Prehospital resuscitation decisions in cases of traumatic cardiopulmonary arrest: assessing the risk of legal liability & the impact of TOR guidelines

Karen Jordan – Louis D. Brandeis School of Law
Mary E. Fallat, MD – School of Medicine
University of Louisville

DISCLOSURE

I have no relevant financial relationships with the manufacturers(s) of any commercial products(s) and/or provider of commercial services discussed

I do not intend to discuss an unapproved/investigative use of a commercial product/device in my presentation

- I am funded by HRSA for a targeted issues grant and I am the Progam Director for EMSC in Kentucky

University of Louisvile

- one of the first civilian ambulance
- one of the nation's first accident services or emergency room (ER)
- one of the first blood banks in the US

KOSAIR CHILDREN'S HOSPITAL

- Free-standing full service children's hospital in KY
- Opened in 1986
- 263 beds
- Level I Trauma Center for Western KY

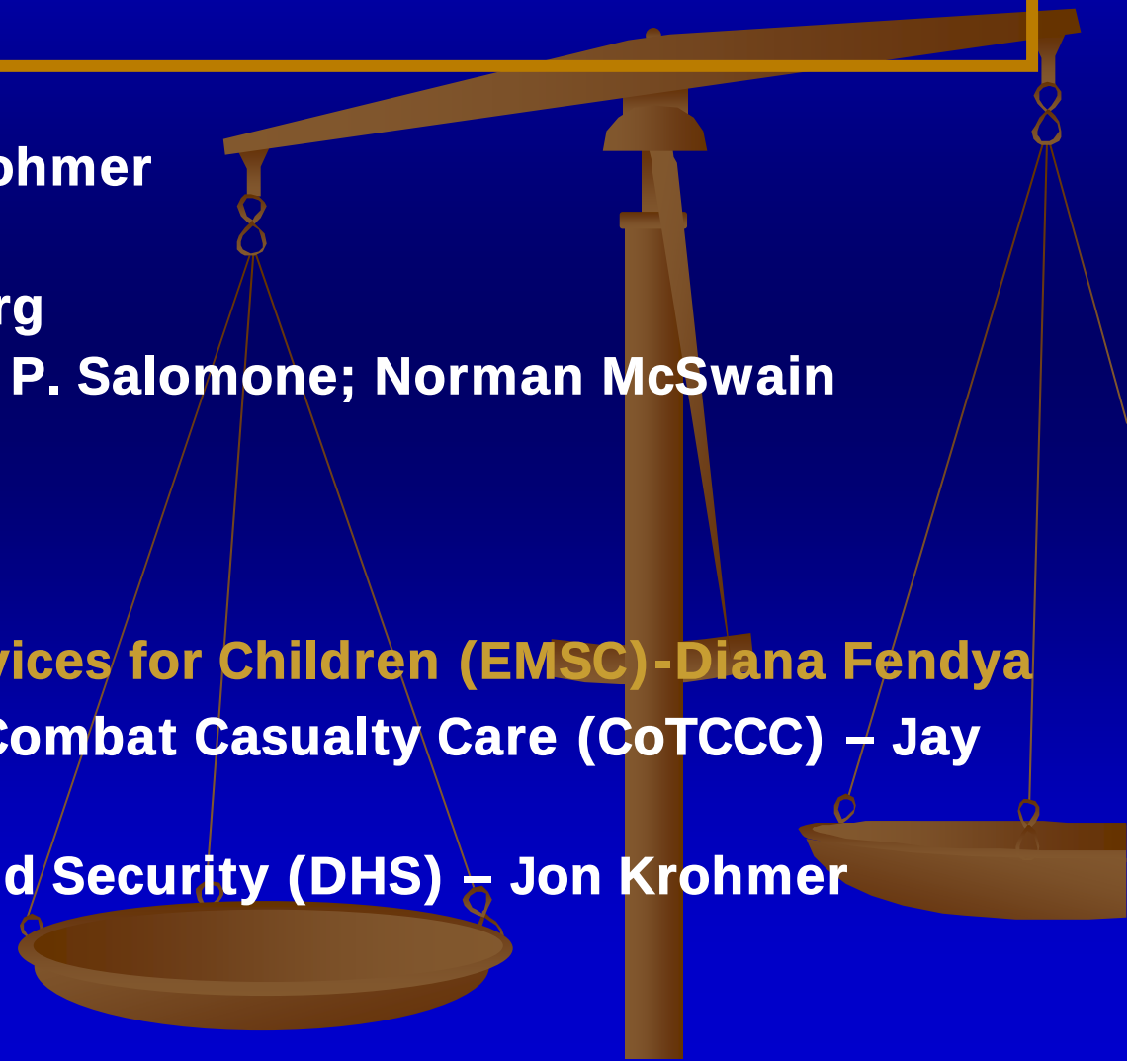
KOSAIR CHILDREN'S HOSPITAL

- Free-standing full service children's hospital in KY
- Opened in 1986
- 263 beds
- Level I Trauma Center for Western KY

AMERICAN COLLEGE OF SURGEONS COMMITTEE ON TRAUMA

1922 COMMITTEE ON FRACTURES
1939 MERGED WITH COMMITTEE ON INDUSTRIAL TRAUMA AND TRAUMATIC SURGERY
1950 BECAME THE COMMITTEE ON TRAUMA
1972 EARLY CARE OF THE INJURED PATIENT
1980 ATLS
1987 VERIFICATION/CONSULTATION PROGRAM
1989 NTRACS AND NRDB
1996 TRAUMA SYSTEMS CONSULTATION PROGRAM

BENEFITS OF PARTNERSHIP AND OPPORTUNITIES FOR COLLABORATION ACS ES-PREHOSPITAL LIAISONS 2007

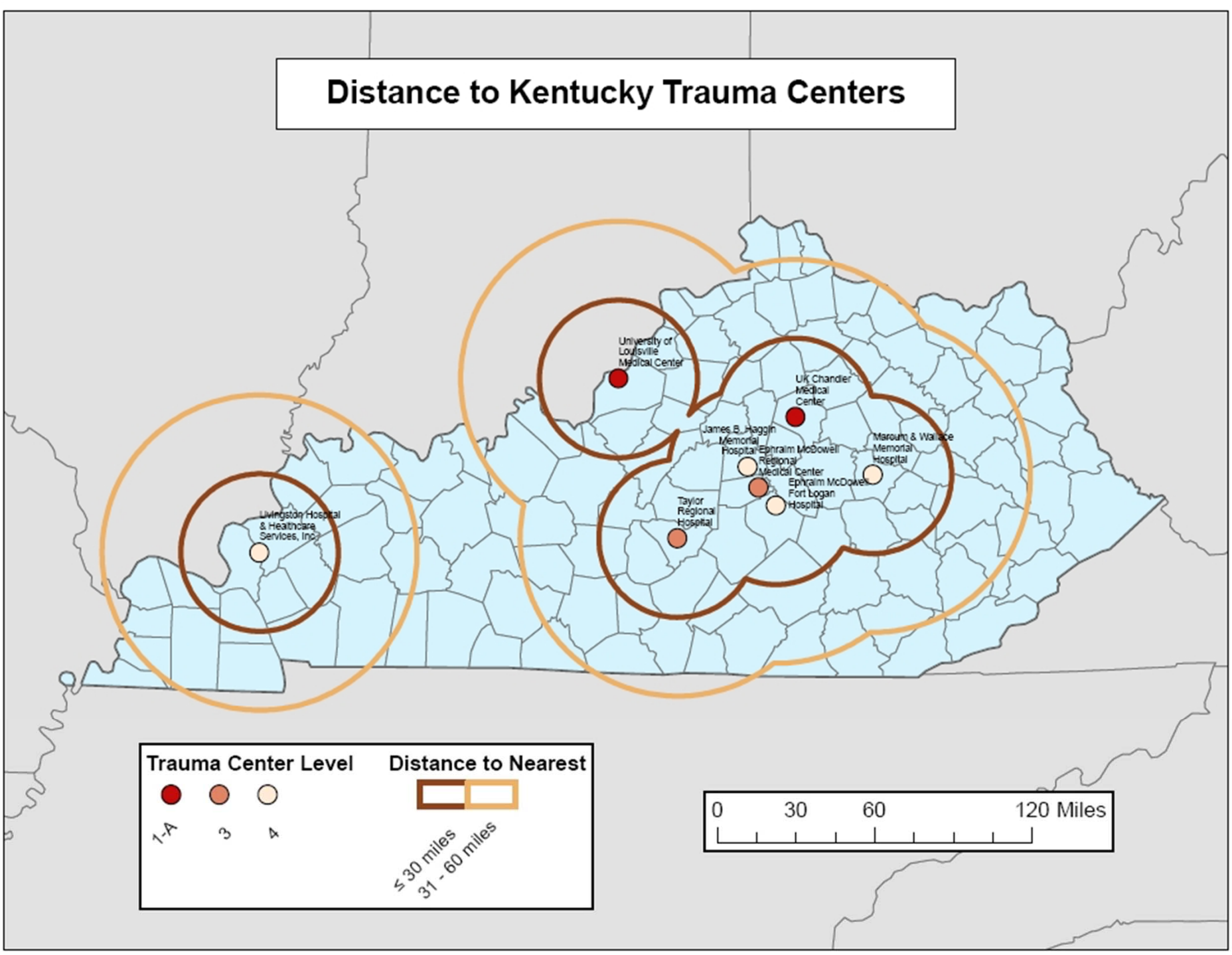


- ACEP, NAEMSP - Jon Krohmer
- ACEP - Alasdair Conn
- CoAEMSP - Seth Izenberg
- PHTLS, NREMT - Jeffrey P. Salomone; Norman McSwain
- CDC - Richard Hunt
- NHTSA - Drew Dawson
- NDMS - Susan Briggs
- Emergency Medical Services for Children (EMSC)-Diana Fendya
- Committee on Tactical Combat Casualty Care (CoTCCC) – Jay Johannigman
- Department of Homeland Security (DHS) – Jon Krohmer

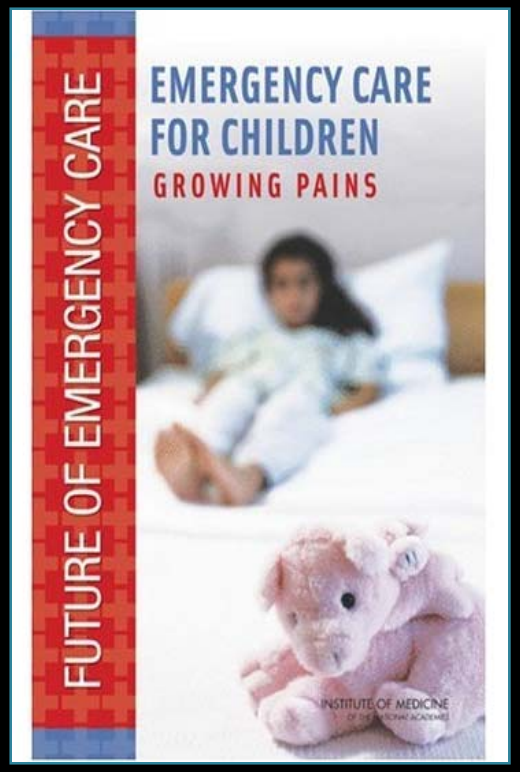
Systems – Trauma an Example

- Paramedic Training
- Regional EMS systems
- 911
- ATLS
- Trauma Care standards
- Verification
- National Trauma Data Bank
- Advocacy

Disease Management Model


Distance to Kentucky Trauma Centers
University of Louisville Medical Center
UK Chandler Medical Center
James B. Haggin Memorial Hospital
Ephraim McDowell Regional Medical Center
Ephraim McDowell Fort Logan Hospital
Marcum & Wallace Memorial Hospital
Taylor Regional Hospital
Livingston Hospital & Healthcare Services, Inc.
Trauma Center Level
1-A
3
4
Distance to Nearest
≤ 30 miles
31 - 60 miles
0
30
60
120 Miles

IOM's Committee on Emergency Care for Children (2007)

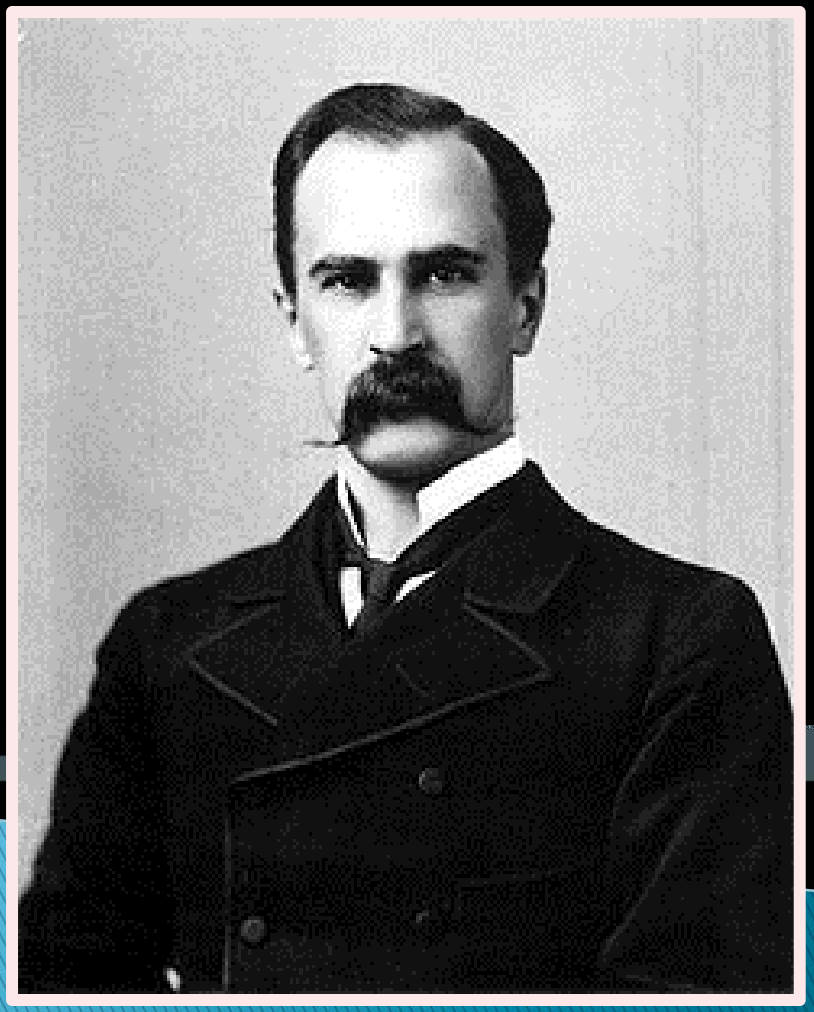


- Objective to "provide the most optimal care, at the optimal location, with the minimum delay" and "to meet the needs of children to the best of (the EMS system's) ability"

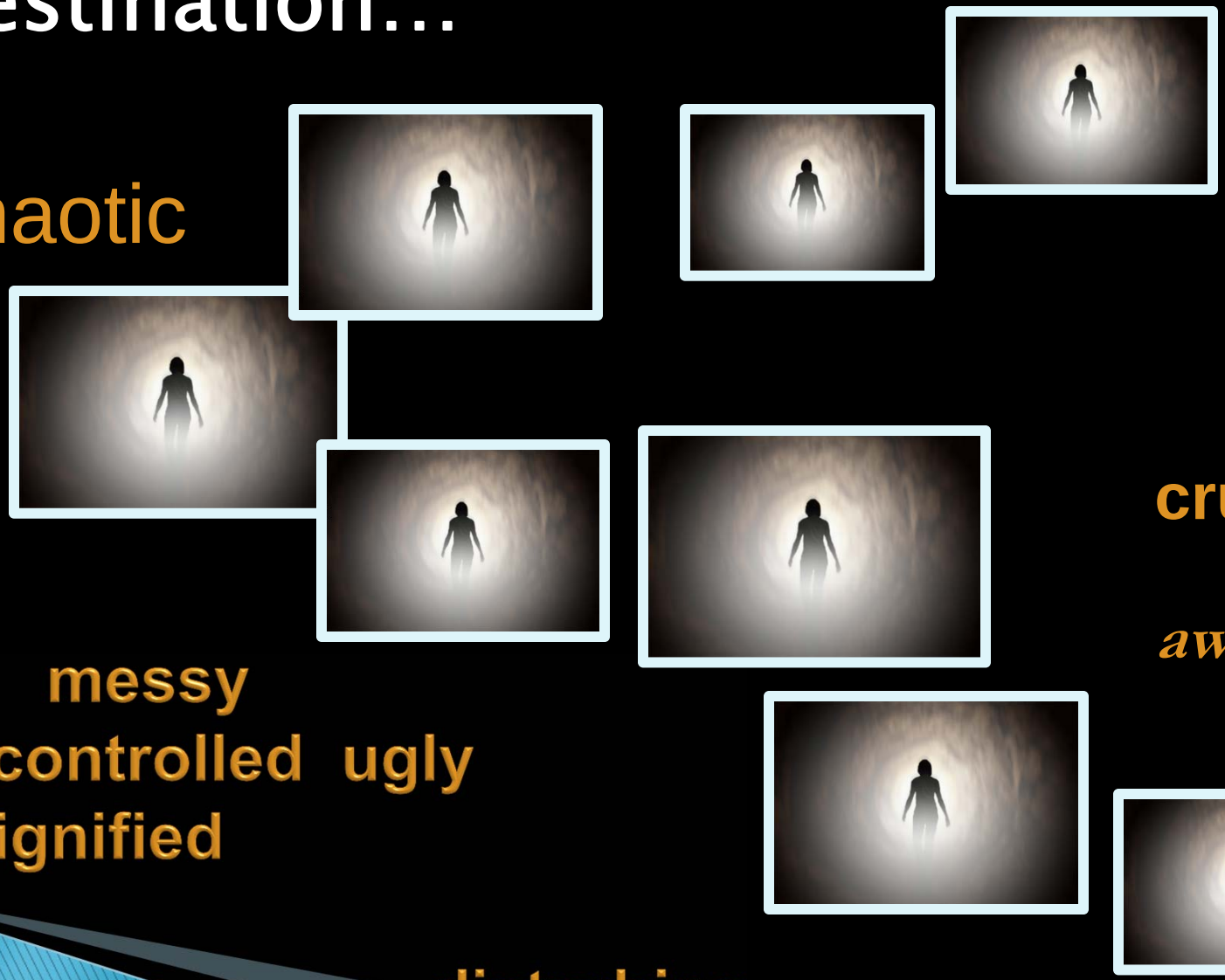
When families' needs are better met, the quality of pediatric emergency care is better.

SIR WILLIAM OSLER

"The practice of medicine is an art…a calling in which your heart will be exercised equally with your head"



- Death is not usually a destination…



DEATH IN THE FIELD

- Pediatric OOH deaths represent nearly one third of pediatric deaths in the US (Martin, et al, Pediatrics, 2008; 121:788-801)
- The most common cause of death in children $\leq$ 18 years is trauma

10 Leading Causes of Death by Age Group, United States – 2006

	Age Groups										
Rank	<1	1-4	5-9	10-14	15-24	25-34	35-44	45-54	55-64	65+	Total
1	Congenital Anomalies 5,819	**Unintentional Injury 1,610**	**Unintentional Injury 1,044**	**Unintentional Injury 1,214**	**Unintentional Injury 16,229**	**Unintentional Injury 14,954**	**Unintentional Injury 17,534**	Malignant Neoplasms 50,334	Malignant Neoplasms 101,454	Heart Disease 510,542	Heart Disease 631,636
2	Short Gestation 4,841	Congenital Anomalies 515	Malignant Neoplasms 459	Malignant Neoplasms 448	**Homicide 5,717**	**Suicide 4,985**	Malignant Neoplasms 13,917	Heart Disease 38,095	Heart Disease 65,477	Malignant Neoplasms 387,515	Malignant Neoplasms 559,888
3	SIDS 2,323	Malignant Neoplasms 377	Congenital Anomalies 182	**Homicide 241**	**Suicide 4,189**	**Homicide 4,725**	Heart Disease 12,339	**Unintentional Injury 19,675**	Chronic Low. Respiratory Disease 12,375	Cerebro-vascular 117,010	Cerebro-vascular 137,119
4	Maternal Pregnancy Comp. 1,683	**Homicide 366**	**Homicide 149**	**Suicide 216**	Malignant Neoplasms 1,664	Malignant Neoplasms 3,656	**Suicide 6,591**	Liver Disease 7,712	**Unintentional Injury 11,446**	Chronic Low. Respiratory Disease 106,845	Chronic Low. Respiratory Disease 124,583
5	**Unintentional Injury 1,147**	Heart Disease 161	Heart Disease 90	Heart Disease 163	Heart Disease 1,076	Heart Disease 3,307	HIV 4,010	**Suicide 7,426**	Diabetes Mellitus 11,432	Alzheimer's Disease 71,660	**Unintentional Injury 121,599**
6	Placenta Cord Membranes 1,140	Influenza & Pneumonia 125	Chronic Low. Respiratory Disease 52	Congenital Anomalies 162	Congenital Anomalies 460	HIV 1,182	**Homicide 3,020**	Cerebro-vascular 6,341	Cerebro-vascular 10,518	Diabetes Mellitus 52,351	Diabetes Mellitus 72,449
7	Respiratory Distress 825	Septicemia 88	Cerebro-vascular 45	Chronic Low. Respiratory Disease 63	Cerebro-vascular 210	Diabetes Mellitus 673	Liver Disease 2,551	Diabetes Mellitus 5,692	Liver Disease 7,217	Influenza & Pneumonia 49,346	Alzheimer's Disease 72,432
8	Bacterial Sepsis 807	Perinatal Period 65	Influenza & Pneumonia 40	Cerebro-vascular 50	HIV 206	Cerebro-vascular 527	Cerebro-vascular 2,221	HIV 4,377	**Suicide 4,583**	Nephritis 37,377	Influenza & Pneumonia 56,326
9	Neonatal Hemorrhage 618	Benign Neoplasms 60	Septicemia 40	Septicemia 44	Influenza & Pneumonia 184	Congenital Anomalies 437	Diabetes Mellitus 2,094	Chronic Low. Respiratory Disease 3,924	Nephritis 4,368	**Unintentional Injury 36,689**	Nephritis 45,344
10	Circulatory System Disease 543	Cerebro-vascular 54	Benign Neoplasms 38	Benign Neoplasms 38	Complicated Pregnancy 179	Influenza & Pneumonia 335	Septicemia 870	Viral Hepatitis 2,911	Septicemia 4,032	Septicemia 26,201	Septicemia 34,234

Source: National Vital Statistics System, National Center for Health Statistics, CDC.

Produced by: Office of Statistics and Programming, National Center for Injury Prevention and Control, CDC.

SURVIVAL AFTER OOH PEDIATRIC ARREST FROM A VARIETY OF CAUSES

Topjian et al (2008)

- 5-10% of pediatric OOH arrest victims survive to hospital discharge
- 0-12% have good neurologic outcomes

Young et al (2004)

- 3-year prospective study of OOH arrests in children < 12 years old
  - 8.6% survived, 1/3 had good neurologic outcome
  - No survival if ≥ 3 doses of epinephrine or ≥ 31 min of emergency department resuscitation

ON BALANCE

- LIMITS OF RESUSCITATION ONCE CPR IS INITIATED ARE RELATIVELY NONEXISTENT FOR CHILDREN
- Lines are blurred between what CAN BE DONE and WHAT SHOULD BE DONE
- LOCATION OF THE ARREST CAN HAVE BEARING ON CHOICES

WHAT FACTORS IMPACT SURVIVAL IN PEDIATRIC OOH CPA?

- Witnessed arrest
- Early bystander cardiopulmonary resuscitation (CPR)
- Initial shockable rhythm
- Return of spontaneous circulation (ROSC) within 20 minutes

Hopson LR, Hirsh E, Delgado J, Domeier RM, McSwain NE, Krohmer J. Guidelines for withholding or termination of resuscitation in prehospital cardiac arrest: joint position statement of the National Association of EMS Physicians and the American College of Surgeons Committee on Trauma.

J Am Coll Surg, 2003;196:106-112.

- published guidelines for OOH withholding or TOR for adult victims of traumatic CPA who meet specific criteria
- recommendations do not extend to the pediatric population

Resuscitation efforts may be withheld in any blunt trauma patient who is found…

- apneic
- pulseless
- without organized ECG activity

upon arrival of EMS at the scene

Resuscitation efforts may be withheld in any blunt trauma patient…

- Termination of resuscitation efforts should be considered in trauma patients with EMS- witnessed cardiopulmonary arrest and 15 minutes of unsuccessful resuscitation and cardiopulmonary resuscitation (CPR).
- Traumatic cardiopulmonary arrest patients with a transport time to an ED or trauma center of more than 15 minutes after the arrest is identified may be considered nonsalvageable, and termination of resuscitation should be considered

Multi-disciplinary Literature Review of Pediatric Traumatic OOH CPA

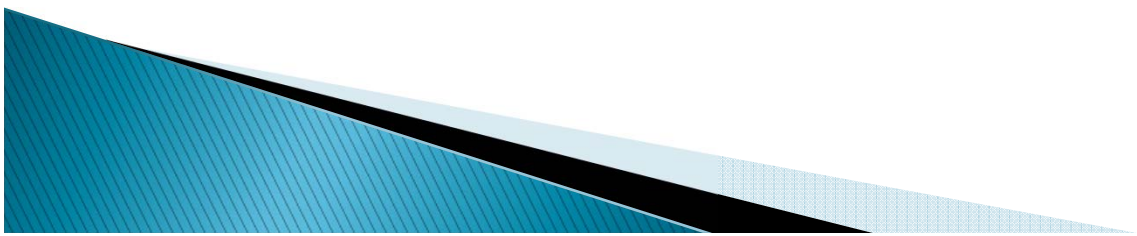
- American College of Surgeons Committee on Trauma, Emergency Services/Prehospital and Pediatric Subcommittees
- American Academy of Pediatrics, Committee on Pediatric Emergency Medicine
- National Association of EMS Physicians, Pediatric Subcommittee
- American College of Emergency Physicians, Pediatric Section

GOALS OF THE EVIDENCE EVALUATION

- Include individuals $\leq$ 18 years old
- Determine specific criteria that would support OOH withholding or termination of resuscitation for pediatric traumatic cardiopulmonary arrest (PCPA) victims
- Determine outcome of those who had successful return of spontaneous circulation (ROSC): did they survive to reach the hospital, survive to hospital discharge, normal vs neurologically impaired

METHODOLOGY

- EAST guidelines
- Class I: prospective randomized controlled trial
- Class II: clinical studies in which the data was collected prospectively, or retrospective analyses which were based on clearly reliable data
- Class III: study based on retrospectively collected data



INCLUSIONS & EXCLUSIONS

- Studies that included both adults and children were used if the children were evaluated separately
- Studies that mixed trauma and arrests from other causes were used if the trauma cohort was described independently
- Excluded drowning, hanging

METHODOLOGY

- EACH PUBLISHED PAPER WAS REVIEWED BY A MINIMUM OF TWO INDIVIDUALS (BLINDED)
- DISCREPANCY IN CLASS RESOLVED BY LEAD AUTHOR
- LEAD AUTHOR VERIFIED ALL INFORMATION

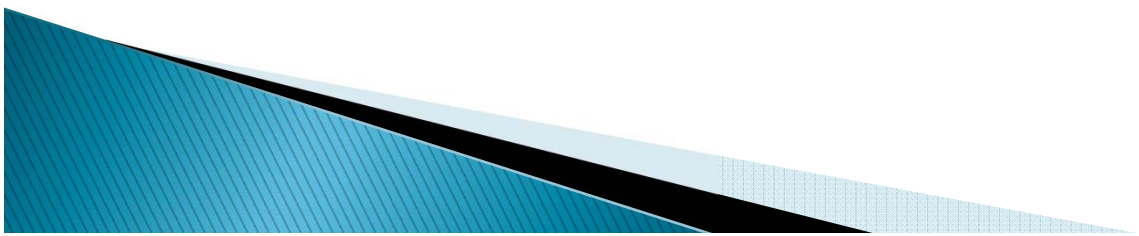
INCLUSIONS

- FOR AN INDIVIDUAL CHILD TO BE INCLUDED, HAD TO BE ABLE TO FOLLOW SUBJECT THROUGH THE PAPER TO AT LEAST DETERMINE SURVIVAL AND, IDEALLY, TO DETERMINE NEUROLOGIC OUTCOME
- NEUROLOGIC OUTCOME WAS NOT DEFINED UNIFORMLY

EVIDENCE EVALUATION

- Articles were identified through 2011
- 27 articles were reviewed and 19 articles had potentially useful information
- 5 Class II, 22 Class III studies
- Results: denominator of 1114 patients with 60 survivors to hospital discharge (5.4%)
- Outcome data was available for 51/60 of these patients: 29 suffered neurologic devastation,

  3 patients had moderate disability, 19 had a good or full recovery



Interval to CPR in minutes

Survivor	Nonsurvivor	n
2.3	6.5	41
3	13	

Duration of CPR

Survivors	Nonsurvivors
11.4 (ED)	
14+/−2.5 (ED)	
57.8+/−25.5*	
7	42 (>15)
18.5	41

* All severely disabled

PENETRATING TRAUMA AND RESUSCITATIVE THORACOTOMY

- 36 patients suffered an OOH TCPA from penetrating trauma
- At least 9 had a resuscitative thoracotomy in an Emergency Department and all died
- All 36 patients died with or without thoracotomy
- Resuscitative thoracotomy was performed at the scene, in the ED, or in the OR in 30 combined blunt and penetrating trauma victims and all died

Brindis SL, Gausche-Hill M, Young KD, et al. Universally poor outcomes of pediatric traumatic arrest: a prospective case series and review of the literature. Pediatr Emerg Care. 2011;27(7):616-21

- data regarding the outcomes of traumatic pediatric CPA continue to demonstrate near total futility in providing such interventions, prompting Brindis et al to conclude that there is “no subset of patients that can be identified for whom resuscitative attempts and transport is indicated”

Capizzani et al: *J Ped Surg 2010*

- Determined survival of 30 pediatric patients meeting COT and NAEMSP criteria
- CPR>15 min, nonreactive pupils, absent pulse, disorganized rhythm on ECG
- No survivors in those meeting all 4 criteria

If the child has arrested and resuscitation has already exceeded 30 minutes and the distance to the nearest facility is more that 30 minutes away, involvement of parents and family of these children in the decision making process and with assistance and guidance from medical professionals should be considered as part of an emphasis on family centered care, as the evidence suggests that either death or a poor outcome is inevitable

Withholding or termination of resuscitation in pediatric out-of-hospital traumatic cardiopulmonary arrest

publ 2014 in Pediatrics and Ann Emerg Med

PREHOSPITAL SURVEY

- 37-item survey
- An IRB protocol for the survey was submitted to the University of Louisville IRB (tracking number #08.0595) and marked as exempt.
- The survey was validated by several members of the Kentucky EMS community and no modifications were needed
- Survey link was incorporated in a letter to the National Association of EMS Officials (NASEMSO), which distributed the letter to each State EMS Director

CRITICAL FINDINGS

- 1264 respondents
- Respondents were EMS providers with an average of 19.6 years experience
- 71.3% had encountered a child who was dead at the scene
- Fewer than half had any training regarding communication at the scene with families of children who had died

CRITICAL FINDINGS

- When resuscitation efforts are made on a dead child, the main reasons are perception of benefit for family members who are at the scene (60%), and that “every chance” was given to the child to survive (50%)

STATE TOR and DOD PROTOCOLS

- One is the decision to stop and one is the decision not to start and adults and children are often managed differently

STATE STATISTICS FOR ADULTS

	TOR	DOD or DNAR
YES	56.4%	76.3%
NO	43.6%	23.7%
State Protocols/Guidelines	39.5%	48.6%
Individual EMS policies	39.5%	24.3%
BOTH STATE AND INDIVIDUAL	10.5%	24.3%
N/A	10.5%	2.7%

STATE STATISTICS FOR CHILDREN

	TOR	DOD or DNAR
YES	33.3%	59%
NO	66.7%	41%
State Protocols/Guidelines	28.9%	37.8%
Individual EMS policies	34.2%	21.6%
BOTH STATE AND INDIVIDUAL	5.3%	21.6%
N/A	31.6%	18.9%

FIELD TRIAGE OF CHILDREN

Pediatric TOR state protocol is in place and routinely followed	30.3%
No pediatric TOR protocol is in place; the patient is typically transported to the nearest hospital	54.5%
No Pediatric TOR protocol is in place; all efforts are made to transport the patient to the nearest hospital with pediatric expertise	15.2%

There is still an opportunity to participate

NO RESPONSE YET*

Arkansas
Louisiana
New Jersey
Illinois
North Carolina
South Carolina

Nevada
Mississippi
North Dakota
New Mexico
West Virginia
Michigan

Missouri
California
New York

OBSERVATION

Although the results of the literature based evidence evaluation suggest that the recommendations for withholding or TOR for adult TCPA victims could be applied to children, the majority of current state TOR protocols in the US exclude individuals $\leq$18 years

There are no studies to support the common assumption that families benefit from continuation of futile resuscitative measures and transport of a dead child to the hospital

National survey of first responders regarding pediatric CPA in the field and its management

- “EMS providers fear legal action by families or authorities”
- “consulting physicians and the EMS system in general are reluctant to admit a child has died due to the possible legal consequences”

DEFENSE AGAINST A CLAIM OF NEGLIGENCE

- The provision of emergency medical services by EMS providers is heavily regulated
- Existence of state statutes and protocols
- Medical control
- Guidelines that are implemented into practice

Prehospital resuscitation decisions in cases of traumatic cardiopulmonary arrest: assessing the risk of legal liability & the impact of TOR guidelines

Karen Jordan – Louis D. Brandeis School of Law
Mary E. Fallat, MD – School of Medicine
University of Louisville

Manuscript

- Part I Introduction
- Part II explains various protective immunities at the state level
- Part III factors working in favor of EMS provider in event of litigation threat or suit
- Part IV relevant legislative considerations
- Appendix: Vermont protocol as model

Legislative immunity provisions

- Governmental immunity
- Good Samaritan Laws
- Immunity for EMS Providers
- Implications

Legislative immunity provisions Governmental immunity

- About 1/3 of EMS providers are sponsored by, employed by, or have association with public entities
- Protection varies from state to state
- Acts or omissions constituting ordinary negligence (i.e. failure to act reasonably)
- Compliance with resuscitation protocols

Legislative immunity provisions Good Samaritan Laws

- Partial immunity to HCW who voluntarily provide assistance with medical emergencies
- Gratuitously provided care
- Often limit immunity to emergency care provided at the scene

Legislative immunity provisions Immunity for EMS Providers

- Many states have immunity shields designed to insulate EMS providers from civil liability
- Generally, providers are not liable for damages only if their actions measure up to a standard of reasonable care

Legislative immunity provisions Implications: key questions

- Given my particular circumstances (public v. private entity; volunteer v. employee; level of training, or type of license or certification, etc.) are my actions in providing emergency medical services while on-duty covered by a law limiting civil liability arising from those actions?
- If so, are there limitations, such as the services needing to be provided "on the scene," or provided gratuitously or without remuneration?
- How far does the protection extend: To reasonable acts or omissions? To acts or omissions falling below a standard of reasonable care? To any good faith provision of services (including, e.g., acts or omissions considered faultier than ordinary negligence)?

Basic Negligence Principles

- Proving causation
- Proving breach of duty
  - Customary v. reasonable practice
  - The impact of TOR guidelines

Basic Negligence Principles

- analysis of negligence principles shows that plaintiffs likely would face significant difficulties proving a claim of negligence in a case arising from the withholding or termination of resuscitation consistent with carefully formulated protocols
- existing case law supports this conclusion
  1. few published judicial decisions exist involving claims against EMS providers arising from withholding or termination of resuscitation
  2. existing judicial decisions show that EMS providers have successfully defended the case

Although relatively rare, lawsuits have been filed as a result of a decision to terminate resuscitation

- 4 cases
- 3 were out of hospital, one involved an OOH decision by a physician
- 2 involved EMS providers in Neb and W Va

Basic Negligence Principles Require plaintiff to prove 4 key elements

- 1) that the defendant provider owed a duty of care to the person injured
- 2) that the defendant breached this duty
- 3) that the breach was the proximate cause of the injuries
- 4) that the plaintiff actually incurred damages as a result of the provider's conduct
  - Assume existence of 1 and 2; proof of 3 and 4 would provide challenges for the defense

Basic Negligence Principles Proving causation

- The element of causation in a negligence claim is typically referred to as proximate cause
- Proximate cause encompasses two concepts: causation in fact and legal causation

Basic Negligence Principles
Proving causation

- causation in fact: the plaintiff must show that the act or omission "in all probability" caused the injury, using the term "probability" to mean more likely than not
- it may be difficult to prove that the cause of the death was the resuscitation decision – as opposed to the pre-existing traumatic injury and lack of cardiac function
- defendant provider likely will be able to produce evidence that the death likely would have occurred regardless of the EMS provider's allegedly negligent act or omission

Basic Negligence Principles

- Proving breach of duty
  - Customary v. reasonable practice
- a health care provider typically is expected to exercise that degree of care which would be exercised by a provider in good standing (i.e., using such reasonable diligence, skill, competence, and prudence as are practiced by minimally competent providers), in the same specialty, in a similar community, and in like circumstances (i.e., considering available facilities, equipment, options, etc.)

Basic Negligence Principles

- Proving breach of duty
  - Customary v. reasonable practice
  - several states have retreated from use of the customary standard, adopting in medical malpractice cases the more traditional "reasonable physician/practitioner" standard

Basic Negligence Principles

Customary v. reasonable practice

- regardless of the applicable standard of care, the current practice of EMS providers to continue resuscitation efforts (again perhaps especially for pediatric victims) – even if futile – may render any decision to withhold or terminate susceptible to a charge of negligence, even if supported by evidence
- existence of guidelines or protocols bearing on an allegedly negligent treatment decision becomes very relevant

Basic Negligence Principles

- Proving breach of duty: The impact of TOR guidelines
  - Regardless of the approach to the issue of the standard of care, the TOR Guidelines – and governing protocols implementing them – likely would be admissible at trial, and also likely would be considered weighty evidence of the standard of care

Basic Negligence Principles

- PITFALLS:

1. the perceived importance of allowing state-level modifications (e.g., the fear that national standards would be too burdensome)
2. preserving flexibility (and thus provider discretion) resulted in qualifications that rendered the guidelines too equivocal to be meaningful

To-date, therefore, practice guidelines have played a fairly insignificant role in malpractice litigation

Basic Negligence Principles: jurors likely would give substantial weight to practice guidelines that were

- developed by respected entities or organizations with appropriate medical expertise,
- based on sound, peer-reviewed, and up-to-date research demonstrating medical effectiveness of the recommended treatment decisions;
- sufficiently specific and consistent to provide a clear standard against which to measure a practitioner's conduct;
- sufficiently prescriptive or mandatory, rather than merely providing a range of options or diluting the force of the recommendation with qualifications or disclaimers; and
- widely distributed and adopted for use

Implementation Consideratiosn

- Developing governing protocols
- Legislative components
  1. Core legislative components
  2. Statutory Authorization for DOD in the field

Implementation Consideratiosn

- Developing governing protocols
- Striving for clarity and effectiveness in ensuring optimal in-the-field management of patients
- Importance of factors that will bolster evidentiary value in litigation, namely, the source and basis of the protocols, the degree of specificity and definitiveness, and the scope of dissemination and use

Implementation Considerationsn

- Legislative components
  1. Core legislative components
     - Formulation at the state-level – as opposed to a more local or system-level – will lend weight to protocols, and will foster consistency and uniformity
     - A key aspect of making the protocol mandatory is legislation requiring EMS providers to follow the state-level protocol.

Implementation Considerations

- Legislative components
  1. Statutory Authorization for DOD in the field: authorization for EMS providers to make a declaration of death in the field
  2. Not as crucial as the other legislative components, but it could be helpful. If EMS providers are not authorized to make a declaration of death, they can be placed in a difficult situation

SUMMARY OF DEFENSE AGAINST A CLAIM OF NEGLIGENCE

- The provision of emergency medical services by EMS providers is heavily regulated
- Existence of state statutes and protocols
- Medical control
- Guidelines that are implemented into practice

CONCLUSIONS

- THE INCLUSION OF CHILDREN IN STATE TOR PROTOCOLS SHOULD BE CONSIDERED AND IMPLEMENTED
- FOSTERING FAMILY CENTERED CARE IN THE FIELD AFTER AN OOH DEATH WILL REQUIRE A PARADIGM SHIFT
- THESE ARE NOT UNREALISTIC GOALS IN THE FACE OF A GROWING BODY OF KNOWLEDGE AND THE RURAL ENVIRONMENT OF MANY PARTS OF OUR COUNTRY

Prehospital resuscitation decisions in cases of traumatic cardiopulmonary arrest: assessing the risk of legal liability & the impact of TOR guidelines Karen Jordan and Mary Fallat

- Available at SSRN: http://ssrn.com/abstract=2486705 or http://dx.doi.org/10.2139/ssrn.2486705