Why research ethics is important...
**Ethical lapses**

“Ethical lapses are almost never a case of bad people, doing bad things, for no good reason. More often they are good people, doing bad things, for good reasons”

– M. Angell

**Why is PICU research necessary?**

- Inform practice [“evidence based care”]
- Improve care
  - Ensure treatment is effective and safe
  - Optimise patient outcomes
- Burden of critical illness growing globally
  - Human and financial cost
- Medical care should be based on best available evidence.
  - Balance between discovering new knowledge and protecting patients

ATS Statement *Am J Respir Crit Care Med* 170: 1375 - 1384
In PICU….

• Medical management still largely based on experience, anecdote and adult/animal studies.
• … “therapeutic orphans”
  • Dr. Harry Shirkey, the “father of pediatric therapeutics in the U.S”, 1960s

... sickest, most vulnerable children are subjected to the most anecdotally based medical practice

Extrapolating results from adult trials is not appropriate

Research must be done in the PICU population

Ethical challenges in PICU research

Ethically acceptable research can be conducted in vulnerable populations

Additional safeguards needed

Emmanuel et al (2000) JAMA 283; 2701 - 2711

Belmont Report’s Three Ethical Concepts

- **Respect for persons**, requiring researchers to obtain subjects’ informed consent to study participation.
- **Justice**, requiring equitable distribution of research burdens and benefits.
- **Beneficence**, requiring that risks to human subjects be justified by the value of the knowledge the study is expected to generate.

https://www.fpm.org.uk/blog
Independent ethics review

Societal value
Collaborative partnership

Health research in a connected and participative society
Scientific validity

Acceptable risk : benefit

- Sufficient belief to justify exposing subjects to treatment
- Sufficient doubt to justify withholding treatment from subjects
Fair selection (Justice)

Informed > Consent > Process

- Having full knowledge and understanding
- Decision to Voluntarily accept/provide permission
- Continuous/ongoing consent
• Obtaining informed consent is particularly difficult in
  – emergency situations
  – research involving children


• “When the two sets of circumstances combine, as they do when research involves
  the care and treatment of critically ill infants and children, there may be particular
  difficulties in satisfying the requirement to obtain voluntary informed consent”

Informed consent...issues and options

- Children have no legal authority to make decisions for themselves
- Parent/s or legal guardian make the decision for the child


Parental consent for child participation

- Requirements for valid consent:
  - Intact decisional capacity
  - Legally competent
  - Fully informed (and understandable)
  - Voluntary – no coercion or undue influence

http://www.medicalprotection.org/southafrica/booklets/consent/introduction
Parental consent for child participation

- Requirements for valid consent:
  - Intact decisional capacity
  - Legally competent
  - Fully informed (and understandable)
  - Voluntary – no coercion or undue influence

Parental incapacity

- if at the time a decision needs to be made he or she is unable, temporarily or permanently and irrespective of the cause –
  - to make the decision for him or herself on the matter in question; or
  - to communicate his or her decision on that matter.

- if he or she is unable
  - to understand or retain the information relevant to the decision; or
  - to make an informed, rational decision based on that information.

In order to make decisions for their children, the parent would need to display:
- commitment to the child's best interests
- adequate knowledge and information
- emotional stability
- the ability to make reasoned judgements
  (Childress 1985)

Only a parent with decisional capacity can give truly informed consent


Problems with obtaining consent from a parent with a critically ill child
- Impracticability (parent absent or urgent action needs to be taken, e.g. resuscitation)

- Concern about validity of consent:
  - Severe illness of a child has significant emotional and psychological effects on parents which may impair capacity for rational informed decision making, including decisions relating to research
  - Levels of stress approach panic at times
  - May be completely unable to assimilate study information under the circumstances

Clinical Research vs Clinical care

**Clinical Research**
- Generate generaliseable knowledge for future patients

**Clinical care**
- Provide benefit to individual patient (now)

Silverman et al 2005 Crit Care Med 33(4) 867 - 882

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Therapeutic misconception

- Inability to distinguish between research and clinical care
- Conflate research participation with receiving “cutting edge” care
  - Unwarranted belief or hope of benefit

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Not a “Patient” a “Participant”
Research in critically ill or injured children may be ethically justifiable without full voluntary informed consent if

- potential to benefit the population by producing evidence or a better understanding of best treatment,
- and where the intervention has only minimally increased risk in the context of the child’s underlying condition.


Informed consent models

- Prospective IC (>minimal risk)
  - E.g. Drug trials
- Deferred (low risk/emergency Rx)
  - E.g. paed CPR
- Waived (very low risk)
  - E.g. folder reviews/audits
“Learning health systems”


"Research needs to be woven into the fabric of our work, so we can understand the issues, move quickly to address them, and continue to deliver an exceptional care experience for our patients."

https://medium.com/@KPWaResearch/learning-health-system-initiative-weaves-research-into-kaiser-permanente-washington-health-care-9afe1d4ed009