

# Statistics is an essential part of ethical research

Professor Jane L Hutton

[go.warwick.ac.uk/jlhutton](http://go.warwick.ac.uk/jlhutton)  
Department of Statistics  
University of Warwick  
Coventry  
UK

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# Why is statistics essential to good research?

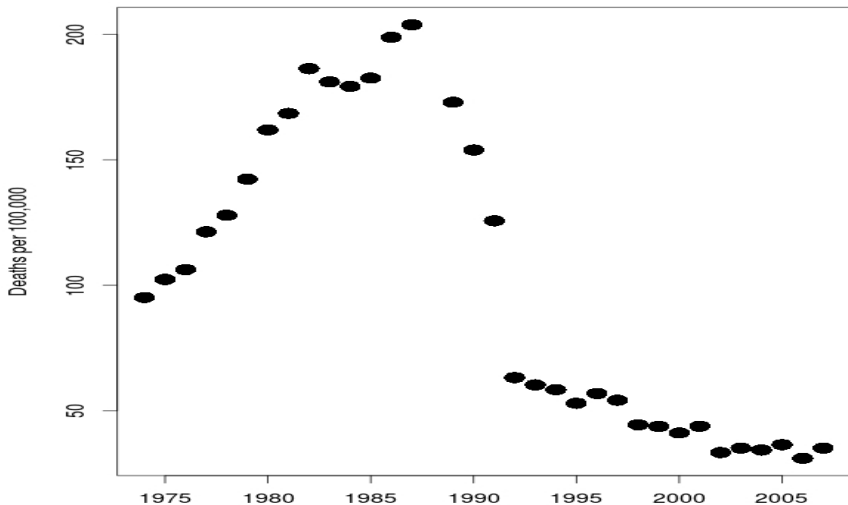
In science, medicine, education, psychology, agriculture, . . .

simply do what is best for the greatest benefit.

Consider a graph

# What happened in the UK 1974-2007?

Death rates 1974-2007, children under 1 year



It must be a good idea!

- Medical advice to put babies to sleep on their stomachs  
Sudden infant death syndrome
- Human albumin given to critically ill patients: average of 6 extra deaths per 100 patients treated (1998)
- Oxygen to premature babies: retinopathy of prematurity

Randomised controlled trials for interventions:  
not only drugs, also surgery, complex interventions  
(multi-disciplinary teams to prevent falls)

For epidemiology, other designs.

# Why is statistics essential to good research?

In science, medicine, education, psychology, agriculture, ...  
simply do what is best for the greatest benefit.

- How do you know what is best?
- Which ethics: deontological, utilitarian or consequentialist?
- Virtue & habitual ethics.
  - Prudence, wisdom
  - Courage, fortitude
  - Temperance, restraint
  - Justice, righteousness
  - Faith
  - Hope
  - Love

“Not my problem” is the problem: cowardice, lack of courage.

Routinely collected health data (RCD), or  
Randomised controlled trials (RCT)?

- RCTs inadequately concealed allocation . . .  
“Odds ratios were exaggerated by 41% for inadequately concealed trials and by 30% for unclearly concealed trials”  
Schulz et al, JAMA, (1995),  
doi = 10.1001/jama.1995.03520290060030
- “RCD studies systematically and **substantially overestimate mortality benefits** . . . compared with subsequent RCTs”  
Hemkins et al, BMJ, (2017), doi = 10.1136/bmj.i493

UK, USA and Scandinavia differ on concept of privacy, role and type of consent

- Popular versions of uninformed consent
- Unpopular choices: society, privacy, accuracy
- Metal-on-metal hip replacement:  
The Judge found UK NJR data was unreliable . . .  
compliance rates for 2004 to 2010 ranged from 43% to 114%,  
consent from 63% to 88%, linkability 57% to 95%  
Swedish Hip A. Register: national coverage of individual total  
hip replacements is 98%

JF Ludvigsson et al, Clin Epidemiol, (2015) "Ethical aspects of registry-based research in the Nordic countries."

Option E parallel session

# Statistics in medicine: power?

- Statisticians reviewing papers
- Statisticians reviewing ethics committee applications
- Statisticians reviewing grants
- Statisticians required for drug and device licensing
- Statisticians required on multi-centre RECs
- International register of clinical trials: publication bias.
- Publication guidelines: Equator network  
<http://www.equator-network.org/>

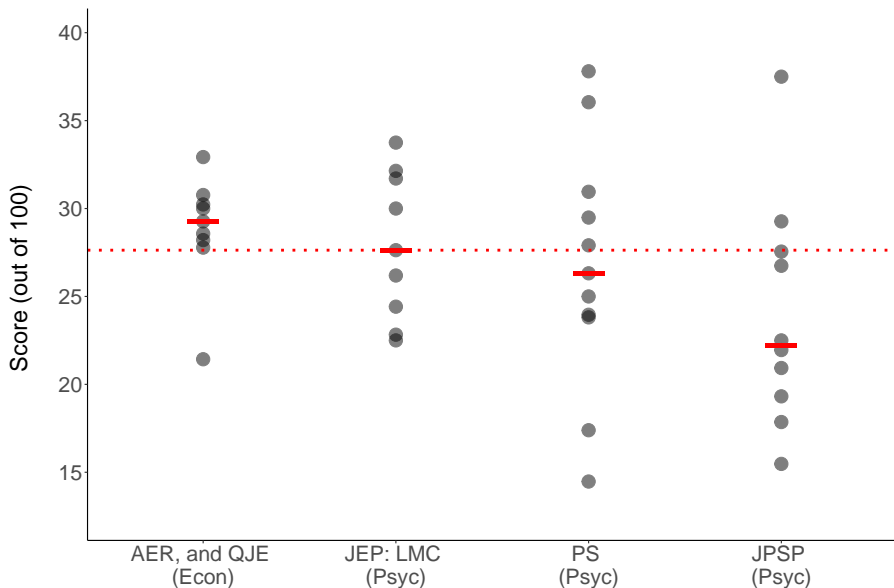
Options A, C parallel sessions



# Nudging and reproducing

- “Nudge Unit” Behavioural Insights team, UK 2010.
- Tried to replicate 100 psychology and 18 economics studies published most influential journals. Only 36/100 psychology and 11/18 economics studies . . . broadly similar results.
- “The basic conclusion is that randomization should be employed whenever possible . . .”  
D B Rubin, J Educ Psych, (1974)
- American Psychological Association, mid 1990s:  
“Statistical methods in psychology journals:  
Guidelines and explanations”,  
Wilkinson and the Task Force on Statistical Inference,  
Amer. Psychol. (1999)
- Checklist from Task Force, applied to replication papers:  
30 psychology, 9 economics (Kenneth Lim)

# Not reproducing - and not nudging?



## society:

- consider conflicting interests,
- guard against misuse, misinterpretation,
- extend statistics for maximum benefit,
- pursue objectivity, open about limitations.

## funders and employers:

- clarity about roles and responsibilities,
- impartial assessment of possible methods,
- no pre-emption of outcomes,
- safeguard privileged data, reveal methods

## colleagues:

- maintaining confidence in statistics,
- transparency of methods,
- know own + collaborators' ethics.

neither over- nor under-state validity or generalisability of data

## subjects:

- individual people, households, corporations
- adequacy of information and of consent
- even if a “gate-keeper” blocking access.
- harm by virtue of group membership  
→ rare inquiry is devoid of possible harm