reliance on the written record likely biases our results towards underestimation of errors.[36] Though a standard definition was used, assessment of harm was based on the judgment of chart reviewers.
and is inherently subjective, although this practice has been used in other landmark patient safety studies.[2,3] We used a rigorous chart review tool development and training process with multiple blinded reviewers to mitigate this source of bias. Finally, this study was conducted in a well-developed EMS system with short response times utilizing paramedics as initial responders to all calls, available medication facilitated intubation, and with a relatively high cardiac arrest survival.[22] In general this is a “high functioning” EMS system which may have lower rates of errors than in other systems. Our findings may not be generalizable to other EMS systems. Categories of nominal predictor variables with one or less case of severe airway error were not included when performing the Chi-square test on reason for dispatch; we chose to focus on categories of dispatch reason in which there was more than one severe airway error reported. Due to the small number of cases in this sample, we cannot be sure that severe airway error would not be present in greater numbers in certain categories of reason for dispatch (poisoning, allergy or anaphylaxis, and pain) when looking at a larger sample. The small sample size precluded the inclusion of interaction terms to investigate possible effect modification in the multiple regression model.

In conclusion, our study finds high error rates in pediatric out-of-hospital airway management. ETI was the modality associated with the highest rate of errors, and the youngest patients as well as those with cardiopulmonary arrests were at highest risk of errors. These findings raise serious concerns about the safety of advanced airway management procedures. Future directions for this work could include expanding this research to other types of EMS systems and conducting prospective trials assessing the efficacy of different airway management strategies.
Contributorship statement
MH contributed to the design of the study, and analysis of data, and writing of the manuscript. GM and WL and JMG contributed to the design of the study, development of data collection tools, collection, validation, and analysis of data, and critical review of the manuscript. CK and KD contributed to the design of the study, development of data collection tools, collection, validation, and analysis of data and provided critical review of the manuscript. JVO contributed to the analysis of data and provided critical review of the manuscript.

Competing Interests
All authors had financial support from the National Institute of Child Health and Human Development (NICHD) grant (R01HD062478) for the submitted work; no financial relationships with any organizations that might have an interest in the submitted work in the previous three years; no other relationships or activities that could appear to have influenced the submitted work.

Funding
This work is supported by the National Heart Lung and Blood Institute (NHLBI) grant number 5K12HL108974-03. This work is also supported by the National Institute of Child Health and Human Development grant: “Epidemiology of Preventable Safety Events in Pre-hospital EMS of Children,” Grant #1R01HD062478-04. The content is solely the responsibility of the authors and does not necessarily represent the official views of the National Heart, Lung, and Blood Institute, the National Institute of Child Health and Human Development, or the National Institutes of Health. All researchers had independence from the funder with regard to design, conduct, and analysis of the study.

Data Sharing
There is no additional data available.

PRISMA Guidelines
This paper follows the STROBE guidelines for observational research.
References:


17 Michael J Murray MJV. Evaluation of prehospital insertion of the laryngeal mask airway by primary care paramedics with only classroom mannequin training. CJEM 2002;4:338–43.


Figure Legends:

Figure 1. Severity of airway management errors by patient age.

Figure 2. Severity of airway management errors by type of procedure. \(02=\)oxygen; BVM = Bag-Valve-Mask Ventilation. UNSEM = Unintended consequence, Near Miss, Suboptimal Action, Error, Management Complication.
215x279mm (300 x 300 DPI)
**Purpose:** We are interested in capturing a broad range of potential challenges or errors in the pre-hospital care of children. This tool is intended to understand and describe the circumstances that could have caused such events, which we are referring to as "UNSEMs."

**UNSEM is defined as:**

- Unintended injury or consequence
- Near miss (not a planned event)
- Suboptimal action that can be improved
- Error
- Management complication

The act of responding to a call and providing care may have resulted in a UNSEM. We appreciate that professionals talk about these events in different ways and use different terms to describe them; more than one UNSEM can occur in any particular situation. In addition, we consider overtreatment or unnecessary treatment to be an UNSEM (e.g. inappropriate Code 3, unnecessary trauma registration, unnecessary IV, and unnecessary medication).

There may be times when you do not see documentation of clinical information in the pre-hospital record. We are interested in your synthesis of the entire chart; if an item or event is not documented, **assume it did not happen.** [Please note: as long as it is documented in one of the charts (e.g. in the fire chart but not in the AMR chart), it is OK.]

Please note: Sections have overlap; it is okay to mention items, ideas, issues, etc. in multiple sections.
**SECTION 1: REVIEWER INFORMATION**

1. **Reviewer Initials:**

2. **Study ID:**

3. **Is there a Fire chart? (If you only received one chart, assume there is no Fire chart.)**
   - Yes
   - No

4. **Reason For Call (chief complaint):**

5. **Please use your judgment to assess the nature of the patient's condition overall:**
   - Mild (expected to recover within days)
   - Moderate
   - Critical/Severe or potentially permanent
   - Death
   - Cannot reasonably judge

6. **Among pediatric dispatches, how common is this type of chief complaint?**
   - Very Rare (<1%)
   - Rare (1-9%)
   - Occasional (10-24%)
   - Frequent (>25%)
SECTION 2: RESUSCITATION

Remember, if you do not see it documented, assume it did not happen.

"Resuscitation" refers to the treatment of: respiratory distress or failure, compensated or decompensated shock, altered mental status, and/or ongoing seizure activity (e.g. treatment of an asthmatic who is wheezing and receiving albuterol).

UNSEM (Unintended Injury or Consequence, Near Miss, Suboptimal Action, Error, Management Complication)

1. Did resuscitation occur at any point during this call? (Refer to your manual before answering this question.)

☐ Yes

☐ No
SECTION 2: RESUSCITATION

1. Should resuscitation have occurred? (Refer to your manual before answering this question.)
   - Yes
   - No
1. Was there a(n) UNSEM related to resuscitation?

- Yes
- No
- Not Sure

If you checked Yes or Not Sure in the above question, please describe.
SECTION 2: RESUSCITATION

1. Please elaborate:

[Blank space for response]
SECTION 2: RESUSCITATION

1. Please feel free to provide additional comments:

2. What was the condition(s) that led to the need for resuscitation?

- Cardiac arrest (specify below)
- Respiratory failure/arrest (specify below)
- Altered mental status (specify below)
- Seizures (specify below)
- Poisoning (e.g. drug overdose) (specify below)
- Drowning (specify below)
- Trauma (specify below)
- Metabolic disorder (e.g. hypoglycemia) (specify below)
- Infection/Sepsis (specify below)
- Other (specify below)

Please specify your response from above.
**SECTION 2: RESUSCITATION**

1. Was there a delay, omission, or confusion in dealing with the resuscitation-related issue?

- [ ] Yes, delay
- [ ] Yes, omission
- [ ] Yes, confusion
- [ ] No
- [ ] Not Sure
### SECTION 2: RESUSCITATION

1. Please check all that apply:
   - Equipment not available
   - Required drug(s) not available
   - Scene management issue
   - Failure to recognize age-based norms
   - Failure to obtain needed tests (glucose, O2 Sat)
   - Failure to obtain needed monitoring
   - Other

   If Other, please specify here:

   

2. Was the resuscitation-related UNSEM avoidable?
   - Yes
   - Possibly
   - No

   Please explain your response.

3. Specific to this clinical scenario, how often is this resuscitation issue or cascade of issues likely to occur? If more than one issue or cascade of issues occurred, select the corresponding frequencies and explain in the provided text box below.
   - Very Rarely (<1%)
   - Rarely (1-9%)
   - Occasionally (10-24%)
   - Frequently (> 25%)

   Please provide additional details:
4. Using your best clinical judgment, to what degree could the resuscitation management issue have harmed the patient?

- No harm likely or a near miss
- Mild or temporary harm, including additional treatment
- Permanent or severe permanent harm, including death

5. Pertains only to cases with 2 charts:
Is there concordance regarding resuscitation between the 2 charts?

- Yes
- No (Please explain below)

If you checked No, please explain and include potential impacts to the patient.
**SECTION 2: ASSESSMENT, IMPRESSION/DIAGNOSIS, AND CLINICAL DECISION MAKING**

“Assessment, Impression/Diagnosis, and Clinical Decision Making” refers to the assessment or diagnosis of the patient (recognizing abnormal vital signs or if the patient is sick or not sick, etc.), and/or the decisions made regarding the patient’s care. For example, a child with stridor from croup could be assessed as having wheezing from asthma, which would result in inappropriate subsequent management of the patient. (The patient actually has upper airway obstruction, but was thought to have lower airway obstruction.)

**UNSEM (Unintended Injury or Consequence, Near Miss, Suboptimal Action, Error, Management Complication)**

1. Was there an issue related to: (Please refer to the manual & then check all that apply)

   - Clinical history (specify below)
   - Physical exam (specify below)
   - Taking account of comorbidity (specify below)
   - Recognizing age-based norms (specify below)
   - Reassessing patient response to care/intervention (specify below)
   - Applying appropriate monitors (specify below)
   - Monitoring vital signs (specify below)
   - Communicating impressions to the rest of the team (specify below)
   - Other (specify below)
   - No issue

   Please specify your response(s) from above.

2. Was there a(n) UNSEM related to assessment, impression/diagnosis, and/or clinical decision making?

   - Yes
   - No
   - Not Sure

   If you checked Yes or Not Sure to the above question, please describe.
SECTION 2: ASSESSMENT, IMPRESSION/DIAGNOSIS, AND CLINICAL DECISION MAKING

1. Was there a delay, omission, or confusion in assessment, impression/diagnosis, and/or clinical decision making?

- [ ] Yes, delay
- [ ] Yes, omission
- [ ] Yes, confusion
- [ ] No
- [ ] Not Sure

If Yes or Not Sure, please describe:

2. Given the information the EMS professional had at the time, was the assessment, impression/diagnosis, and/or clinical decision making issue avoidable?

- [ ] Yes
- [ ] Possibly
- [ ] No

Please explain your response.

3. Specific to this clinical scenario, how often is this assessment, impression/diagnosis, and/or clinical decision making issue or cascade of issues likely to occur? If more than one issue or cascade of issues occurred, select the corresponding frequencies and explain in the provided text box below.

- [ ] Very Rarely (<1%)
- [ ] Rarely (1-9%)
- [ ] Occasionally (10-24%)
- [ ] Frequently (> 25%)

Please provide additional details:
4. Using your best clinical judgment, to what degree could the assessment, impression/diagnosis, and/or clinical decision making issue have harmed the patient?

- No harm likely or a near miss
- Mild or temporary harm, including additional treatment
- Permanent or severe permanent harm, including death

5. Pertains only to cases with 2 charts:
Is there concordance regarding assessment, impression/diagnosis, and/or clinical decision making between the 2 charts?

- Yes
- No (Please explain below)

If you checked No, please explain and include potential impacts to the patient.
“Airway/Breathing” refers to management of the patient’s airway and/or breathing, including use/misuse of basic and advanced airway adjuncts (including administration of Oxygen). Please note that administration of medication for breathing problems is considered airway management (and also considered medication administration).

UNSEM (Unintended Injury or Consequence, Near Miss, Suboptimal Action, Error, Management Complication)

1. Did airway management occur at any point during this call?

☐ Yes

☐ No
SECTION 2: AIRWAY/BREATHING

1. Please feel free to provide additional comments:

[Blank text box]
SECTION 2: AIRWAY/BREATHING

*1. Please elaborate:
1. Should airway management have occurred?

- [ ] Yes
- [ ] No
SECTION 2: AIRWAY/BREATHING

1. Was the airway management performed indicated?
   - Yes
   - No
   - Not Sure

   If you checked No or Not Sure, please explain.

2. Please check all types of airway management that occurred.
   - O2 (Nasal/Mask/Blow-by)
   - BVM
   - Surgical Airway (specify below)
   - Delay in airway management (specify below)
   - Airway Adjuncts: (Please select either Oral or Nasal Airway)
     - Oral Airway
     - Nasal Airway
   - Intubation (Please select which device was used)
     - ETT
     - King Airway
     - LMA
     - Other

   If needed, please specify here:
### SECTION 2: AIRWAY/BREATHING

1. **Did the patient need medication-facilitated intubation?**
   - [ ] Yes
   - [ ] No

   If No, should RSI medications have been used? Please explain.

2. **If the patient needed medication-facilitated intubation, what were the medications, dosages, and routes? (Please separate responses with a comma)**

<table>
<thead>
<tr>
<th>Medication</th>
<th>Dosage</th>
<th>Route</th>
<th>Time Administered</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
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<td></td>
</tr>
</tbody>
</table>

3. **Was difficulty of intubation noted?**
   - [ ] Yes
   - [ ] No

4. **Was confirmation obtained?**
   - [ ] Yes
   - [ ] No
   - [ ] Unable to Determine
SECTION 2: AIRWAY/BREATHING

1. Please check the method(s) of confirmation that were used: (Check all that apply)

- ETCO2 (waveform)
- ETCO2 (colorimetric)
- Direct visualization of the cords
- Absent gastric sounds
- Mist in endotrachael tube
- Bilateral chest rise
- O2 stat prior/after
- Missing
- Unclear
- Other

If Other, please specify here:

[Text box for Other specification]
SECTION 2: AIRWAY/BREATHING

1. Was there a(n) UNSEM related to airway management?

- Yes
- No
- Not Sure

If you checked Yes or Not Sure, please describe.
SECTION 2: AIRWAY/BREATHING

1. Was there a delay, omission, or confusion in dealing with the airway-related issue?
   - Yes, delay
   - Yes, omission
   - Yes, confusion
   - No
   - Not Sure

If Yes or Not Sure, please explain.

2. Given the information the EMS professional had at the time, was the airway management issue avoidable?
   - Yes
   - Possibly
   - No

Please explain your response.

3. Specific to this clinical scenario, how often is this airway management issue or cascade of issues likely to occur? If more than one issue or cascade of issues occurred, select the corresponding frequencies and explain in the provided text box below.
   - Very Rarely (<1%)
   - Rarely (1-9%)
   - Occasionally (10-24%)
   - Frequently (> 25%)

Please provide additional details:
4. Using your best clinical judgment, to what degree could the airway management issue have harmed the patient?

- No harm likely or a near miss
- Mild or temporary harm, including additional treatment
- Permanent or severe permanent harm, including death

5. Pertains only to cases with 2 charts:
Is there concordance regarding airway management between the 2 charts?

- Yes
- No

If you checked No, please explain and include potential impacts to the patient.
"Fluids" refers to the administration of IV/IO fluids (e.g. saline, LR, dextrose/glucose rather than specific IV medications) or the failure to administer IV fluids when indicated. It does NOT refer to specific IV medications. Also, 10cc of normal saline is a flush, and does not refer to fluid administration (this is generally given to keep the line open).

"Medication" refers to drug choice, dosage, and route of administration, as well as adverse drug reactions and failure to administer an indicated medication. (Not including supplemental O2.)

**UNSEM (Unintended Injury or Consequence, Near Miss, Suboptimal Action, Error, Management Complication)**

1. Was patient weight documented?

   - [ ] Yes
   - [ ] No
1. How was weight obtained?

- Parental Report
- Length-based Estimate
- Method Not Specified
1. Is the documented weight within age-based norms?
   - Yes
   - No, low for patient age
   - No, high for patient age

2. The next several questions pertain to administration of IV/IO fluids ONLY, NOT medications.

   Were fluids administered?
   - Yes
   - No
SECTION 2: FLUIDS & MEDICATION

1. Please indicate the route and volume:

[Blank space for input]

For peer review only - http://bmjopen.bmj.com/site/about/guidelines.xhtml
SECTION 2: FLUIDS & MEDICATION

1. Should fluids have been administered?
   ○ Yes
   ○ No
### SECTION 2: FLUIDS & MEDICATION

1. Please elaborate:
## SECTION 2: FLUIDS & MEDICATION

1. Was there an UNSEM related to fluid administration?

- [ ] Yes
- [ ] No
- [ ] Not Sure
SECTION 2: FLUIDS & MEDICATION

1. Please describe:

2. Was there a delay, omission, or confusion in dealing with the fluids-related issue?
   - Yes, delay
   - Yes, omission
   - Yes, confusion
   - No
   - Not Sure
SECTION 2: FLUIDS & MEDICATION

1. Please explain:

2. What was the nature of the fluids-related UNSEM?
   - Unpredictable reaction
   - Predictable reaction
   - Incorrect concentration
   - Fluids contraindicated in this case
   - Incorrect volume
   - Incorrect route
   - Inadequate monitoring
   - Failure to administer fluids
   - Other

   Please specify choices above:

3. Even with the knowledge beforehand that this adverse effect could occur, was it reasonable to administer the fluids?
   - Yes
   - No
   - No fluids were administered

4. What additional treatment was provided as a result of the fluids-related UNSEM?

5. Given the information the EMS professional had at the time, was the fluids-related issue avoidable?

- Yes
- Possibly
- No

Please explain

6. Specific to this clinical scenario, how often is this fluids-related issue or cascade of issues likely to occur? If more than one issue or cascade of issues occurred, select the corresponding frequencies and explain in the provided text box below.

- Very Rarely (<1%)
- Rarely (1-9%)
- Occasionally (10-24%)
- Frequently (>25%)

Please provide additional details:

7. Using your best clinical judgment, to what degree could the fluids-related issue have harmed the patient?

- No harm likely or a near miss
- Mild or temporary harm, including additional treatment
- Permanent or severe permanent harm, including death

8. Pertains only to cases with 2 charts: Is there concordance regarding fluids management between the 2 charts?

- Yes
- No; please explain and include potential impacts to the patient below

Please explain:
9. The remaining questions in this section pertain to medications ONLY, NOT fluids

*In this section, please include albuterol or other airway medications that were given. If pain medications should have been given but were not, this is considered an UNSEM.*

**Was medication administered?**

- [ ] Yes
- [ ] No
### SECTION 2: FLUIDS & MEDICATION

1. Please feel free to provide comments:
SECTION 2: FLUIDS & MEDICATION

1. Should medication have been administered?
   ○ Yes
   ○ No
SECTION 2: FLUIDS & MEDICATION

1. Please elaborate:


SECTION 2: FLUIDS & MEDICATION

1. Please feel free to provide comments:

2. Was the medication indicated?
   - Yes
   - No
   - Not Sure

   If No or Not Sure, please explain.

3. What type of medication(s) was administered?
   - Sedative or hypnotic
   - Nausea
   - Allergy/Anaphylaxis treatment
   - Antidote (e.g. Narcan)
   - Anti-seize
   - Narcotic
   - Anti-diabetic (glucagon)
   - Diuretics
   - Cardiovascular
   - Antipsychotic
   - Respiratory (including inhaled)
   - RSI (including pre-meds)
   - Other

   If Other, please specify

4. Other than what you have already described in airway management, please list the medication(s) administered:
5. How was the medication(s) administered (route of administration)?

- Intravenous
- Orally
- IO
- ET Tubes
- Intramuscular
- Sublingual
- Rectal
- Subcutaneous
- Intranasal
- Not documented
- Other

If Other or multiple options were selected, please specify:
### SECTION 2: FLUIDS & MEDICATION

1. Was there a(n) UNSEM related to medication?

<p>| | | | | |</p>
<table>
<thead>
<tr>
<th></th>
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<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Yes</td>
<td>No</td>
<td>Not Sure</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

If Yes or Not Sure, please describe.

[Blank space for description]
### SECTION 2: FLUIDS & MEDICATION

**1. Was there a delay, omission, or confusion in dealing with the medication-related issue?**

<p>| | |</p>
<table>
<thead>
<tr>
<th></th>
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</thead>
<tbody>
<tr>
<td>Yes, delay</td>
<td></td>
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<tr>
<td>Yes, omission</td>
<td></td>
</tr>
<tr>
<td>Yes, confusion</td>
<td></td>
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<tr>
<td>No</td>
<td></td>
</tr>
<tr>
<td>Not Sure</td>
<td></td>
</tr>
</tbody>
</table>

If Yes or Not Sure, please explain.

**2. What was the nature of the medication-related UNSEM?**

<p>| | |</p>
<table>
<thead>
<tr>
<th></th>
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</tr>
</thead>
<tbody>
<tr>
<td>Drug less effective than expected (specify below)</td>
<td></td>
</tr>
<tr>
<td>Unpredictable reaction (specify below)</td>
<td></td>
</tr>
<tr>
<td>Predictable reaction (specify below)</td>
<td></td>
</tr>
<tr>
<td>Incorrect drug (specify below)</td>
<td></td>
</tr>
<tr>
<td>Incorrect concentration (specify below)</td>
<td></td>
</tr>
<tr>
<td>Drug contraindication (specify below)</td>
<td></td>
</tr>
<tr>
<td>Drug-drug interaction (specify below)</td>
<td></td>
</tr>
<tr>
<td>Incorrect dose (specify below)</td>
<td></td>
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<tr>
<td>Incorrect route (specify below)</td>
<td></td>
</tr>
<tr>
<td>Inadequate monitoring (specify below)</td>
<td></td>
</tr>
<tr>
<td>Failure to administer medication (specify below)</td>
<td></td>
</tr>
<tr>
<td>Other (specify below)</td>
<td></td>
</tr>
</tbody>
</table>

Please specify your response(s) from above.

**3. Even with knowledge beforehand that an adverse effect could occur, was it reasonable to administer the medication?**

<p>| | |</p>
<table>
<thead>
<tr>
<th></th>
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</thead>
<tbody>
<tr>
<td>Yes</td>
<td></td>
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<tr>
<td>No</td>
<td></td>
</tr>
<tr>
<td>No medication was administered</td>
<td></td>
</tr>
</tbody>
</table>
SECTION 2: FLUIDS & MEDICATION

1. What additional medication(s) were administered as a result of the UNSEM?


2. Given the information the EMS professional had at the time, was the medication-related issue avoidable?

- Yes
- Possibly
- No

Please explain your response.


3. Specific to this clinical scenario, how often is this medication-related issue or cascade of issues likely to occur? If more than one issue or cascade of issues occurred, select the corresponding frequencies and explain in the provided text box.

- Very Rarely (<1%)
- Rarely (1-9%)
- Occasionally (10-24%)
- Frequently (> 25%)

Please provide additional details:


4. Using your best clinical judgment, to what degree could the medication-related issue have harmed the patient?

- No harm likely or a near miss
- Mild or temporary harm, including additional treatment
- Permanent or severe permanent harm, including death
5. Pertains only to cases with 2 charts:
Is there concordance regarding medication management between the 2 charts?

- Yes
- No

If you checked No, please explain and include potential impacts to the patient.
**SECTION 2: PROCEDURE**

"Procedure" refers to any technical procedure that was performed, other than airway (e.g. vascular access, cardioversion, spinal immobilization, splinting, tourniquet application), or the failure to perform an indicated procedure. Any attempt - whether successful or not - at performing an IV/IO is considered a procedure. Given the clinical context, consider whether the number of attempts and route of access are justified.

**UNSEM (Unintended Injury or Consequence, Near Miss, Suboptimal Action, Error, Management Complication)**

1. Other than resuscitation, airway management, and medication administration, was a procedure(s) performed at any point during this call?

   - [ ] Yes
   - [ ] No
SECTION 2: PROCEDURE

1. Please feel free to provide comments:
SECTION 2: PROCEDURE

1. Should a procedure have been performed that was not?

- Yes
- No
- Not Sure

If Yes, please explain.

[Text box for explanation]
**SECTION 2: PROCEDURE**

1. **Was the procedure(s) indicated?**
   - Yes
   - No
   - Not Sure

   If No or Not Sure, please explain:
   
2. **Please check all that apply:**
   - Vascular access
   - Cardioversion
   - Spinal immobilization
   - Splinting
   - Tourniquet application
   - Other

   If Other, please specify here:

3. **Was there a(n) UNSEM related to procedure?**
   - Yes
   - No
   - Not Sure
SECTION 2: PROCEDURE

1. Please check all that apply.
   - Failure to perform an indicated procedure (specify below)
   - Inappropriate procedural technique (specify below)
   - Delay in performing a procedure (specify below)
   - Difficult task or procedure, including new or untested task (specify below)
   - Other (specify below)

   Please specify your response from above.

2. Was there a delay, omission, or confusion in dealing with the procedure-related issue?
   - Yes, delay
   - Yes, omission
   - Yes, confusion
   - No
   - Not Sure

   If you checked Yes or Not Sure, please explain.

3. What additional procedures (including any additional tests) were performed as a result of the UNSEM?

4. Given the information the EMS professional had at the time, was the procedure-related UNSEM avoidable?
   - Yes
   - Possibly
   - No

   Please explain your response.
5. Specific to this clinical scenario, how often is this procedure-related issue or cascade of issues likely to occur? If more than one issue or cascade of issues occurred, select the corresponding frequencies and explain in the provided text box below.

- Very Rarely (<1%)
- Rarely (1-9%)
- Occasionally (10-24%)
- Frequently (> 25%)

Please provide additional details:

6. Using your best clinical judgment, to what degree could the procedure-related issue have harmed the patient?

- No harm likely or a near miss
- Mild or temporary harm, including additional treatment
- Permanent or severe permanent harm, including death

7. Pertains only to cases with 2 charts:
Is there concordance regarding procedures between the 2 charts?

- Yes
- No

If you checked No, please explain and include potential impacts to the patient.
SECTION 2: EQUIPMENT

“Equipment” refers to implements used when treating a patient. This could include splints, immobilization equipment, Kendrick extrication device, monitoring and testing equipment, etc. (Please note: Radio/communication is dealt with in System.)

UNSEM (Unintended Injury or Consequence, Near Miss, Suboptimal Action, Error, Management Complication)

1. What safety restraints were used for patient transport?

The answer to this question is often contained in the beginning of the chart Narrative or in the Treatment and Response section.

☐ Gurney
☐ Car Seat
☐ Parent's Arms
☐ Bench Seat
☐ Not Documented
☐ Other

If Other, please specify:

[Text field for specifying other restraints]
SECTION 2: EQUIPMENT

1. Was the manner in which the patient was restrained for transport appropriate?

☐ Yes

☐ No
SECTION 2: EQUIPMENT

*1. Please elaborate:

2. Other than safety restraints, were any of the following pieces of equipment used at any point during this call: behavioral restraints, cardiovascular (monitors, defibrillators), backboards/C-Spine, splints/traction splints, or other pieces of equipment not listed here?

☐ Yes
☐ No
SECTION 2: EQUIPMENT

1. Please feel free to provide comments:

[Comment box]
SECTION 2: EQUIPMENT

1. Should equipment have been used that was not?
   - Yes
   - No
**SECTION 2: EQUIPMENT**

1. Please elaborate:

| 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 | 11 | 12 | 13 | 14 | 15 | 16 | 17 | 18 | 19 | 20 | 21 | 22 | 23 | 24 | 25 | 26 | 27 | 28 | 29 | 30 | 31 | 32 | 33 | 34 | 35 | 36 | 37 | 38 | 39 | 40 | 41 | 42 | 43 | 44 | 45 | 46 | 47 | 48 | 49 | 50 | 51 | 52 | 53 | 54 | 55 | 56 | 57 | 58 | 59 | 60 |
1. Was there a(n) UNSEM related to equipment?

- [ ] Yes
- [ ] No
- [ ] Not Sure
SECTION 2: EQUIPMENT

1. If equipment was used, was it indicated?
   - Yes
   - No
   - Not Sure

   If No or Not Sure, please explain.

2. If equipment other than safety restraints was used, please check all that apply:
   - Behavioral restraints
   - Cardiovascular (monitors, defibrillators)
   - Backboards/C-Spine
   - Splints/traction splints
   - Other

   If Other, please specify here:
SECTION 2: EQUIPMENT

1. Please choose all that apply:

☐ Delay in using equipment (specify below)
☐ Correct-sized equipment not available (specify below)
☐ Incorrect-sized equipment used (specify below)
☐ Lack of/incorrect equipment for special needs child (specify below)
☐ Equipment malfunction (specify below)
☐ Failure to use the correct equipment (specify below)
☐ Other (specify below)

Please specify your response from above.

2. Was there a delay, omission, or confusion in dealing with the equipment-related issue?

☐ Yes, delay
☐ Yes, omission
☐ Yes, confusion
☐ No
☐ Not Sure

If Yes or Not Sure, please explain.

3. Given the information the EMS professional had at the time, was the equipment-related UNSEEM avoidable?

☐ Yes
☐ Possibly
☐ No

Please explain your response.
4. Specific to this clinical scenario, how often is this equipment-related issue or cascade of issues likely to occur? If more than one issue or cascade of issues occurred, select the corresponding frequencies and explain in the provided text box below.

- Very Rarely (<1%)
- Rarely (1-9%)
- Occasionally (10-24%)
- Frequently (> 25%)

Please provide additional details:

5. Using your best clinical judgment, to what degree could the equipment-related issue have harmed the patient?

- No harm likely or a near miss
- Mild or temporary harm, including additional treatment
- Permanent or severe permanent harm, including death

6. Pertains only to cases with 2 charts:

Is there concordance regarding equipment between the 2 charts?

- Yes
- No

If you checked No, please explain and include potential impacts to the patient.
**SECTION 2: ENVIRONMENT**

Based on what is included in the History of Present Illness or Narrative sections of the chart, do you think the environment affected the patient's care/played a role in the level of care the patient received?

“Environment” is a broad category that includes:

- Transport: difficult terrain, vehicle accident during EMS transport, etc.
- Scene Characteristics: unsafe environment, weather conditions, location or lack of radio/cell reception, mass casualties incident/multiple simultaneous patients, hostile people on scene, etc.

*UNSEM (Unintended Injury or Consequence, Near Miss, Suboptimal Action, Error, Management Complication)*

1. Was there a(n) UNSEM related to environment?

   - Yes
   - No
   - Not Sure

If Yes or Not Sure, please describe:

[Blank space for description]
1. Given the information the EMS professional had at the time, was the environment-related UNSEM avoidable?

- Yes
- Possibly
- No

Please explain your response:

2. Specific to this clinical scenario, how often is this environment-related issue or cascade of issues likely to occur? If more than one issue or cascade of issues occurred, select the corresponding frequencies and explain in the provided text box below.

- Very Rarely (<1%)
- Rarely (1-9%)
- Occasionally (10-24%)
- Frequently (> 25%)

Please provide additional details:

3. Using your best clinical judgment, to what degree could the environment-related issue have harmed the patient?

- No harm likely or a near miss
- Mild or temporary harm, including additional treatment
- Permanent or severe permanent harm, including death

4. Pertains only to cases with 2 charts:

Is there concordance regarding the environment between the 2 charts?

- Yes
- No, please explain and include potential impacts to the patient:
SECTION 2: SYSTEM

“System” refers to an organized or established set of protocols, guidelines, and/or norms intended to facilitate the response of EMS professionals. “System” also includes aspects of care such as certification level of responding providers and staffing.

UNSEM (Unintended Injury or Consequence, Near Miss, Suboptimal Action, Error, Management Complication)

1. Was the code determination appropriate (e.g. Code 3, lights and sirens)?
   - [ ] Yes
   - [ ] No
SECTION 2: SYSTEM

1. Please elaborate:

2. Was the hospital destination appropriate?
   - Yes
   - No
SECTION 2: SYSTEM

1. Please elaborate:
1. Was there a(n) UNSEM related to the system?

- Yes
- No
- Not Sure
SECTION 2: SYSTEM

1. Please choose all of the following that apply:

- Code determination was inappropriate
- Police, Fire, or other professionals hinder or delay management or transport
- Inadequate online medical control (includes not accessing, conflicting advice, or inappropriate advice)
- Patient did not meet the correct trauma system criteria
- Patient transported to inappropriate facility (nearest vs. tertiary)
- Dispatch information (pre-arrivals) incorrect
- Other

If Other, please specify here:

2. Was there a delay, omission, or confusion in dealing with the system-related issue?

- Yes, delay
- Yes, omission
- Yes, confusion
- No
- Not Sure

If Yes or Not Sure, please explain:

3. Given the information the EMS professional had at the time, was the system-related UNSEM avoidable?

- Yes
- Possibly
- No

Please explain your response:
4. Specific to this clinical scenario, how often is this system-related issue or cascade of likely to occur? If more than one issue or cascade of issues occurred, select the corresponding frequencies and explain in the provided text box below.

- Very Rarely (<1%)
- Rarely (1-9%)
- Occasionally (10-24%)
- Frequently (> 25%)

Please provide additional details:

5. Using your best clinical judgment, to what degree could the system-related issue have harmed the patient?

- No harm likely or a near miss
- Mild or temporary harm, including additional treatment
- Permanent or severe permanent harm, including death

6. Pertains only to cases with 2 charts:
Is there concordance regarding the system between the 2 charts?

- Yes
- No, please explain and include potential impacts to the patient:
SECTION 3: SUMMARY OF PATIENT CONDITION

Remember, if you do not see it documented, assume it did not happen.

UNSEM (Unintended Injury or Consequence, Near Miss, Suboptimal Action, Error, Management Complication)

1. We understand that in many cases the severity of the chief complaint is the major driver of the patient’s outcome. Even in these cases, EMS care has the potential to negatively or positively contribute to the patient's condition. Using your best clinical judgment, please rate on a scale of -3 to +3 the degree to which EMS care contributed to the patient's condition. -3 = large negative contribution to patient's condition and +3 = large positive contribution to patient's condition.

<table>
<thead>
<tr>
<th>EMS Care</th>
<th>-3</th>
<th>-2</th>
<th>-1</th>
<th>0</th>
<th>+1</th>
<th>+2</th>
<th>+3</th>
</tr>
</thead>
<tbody>
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</tbody>
</table>

2. Please explain the numbers you provided above:

3. How adequate were the records in providing information to enable judgments of whether or not there was an UNSEM(s)?

- Medical records were adequate to make a reasonable judgment
- Some deficiencies in the records
- Major deficiencies in the records
- Severe deficiencies in the records, impossible to make judgments about UNSEM(s)

If there were deficiencies in the records, please specify:

4. For cases with 2 charts, what is the overall level of concordance between the 2 charts?

- Almost entirely concordant
- Minor discordance, still able to make judgments
- Concerning discordance, potential for medical/legal ramifications
### SECTION 3: SUMMARY OF UNSEM(s)

1. **Using your best clinical judgment (your gut feeling) and after considering the details of this patient’s management, irrespective of preventability or harm to the patient, do you think there was:** (Please check all that apply)

- U= Unintended injury or consequence (not solely by disease process)
- N= Near miss (not a planned event)
- S= Suboptimal action that can be improved
- E= Error
- M= Management complication
- Other
- Not Sure
- No, patient management was appropriate

2. **Based only on what is documented in the chart(s) and after considering the details of this patient’s management, irrespective of preventability or harm to the patient, do you think there was:** (Please check all that apply)

- U= Unintended injury or consequence (not solely by disease process)
- N= Near miss (not a planned event)
- S= Suboptimal action that can be improved
- E= Error
- M= Management complication
- Other
- Not Sure
- No, patient management was appropriate
## SECTION 3: SUMMARY OF UNSEM(s)

1. Is there documentation in the record that indicates the EMT recognized an UNSEM(s) occurred in any of the below areas?

<table>
<thead>
<tr>
<th>Category</th>
<th>Likely Recognized</th>
<th>Likely Unrecognized</th>
</tr>
</thead>
<tbody>
<tr>
<td>Resuscitation</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Assessment &amp; Diagnosis</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Clinical Decision Making</td>
<td></td>
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<tr>
<td>Airway/Breathing</td>
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<tr>
<td>Medication</td>
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<tr>
<td>Procedure</td>
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<td></td>
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<tr>
<td>Equipment</td>
<td></td>
<td></td>
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<tr>
<td>Environment</td>
<td></td>
<td></td>
</tr>
<tr>
<td>System</td>
<td></td>
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</tbody>
</table>

2. Give details of any key action/inaction and their sequence, when possible, that played a significant part in the causation of the UNSEM(s):

3. In your best clinical judgment, if you had to pick the primary factor (not limited to the items in #1 above) that led to the UNSEM(s), what would it be?

4. Of the UNSEMs that were recognized by the EMTs, was there an error in handling it (them)?
   - Yes
   - No
   - Not Sure
   - UNSEM(s) not recognized
SECTION 3: SUMMARY OF UNSEM(s)

1. Please describe for each potential error:

   [Answer]

2. Please describe the impact of the UNSEM(s) on the patient:

   [Answer]
## SECTION 4: CHART SUMMARY

The following is a list of factors not previously addressed in prior domains. Please tell us the degree to which any of these factors may have contributed to the UNSEM. The category “Not likely to be relevant” includes items that you are not sure if they contributed to the UNSEM.

### 1. Patient, Family, Friend, and/or Bystander Factors

<table>
<thead>
<tr>
<th>Not likely to be Relevant</th>
<th>Possible Contributor</th>
<th>Likely Contributor</th>
<th>Leading Contributor</th>
</tr>
</thead>
<tbody>
<tr>
<td>a) Uncooperative patient, family member, friend, and/or bystander</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
</tr>
<tr>
<td>b) Hostile patient, family member, friend, and/or bystander</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
</tr>
<tr>
<td>c) Patient comorbidity(ies)</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
</tr>
<tr>
<td>d) Child with special health care needs</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
</tr>
<tr>
<td>e) Difficulty understanding/communicating with patient, family member, or other guardian (e.g. language difficulties in absence of interpreter or cultural differences)</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
</tr>
<tr>
<td>f) Other patient, family, friend, and/or bystander characteristics (specify below)</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
</tr>
</tbody>
</table>

Please specify your "other" response (f)

### 2. Provider Factors

<table>
<thead>
<tr>
<th>Not likely to be Relevant</th>
<th>Possible Contributor</th>
<th>Likely Contributor</th>
<th>Leading Contributor</th>
</tr>
</thead>
<tbody>
<tr>
<td>a) Lack of knowledge</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
</tr>
<tr>
<td>b) Lack of skill(s)</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
</tr>
<tr>
<td>c) Other provider factors (specify below)</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
</tr>
</tbody>
</table>

Please specify your "other" response (c)
### 3. Team Factors

<table>
<thead>
<tr>
<th>Not likely to be Relevant</th>
<th>Possible Contributor</th>
<th>Likely Contributor</th>
<th>Leading Contributor</th>
</tr>
</thead>
<tbody>
<tr>
<td>a) Inadequate scene management</td>
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<td>[ ]</td>
</tr>
<tr>
<td>b) Failure to access online medical control</td>
<td>[ ]</td>
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<td>[ ]</td>
</tr>
<tr>
<td>c) Delay in accessing online medical control</td>
<td>[ ]</td>
<td>[ ]</td>
<td>[ ]</td>
</tr>
<tr>
<td>d) Inadequate handover</td>
<td>[ ]</td>
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<tr>
<td>e) Other team factors (specify below)</td>
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</table>

Please specify your "other" response (e):

### 4. Please list the 3 most important contributing factors to the UNSEM:

- Important Factor:
- Important Factor:
- Important Factor:

### 5. Please provide additional details that will assist in determining the top factors that influenced the UNSEM:

**Not likely to be Relevant**: 
- a) Inadequate scene management
- b) Failure to access online medical control
- c) Delay in accessing online medical control
- d) Inadequate handover
- e) Other team factors (specify below)

### 6. Thinking about our domains, please rank the domains in order of importance that each contributed to the UNSEM: [1 = most important]

<table>
<thead>
<tr>
<th>Domain</th>
<th>1</th>
<th>2</th>
<th>3</th>
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<th>5</th>
<th>6</th>
<th>7</th>
<th>8</th>
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<tbody>
<tr>
<td>Resuscitation</td>
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<td>Assessment, Impression/Diagnosis</td>
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<td>Clinical Knowledge/Decision Making</td>
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<td>Airway/Breathing</td>
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7. Did any of the following contribute to the UNSEM? Check all that apply.

- Patient's degree of vulnerability was not recognized
- Risk: Benefit ratio of treatment was not assessed/appreciated
- Age-based norms not appreciated
- Training for this clinical scenario not a required standard
- No
- Other

If Other, please specify here:

8. When UNSEMs occur, they frequently involve a chain of events. While individual elements may vary, we are interested to know how often you think a similar chain of events is likely to occur, given this clinical scenario in the pre-hospital setting?

- Very Rarely (<1%)
- Rarely (1-9%)
- Occasionally (10-24%)
- Frequently (> 25%)

9. Please rate the degree to which the UNSEM as a whole was preventable: 0 (impossible to prevent) to 10 (entirely preventable)

10. All charts have 2 reviewers (an EMT-P and MD). If you think this chart requires a third reviewer, please describe the type of provider best suited for the review and why.
Thank you!

You have finished reviewing this case.
Thank you very much.
STROBE Statement—checklist of items that should be included in reports of observational studies

<table>
<thead>
<tr>
<th>Item No</th>
<th>Recommendation</th>
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<tr>
<td><strong>Title and abstract</strong></td>
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Participants 13*  
(a) Report numbers of individuals at each stage of study—e.g., numbers potentially eligible, examined for eligibility, confirmed eligible, included in the study, completing follow-up, and analysed Page 11
(b) Give reasons for non-participation at each stage Page 11
(c) Consider use of a flow diagram

Descriptive data 14*  
(a) Give characteristics of study participants (e.g., demographic, clinical, social) and information on exposures and potential confounders Table 1
(b) Indicate number of participants with missing data for each variable of interest Page 11
(c) Cohort study—Summarise follow-up time (e.g., average and total amount) N/A

Outcome data 15*  
Cohort study—Report numbers of outcome events or summary measures over time
Case-control study—Report numbers in each exposure category, or summary measures of exposure
Cross-sectional study—Report numbers of outcome events or summary measures Table 1

Main results 16  
(a) Give unadjusted estimates and, if applicable, confounder-adjusted estimates and their precision (e.g., 95% confidence interval). Make clear which confounders were adjusted for and why they were included Table 2
(b) Report category boundaries when continuous variables were categorized Table 2
(c) If relevant, consider translating estimates of relative risk into absolute risk for a meaningful time period

Other analyses 17  
Report other analyses done—e.g., analyses of subgroups and interactions, and sensitivity analyses Table 3

Discussion

Key results 18  
Summarise key results with reference to study objectives Page 17

Limitations 19  
Discuss limitations of the study, taking into account sources of potential bias or imprecision. Discuss both direction and magnitude of any potential bias Page 19

Interpretation 20  
Give a cautious overall interpretation of results considering objectives, limitations, multiplicity of analyses, results from similar studies, and other relevant evidence Page 17-18

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Discuss the generalisability (external validity) of the study results Page 19

Other information

Funding 22  
Give the source of funding and the role of the funders for the present study and, if applicable, for the original study on which the present article is based Page 20

*Give information separately for cases and controls in case-control studies and, if applicable, for exposed and unexposed groups in cohort and cross-sectional studies.

Patient Safety Events in Out-of-Hospital Pediatric Airway Management: A Medical Record Review by the CSI-EMS

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Author contributions: All of the authors have made substantial contributions in 1) the conception and design of the study, acquisition of the data, and/or analysis and interpretation of the data 2) drafting and revising the article for important content and 3) finally approving the submitted version.

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Keywords: pediatrics; airway management; intubation; pediatric cardiac arrest; out-of-hospital pediatric airway management

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ABSTRACT

Objective

To describe the frequency and characterize the nature of patient safety events in pediatric out-of-hospital airway management.

Methods

We conducted a retrospective cross-sectional medical record review of all “lights and sirens” Emergency Medicine Services (EMS) transports from 2008 to 2011 in patients less than 18 years of age in the Portland Oregon metropolitan area. A chart review tool (see appendix) was adapted from landmark patient safety studies and revised after pilot testing. Expert panels of physicians and paramedics performed blinded reviews of each chart, identified safety events, and described their nature. The primary outcomes were presence and severity of patient safety events related to airway management including oxygen administration, bag-valve-mask ventilation (BVM), airway adjuncts, and endotracheal intubation (ETI).

Results

From the 11,328 pediatric transports during the study period, there were 497 “lights and sirens” (code 3) transports (4.4%). Seven transports were excluded due to missing data. Of the 490 transports included in the analysis, 329 had a total of 338 airway management procedures (some had more than one procedure): 61.6% were treated with oxygen, 15.3% with BVM, 8.6% with ETI, and 2% with airway adjuncts. The frequency of errors was: 21% (71/338) related to oxygen use, 9.8% (33/338) related to BVM, 9.5% (32/338) related to intubation, and 0.9% (3/338)
related to airway adjunct use. Fifty-eight percent of intubations required three or more attempts or failed altogether. Cardiac arrest was associated with higher odds of a severe error.

Conclusions

Errors in pediatric out-of-hospital airway management are common, especially in the context of intubations and during cardiac arrest.

Strengths and Limitations of the Study:

Strengths:

- This study provides an in depth look at pediatric out-of-hospital airway management from a patient safety perspective.
- It uses a rigorously developed chart review process.
- This study includes all EMS-performed airway management interventions from a specific geographic area during the study period.

Limitations:

- This study was conducted in a single large urban area in the United States and results may not be generalizable to other geographical areas.
- This is a retrospective study.
INTRODUCTION

The US National Quality Forum defines “Patient Safety” as: the prevention and mitigation of harm caused by errors of omission or commission that are associated with healthcare.[1] The patient safety movement in medicine, triggered by retrospective studies of clinical care, started two decades ago and has triggered massive efforts to improve care in hospital based medicine.[2,3] Out-of-hospital care, in particular pediatric care, has little published literature regarding patient safety and the nature of safety events is largely unknown. This knowledge gap has limited our ability to improve care on a system-based level.

Airway management is a critical component of resuscitation during many pediatric emergencies and includes a set of technical procedures that are potentially high risk for errors. The skillset required for pediatric out-of-hospital airway management includes oxygen administration, bag-valve-mask ventilation (BVM), oral and nasal airway insertion, supraglottic device insertion, and endotracheal intubation (ETI). ETI has long been considered “definitive” airway management for patients of any age and is practiced by many EMS agencies throughout the world.[4] Pediatric ETI is taught in paramedic training programs and is part of the US National Registry of Emergency Medical Technicians (NREMT) practical examination.[5]

Although pediatric ETI is considered an essential skill for paramedics, the single existing controlled trial found no benefit compared to BVM, and reported harm in some subgroups.[6] Other studies have demonstrated low success rates for pediatric out-of-hospital ETI and increased complications compared to in-hospital ETI.[7–10] In addition, paramedics perform pediatric ETI infrequently, perhaps only once every five years, and rapidly lose skills after training.[11–13] As a result of these factors, ETI for children in the out-of-hospital setting is
controversial. There are little data on other aspects of out-of-hospital pediatric airway management such as airway adjuncts and supraglottic devices. Several existing pediatric studies have been conducted in patient simulators and found high success rates, however an adult study on the laryngeal mask airway demonstrated high success in patients simulators (100%) with substantially lower success in practice (64%). [14–17] A national Delphi study recently found that airway management is the most high risk scenario for errors in pediatric out-of-hospital care.[18,19] Another recent study performed in a large national database found that intubation remains the most commonly used pediatric advanced airway technique out-of-hospital with lower success rates than in adults, with the lowest success being among patients less than 1 year of age.[20] Though this study addressed success rates, it did not include detailed review of the charts and was thus unable to identify the rates of specific types of errors in airway management such as tube depth, tube size, and the potential harm associated with the errors.

The objective of this study is to describe the rates and nature of patient safety events related to pediatric out-of-hospital airway management in a cohort of critically ill pediatric transports from a large metropolitan area.

METHODS

Study Design and Setting:

This is a retrospective cross-sectional study representing one portion of the Children’s Safety Initiative-EMS (CSI-EMS) using a chart review designed to capture a broad range of potential and manifest safety events. The CSI-EMS is a National Institutes of Health (NICHD R01HD062478) funded mixed-methods study. The goal of the CSI-EMS is to identify, describe, and classify the occurrence of safety events in out-of-hospital pediatric emergency care.[21] We
sub classified safety events as: unintended injury or consequences, near misses, suboptimal actions, errors, and management complications. This classification scheme had not been previously used but was developed by patient safety experts on our research team to capture the spectrum of errors as broadly as possible.

In this report, we present a retrospective medical record review of individual EMS transports in the Portland, Oregon (USA) metropolitan area. This metro area has a “dual advanced life support (ALS)” system where separate ALS fire and transport agencies respond to all calls. The transport and fire agencies in this study serve a population of over 700,000 residents. Airway management procedures in scope of practice in this system include oxygen administration, BVM, oral and nasal airways, supraglottic airways (King LT), and ETI including rapid sequence intubation (RSI). The cardiac arrest survival in Portland, OR is among the highest in the US, with EMS treated cardiac arrest survival of 10.4% reported in a 2008 study using the Resuscitation Outcomes Consortium sites. These high survival rates likely result from rapid response times and an effective (or ‘high-functioning’) EMS system.[22]

The transport agency units respond with two paramedics in each ambulance. Fire units include four to five person teams with at least one paramedic per team. Though fire units respond to each call, the transporting units can elect to dismiss them. If the fire department responders do not intervene, they do not complete a chart. In this system, fire units respond to 90% of calls in less than seven minutes and transport units respond to 90% of calls in less than eight minutes. Fire department crews work in 24-hour shifts. All transport paramedics work rotating shifts and experienced paramedics are equally distributed during all times of day.
Paramedics in this system are all required to participate in annual airway management training using simulation with adult, pediatric, and infant mannequins. In addition to this training, they are all required to maintain Pediatric Advanced Life Support certification. There were no specific protocols designating which paramedic, among those responding, would perform the intubation. The protocol for pediatric intubation, at the time of the study, called for using BVM or a rescue device if two attempts at intubation failed. However, at the time of the study, the King LT was the rescue device being used and it was not available in sizes suitable for most children under the age of eight. Providers did have access to oral and nasal airways in all pediatric sizes.

Selection of Participants:

We reviewed records for transports from 2008-2011 for all patients less than 18 years of age which were transported “code 3” (lights and sirens) indicating a critical transport. This transport priority is used at the discretion of the treating providers for patients felt to have a life or limb threatening condition. Reviews included charts from the transporting agency, and when applicable, the fire response unit. This group was chosen to identify a subset of patients more likely to need and receive interventions.

Chart Review Tool Development

Our chart review tool and review methods were based on forms from the Harvard Medical Practice Study and the Utah and Colorado Medical Practice Study that were the foundation for the Institute of Medicine Report on patient safety in medicine.[23] In turn, the chart review tool was adjusted to the out-of-hospital setting based on results from our EMS focus group study.[2,3,21] The tool was iteratively revised and finalized in several rounds of testing which included “talk aloud” sessions and pilot reviews using 30 sample EMS charts.
Given the lack of data defining patient safety events in pediatric EMS, the presence or absence of a safety event was based on judgment of the expert chart reviewers. Given the somewhat subjective nature of judging certain potential safety events, each chart was reviewed in tandem by both a paramedic and Emergency Physician using a standardized review tool. A Pediatric Emergency Physician, with expertise in pediatric EMS, performed a third review to arbitrate differences between the initial reviews. Chart reviewers could not be blinded to the study objectives since the review tool specifically focused on safety events. However, reviewers were blinded to results of all interim analysis and study hypotheses. All chart reviewers received a 2-hour training session on the chart review tool, completed test cases before and after the session, and were provided feedback on their test reviews. Based on results of test reviews and questions during feedback sessions, a guidebook was created and provided to all reviewers as a resource to ensure consistency and quality. Reviews were completed online via SurveyMonkey™. The expert chart review panel consisted of 13 paramedics and 7 physicians who were not affiliated with the agencies submitting charts for review. Paramedic reviewers were recruited by word of mouth in the local EMS community, and physician reviewers included one pediatrician and emergency physicians who worked in the pediatric ED of the metro area’s academic medical/trauma center and provide online medical control and one pediatrician.

As a final quality control measure, all charts were arbitrated by one of two pediatric emergency physician investigators with experience in EMS. Inter-rater reliability was established between the two pediatric emergency physician investigators prior to arbitration. A kappa statistic of 0.615 was achieved between the two arbiters on the presence or absence of safety events in the major domains described below. Following the initial blinded review to establish inter-rater reliability, the arbiters met and discussed all discrepancies in the reviews to achieve consensus.
The review tool was designed to identify errors in the following major domains: resuscitation; assessment, impression/diagnosis, and clinical decision making; airway/breathing; fluids and medication; procedures; equipment; environment; and system. Where available, data was abstracted from the chart electronically (scene time, transport time, time of day). Through a series of checkboxes, Likert-type questions, and open-ended responses, the reviewers manually abstracted chart data, not available electronically, including age, sex, weight, scene location, and transport priority. The reviewers then identified details of care including the dispatch complaint, clinical impression, all procedures performed including airway management procedures, whether or not an error occurred with any of the procedures or in other specific domains, details about the nature and cause of the error, and the degree of potential harm to the patient. The degrees of harm were assessed by the chart review tool using the following question: Using your best clinical judgement, to what degree could the (specific domain inserted eg. airway management) issue have harmed the patient. The following were the potential responses: 1) no harm likely or a near miss, 2) mild or temporary harm, including additional treatment, and 3) permanent or severe harm including death.

Analysis

First, we identified the cohort of patients who had airway management procedures including oxygen administration, BVM, airway adjuncts (oral, nasal, supraglottic airways), and endotracheal intubation out of the complete study population of critical transports as indicated by the chart reviewers. Next, we performed a descriptive analysis of the age, sex, scene location, and dispatch complaint of all patients who had airway management interventions. We then described the clinical impression of the paramedics documented in the electronic patient care report in cases where airway management procedures were performed. We then identified all
patients who had an error in airway management indicated by the reviewers. The reviewers also described the potential severity of harm caused by each error using three categories including “no harm,” “mild or temporary harm,” and “permanent or severe harm including death” using their best judgment based on the information available in the EMS patient care report. The reviewers described the nature of the error using a free text field where problems, such as “tube too deep,” could be entered. This list of variables was created based on a priori hypotheses developed by the study team of factors we felt could be associated with errors based on the experience of EMS professionals on the team as well as previous studies. Univariate analysis was performed on variables thought to be predictors of severe airway error and then used to select variables to be put in a regression model for severe airway error. Univariate analysis of continuous variables versus severe airway error was performed using logistic regression. Variables with a p value < 0.2 from univariate logistic regression were entered into the model.

Univariate analysis of categorical variables was performed using chi-square analysis. Fisher’s Exact test was used when there were small counts. The Phi coefficient or Cramer’s V was used to measure the strength of association between severe airway error and variables for which the Chi-square test was found to be significant. Variables with a mild association to very strong association (|Phi or Cramer’s V| greater than or equal to 0.15) were entered into the regression model. Variables with a mild to weak association that were suspected to be effect modifiers were entered into the model. One variable with a Phi or Cramer’s V greater than 0.40 but less than 0.50 was not entered into the model (reason for dispatch) because of concerns that the variable distorted the parameters of the other predictor variables, i.e., collinearity with other predictor variables.
When performing chi-square analysis on nominal variables, categories with cell counts less than five were not included in the analysis. Odds ratios and confidence intervals from 2x2 tables for categorical variables are reported in Table 2 with the results of the univariate analysis.

The study team reviewed the free text responses regarding the specific nature of the airway management errors (eg. tube too deep) and then divided them into specific categories. In addition, one study team member reviewed each cardiac arrest chart and abstracted the airway intervention and medication administration times from the event log in the patient care report to perform an analysis of the time to first epinephrine administration in patients who had advanced airway attempts vs. those who did not as well as total time spent prior to securing the airway (defined as the interval between time of first patient contact and documented success of ETI). The Institutional Review Board from Oregon Health & Science University approved all study components (IRB Number 00006942). Analysis was conducted using SAS software version 9.4 (SAS Institute Inc., Cary, NC, USA).

RESULTS

From a total of 11,328 pediatric transports during the study period, we identified 497 “code 3” transports (4.4%). We eliminated two transports due to missing data and five transports because we were unable to obtain the associated fire department chart, leaving a total of 490 charts for review. Table 1 presents the characteristics of the 490 pediatric patients and details for those who received specific airway interventions. Approximately two-thirds of patients transported code 3 had an airway management intervention of some kind (329/490, 67%) and 25.51% of patients had more than one airway management intervention. The median number of interventions was “1”. Of those transported code 3, 61.6% (302/490) were treated with oxygen, 15.3% (75/490)
with BVM, 8.6% with ETI (42/490), and 2.0% (10/490) with airway adjuncts. Half of all intubations (21/42) were performed in children less than 12 months of age. The most common reason for dispatch among patients with airway management procedures besides oxygen administration was cardiopulmonary arrest, the second most common seizure, and the third most common reason was trauma. In contrast, the most common reason for dispatch in the entire study population was trauma, followed by nearly equal proportions of interfaculty transports and seizures/altered level of consciousness.

Table 1. Characteristics of patients who had airway management procedures

<table>
<thead>
<tr>
<th></th>
<th>All Patients</th>
<th>Any Airway Management</th>
<th>Oxygen</th>
<th>BVM</th>
<th>Airway Adjuncts</th>
<th>Intubation</th>
</tr>
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<tbody>
<tr>
<td></td>
<td>N = 490</td>
<td>N = 329</td>
<td>N = 302</td>
<td>N = 75</td>
<td>N = 10</td>
<td>N = 42</td>
</tr>
<tr>
<td></td>
<td>n (%)</td>
<td>n (%)</td>
<td>n (%)</td>
<td>n (%)</td>
<td>n (%)</td>
<td>n (%)</td>
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<tr>
<td><strong>Age</strong></td>
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<tr>
<td>0-28 days</td>
<td>23 (4.7)</td>
<td>18 (5.5)</td>
<td>12 (4.0)</td>
<td>7 (9.3)</td>
<td>0 (0.0)</td>
<td>6 (14.3)</td>
</tr>
<tr>
<td>29 days – 11 months</td>
<td>61 (12.5)</td>
<td>50 (15.2)</td>
<td>41 (13.6)</td>
<td>22 (29.3)</td>
<td>3 (30.0)</td>
<td>15 (35.7)</td>
</tr>
<tr>
<td>12 months – 5 years</td>
<td>169 (34.5)</td>
<td>117 (35.6)</td>
<td>110 (36.4)</td>
<td>19 (25.3)</td>
<td>0 (0.0)</td>
<td>6 (14.3)</td>
</tr>
<tr>
<td>6-11 years</td>
<td>84 (17.1)</td>
<td>56 (17.0)</td>
<td>55 (18.2)</td>
<td>7 (9.3)</td>
<td>1 (10.0)</td>
<td>2 (4.8)</td>
</tr>
<tr>
<td>12 – 17 years</td>
<td>153 (31.2)</td>
<td>88 (26.8)</td>
<td>84 (27.8)</td>
<td>20 (26.7)</td>
<td>6 (60.0)</td>
<td>13 (31.0)</td>
</tr>
<tr>
<td><strong>Female</strong></td>
<td>195 (39.8)</td>
<td>134 (40.7)</td>
<td>120 (39.7)</td>
<td>33 (44.0)</td>
<td>3 (30.0)</td>
<td>20 (47.6)</td>
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<tr>
<td><strong>Scene Location</strong></td>
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<tr>
<td>Home</td>
<td>219 (44.7)</td>
<td>174 (52.9)</td>
<td>154 (51.0)</td>
<td>51 (68.0)</td>
<td>6 (60.0)</td>
<td>31 (73.8)</td>
</tr>
<tr>
<td>School</td>
<td>25 (5.1)</td>
<td>9 (2.7)</td>
<td>9 (3.0)</td>
<td>3 (4.0)</td>
<td>1 (10.0)</td>
<td>1 (2.4)</td>
</tr>
<tr>
<td>Street/Highway</td>
<td>117 (23.9)</td>
<td>64 (19.5)</td>
<td>63 (20.9)</td>
<td>10 (13.3)</td>
<td>1 (10.0)</td>
<td>7 (16.7)</td>
</tr>
<tr>
<td>Hospital/Clinic</td>
<td>110 (22.5)</td>
<td>69 (21.0)</td>
<td>63 (20.9)</td>
<td>9 (12.0)</td>
<td>0 (0.0)</td>
<td>2 (4.8)</td>
</tr>
<tr>
<td>Recreation/Sport</td>
<td>14 (2.9)</td>
<td>10 (3.0)</td>
<td>10 (3.3)</td>
<td>2 (2.7)</td>
<td>2 (20.0)</td>
<td>1 (2.4)</td>
</tr>
<tr>
<td>Other</td>
<td>5 (1.0)</td>
<td>3 (0.9)</td>
<td>3 (1.0)</td>
<td>0 (0.0)</td>
<td>0 (0.0)</td>
<td>0 (0.0)</td>
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<tr>
<td><strong>First Responder</strong></td>
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<tr>
<td>Ambulance</td>
<td>183 (37.4)</td>
<td>121 (36.8)</td>
<td>112 (37.1)</td>
<td>20 (26.7)</td>
<td>5 (50.0)</td>
<td>13 (31.0)</td>
</tr>
<tr>
<td>Fire</td>
<td>181 (36.9)</td>
<td>129 (39.2)</td>
<td>119 (39.4)</td>
<td>33 (44.0)</td>
<td>3 (30.0)</td>
<td>18 (42.9)</td>
</tr>
<tr>
<td>Police</td>
<td>14 (2.9)</td>
<td>6 (1.8)</td>
<td>6 (2.0)</td>
<td>0 (0.0)</td>
<td>0 (0.0)</td>
<td>1 (2.4)</td>
</tr>
<tr>
<td>Unknown</td>
<td>112 (22.9)</td>
<td>73 (22.2)</td>
<td>65 (21.5)</td>
<td>22 (29.3)</td>
<td>2 (20.0)</td>
<td>10 (23.8)</td>
</tr>
<tr>
<td><strong>Reason for Dispatch</strong></td>
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<tr>
<td>Cardiopulmonary Arrest</td>
<td>35 (7.1)</td>
<td>35 (10.6)</td>
<td>19 (6.3)</td>
<td>33 (44.0)</td>
<td>5 (50.0)</td>
<td>26 (61.9)</td>
</tr>
<tr>
<td>Trauma</td>
<td>203 (41.4)</td>
<td>94 (28.6)</td>
<td>91 (30.1)</td>
<td>11 (14.7)</td>
<td>2 (20.0)</td>
<td>10 (23.8)</td>
</tr>
</tbody>
</table>
Overall, 27.8% (94/338) of charts with airway management were judged to have airway management errors. Errors were related to oxygen use in 21% (71/338) of cases, to BVM in 9.8% (33/338), to airway adjunct use in 0.9% (3/338), and to ETI in 9.5% (32/338). Nine percent of cases had errors in more than one aspect of airway management.

Over 70% of cases in which ETI was performed contained an error of some type. The specific nature of errors relating to ETI were: ETT placed too deep in 25% of cases, incorrect ETT size used in 29% (78% of the time too small), and dislodgement of the ETT during transport in 13% of cases. Reviewers felt that 24% of the time, ETI was not indicated when performed. The most common type of error in ETI was technical difficulty with the procedure, accounting for 58% of errors, defined as failure to secure ETI or requiring three or more attempts.

The most common clinical scenario in which ETI was performed was cardiac arrest. In cardiac arrest scenarios, intubation was attempted 74% of the time. On average, in cardiac arrest cases where ETI was attempted the mean time to the first dose of epinephrine was 11 minutes. In cases where ETI was not attempted, the mean time to the first dose of epinephrine was 7 minutes. In addition, in cases where ETI was attempted, 10 minutes passed on average prior to securing an

---

**Table:**

<table>
<thead>
<tr>
<th>Condition</th>
<th>Value</th>
<th>Value</th>
<th>Value</th>
<th>Value</th>
<th>Value</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Seizure or ALOC&lt;sup&gt;b&lt;/sup&gt;</td>
<td>107 (21.8)</td>
<td>95 (28.9)</td>
<td>93 (30.8)</td>
<td>17 (22.7)</td>
<td>1 (10.0)</td>
<td>2 (4.8)</td>
</tr>
<tr>
<td>Ingestion/Poisoning/Intoxication</td>
<td>29 (5.9)</td>
<td>15 (4.6)</td>
<td>15 (5.0)</td>
<td>4 (5.3)</td>
<td>2 (20.0)</td>
<td>2 (4.8)</td>
</tr>
<tr>
<td>Respiratory Distress</td>
<td>79 (16.1)</td>
<td>73 (22.2)</td>
<td>68 (22.5)</td>
<td>9 (12.0)</td>
<td>0 (0.0)</td>
<td>2 (4.8)</td>
</tr>
<tr>
<td>Allergic Reaction/Anaphylaxis</td>
<td>11 (2.2)</td>
<td>7 (2.1)</td>
<td>7 (2.3)</td>
<td>1 (1.3)</td>
<td>0 (0.0)</td>
<td>0 (0.0)</td>
</tr>
<tr>
<td>Pain (non-trauma)</td>
<td>12 (2.5)</td>
<td>5 (1.5)</td>
<td>5 (1.7)</td>
<td>0 (0.0)</td>
<td>0 (0.0)</td>
<td>0 (0.0)</td>
</tr>
<tr>
<td>Other</td>
<td>14 (2.9)</td>
<td>5 (1.5)</td>
<td>4 (1.3)</td>
<td>0 (0.0)</td>
<td>0 (0.0)</td>
<td>0 (0.0)</td>
</tr>
</tbody>
</table>

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<sup>a</sup>BVM = Bag-Valve-Mask Ventilation  
<sup>b</sup>ALOC = Altered Level of Consciousness  
<sup>c</sup>Airway Adjuncts: Airway adjuncts in the chart review included nasopharyngeal or oropharyngeal airways n=9 and one King LT supraglottic airway device.
airway or abandoning further attempts. This may indicate that on average providers conclude advanced airway management prior to administration of epinephrine.

Further analysis of other types of airway management errors found that 48% of the time, oxygen was administered when it was not indicated, and 32% of the time oxygen was not administered when it was indicated. There was a broad range of clinical scenarios where oxygen was applied and reviewers felt it was not indicated. Errors related to BVM were most commonly due to lack of use when indicated or failure to attempt for a long enough period prior to performing ETI. Airway adjuncts were infrequently used (n=10) and all errors identified were related to lack of use when indicated, rather than inappropriate use or a complication related to their use.

Figure 1 presents the distribution of errors in airway management by age. Neonates had the highest rate of severe errors followed by infants, with a trend towards decreased rate of severe errors with increasing age. Figure 2 shows the level of harm of the errors according to airway management procedures. Intubation had the highest rate of severe errors among the airway management procedures.

Errors in airway management were commonly associated with errors in other domains of care. In cases with any airway management error, 64% had errors in decision making, 62% in resuscitation, and 48% in medications (p < 0.01 for all). In cases where there were errors in BVM or ETI, more than 90% of cases also had an error identified in resuscitation, over 65% had errors in assessment/decision-making, and over 60% had errors in medications (p < 0.01 for all).

We performed univariate analyses to identify factors associated with severe airway management errors (Table 2). In these unadjusted analyses, an increased risk of a severe error related to airway management was strongly associated with patient age less than 28 days (OR 6.62, 95%
CI 1.68 – 26.0), less than 12 months (OR = 5.73, 95% CI 1.91 – 17.20) patients in cardiopulmonary arrest (OR = 15.61, 95% CI 5.65 – 43.12), fire department involvement (fire department team and transport team both provided significant care) (OR = 2.75, 95% CI 1.30-5.82), and calls occurring between 10pm and 8am (OR=2.21, 95% CI 1.05-4.62).

Table 2. Univariate analysis of factors associated with a severe airway management error

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>Odds Ratio</th>
<th>95% CI</th>
<th>P Value</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Patient Characteristic</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Age</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>0-28 days</td>
<td>6.62</td>
<td>1.68 – 26.0</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>29 days – 11 months</td>
<td>5.73</td>
<td>1.91 – 17.2</td>
<td></td>
</tr>
<tr>
<td>1-5 years</td>
<td>1.07</td>
<td>0.33- 3.47</td>
<td></td>
</tr>
<tr>
<td>6 – 11 years</td>
<td>1.65</td>
<td>0.46 – 5.99</td>
<td></td>
</tr>
<tr>
<td>12–17 years (reference category)</td>
<td>1</td>
<td>--</td>
<td></td>
</tr>
<tr>
<td>Gender</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Male</td>
<td>0.79</td>
<td>0.39 – 1.60</td>
<td>0.51</td>
</tr>
<tr>
<td><strong>Call Characteristic</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Reason for Dispatch</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Trauma (reference category)</td>
<td>1</td>
<td>--</td>
<td>&lt;.001</td>
</tr>
<tr>
<td>Seizure or ALOC</td>
<td>0.14</td>
<td>0.02 – 1.12</td>
<td></td>
</tr>
<tr>
<td>Respiratory Distress</td>
<td>1.4</td>
<td>0.47 – 4.16</td>
<td></td>
</tr>
<tr>
<td>Cardiorespiratory Arrest</td>
<td>15.61</td>
<td>5.65 – 43.1</td>
<td></td>
</tr>
<tr>
<td>Other (including Birth/Delivery)</td>
<td>0.95</td>
<td>0.05 – 18.5</td>
<td></td>
</tr>
<tr>
<td>Fire Department Involvement</td>
<td></td>
<td></td>
<td>0.006</td>
</tr>
<tr>
<td>Fire chart</td>
<td>2.75</td>
<td>1.30 – 5.82</td>
<td></td>
</tr>
<tr>
<td>Call During the Night</td>
<td></td>
<td></td>
<td>0.032</td>
</tr>
<tr>
<td>(10pm-8am)</td>
<td>2.21</td>
<td>1.05 – 4.62</td>
<td></td>
</tr>
<tr>
<td>Scene Time</td>
<td></td>
<td></td>
<td>0.14</td>
</tr>
<tr>
<td>(per one minute increase)</td>
<td>1.03</td>
<td>0.99 – 1.07</td>
<td></td>
</tr>
<tr>
<td>Transportation Time</td>
<td></td>
<td></td>
<td>0.10</td>
</tr>
<tr>
<td>(per one minute increase)</td>
<td>0.96</td>
<td>0.91 – 1.01</td>
<td></td>
</tr>
</tbody>
</table>

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a338 observations (338 out of 490 charts reviewed; airway error information not available for 152 charts)
bOdds ratios and confidence intervals calculated from 2x2 tables of each category against the reference category. Reported P-value from a Fisher’s exact test performed on all categories. Cramer’s V was found to be > 0.20 from analysis of a table of age group and severe airway management error that included four age groups (0 days – 11 months, 1-5 years, 6-11 years, and 12-17 years) so that the expected value for each cell in the table was greater than five.
In multivariate logistic regression analyses (Table 3), 0-28 days and age < 12 months remained statistically significant with strong associations with severe errors. We noted fire department involvement was associated with increased odds of severe errors, increased transport time was mildly protective against severe errors, while increased scene time was associated with increased odds of severe errors.

Table 3. Multivariate analysis of factors associated with a severe airway management error\textsuperscript{a,b}

<table>
<thead>
<tr>
<th>Characteristics</th>
<th>Odds Ratio</th>
<th>95% CI</th>
<th>P Value</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Patient Characteristic</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Age</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Newborn (0-28 days)</td>
<td>7.50</td>
<td>2.11 – 26.6</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Infant (29 days through 11 months)</td>
<td>5.69</td>
<td>1.13 – 28.8</td>
<td>0.02</td>
</tr>
<tr>
<td>1-5 years</td>
<td>1.52</td>
<td>0.34 – 6.86</td>
<td>0.22</td>
</tr>
<tr>
<td>6-11 years</td>
<td>0.96</td>
<td>0.4 – 3.92</td>
<td>0.43</td>
</tr>
<tr>
<td>12–17 years (reference category)</td>
<td>1</td>
<td>--</td>
<td>--</td>
</tr>
<tr>
<td><strong>EMS Scene Care</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Fire department involvement</td>
<td>3.91</td>
<td>1.55 – 9.85</td>
<td>0.004</td>
</tr>
<tr>
<td>Transport time in minutes</td>
<td>0.94</td>
<td>0.88 – 1.00</td>
<td>0.04</td>
</tr>
<tr>
<td>Scene time in minutes</td>
<td>1.04</td>
<td>1.00 – 1.09</td>
<td>0.03</td>
</tr>
</tbody>
</table>

\textsuperscript{a}331 observations (out of 490 charts, after excluding charts with missing info on airway errors, gender, and scene time and excluding outliers); Likelihood-based pseudo R-square = 0.12 Max-rescaled R-Square = 0.26

\textsuperscript{b}Four outliers with a standardized deviance residual of greater than 2.50 were removed from the final model.
DISCUSSION

In this analysis we found that airway management errors are relatively common, occurring in >25% of cases where airway management was performed, and that a high proportion of errors had the potential to cause severe patient harm. Patients less than 12 months of age and those with cardiac or respiratory arrest were at highest risk for severe airway management errors and were the patient populations who most commonly needed airway management. Of airway management procedures, ETI had the highest proportion of errors and required three or more attempts or was unsuccessful 58% of the time bringing into question the safety of this procedure. Airway adjuncts and BVM were judged to be under-utilized.

Several previous investigations have documented pediatric ETI success rates from 50 to 100%, and major complications between 1.8% and 50%.[24–27] The only controlled trial on out-of-hospital pediatric ETI found no benefit compared to BVM but has been criticized for inadequate training.[6] Our study also provides additional insight into the nature of ETI related errors by identifying incorrect tube size, incorrect tube depth, multiple attempts, failure to successfully place the tube, and unnecessary intubation as the specific types of errors.

We also found that patients with cardiac arrest had significantly increased odds of an airway management error. In these cases, EMS providers may face cognitive and emotional overload.[28] Similar to our study, an analysis of more than 10 years of data from San Diego, California found that the majority of pediatric out-of-hospital intubations are for cardiac arrest, indicating this is an important area of focus.[29]

Infants experience a disproportionate portion of airway management errors. The airway anatomy of children less than one year of age differs substantially from that of older children. In addition,
the small size of the patient makes performing simultaneous interventions such as airway management and CPR challenging. In cases with airway management errors, we also found high rates of errors in resuscitation, assessment/decision-making, and medication administration. This indicates that airway management errors are not likely due to one specific skill deficit, but while multiple critical decisions and interventions are being performed quickly.

One reason pediatric ETI may not benefit patients is that the potential advantages of an endotracheal tube securing the airway are mitigated by procedural complications and by detrimental effects on other aspects of resuscitation. A recent study done in the Emergency Department found that significant adverse events increase rapidly with the number of intubation attempts.[30] We found that in cases of cardiac arrest, on average, ETI was being performed prior to administration of epinephrine, which contradicts American Heart Association guidelines.[31,32] This suggests that ETI may have a negative effect on other important components of out-of-hospital pediatric resuscitation.

Our analysis adds to the literature by evaluating a broad range of airway interventions. We found that BVM and airway adjuncts were at times not used when indicated. Previous simulation studies have found technical problems with prehospital BVM which may reflect the challenging nature of this procedure in children or lack of experience in its use.[33,34] In addition, BVM in pediatric patients may be resource intensive and require two providers to achieve adequate mask seal.

Airway adjuncts such as supraglottic devices, OPAs, and NPAs appear to be used very infrequently in children, even when indicated. Simulation-based studies have shown high success rates with supraglottic devices in pediatric manikins placed by EMS providers and may be a promising solution.[16,35]
We found that the presenting complaint of seizure/altered level of consciousness trended towards decreased odds of errors. We believe this is because these patients were likely over-triaged to code 3 transport, given the benign natural course of most pediatric seizures. Errors were not unexpectedly associated with calls during the nighttime hours. Increased scene time was associated with increased odds of errors likely reflecting increased time at risk. Increased transport time was associated with reduced odds of errors after controlling for scene time. This could be due to more stable patients at lower risk for errors being transported longer distances due to bypassing the nearest hospital in favor of a children’s hospital a greater distance away. Finally, we found that fire department involvement had a significant association with increased odds of a severe error. This is most likely due to confounding by indication since locally the fire department only provides ongoing care to the most severely ill patients.

There are several potential mechanisms to improve the safety of pediatric airway management based on the results of this study. Each provider in our system undergoes pediatric airway simulation training, but it is clearly not adequate. Increased time in simulation training low cost models that are more realistic are potential solutions. Simulation training is resource intensive so this may not be sustainable or generalizable. Given the highest rate of errors was in the youngest patients, limiting intubation to older children may be reasonable. This study was not powered to detect differences by age group so we cannot comment on what the correct age should be. Increased use of supraglottic airways may be a promising option in children as well, though further study is needed.

Limitations:
Our study has several limitations. First, it was conducted in a single metropolitan area. Next this is a retrospective study and limited to the data available in the medical record. Our reliance on the written record likely biases our results towards underestimation of errors.[36] Though a standard definition was used, assessment of harm was based on the judgment of chart reviewers and is inherently subjective, although this practice has been used in other landmark patient safety studies.[2,3] We used a rigorous chart review tool development and training process with multiple blinded reviewers to mitigate this source of bias. Finally, this study was conducted in a well-developed EMS system with short response times utilizing paramedics as initial responders to all calls, available medication facilitated intubation, and with a relatively high cardiac arrest survival.[22] In general this is a “high functioning” EMS system which may have lower rates of errors than in other systems. Our findings may not be generalizable to other EMS systems. Categories of nominal predictor variables with one or less case of severe airway error were not included when performing the Chi-square test on reason for dispatch; we chose to focus on categories of dispatch reason in which there was more than one severe airway error reported. Due to the small number of cases in this sample, we cannot be sure that severe airway error would not be present in greater numbers in certain categories of reason for dispatch (poisoning, allergy or anaphylaxis, and pain) when looking at a larger sample. The small sample size precluded the inclusion of interaction terms to investigate possible effect modification in the multiple regression model.

In conclusion, our study finds high error rates in pediatric out-of-hospital airway management. ETI was the modality associated with the highest rate of errors, and the youngest patients as well as those with cardiopulmonary arrests were at highest risk of errors. These findings raise serious concerns about the safety of advanced airway management procedures. Future directions for this
work could include expanding this research to other types of EMS systems and conducting prospective trials assessing the efficacy of different airway management strategies.
Contributorship statement
MH contributed to the design of the study, and analysis of data, and writing of the manuscript. GM and WL and JMG contributed to the design of the study, development of data collection tools, collection, validation, and analysis of data, and critical review of the manuscript. CK and KD contributed to the design of the study, development of data collection tools, collection, validation, and analysis of data and provided critical review of the manuscript. JVO contributed to the analysis of data and provided critical review of the manuscript.

Competing Interests
All authors had financial support from the National Institute of Child Health and Human Development (NICHD) grant (R01HD062478) for the submitted work; no financial relationships with any organizations that might have an interest in the submitted work in the previous three years; no other relationships or activities that could appear to have influenced the submitted work.

Funding
This work is supported by the National Heart Lung and Blood Institute (NHLBI) grant number 5K12HL108974-03. This work is also supported by the National Institute of Child Health and Human Development grant: “Epidemiology of Preventable Safety Events in Pre-hospital EMS of Children,” Grant # 1R01HD062478-04. The content is solely the responsibility of the authors and does not necessarily represent the official views of the National Heart, Lung, and Blood Institute, the National Institute of Child Health and Human Development, or the National Institutes of Health. All researchers had independence from the funder with regard to design, conduct, and analysis of the study.

Data Sharing
There is no additional data available

PRISMA Guidelines
This paper follows the STROBE guidelines for observational research.
References:


Figure Legends:

Figure 1. Severity of airway management errors by patient age.

Figure 2. Severity of airway management errors by type of procedure. 02=Oxygen; BVM = Bag-Valve-Mask Ventilation. UNSEM = Unintended consequence, Near Miss, Suboptimal Action, Error, Management Complication.
Purpose: We are interested in capturing a broad range of potential challenges or errors in the pre-hospital care of children. This tool is intended to understand and describe the circumstances that could have caused such events, which we are referring to as “UNSEMs.”

UNSEM is defined as:

- Unintended injury or consequence
- Near miss (not a planned event)
- Suboptimal action that can be improved
- Error
- Management complication

The act of responding to a call and providing care may have resulted in an UNSEM. We appreciate that professionals talk about these events in different ways and use different terms to describe them; more than one UNSEM can occur in any particular situation. In addition, we consider overtreatment or unnecessary treatment to be an UNSEM (e.g. inappropriate Code 3, unnecessary trauma registration, unnecessary IV, and unnecessary medication).

There may be times when you do not see documentation of clinical information in the pre-hospital record. We are interested in your synthesis of the entire chart; if an item or event is not documented, assume it did not happen. [Please note: as long as it is documented in one of the charts (e.g. in the fire chart but not in the AMR chart), it is OK.]

Please note: Sections have overlap; it is okay to mention items, ideas, issues, etc. in multiple sections.
SECTION 1: REVIEWER INFORMATION

1. Reviewer Initials:

2. Study ID:

3. Is there a Fire chart? (If you only received one chart, assume there is no Fire chart.)
   - Yes
   - No

4. Reason For Call (chief complaint):

5. Please use your judgment to assess the nature of the patient's condition overall:
   - Mild (expected to recover within days)
   - Moderate
   - Critical/Severe or potentially permanent
   - Death
   - Cannot reasonably judge

6. Among pediatric dispatches, how common is this type of chief complaint?
   - Very Rare (<1%)
   - Rare (1-9%)
   - Occasional (10-24%)
   - Frequent (> 25%)
SECTION 2: RESUSCITATION

Remember, if you do not see it documented, assume it did not happen.

"Resuscitation" refers to the treatment of: respiratory distress or failure, compensated or decompensated shock, altered mental status, and/or ongoing seizure activity (e.g. treatment of an asthmatic who is wheezing and receiving albuterol).

UNSEM (Unintended Injury or Consequence, Near Miss, Suboptimal Action, Error, Management Complication)

1. Did resuscitation occur at any point during this call? (Refer to your manual before answering this question.)
   
   - [ ] Yes
   - [ ] No
SECTION 2: RESUSCITATION

1. Should resuscitation have occurred? (Refer to your manual before answering this question.)

- [ ] Yes
- [ ] No
SECTION 2: RESUSCITATION

1. Was there a(n) UNSEM related to resuscitation?

- [ ] Yes
- [ ] No
- [ ] Not Sure

If you checked Yes or Not Sure in the above question, please describe.

[Blank Space]
SECTION 2: RESUSCITATION

1. Please elaborate:
SECTION 2: RESUSCITATION

1. Please feel free to provide additional comments:

2. What was the condition(s) that led to the need for resuscitation?

- [ ] Cardiac arrest (specify below)
- [ ] Respiratory failure/arrest (specify below)
- [ ] Altered mental status (specify below)
- [ ] Seizures (specify below)
- [ ] Poisoning (e.g. drug overdose) (specify below)
- [ ] Drowning (specify below)
- [ ] Trauma (specify below)
- [ ] Metabolic disorder (e.g. hypoglycemia) (specify below)
- [ ] Infection/Sepsis (specify below)
- [ ] Other (specify below)

Please specify your response from above.
1. Was there a delay, omission, or confusion in dealing with the resuscitation-related issue?

- [ ] Yes, delay
- [ ] Yes, omission
- [ ] Yes, confusion
- [ ] No
- [ ] Not Sure
SECTION 2: RESUSCITATION

1. Please check all that apply:

- [ ] Equipment not available
- [ ] Required drug(s) not available
- [ ] Scene management issue
- [ ] Failure to recognize age-based norms
- [ ] Failure to obtain needed tests (glucose, O2 Sat)
- [ ] Failure to obtain needed monitoring
- [ ] Other

If Other, please specify here:

2. Was the resuscitation-related UNSEM avoidable?

- [ ] Yes
- [ ] Possibly
- [ ] No

Please explain your response.

3. Specific to this clinical scenario, how often is this resuscitation issue or cascade of issues likely to occur? If more than one issue or cascade of issues occurred, select the corresponding frequencies and explain in the provided text box below.

- [ ] Very Rarely (<1%)
- [ ] Rarely (1-9%)
- [ ] Occasionally (10-24%)
- [ ] Frequently (> 25%)

Please provide additional details:
4. Using your best clinical judgment, to what degree could the resuscitation management issue have harmed the patient?

- No harm likely or a near miss
- Mild or temporary harm, including additional treatment
- Permanent or severe permanent harm, including death

5. Pertains only to cases with 2 charts:
Is there concordance regarding resuscitation between the 2 charts?

- Yes
- No (Please explain below)

If you checked No, please explain and include potential impacts to the patient.
SECTION 2: ASSESSMENT, IMPRESSION/DIAGNOSIS, AND CLINICAL DECISION MAKING...

"Assessment, Impression/Diagnosis, and Clinical Decision Making" refers to the assessment or diagnosis of the patient (recognizing abnormal vital signs or if the patient is sick or not sick, etc.), and/or the decisions made regarding the patient’s care. For example, a child with stridor from croup could be assessed as having wheezing from asthma, which would result in inappropriate subsequent management of the patient. (The patient actually has upper airway obstruction, but was thought to have lower airway obstruction.)

UNSEM (Unintended Injury or Consequence, Near Miss, Suboptimal Action, Error, Management Complication)

1. Was there an issue related to: (Please refer to the manual & then check all that apply)

- [ ] Clinical history (specify below)
- [ ] Physical exam (specify below)
- [ ] Taking account of comorbidity (specify below)
- [ ] Recognizing age-based norms (specify below)
- [ ] Reassessing patient response to care/intervention (specify below)
- [ ] Applying appropriate monitors (specify below)
- [ ] Monitoring vital signs (specify below)
- [ ] Communicating impressions to the rest of the team (specify below)
- [ ] Other (specify below)
- [ ] No issue

Please specify your response(s) from above.

2. Was there a(n) UNSEM related to assessment, impression/diagnosis, and/or clinical decision making?

- [ ] Yes
- [ ] No
- [ ] Not Sure

If you checked Yes or Not Sure to the above question, please describe.
SECTION 2: ASSESSMENT, IMPRESSION/DIAGNOSIS, AND CLINICAL DECISION MAKING

1. Was there a delay, omission, or confusion in assessment, impression/diagnosis, and/or clinical decision making?
   - [ ] Yes, delay
   - [ ] Yes, omission
   - [ ] Yes, confusion
   - [ ] No
   - [ ] Not Sure

If Yes or Not Sure, please describe:

2. Given the information the EMS professional had at the time, was the assessment, impression/diagnosis, and/or clinical decision making issue avoidable?
   - [ ] Yes
   - [ ] Possibly
   - [ ] No

Please explain your response.

3. Specific to this clinical scenario, how often is this assessment, impression/diagnosis, and/or clinical decision making issue or cascade of issues likely to occur? If more than one issue or cascade of issues occurred, select the corresponding frequencies and explain in the provided text box below.
   - [ ] Very Rarely (<1%)
   - [ ] Rarely (1-9%)
   - [ ] Occasionally (10-24%)
   - [ ] Frequently (> 25%)

Please provide additional details:
4. Using your best clinical judgment, to what degree could the assessment, impression/diagnosis, and/or clinical decision making issue have harmed the patient?

- No harm likely or a near miss
- Mild or temporary harm, including additional treatment
- Permanent or severe permanent harm, including death

5. Pertains only to cases with 2 charts:
Is there concordance regarding assessment, impression/diagnosis, and/or clinical decision making between the 2 charts?

- Yes
- No (Please explain below)

If you checked No, please explain and include potential impacts to the patient.
**SECTION 2: AIRWAY/BREATHING**

“Airway/Breathing” refers to management of the patient’s airway and/or breathing, including use/misuse of basic and advanced airway adjuncts (including administration of Oxygen). Please note that administration of medication for breathing problems is considered airway management (and also considered medication administration).

**UNSEM (Unintended Injury or Consequence, Near Miss, Suboptimal Action, Error, Management Complication)**

**1. Did airway management occur at any point during this call?**

- [ ] Yes
- [ ] No
SECTION 2: AIRWAY/BREATHING

1. Please feel free to provide additional comments:
SECTION 2: AIRWAY/BREATHING

*1. Please elaborate:

[Blank space for response]
SECTION 2: AIRWAY/BREATHING

1. Should airway management have occurred?

☐ Yes

☐ No
SECTION 2: AIRWAY/BREATHING

1. Was the airway management performed indicated?

- Yes
- No
- Not Sure

If you checked No or Not Sure, please explain.

2. Please check all types of airway management that occurred.

- O2 (Nasal/Mask/Blow-by)
- BVM
- Surgical Airway (specify below)
- Delay in airway management (specify below)
- Airway Adjuncts: (Please select either Oral or Nasal Airway)
- Oral Airway
- Nasal Airway
- Intubation (Please select which device was used)
- ETT
- King Airway
- LMA
- Other

If needed, please specify here:
SECTION 2: AIRWAY/BREATHING

1. Did the patient need medication-facilitated intubation?
   - Yes
   - No

   If No, should RSI medications have been used? Please explain.

2. If the patient needed medication-facilitated intubation, what were the medications, dosages, and routes? (Please separate responses with a comma)
   - Medication
   - Dosage
   - Route
   - Time Administered

3. Was difficulty of intubation noted?
   - Yes
   - No

4. Was confirmation obtained?
   - Yes
   - No
   - Unable to Determine
SECTION 2: AIRWAY/BREATHING

1. Please check the method(s) of confirmation that were used: (Check all that apply)

- [ ] ETCO2 (waveform)
- [ ] ETCO2 (colorimetric)
- [ ] Direct visualization of the cords
- [ ] Absent gastric sounds
- [ ] Mist in endotrachael tube
- [ ] Bilateral chest rise
- [ ] O2 stat prior/after
- [ ] Missing
- [ ] Unclear
- [ ] Other

If Other, please specify here:

[ ]
### SECTION 2: AIRWAY/BREATHING

**1. Was there a(n) UNSEM related to airway management?**

- [ ] Yes
- [ ] No
- [ ] Not Sure

If you checked Yes or Not Sure, please describe.

```markdown

```
SECTION 2: AIRWAY/BREATHING

1. Was there a delay, omission, or confusion in dealing with the airway-related issue?
   - Yes, delay
   - Yes, omission
   - Yes, confusion
   - No
   - Not Sure

   If Yes or Not Sure, please explain.

2. Given the information the EMS professional had at the time, was the airway management issue avoidable?
   - Yes
   - Possibly
   - No

   Please explain your response.

3. Specific to this clinical scenario, how often is this airway management issue or cascade of issues likely to occur? If more than one issue or cascade of issues occurred, select the corresponding frequencies and explain in the provided text box below.
   - Very Rarely (<1%)
   - Rarely (1-9%)
   - Occasionally (10-24%)
   - Frequently (> 25%)

   Please provide additional details:
4. Using your best clinical judgment, to what degree could the airway management issue have harmed the patient?

- No harm likely or a near miss
- Mild or temporary harm, including additional treatment
- Permanent or severe permanent harm, including death

5. Pertains only to cases with 2 charts:

Is there concordance regarding airway management between the 2 charts?

- Yes
- No

If you checked No, please explain and include potential impacts to the patient.
SECTION 2: FLUIDS & MEDICATION

"Fluids" refers to the administration of IV/IO fluids (e.g. saline, LR, dextrose/glucose rather than specific IV medications) or the failure to administer IV fluids when indicated. It does NOT refer to specific IV medications. Also, 10cc of normal saline is a flush, and does not refer to fluid administration (this is generally given to keep the line open).

"Medication" refers to drug choice, dosage, and route of administration, as well as adverse drug reactions and failure to administer an indicated medication. (Not including supplemental O2.)

UNSEM (Unintended Injury or Consequence, Near Miss, Suboptimal Action, Error, Management Complication)

1. Was patient weight documented?

   ○ Yes
   ○ No
SECTION 2: FLUIDS & MEDICATION

1. How was weight obtained?

- Parental Report
- Length-based Estimate
- Method Not Specified
1. Is the documented weight within age-based norms?
   - Yes
   - No, low for patient age
   - No, high for patient age

2. The next several questions pertain to administration of IV/IO fluids ONLY, NOT medications.

Were fluids administered?
   - Yes
   - No
SECTION 2: FLUIDS & MEDICATION

1. Please indicate the route and volume:
### SECTION 2: FLUIDS & MEDICATION

1. Should fluids have been administered?

- [ ] Yes
- [ ] No
SECTION 2: FLUIDS & MEDICATION

1. Please elaborate:

   [Blank space for text input]
SECTION 2: FLUIDS & MEDICATION

1. Was there an UNSEM related to fluid administration?

- [ ] Yes
- [ ] No
- [ ] Not Sure
SECTION 2: FLUIDS & MEDICATION

1. Please describe:

[Text area]

2. Was there a delay, omission, or confusion in dealing with the fluids-related issue?

- [ ] Yes, delay
- [ ] Yes, omission
- [ ] Yes, confusion
- [ ] No
- [ ] Not Sure
**SECTION 2: FLUIDS & MEDICATION**

1. Please explain:

2. What was the nature of the fluids-related UNSEM?

- Unpredictable reaction
- Predictable reaction
- Incorrect concentration
- Fluids contraindicated in this case
- Incorrect volume
- Incorrect route
- Inadequate monitoring
- Failure to administer fluids
- Other

   Please specify choices above:

3. Even with the knowledge beforehand that this adverse effect could occur, was it reasonable to administer the fluids?

- Yes
- No
- No fluids were administered

4. What additional treatment was provided as a result of the fluids-related UNSEM?
5. Given the information the EMS professional had at the time, was the fluids-related issue avoidable?

- Yes
- Possibly
- No

Please explain

6. Specific to this clinical scenario, how often is this fluids-related issue or cascade of issues likely to occur? If more than one issue or cascade of issues occurred, select the corresponding frequencies and explain in the provided text box below.

- Very Rarely (<1%)
- Rarely (1-9%)
- Occasionally (10-24%)
- Frequently (>25%)

Please provide additional details:

7. Using your best clinical judgment, to what degree could the fluids-related issue have harmed the patient?

- No harm likely or a near miss
- Mild or temporary harm, including additional treatment
- Permanent or severe permanent harm, including death

8. Pertains only to cases with 2 charts: Is there concordance regarding fluids management between the 2 charts?

- Yes
- No; please explain and include potential impacts to the patient below

Please explain:
9. The remaining questions in this section pertain to medications ONLY, NOT fluids

*In this section, please include albuterol or other airway medications that were given. If pain medications should have been given but were not, this is considered an UNSEM.*

**Was medication administered?**

- [ ] Yes
- [ ] No
SECTION 2: FLUIDS & MEDICATION

1. Please feel free to provide comments:
### SECTION 2: FLUIDS & MEDICATION

1. Should medication have been administered?

- [ ] Yes
- [ ] No
**SECTION 2: FLUIDS & MEDICATION**

**1. Please elaborate:**

[Blank space for input]
SECTION 2: FLUIDS & MEDICATION

1. Please feel free to provide comments:

2. Was the medication indicated?
   - Yes
   - No
   - Not Sure
   If No or Not Sure, please explain.

3. What type of medication(s) was administered?
   - Sedative or hypnotic
   - Nausea
   - Allergy/Anaphylaxis treatment
   - Antidote (e.g. Narcan)
   - Anti-seizure
   - Narcotic
   - Anti-diabetic (glucagon)
   - Diuretics
   - Cardiovascular
   - Antipsychotic
   - Respiratory (including inhaled)
   - RSI (including pre-meds)
   - Other
   If Other, please specify

4. Other than what you have already described in airway management, please list the medication(s) administered:
5. How was the medication(s) administered (route of administration)?

- Intravenous
- Orally
- IO
- ET Tubes
- Intra-muscular
- Sublingual
- Rectal
- Subcutaneous
- Intranasal
- Not documented
- Other

If Other or multiple options were selected, please specify:
1. Was there a(n) UNSEM related to medication?

- Yes
- No
- Not Sure

If Yes or Not Sure, please describe.
### SECTION 2: FLUIDS & MEDICATION

**1. Was there a delay, omission, or confusion in dealing with the medication-related issue?**

- [ ] Yes, delay
- [ ] Yes, omission
- [ ] Yes, confusion
- [ ] No
- [ ] Not Sure

If Yes or Not Sure, please explain.

**2. What was the nature of the medication-related UNSEM?**

- [ ] Drug less effective than expected (specify below)
- [ ] Unpredictable reaction (specify below)
- [ ] Predictable reaction (specify below)
- [ ] Incorrect drug (specify below)
- [ ] Incorrect concentration (specify below)
- [ ] Drug contraindication (specify below)
- [ ] Drug-drug interaction (specify below)
- [ ] Incorrect dose (specify below)
- [ ] Incorrect route (specify below)
- [ ] Inadequate monitoring (specify below)
- [ ] Failure to administer medication (specify below)
- [ ] Other (specify below)

Please specify your response(s) from above.

**3. Even with knowledge beforehand that an adverse effect could occur, was it reasonable to administer the medication?**

- [ ] Yes
- [ ] No
- [ ] No medication was administered
SECTION 2: FLUIDS & MEDICATION

1. What additional medication(s) were administered as a result of the UNSEM?

2. Given the information the EMS professional had at the time, was the medication-related issue avoidable?
   - Yes
   - Possibly
   - No

Please explain your response.

3. Specific to this clinical scenario, how often is this medication-related issue or cascade of issues likely to occur? If more than one issue or cascade of issues occurred, select the corresponding frequencies and explain in the provided text box.
   - Very Rarely (<1%)
   - Rarely (1-9%)
   - Occasionally (10-24%)
   - Frequently (> 25%)

Please provide additional details:

4. Using your best clinical judgment, to what degree could the medication-related issue have harmed the patient?
   - No harm likely or a near miss
   - Mild or temporary harm, including additional treatment
   - Permanent or severe permanent harm, including death
5. Pertains only to cases with 2 charts:
Is there concordance regarding medication management between the 2 charts?

- [ ] Yes
- [ ] No

If you checked No, please explain and include potential impacts to the patient.
“Procedure” refers to any technical procedure that was performed, other than airway (e.g. vascular access, cardioversion, spinal immobilization, splinting, tourniquet application), or the failure to perform an indicated procedure. Any attempt - whether successful or not - at performing an IV/IO is considered a procedure. Given the clinical context, consider whether the number of attempts and route of access are justified.

UNSEM (Unintended Injury or Consequence, Near Miss, Suboptimal Action, Error, Management Complication)

1. Other than resuscitation, airway management, and medication administration, was a procedure(s) performed at any point during this call?

- Yes
- No
SECTION 2: PROCEDURE

1. Please feel free to provide comments:

[Comment Field]
SECTION 2: PROCEDURE

1. Should a procedure have been performed that was not?

☐ Yes

☐ No

☐ Not Sure

If Yes, please explain.


**SECTION 2: PROCEDURE**

1. **Was the procedure(s) indicated?**
   - [ ] Yes
   - [ ] No
   - [ ] Not Sure

   If No or Not Sure, please explain:
   
   

2. **Please check all that apply:**
   - [ ] Vascular access
   - [ ] Cardioversion
   - [ ] Spinal immobilization
   - [ ] Splinting
   - [ ] Tourniquet application
   - [ ] Other

   If Other, please specify here:
   
   

3. **Was there a(n) UNSEM related to procedure?**
   - [ ] Yes
   - [ ] No
   - [ ] Not Sure
### SECTION 2: PROCEDURE

**1. Please check all that apply.**

- [x] Failure to perform an indicated procedure (specify below)
- [x] Inappropriate procedural technique (specify below)
- [x] Delay in performing a procedure (specify below)
- [x] Difficult task or procedure, including new or untested task (specify below)
- [x] Other (specify below)

Please specify your response from above.

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<tr>
<th>Failure to perform an indicated procedure</th>
<th>Inappropriate procedural technique</th>
<th>Delay in performing a procedure</th>
<th>Difficult task or procedure, including new or untested task</th>
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**2. Was there a delay, omission, or confusion in dealing with the procedure-related issue?**

- [x] Yes, delay
- [x] Yes, omission
- [x] Yes, confusion
- [ ] No
- [ ] Not Sure

If you checked Yes or Not Sure, please explain.

<table>
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<tr>
<th>Yes, delay</th>
<th>Yes, omission</th>
<th>Yes, confusion</th>
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**3. What additional procedures (including any additional tests) were performed as a result of the UNSEM?**

<table>
<thead>
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<th>Additional procedures</th>
<th>Additional tests</th>
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**4. Given the information the EMS professional had at the time, was the procedure-related UNSEM avoidable?**

- [ ] Yes
- [ ] Possibly
- [x] No

Please explain your response.

<table>
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<th>Yes</th>
<th>Possibly</th>
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</table>
5. Specific to this clinical scenario, how often is this procedure-related issue or cascade of issues likely to occur? If more than one issue or cascade of issues occurred, select the corresponding frequencies and explain in the provided text box below.

- Very Rarely (<1%)
- Rarely (1-9%)
- Occasionally (10-24%)
- Frequently (> 25%)

Please provide additional details:

6. Using your best clinical judgment, to what degree could the procedure-related issue have harmed the patient?

- No harm likely or a near miss
- Mild or temporary harm, including additional treatment
- Permanent or severe permanent harm, including death

7. Pertains only to cases with 2 charts:
Is there concordance regarding procedures between the 2 charts?

- Yes
- No

If you checked No, please explain and include potential impacts to the patient.
“Equipment” refers to implements used when treating a patient. This could include splints, immobilization equipment, Kendrick extrication device, monitoring and testing equipment, etc. (Please note: Radio/communication is dealt with in System.)

UNSEM (Unintended Injury or Consequence, Near Miss, Suboptimal Action, Error, Management Complication)

1. What safety restraints were used for patient transport?

The answer to this question is often contained in the beginning of the chart Narrative or in the Treatment and Response section.

- Gurney
- Car Seat
- Parent's Arms
- Bench Seat
- Not Documented
- Other

If Other, please specify:
1. Was the manner in which the patient was restrained for transport appropriate?

- Yes
- No
SECTION 2: EQUIPMENT

*1. Please elaborate:

2. Other than safety restraints, were any of the following pieces of equipment used at any point during this call: behavioral restraints, cardiovascular (monitors, defibrillators), backboards/C-Spine, splints/traction splints, or other pieces of equipment not listed here?

- Yes
- No
SECTION 2: EQUIPMENT

1. Please feel free to provide comments:
### SECTION 2: EQUIPMENT

1. Should equipment have been used that was **not**?

- [ ] Yes
- [ ] No
SECTION 2: EQUIPMENT

*1. Please elaborate:

[Text box for elaboration]
SECTION 2: EQUIPMENT

1. Was there a(n) UNSEM related to equipment?
   
   ○ Yes
   ○ No
   ○ Not Sure
SECTION 2: EQUIPMENT

1. If equipment was used, was it indicated?
   - Yes
   - No
   - Not Sure

   If No or Not Sure, please explain.

2. If equipment other than safety restraints was used, please check all that apply:
   - Behavioral restraints
   - Cardiovascular (monitors, defibrillators)
   - Backboards/C-Spine
   - Splints/traction splints
   - Other

   If Other, please specify here:
SECTION 2: EQUIPMENT

1. Please choose all that apply:
   - [ ] Delay in using equipment (specify below)
   - [ ] Correct-sized equipment not available (specify below)
   - [ ] Incorrect-sized equipment used (specify below)
   - [ ] Lack of/incorrect equipment for special needs child (specify below)
   - [ ] Equipment malfunction (specify below)
   - [ ] Failure to use the correct equipment (specify below)
   - [ ] Other (specify below)

   Please specify your response from above.

2. Was there a delay, omission, or confusion in dealing with the equipment-related issue?
   - [ ] Yes, delay
   - [ ] Yes, omission
   - [ ] Yes, confusion
   - [ ] No
   - [ ] Not Sure

   If Yes or Not Sure, please explain.

3. Given the information the EMS professional had at the time, was the equipment-related UNSEM avoidable?
   - [ ] Yes
   - [ ] Possibly
   - [ ] No

   Please explain your response.
4. Specific to this clinical scenario, how often is this equipment-related issue or cascade of issues likely to occur? If more than one issue or cascade of issues occurred, select the corresponding frequencies and explain in the provided text box below.

- Very Rarely (<1%)
- Rarely (1-9%)
- Occasionally (10-24%)
- Frequently (> 25%)

Please provide additional details:

5. Using your best clinical judgment, to what degree could the equipment-related issue have harmed the patient?

- No harm likely or a near miss
- Mild or temporary harm, including additional treatment
- Permanent or severe permanent harm, including death

6. Pertains only to cases with 2 charts:
Is there concordance regarding equipment between the 2 charts?

- Yes
- No

If you checked No, please explain and include potential impacts to the patient.
SECTION 2: ENVIRONMENT

Based on what is included in the History of Present Illness or Narrative sections of the chart, do you think the environment affected the patient's care/played a role in the level of care the patient received?

"Environment" is a broad category that includes:

- Transport: difficult terrain, vehicle accident during EMS transport, etc.
- Scene Characteristics: unsafe environment, weather conditions, location or lack of radio/cell reception, mass casualties incident/multiple simultaneous patients, hostile people on scene, etc.

**UNSEM** (Unintended Injury or Consequence, Near Miss, Suboptimal Action, Error, Management Complication)

1. Was there a(n) UNSEM related to environment?

   - [ ] Yes
   - [ ] No
   - [ ] Not Sure

If Yes or Not Sure, please describe:

[Blank space for description]
SECTION 2: ENVIRONMENT

1. Given the information the EMS professional had at the time, was the environment-related UNSEM avoidable?
   - Yes
   - Possibly
   - No

   Please explain your response:

2. Specific to this clinical scenario, how often is this environment-related issue or cascade of issues likely to occur? If more than one issue or cascade of issues occurred, select the corresponding frequencies and explain in the provided textbox below.

   - Very Rarely (<1%)
   - Rarely (1-9%)
   - Occasionally (10-24%)
   - Frequently (> 25%)

   Please provide additional details:

3. Using your best clinical judgment, to what degree could the environment-related issue have harmed the patient?
   - No harm likely or a near miss
   - Mild or temporary harm, including additional treatment
   - Permanent or severe permanent harm, including death

4. Pertains only to cases with 2 charts:
Is there concordance regarding the environment between the 2 charts?
   - Yes
   - No, please explain and include potential impacts to the patient:
“System” refers to an organized or established set of protocols, guidelines, and/or norms intended to facilitate the response of EMS professionals. “System” also includes aspects of care such as certification level of responding providers and staffing.

UNSEM (Unintended Injury or Consequence, Near Miss, Suboptimal Action, Error, Management Complication)

1. Was the code determination appropriate (e.g. Code 3, lights and sirens)?
   - [ ] Yes
   - [ ] No
**SECTION 2: SYSTEM**

1. Please elaborate:

2. Was the hospital destination appropriate?
   - Yes
   - No
SECTION 2: SYSTEM

*1. Please elaborate:

[Blank space for elaboration]
1. Was there a(n) UNSEM related to the system?

[ ] Yes

[ ] No

[ ] Not Sure
SECTION 2: SYSTEM

1. Please choose all of the following that apply:

- Code determination was inappropriate
- Police, Fire, or other professionals hinder or delay management or transport
- Inadequate online medical control (includes not accessing, conflicting advice, or inappropriate advice)
- Patient did not meet the correct trauma system criteria
- Patient transported to inappropriate facility (nearest vs. tertiary)
- Dispatch information (pre-arrivals) incorrect
- Other

If Other, please specify here: 

2. Was there a delay, omission, or confusion in dealing with the system-related issue?

- Yes, delay
- Yes, omission
- Yes, confusion
- No
- Not Sure

If Yes or Not Sure, please explain:

3. Given the information the EMS professional had at the time, was the system-related UNSEM avoidable?

- Yes
- Possibly
- No

Please explain your response:
4. Specific to this clinical scenario, how often is this system-related issue or cascade of likely to occur? If more than one issue or cascade of issues occurred, select the corresponding frequencies and explain in the provided text box below.

- Very Rarely (<1%)
- Rarely (1-9%)
- Occasionally (10-24%)
- Frequently (> 25%)

Please provide additional details:

5. Using your best clinical judgment, to what degree could the system-related issue have harmed the patient?

- No harm likely or a near miss
- Mild or temporary harm, including additional treatment
- Permanent or severe permanent harm, including death

6. Pertains only to cases with 2 charts:
   Is there concordance regarding the system between the 2 charts?

- Yes

- No, please explain and include potential impacts to the patient:
SECTION 3: SUMMARY OF PATIENT CONDITION

Remember, if you do not see it documented, assume it did not happen.

UNSEM (Unintended Injury or Consequence, Near Miss, Suboptimal Action, Error, Management Complication)

1. We understand that in many cases the severity of the chief complaint is the major driver of the patient’s outcome. Even in these cases, EMS care has the potential to negatively or positively contribute to the patient’s condition. Using your best clinical judgment, please rate on a scale of -3 to +3 the degree to which EMS care contributed to the patient’s condition. 

-3 = large negative contribution to patient’s condition and +3 = large positive contribution to patient’s condition

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<th>-1</th>
<th>0</th>
<th>+1</th>
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2. Please explain the numbers you provided above:

3. How adequate were the records in providing information to enable judgments of whether or not there was an UNSEM(s)?

- Medical records were adequate to make a reasonable judgment
- Some deficiencies in the records
- Major deficiencies in the records
- Severe deficiencies in the records, impossible to make judgments about UNSEM(s)

If there were deficiencies in the records, please specify:

4. For cases with 2 charts, what is the overall level of concordance between the 2 charts?

- Almost entirely concordant
- Minor discordance, still able to make judgments
- Concerning discordance, potential for medical/legal ramifications
### SECTION 3: SUMMARY OF UNSEM(s)

1. **Using your best clinical judgment (your gut feeling)** and after considering the details of this patient's management, irrespective of preventability or harm to the patient, do you think there was: (Please check all that apply)

   - [ ] U= Unintended injury or consequence (not solely by disease process)
   - [ ] N= Near miss (not a planned event)
   - [ ] S= Suboptimal action that can be improved
   - [ ] E= Error
   - [ ] M= Management complication
   - [ ] Other
   - [ ] Not Sure
   - [ ] No, patient management was appropriate

2. **Based only on what is documented in the chart(s)** and after considering the details of this patient's management, irrespective of preventability or harm to the patient, do you think there was: (Please check all that apply)

   - [ ] U= Unintended injury or consequence (not solely by disease process)
   - [ ] N= Near miss (not a planned event)
   - [ ] S= Suboptimal action that can be improved
   - [ ] E= Error
   - [ ] M= Management complication
   - [ ] Other
   - [ ] Not Sure
   - [ ] No, patient management was appropriate

---

For peer review only - http://bmjopen.bmj.com/site/about/guidelines.xhtml
SECTION 3: SUMMARY OF UNSEM(s)

1. Is there documentation in the record that indicates the EMT recognized an UNSEM(s) occurred in any of the below areas?

<table>
<thead>
<tr>
<th></th>
<th>Likely Recognized</th>
<th>Likely Unrecognized</th>
</tr>
</thead>
<tbody>
<tr>
<td>Resuscitation</td>
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<td>Assessment &amp; Diagnosis</td>
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<td>Clinical Decision Making</td>
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2. Give details of any key action/inaction and their sequence, when possible, that played a significant part in the causation of the UNSEM(s):

3. In your best clinical judgment, if you had to pick the primary factor (not limited to the items in #1 above) that led to the UNSEM(s), what would it be?

4. Of the UNSEMs that were recognized by the EMTs, was there an error in handling it (them)?

- [ ] Yes
- [ ] No
- [ ] Not Sure
- [ ] UNSEM(s) not recognized
SECTION 3: SUMMARY OF UNSEM(s)

1. Please describe for each potential error:

2. Please describe the impact of the UNSEM(s) on the patient:
### SECTION 4: CHART SUMMARY

The following is a list of factors not previously addressed in prior domains. Please tell us the degree to which any of these factors may have contributed to the UNSEM. The category “Not likely to be relevant” includes items that you are not sure if they contributed to the UNSEM.

#### 1. Patient, Family, Friend, and/or Bystander Factors

<table>
<thead>
<tr>
<th>Factor</th>
<th>Not likely to be Relevant</th>
<th>Possible Contributor</th>
<th>Likely Contributor</th>
<th>Leading Contributor</th>
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<tbody>
<tr>
<td>a) Uncooperative patient, family member, friend, and/or bystander</td>
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<td>b) Hostile patient, family member, friend, and/or bystander</td>
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<td>c) Patient comorbidity(ies)</td>
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<td>d) Child with special health care needs</td>
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<td>e) Difficulty understanding/communicating with patient, family member,</td>
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<td>or other guardian (e.g. language difficulties in absence of interpreter</td>
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<td>or cultural differences)</td>
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<tr>
<td>f) Other patient, family, friend, and/or bystander characteristics</td>
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</table>

Please specify your "other" response (f)

#### 2. Provider Factors

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<thead>
<tr>
<th>Factor</th>
<th>Not likely to be Relevant</th>
<th>Possible Contributor</th>
<th>Likely Contributor</th>
<th>Leading Contributor</th>
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</thead>
<tbody>
<tr>
<td>a) Lack of knowledge</td>
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<tr>
<td>b) Lack of skill(s)</td>
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<tr>
<td>c) Other provider factors</td>
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Please specify your "other" response (c)
3. Team Factors

Not likely to be Relevant  Possible Contributor  Likely Contributor  Leading Contributor

a) Inadequate scene management
b) Failure to access online medical control
c) Delay in accessing online medical control
d) Inadequate handover
e) Other team factors (specify below)

Please specify your "other" response (e)

4. Please list the 3 most important contributing factors to the UNSEM:

Important Factor:

Important Factor:

Important Factor:

5. Please provide additional details that will assist in determining the top factors that influenced the UNSEM:

6. Thinking about our domains, please rank the domains in order of importance that each contributed to the UNSEM: [1 = most important]

<table>
<thead>
<tr>
<th>Domain</th>
<th>1</th>
<th>2</th>
<th>3</th>
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<th>5</th>
<th>6</th>
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<td>Resuscitation</td>
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<td>Assessment, Impression/Diagnosis</td>
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<td>Clinical Knowledge/Decision Making</td>
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</table>
7. Did any of the following contribute to the UNSEM? Check all that apply.

- [ ] Patient's degree of vulnerability was not recognized
- [ ] Risk: Benefit ratio of treatment was not assessed/appreciated
- [ ] Age-based norms not appreciated
- [ ] Training for this clinical scenario not a required standard
- [ ] No
- [ ] Other

If Other, please specify here:

8. When UNSEMs occur, they frequently involve a chain of events. While individual elements may vary, we are interested to know how often you think a similar chain of events is likely to occur, given this clinical scenario in the pre-hospital setting?

- [ ] Very Rarely (<1%)
- [ ] Rarely (1-9%)
- [ ] Occasionally (10-24%)
- [ ] Frequently (>25%)

9. Please rate the degree to which the UNSEM as a whole was preventable: 0 (impossible to prevent) to 10 (entirely preventable)

10. All charts have 2 reviewers (an EMT-P and MD). If you think this chart requires a third reviewer, please describe the type of provider best suited for the review and why.
Thank you!

You have finished reviewing this case.
Thank you very much.
STROBE Statement—checklist of items that should be included in reports of observational studies

<table>
<thead>
<tr>
<th>Item No</th>
<th>Recommendation</th>
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<tr>
<td><strong>Title and abstract</strong></td>
<td>1</td>
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<td></td>
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<tr>
<td><strong>Introduction</strong></td>
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<td><strong>Methods</strong></td>
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<td>Study design</td>
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<td>Setting</td>
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<td>Participants</td>
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<td>Variables</td>
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<td>Data sources/ measurement</td>
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Results

Participants 13* (a) Report numbers of individuals at each stage of study—e.g., numbers potentially eligible, examined for eligibility, confirmed eligible, included in the study, completing follow-up, and analysed Page 11

(b) Give reasons for non-participation at each stage Page 11

(c) Consider use of a flow diagram

Descriptive data 14* (a) Give characteristics of study participants (e.g., demographic, clinical, social) and information on exposures and potential confounders Table 1

(b) Indicate number of participants with missing data for each variable of interest Page 11

(c) Cohort study—Summarise follow-up time (e.g., average and total amount) N/A

Outcome data 15* Cohort study—Report numbers of outcome events or summary measures over time

Case-control study—Report numbers in each exposure category, or summary measures of exposure

Cross-sectional study—Report numbers of outcome events or summary measures Table 1

Main results 16 (a) Give unadjusted estimates and, if applicable, confounder-adjusted estimates and their precision (e.g., 95% confidence interval). Make clear which confounders were adjusted for and why they were included Table 2

(b) Report category boundaries when continuous variables were categorized Table 2

(c) If relevant, consider translating estimates of relative risk into absolute risk for a meaningful time period

Other analyses 17 Report other analyses done—e.g., analyses of subgroups and interactions, and sensitivity analyses Table 3

Discussion

Key results 18 (a) Summarise key results with reference to study objectives Page 17

Limitations 19 (a) Discuss limitations of the study, taking into account sources of potential bias or imprecision. Discuss both direction and magnitude of any potential bias Page 19

Interpretation 20 (a) Give a cautious overall interpretation of results considering objectives, limitations, multiplicity of analyses, results from similar studies, and other relevant evidence Page 17-18

Generalisability 21 (a) Discuss the generalisability (external validity) of the study results Page 19

Other information

Funding 22 (a) Give the source of funding and the role of the funders for the present study and, if applicable, for the original study on which the present article is based Page 20

*Give information separately for cases and controls in case-control studies and, if applicable, for exposed and unexposed groups in cohort and cross-sectional studies.