# *The studies that EMS must do*

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## Disclosures

- Prior EMS research grant funding from:
  - Centers for Disease Control & Prevention
  - Laerdal Foundation for Acute Medicine
  - National Academies of Emergency Dispatch
- No conflicts of interest relevant to this presentation

## Objectives

- At the end of the presentation, the attendee should be able to:
  - Describe the existing knowledge gaps in prehospital care, and the priorities for research addressing these gaps.
  - Give three examples of types of EMS research that EMS physicians can pursue
  - List three barriers to conducting high-quality EMS / out-of-hospital research

## Key Informants

- Jane Brice: UNC-Chapel Hill
- Mike Sayre: Univ. of Washington
- Henry Wang: Univ. of Alabama – Birm.


## 2006 IOM Report: EMS at the Crossroads

- **Sec. 7: Optimizing Prehospital Care Through Research**
  - An Inadequate Research Base to Support EMS
  - Key Barriers to EMS Research
  - Research Conducted in the Prehospital Setting
  - Expanding the Evidence Base

## EMS Research Objectives

- 7.1: "Federal agencies that fund emergency and trauma care research should target an increased share of research funding at prehospital EMS research, with an emphasis on systems and outcomes research"
- 7.3: DHHS "…should conduct a study to examine the research gaps and opportunities in emergency and trauma care research, and recommend a strategy for the optimal organization and funding of the research effort"

## FICEMS EMS Research Gap Analysis

- The literature in the prehospital setting continues to be largely non randomized clinical trials conducted as retrospective observational studies.
- The most frequently studied areas include cardiac and airway management.
- The majority of the recommendations of research agendas continue to be unmet with a particular need for research in optimal methods of education and competency assessment, patient safety and quality, pediatrics, and trauma management.

## NIH: Key Barriers to EMS Research

- 1. Lack of trained investigators who elect to focus their work in this area of medicine
- 2. Poorly defined professional research tracks
- 3. Lack of funding directed specifically to support emergency medicine research
- 4. Limited interdisciplinary collaboration and multi-institutional research networks

## *Not to mention…*

- "EMS research is hard to do. It has unique technological, clinical, cultural, and other barriers."
  - Henry Wang - UAB

## *What existing gaps in EMS research should be prioritized?*

- Lots of "lists" of EMS research priorities have been generated
- Common themes emerge
- Can these lists be used as leverage when seeking funding?

## EMS Outcomes Project 1 - 1999: Prioritizing Conditions for Outcomes Research

*Ann Emerg Med* 1999;33:423

**Table 5.**
*Weighted score for top quartile conditions by outcome category—children.*

| Condition | Survival | Impaired Physiology | Limit Disability | Alleviate Discomfort | Satisfaction | Cost-Effectiveness |
|---|---|---|---|---|---|---|
| Minor trauma | 3.7 | 6.8 | 10.7 | 16.3 | 15.3 | 9.5 |
| Major trauma | 20.1 | 18.1 | 19.0 | 16.3 | 16.7 | 14.2 |
| Respiratory distress | 14.7 | 18.0 | 12.6 | 18.8 | 16.7 | 11.7 |
| Airway obstruction | 24.3 | 20.1 | 18.4 | 16.9 | 17.3 | 13.4 |
| Respiratory arrest | 23.5 | 21.0 | 20.4 | 10.5 | 13.8 | 13.0 |
| Cardiac arrest | 21.2 | 20.0 | 19.0 | 5.9 | 13.6 | 12.5 |
| Seizure | 7.0 | 10.9 | 9.7 | 9.7 | 11.1 | 7.4 |

**Table 6.**
*Weighted score for top quartile conditions by outcome category—adults.*

| Condition | Survival | Impaired Physiology | Limit Disability | Alleviate Discomfort | Satisfaction | Cost-Effectiveness |
|---|---|---|---|---|---|---|
| Minor trauma | 4.1 | 6.8 | 12.2 | 17.2 | 15.6 | 11.0 |
| Respiratory distress | 14.9 | 18.1 | 13.1 | 19.4 | 17.3 | 12.3 |
| Chest pain | 14.2 | 14.3 | 12.1 | 20.5 | 17.6 | 12.5 |
| Major trauma | 20.1 | 17.3 | 19.6 | 15.9 | 16.8 | 14.9 |
| Cardiac arrest | 22.4 | 20.9 | 19.5 | 7.3 | 14.8 | 14.9 |
| Airway obstruction | 24.0 | 19.3 | 18.6 | 18.1 | 16.4 | 12.4 |
| Respiratory arrest | 23.7 | 20.4 | 20.7 | 11.0 | 13.4 | 13.6 |

## National EMS Research Agenda: 2002

- One of eight recommendations: National EMS Research Strategic Plan

TABLE 1. Priority Topics within EMS Research

| Clinical Issues | System Issues and Medical Science |
|---|---|
| Airway and breathing | EMS provider education |
| Cardiovascular disease and stroke | EMS system design and operation |
| General medical | Improving global outcomes |
| Pediatrics | Research and evaluation methods |
| Trauma | |

*Prehosp Emerg Care* 2005;9:255–266

## CDC Acute Injury Care Research Agenda

- 2003: NCIPC "…identified gaps that exist and need to be addressed through research."
- Published May 2005
- Disclosure: I was on the writing team.

## CDC Research Agenda

- C. Determine and evaluate the components of trauma systems that contribute to improved outcomes for the acutely injured.
  - Evaluate data collection and use
  - Determine health outcome effects of dispatch, response, scene time…
  - Evaluate the impact of prehospital care on overall trauma care and outcomes

## CDC Research Agenda

- G. Identify and evaluate new or existing health measures to better assess both short-term and long-term outcomes for persons treated in a prehospital and hospital acute injury care setting.
  - Not just mortality.

# EMSC Research Agenda

- MCHB / NHTSA
- Consensus Conf. 7/96

**Figure 2.**
*EMSC research topics ranked by priority.*

**Research topics**

1. Management of major clinical entities such as:
   - Shock
   - Respiratory distress
   - Asthma
   - Brain injury
   - Multiple organ trauma
   - Seizures
   - Poisoning
   - Behavioral disorders
   - Burns
   - Fever
2. Development and validation of practical, functional, and other outcome measures
3. Injury prevention: strategies, outcome and cost-effectiveness
4. Fundamental issues in the development of medical informatics for EMS
5. Effective ways to measure, improve, and upgrade the quality of EMS care and systems
6. Prevention and relief of physical and emotional pain and suffering of patients
7. Evaluation of the effect and cost of out-of-hospital EMS interventions
8. Pediatric resuscitation
9. Costs of emergency medical services for children: direct, indirect, and marginal
10. Extent to which pediatric patients who need emergency services receive them
11. Development and validation of injury and illness scoring scales for children
12. Effective ways to provide professional education, training, and retraining to maximize skill acquisition and retention and to improve practice patterns and patient outcomes
13. Public education methods of effecting behavioral changes in the areas of injury prevention, basic emergency care skills, and the use of EMS systems
14. Triage methods: out-of-hospital and in ED
15. Children with special health care needs

*Ann Emerg Med* 1999;33:206 – editorial on page 214

# Priorities Identified in IOM Report

**BOX 7-4 Research Topics Identified by the Committee**

**Clinical Research**

- Impact of prehospital ventilation and intubation on head injured patients.
- Identification of the safest and most effective technique for managing respiratory insufficiency in the prehospital setting.
- Testing the administration of IV fluid to correct hypotension prior to surgery for trauma.
- Performance of new CPR techniques, including chest compression only CPR.
- Impact on outcomes of performing prehospital 12-lead EKGs for patients with acute ST segment elevation myocardial infarction.
- Impact on outcomes of prehospital administration of medications for selected medical conditions (e.g., asthma, CHF, diabetes, AMI).

**Systems Research**

- Impact of level of training (e.g., EMT-B, paramedic) on condition upon arrival and long-term outcome.
- Cost and effectiveness of EMS systems and in particular how they are impacted by the characteristics of the system.
- Time interval modeling identifying when and where and what changes outcomes in the prehospital setting.
- Cost effectiveness of procedures: needed for a range of conditions in a range of settings, including non-emergent care.
- Safety and impact of routing non-emergency 9-1-1 calls to nurse advice lines
- Safety and impact of treat and release policies versus EMS transport.
- Impact of medical direction on performance of EMS systems.
- Effectiveness of EMS with respect to injury and acute disease.
- Incremental value of advanced life support over basic techniques in trauma care
- Effectiveness of new communication techniques (streaming video, etc) and information technology.
- Impact of technology on error reduction or improved decision making (e.g., electronic algorithms, electronic monitor, patient video, and smart implanted chips).
- Impact of pre-arrival instructions by dispatchers on the condition of patient upon arrival at hospital and long-term outcome.

p. 174

# Themes

- 1. Need outcomes measures – we often don't even know WHAT to measure, never mind HOW to measure, or what to do with findings.

The Six "D"s of Outcome:
1. Death
2. Disease
3. Discomfort
4. Disability
5. Dissatisfaction
6. Destitution (cost)

- 2. Informatics / data
- 3. Clinical entities of high impact, high frequency, or both

## 1. EMS Provider Proficiency

- "I think we need to figure out how to better measure minimum competency and then hold all prehospital professionals to those standards. In my new role, I have become exposed to a whole different level of expectations for minimum competency in order to function as a paramedic. I am not sure what the right answer is, and it needs to be studied."
  - Michael Sayre, MD – University of Washington

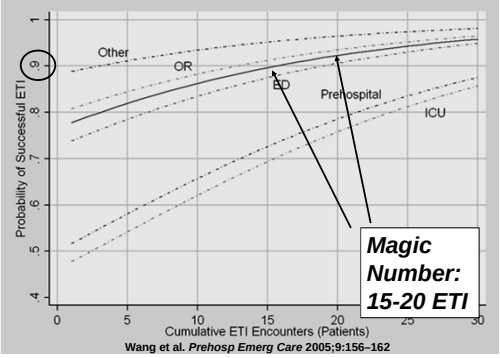
## EMS Provider Competency

- How do we decide that an EMS provider is "competent" or "proficient"?
  - Hours, "touches", repetitions of procedure?
  - Relative merits of classroom, distance learning, hands-on learning?
  - National certification?
  - In-field observation?
- How do we assess skills decay over time, and remediate deficiencies?
  - Particular problem for rural agencies/personnel

## Training: How to <u>obtain</u> proficiency

- How many "live" intubations are needed to obtain proficiency?
  - EM residents: 35
  - Anesthesiologists: 25-50
  - Nurse anesthetists: 200
  - Paramedics: 5

Learning Curve:
7635 intubations by 802 medic students



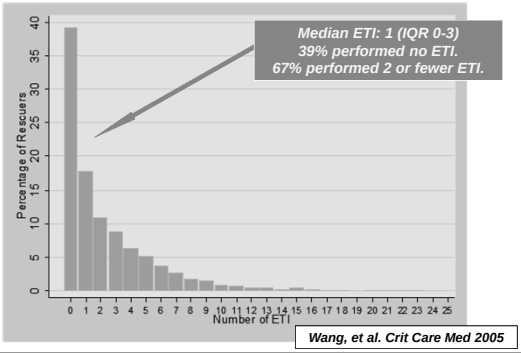

Wang et al. *Prehosp Emerg Care* 2005;9:156–162

# How to Maintain Proficiency: Procedural Experience

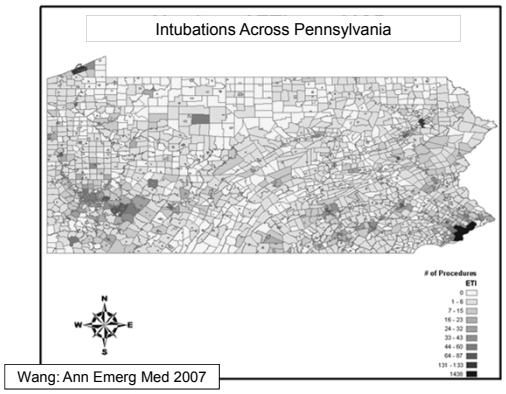
- Wang and colleagues: Pennsylvania state EMS database of 1.5 million runs in 2003
- Total 11,484 intubations linked to 5,245 providers

Wang HE et al. *Crit Care Med* 2005;33:1718-1721

Per-Rescuer ETI Frequency for Pennsylvania Rescuers (2003)




*Wang, et al. Crit Care Med 2005*




Wang: Ann Emerg Med 2007

## Similar Study: Maine

- Statewide EMS database 1997-2001
- Average of 41% of paramedics attempted an ETI in each calendar year
  - Average of 27 ALS providers (2%) attempted pediatric intubation each year
- Average of 18 ALS (1.3%) had >5 ETI attempts in any given year

Burton JH et al. *Prehosp Emerg Care* 2003;7:352

## 2. Prehospital Intubation

- We are fairly sure that prehospital intubation, as currently practiced, is NOT HELPFUL and may even be harmful for patients with moderate/severe brain injury
- We know ESSENTIALLY NOTHING about the benefits (if any) of any particular airway management strategy in “medical” cardiac arrest

## Prehospital RSI for Brain Injury

- Several studies have found an association between rapid sequence intubation performed by paramedics in the field and higher morbidity and mortality rates in brain-injured patients
- None were controlled, randomized trials, though some were prospective

## San Diego Paramedic RSI Trial 2: Outcomes

- Prospective enrollment of 209 patients
- Three historical controls hand-matched to each enrolled patient (627 controls)
  - Age
  - Sex
  - Mechanism of injury
  - AIS for each body system

***J Trauma*** **2003;54:444-453.**

## San Diego Paramedic RSI Trial 2: Outcomes

- Higher mortality in RSI group
  - 24.2% control vs 33.0% RSI, $p<0.05$
- Lower incidence of a "good outcome"
  - Discharged, transferred to rehabilitation, etc.
  - 57.9% control vs 45.5% RSI, $p<0.01$

**Davis et al. *J Trauma* 2003;54:444-453.**

## San Diego Paramedic RSI Trial 2: Outcomes

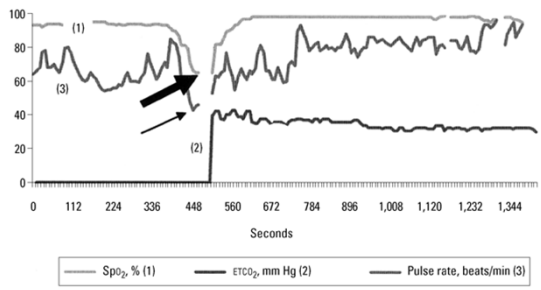
- Possibly due to:
  - Transient hypoxia during intubation
  - Inadvertent hyperventilation after intubation
  - Longer scene times (mean 16.4 vs 22.8 min)
- "Ultimately, a randomized trial is warranted to further investigate the impact of prehospital RSI on outcome in head-injured patients."

Davis et al. *J Trauma* 2003;54:444-453.

## San Diego Paramedic RSI Trial: 3 Hypoxia and heart rate reactivity

- Subset of 54 patients with continuous pulse ox, $ETCO_2$, and heart rate recording
- Transient hypoxia in 31 (57%)
  - 84% of these started with saturation > 90%
  - Median duration 160 seconds (IQR 48-272)
  - Median decrease 22%
  - HR < 50 in 19%
  - 84% described as "easy" tubes by medics

***Ann Emerg Med* 2003;42:721-8**




Dunford, et al. *Ann Emerg Med* 2003 Dec;42(6):721-8

## San Diego: Registry Review

- Patients with head/neck AIS ≥ 2, 1987-2003
- 2665 intubated in field, 2220 in ED
- Adjusted for age, sex, mechanism, GCS, head/neck AIS, ISS, hypotension
- Higher mortality in field-intubated group:
  - 56.3% vs. 16.8%

*J Trauma* 2005;59:794

## Wang et al: Pennsylvania

- 2000-2002: 4098 patients
- Adjusted for age, sex, head/neck AIS, ISS, mechanism (penetrating / blunt), admission systolic BP, mode of transport, use of paralytics in the field
- Inclusion criteria:
  - Head / neck AIS >3
  - Intubated in field (n=1797) or ED (n=2301)

***Ann Emerg Med* 2004;44:439-450**

## Adjusted Odds Ratios

- Death: OR 3.99
  - 95% CI 3.21-4.93
- Poor neurologic outcome: OR 1.61
  - 95% CI 1.15-2.26

***Ann Emerg Med* 2004;44:439-450**

## Accompanying Editorial

- "The accumulated weight of evidence from Wang et al. and other recent studies indicates that out-of-hospital endotracheal intubation of patients with severe traumatic brain injury is not helpful, and may be harmful… If we were dealing with a drug that had such a negative association with patient outcomes, it would likely be pulled from the market."

*Zink BJ & Maio RF, Ann Emerg Med 2004;44:451*

RESEARCH

**The OPALS Major Trauma Study: impact of advanced life-support on survival and morbidity**

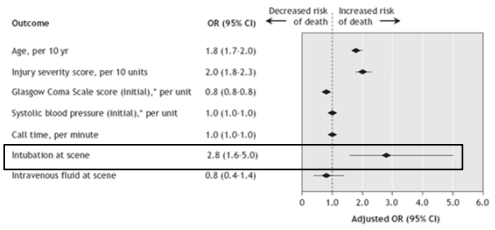
Ian G. Stiell MD MSc, Lisa P. Nesbitt MHA, William Pickett PhD, Douglas Munkley MD, Daniel W. Spaite MD, Jane Banek CHIM, Brian Field MBA EMCA, Lorraine Luinstra-Toohey BScN MHA, Justin Maloney MD, Jon Dreyer MD, Marion Lyver MD, Tony Campeau MAEd PhD, George A. Wells PhD, for the OPALS Study Group

- Before-after trial in 17 Canadian cities, total population 2.5 million
- 2867 trauma patients >16 y/o, ISS>12
  - 1373 before (BLS) – 81.8% survival
  - 1494 after (ALS) – 81.1% survival
  - 6.8% intubated (71.8% success rate!)

CMAJ 2008;178:1141-1152

## OPALS Findings

- Intubation in the field was associated with increased mortality
  - adjusted OR 2.8, 95% CI 1.6–5.0



## What we really need:

- A prospective, randomized, controlled trial of rapid sequence intubation by paramedics for brain-injured patients, adequately powered to detect clinically meaningful differences in outcome.
  - Sounds easy enough…

## Designing the study

- What is the control group?
  - Bag-valve-mask, Combitube, LMA, no ventilation, any?
- Can't be blinded
- Which drugs to use (if any)?
- What outcomes do we measure?
- For each outcome, what is a clinically meaningful difference?

## Other potentially high-yield clinical questions

- Is there a role for epinephrine in the management of out-of-hospital arrest?
  - Systematic review, *Resuscitation* 8/12
- What is the role of adenosine in the management of monomorphic wide-complex tachycardia?

## 3. “Triage” by EMS Personnel

- “I think the whole concept of triage from the field for a variety of disease states is a pressing issue. We are embracing this “regionalization of care” paradigm and it is beginning to fall on the shoulders of our EMS folks to make the call from the field with very little information or assessment capability - trauma, stroke, STEMI, sepsis, need for transport at all. Can EMS do this? What additional tools or training do they need to do it well?”
  - Jane Brice, MD – UNC / Chapel Hill

## EMS “Triage” in CT

- Trauma (including burns): two decades
- STEMI: 2008
- Stroke: soon (?)
- Pediatric arrest / critical care: topic raised at a state meeting 2-3 yrs ago
- Sepsis
- Cardiac arrest

## EMS Triage of Stroke: Sample Research Questions

- Can EMS personnel identify stroke?
  - At least 4 prehospital stroke scales in use
    - Cincinnati Prehospital Stroke Scale “validated” in the hospital, not the field (Kothari 1999)
- Surprisingly little work on this
  - High false-positives at my shop…

## EMS Triage of Stroke: Sample Research Questions

- Can dispatchers identify stroke?
  - MPDS Protocol #28:
    - Ellison et al 2004: sensitivity 61%, specificity 20%
    - Buck et al 2009: sensitivity 40%
    - Rosamond et al 2005: 31% of pts discharged as stroke/TIA were assessed as stroke by dispatchers
    - Ramanujam et al 2008: sensitivity 83%, PPV 42%
      - Paramedics: sensitivity 44%, PPV 40% via CPSS

## EMS Triage of Stroke: Sample Research Questions

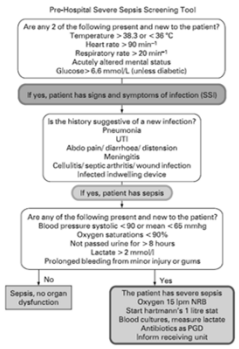
- Benefit to preferentially transporting stroke patients to stroke centers?
  - What is a stroke center?
    - TJC Primary Stroke Center (>900, incl 17 in IN)
    - TJC/AHA/ASA Comprehensive Stroke Center
      - "specific abilities to receive and treat the most complex stroke cases"
  - Process improvements (higher % of patients receiving lytics, shorter door to needle)
  - Outcome improvements

## Process Improvement: Observational Study in NJ

- 114 with notification, 115 without
- tPA 27% vs 15%
  - Unadjusted p=0.024
  - After adjusting for baseline covariates (e.g. notification pts were older) and stroke severity (NIHSS 11.1 vs 6.9) → OR 1.81, 95%CI 0.84-3.92, p=0.13
    - McKinney JS et al. Hospital prenotification of stroke patients by emergency medical services improves stroke time targets. *J Stroke Cerebrovasc Dis* 2011 Aug 4 epub.

## Field Triage of Sepsis?

- Robson, Nutbeam, and Daniels, *Emerg Med J* 2009;26:535
- Additional IV fluids?
- Prehospital IV antibiotics?
- Destination selection?




## Other Operational Issues

- Helicopter transport
  - Fairly good data showing benefit for <u>selected</u> major trauma patients
  - Little data on flying patients to improve access to hyperacute stroke care, PCI for STEMI, and post-arrest care (hypothermia, cath lab)


## Other Operational Issues

- How many paramedics do you need?
  - On a truck?
  - In your city?
- "Less is more" – fewer paramedics means more skills exposure for those medics

## Summary

- Key areas of study for EMS:
  - 1. Personnel competency/proficiency, skills maintenance, and education in general
  - 2. High-risk, high-yield clinical issues such as intubation
  - 3. Systems issues such as regionalization of care and the role of EMS in patient “triage”
- Many possible questions; no single approach to answering them…