Lessons From Infection Prevention Research in Emergency Medicine: Methods and Outcomes

Patricia W. Stone, PhD, RN FAAN
Centennial Professor in Health Policy
Director PhD Program and Director Center for Health Policy
Columbia University School of Nursing
ps2024@columbia.edu
Central line-associated bloodstream infection rate in 66 ICUs, Southwestern Pennsylvania, April 2001-March 2005

An overall decrease of **68%** from 4.31 to 1.36 (p < .001)

MMWR, Oct 14, 2005/54(40); 1013-1016
The CDC Central Line Bundle

- Maximal barrier precautions
- Chlorhexidine skin antisepsis
- Optimal catheter site selection, with avoidance of using the femoral vein for central venous access in adult patients
- Daily review of line necessity, with prompt removal of unnecessary lines
The Keystone Project CL-BSI Bundle

• The CDC bundle +
• Interdisciplinary teamwork
  – 1 physician, 1 nurse team leader
    • Team leaders educated on patient safety
• Checklist used to ensure adherence
  – Clinicians stopped in non-emergent situations if non-adherent
• Goals discussed at daily rounds
• Teams given feedback
• A change in culture!

Pronovost et al., N Engl J Med;
ICUs and EDs are Different...!...?
Science

Randomized Controlled Trial
The Research Question

• PICO
  – Patient
  – Intervention
  – Comparison
  – Outcome
Who is the true superhero?

Experimental

Non-experimental
Hazardous Journeys

Parachute use to prevent death and major trauma related to gravitational challenge: systematic review of randomised controlled trials

Gordon C S Smith, Jill P Pell

BMJ VOLUME 327 20–27 DECEMBER 2003  bmj.com
Conclusions As with many interventions intended to prevent ill health, the effectiveness of parachutes has not been subjected to rigorous evaluation by using randomised controlled trials. Advocates of evidence based medicine have criticised the adoption of interventions evaluated by using only observational data. We think that everyone might benefit if the most radical protagonists of evidence based medicine organised and participated in a double blind, randomised, placebo controlled, crossover trial of the parachute.
As always....

• It is the research question that leads to the appropriate design
Well designed research showing that an ED-based intervention reduced HAIs would change providers practice at my ED.

True 671530

False 671531
Can’t We (Different Study Types) Just Get Along

“Experiment, observation, and mathematics, individually and collectively, have a crucial role in providing the evidential basis for modern therapeutics. Arguments about the relative importance are an unnecessary distraction. Hierarchies of evidence should be replaced by accepting—indeed embracing—a diversity of approaches”

-Sir Michael Rawlins, head, National Institute for Health and Clinical Effectiveness (NICE), Lancet 2008
The Balancing Act

- Strong internal validity
- Balanced groups
- Outcomes clearly defined
- Different than routine care
- Defined patient population
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- Longer follow-up
- Strong external validity
- Confounded by life
- Real world settings
- Large sample size

Experimental vs. Non-experimental

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- The natural

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Center for Health Policy
http://cumc.columbia.edu/dept/nursing/chpnr/
The Natural Experiment

• An occurrence that creates a random or haphazard allocation of exposure / treatment
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• An occurrence that creates a random or haphazard allocation of exposure / treatment

....that is, there is variation in the independent variable (or intervention) of interest
Cluster RCTs that involve randomization at different levels (eg at the ER unit)

Quasi-experimental and mixed methods designs
Observational Studies

- Methodological Challenges
  - Bias (systematic error)
  - Confounding (mixing different effects together)

- Advantages
  - Longer follow-up
  - Less costly than RCTs
  - Meaningful subgroups and comparisons

- Necessary conditions
  - Variability in process/treatment
  - Groups being compared should have reasonable amount of overlap
Observational Studies Usefulness

- Rare outcomes
- Larger studies are needed
- Unable to conduct RCT due to ethical considerations

- Variability in treatment due to
  - Examining multiple treatment paradigms
  - Treatment adherence differs
  - Provider training differs
A diagram

- **Confounder**
  - **Treatment**
  - **Outcome**

[Diagram showing the relationship between confounder, treatment, and outcome.]
Solutions

- Instrumental Variables
- Propensity Scores
- Difference in difference analyses
Correcting for bias when estimating the cost of hospital-acquired infection: an analysis of lower respiratory tract infections in non-surgical patients

Nicholas Graves a,b,⁎, Diana Weinhold c and Jennifer A. Roberts d
a Centre for Healthcare Related Infection, Surveillance and Prevention, Princess Alexandra Hospital, Queensland, Australia
b School of Public Health, Queensland University of Technology, Australia
c London School of Economics, UK
d London School of Hygiene & Tropical Medicine, UK

Estimating Influenza Vaccine Effectiveness in Community-Dwelling Elderly Patients Using the Instrumental Variable Analysis Method

Kenny Wong, MPH; Michael A. Campitelli, MPH; Thérèse A. Stukel, PhD; Jeffrey C. Kwong, MD, MSc

ARCH INTERN MED/VOL 172 (NO. 6), MAR 26, 2012
Conclusions

• All research will not be a RCT!

• Comparative effectiveness designs that include mixed methods (quantitative and qualitative aspects) are needed
  – Interdisciplinary research teams with synergistic expertise are required

• Using existing data sources offers benefits
  – Selection bias must be addressed and there are many different ways in which to do this
“The right objective for health care is to increase value for patients, which is the quality of patient outcomes relative to the dollars expended.”

-Michael Porter

Bishop William Lawrence University Professor