Challenges of Informed Consent in Emergency Care Research

Deborah B. Diercks, MD
Associate Professor
Department of Emergency Medicine
University of California, Davis
Sacramento, CA
Challenges Unique to Emergency Medicine

- Emergency Medical Services
- Children
- Lack of time
- Diverse patient population
- Time dependent treatments
An investigator would like to study a new treatment for pediatric seizures.

- It will be administered as a first line agent
- It has a good safety profile in adults

However the investigator would like to obtain blood draws for kinetic information and an MRI in children that have not had one.
How do you suggest this study is done?

- How to you obtain consent and still meet the objective of the trial?
- What are the aspects of consent that are unique to children?
How do you obtain consent?

- Exemption from informed consent
- Alternative methods of consent
Exception from Informed Consent in Emergency Research

- Designed for implementation of research in emergency settings when exception from informed consent is requested under 21 CFR 50.24

http://www.fda.gov/ora/compliance_ref/bimo/er_guide.htm
Criteria

The exception applies when:

- Human subjects cannot give informed consent because of emerging, life-threatening medical condition
- Available treatments for the condition are unproven or unsatisfactory
- The intervention must be administered before informed consent is feasible
Benefits and Risks

- Participation must hold out prospect of direct benefit to the subject
  - If placebo design is used, standard care must be given to all subjects
- Risks of the study are reasonable in relation to:
  - What is known about the medical condition of the potential subjects?
  - The risks and benefits of standard therapy
  - Any benefits of the proposed treatment?
Study Design

- Design should be adequate to answer the question
- The therapeutic window must be defined
- The amount of time spent trying to obtain consent must be defined.
Contact of Family Members

- Attempts should be within the therapeutic window

- The effect of delaying study treatment must be balanced when spending time to contact family.
Public Disclosure and Community Consultation

Prior to start of the study -- public disclosure is required:

- the nature and purpose of the study
- the fact that informed consent will not be obtained for most study subjects

Following completion of the study information about the study results must be disclosed:

- to the community where the research was done
- the research community should have access to comprehensive summary data
IRB Responsibilities Specific to Waiver of Consent

- Review/approve proposed plan and procedures for contacting LAR/family
- Review/approve community notification and consultation plan
- Attend/participate in community outreach
Alternative Methods

- Consent subjects prior to enrollment
  - Pediatric neurology clinics
- Requires a closed system for optimal results
- Requires a sophisticated system to document subjects willingness to participate
Example

- NIH funded study comparing lorazepam to diazepam in children with seizures
  - Used both methods
    - Pre-consent
    - Waiver of consent
      - Community meetings
      - Local pediatricians
      - Local neurologist
Challenges Unique to children

- **Assessment of Risk**
  - 4 categories
    - Research not involving greater than minimal risk
    - Research involving greater than minimal risk, but presenting the prospect of direct benefit to an individual subject
    - Research involving greater than minimal risk with no prospect of direct benefit to individual subjects, but likely to yield generalizable knowledge about the subject's disorder or condition.
    - Research that is not otherwise approvable, but which presents an opportunity to understand, prevent, or alleviate a serious problem affecting the health or welfare of children.
Challenges Unique to Children

- **How do you define risk?**
  - Based on expected risk from daily activity or routine doctors office

- **Implications for research**
  - Guides who needs to consent
    - Single parent
    - Both parents
What to you tell the investigator?

- If it is a closed system it is always easier to pre-consent.
- If not, employ emergency medical services waiver of consent:
  - Plan extra time
  - Plan extra money
- Keep the researcher aware of the implications of extra tests that attract from the objective of the study.
The future

- As more studies use waiver of consent:
  - Networks will be established
  - Potential for public backlash will be addressed

- Creativity is a necessity
  - Work with the regulatory bodies locally/nationally to create ED based consent standards
The need

To study the benefit of time dependant treatments we need to implement practical mechanisms for consent

- Improves patient care
- Improves our research
- Establishes emergency medicine as a essential component of acute care research