

CONDUCTING CLINICAL RESEARCH IN THE PREHOSPITAL SETTING: CHALLENGES AND PITFALLS


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How is EMS research different?

- See Dan Spaite's article on "systems research", as opposed to "component research."
 - Spaite DW, Criss EA, Valenzuela TD, Guisto J. Emergency medical service systems research: problems of the past, challenges of the future. *Ann Emerg Med* Aug 1995; 26: 146-152.
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Traditional medical research


- “...clinical research is carried out mostly by expert subspecialists on a specific disease process and generally focuses on a single therapeutic intervention delivered in a controlled environment”
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“Component Research”

- Classic clinical research:
 - focused, directed questions
 - few data points, easily obtained
 - few data collectors (including investigators)
 - single agency / institution
 - fairly simple statistics
 - tightly controlled environment
- Doesn't work well in EMS!



“Systems Research”

- Complex interrelated questions
 - Diverse data points
 - Many data collectors
 - Multiple agencies / disciplines
 - Complex, uncontrolled environment
 - Complex mathematical models
 - Examples: trauma systems, cardiac arrest “chain of survival”
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Systems Research


- Who does it? Whose ideas and research methods can we use?
 - **Public health / epidemiology**
 - Economics
 - Engineering
 - Social science
 - Public administration

Practical Tips & Pitfalls

- Read lots of EMS research papers to see how different projects managed these issues
- Handout:
 - Three chapters on research from NAEMSP's 2009 textbook
 - 1993 methodology article by Pepe
 - 1999 editorial by Cone
 - Read editorials to learn about methodologies



Know Your Baseline

- **Can your system do this research?**
 - **Skills:** Is your baseline CPR performance good enough to participate in a trial of a CPR assist device?
 - **Numbers:** Where on the Utstein template does the target patient population fall? Is your system large enough to provide enough patients?
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Study design: automation

- As much as possible, avoid changing the routine of the EMS personnel
- Do not distract the EMS personnel from patient care activities
- Consider adding field personnel if the EMS crew cannot do their usual tasks, plus manage the study



Data collection

- An additional data collection form is less likely to meet with compliance than are additional data fields on the existing patient care report
 - Much easier to deal with if electronic

Validation of data

- Are you measuring what you think you are measuring?
 - *Example: Spaite's observational study of blood pressure measurement in EMS*
 - Spaite DW, Criss EA, Valenzuela TD, et al: A prospective validation of prehospital patient assessment by direct in-field observation: Failure of ALS personnel to measure vital signs. *Prehospital Disaster Medicine* 1990;5:325-334.
- Are you sure that everybody is measuring it the same way?
 - *Ex: Are you using the Utstein definitions for your cardiac arrest patient populations?*
 - *Ex: labeling of fine VF vs. asystole*



Statistical Involvement

- Get statistical help when **designing** the study, not while collecting data
- Be sure to collect enough of a sample to adequately power the study

Hospital Data

- Are the hospitals in your system willing to give you any ED, in-house, or other outcome data?
 - Paul Pepe says this is the biggest obstacle
- You will likely need IRB approval from **every hospital** from which you want data
 - Ex: Gausche's pediatric intubation study involved IRB approval from >100 hospitals

Getting “buy-in” from EMS

- How do you convince an EMS agency or system to participate in research?
- How do you convince EMS personnel to participate in research?
- You may have the authority to force participation, but this may not be the best way to get “buy-in”

Buy-In: from the EMS system

- Ownership: of the idea, of the glory
- Look for a topic that makes the system or service look good
 - Pinellas County (Florida) EMS pediatric drowning prevention program
 - Pittsburgh EMS influenza vaccinations



Buy-In: from EMS personnel

- Develop a group of interested and committed field personnel
- *Ex: Akron's "Supergroup" (Summit County Prehospital EMS Research Group) – Lynn J. White, MS*

Training


- Consider union issues, including overtime
- Provide data collectors with a pocket card or other simple reference
- Provide a study hotline or pager access to investigator
- Provide CME credit when possible

Pilot / Phase-In Period

- Extremely important in the poorly controlled field environment
- You WILL discover many things you had not thought of
 - EMS personnel will find problems and “glitches” that the study physicians did not consider
 - VERY IMPORTANT to involve EMS personnel in the design of the study



Feedback

- Study newsletter
 - Study website
 - Timely memos to top performers
 - Stay involved – don't assume the study will continue to run itself on "auto-pilot"
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Rewards: The Four P's

- **P**ride: their efforts will lead to the success of the study – “we cannot do it without you!”
- **P**ublicity: allow the system or service to publicize its efforts
- **P**ublication: allow the system or service, or lead personnel, to share in the credit
- **P**izza
 - Textbooks
 - Conference registration





Summary

- EMS research is very different from classic clinical research
 - Environment is different – less controlled
 - Personnel are different – large group of data collectors, with different skills and incentives
 - Physician involvement is key to success
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