

Evidence and Ethics: *Why Should We Use Evidence?*

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What's ethics got
to do
with it?

???

???

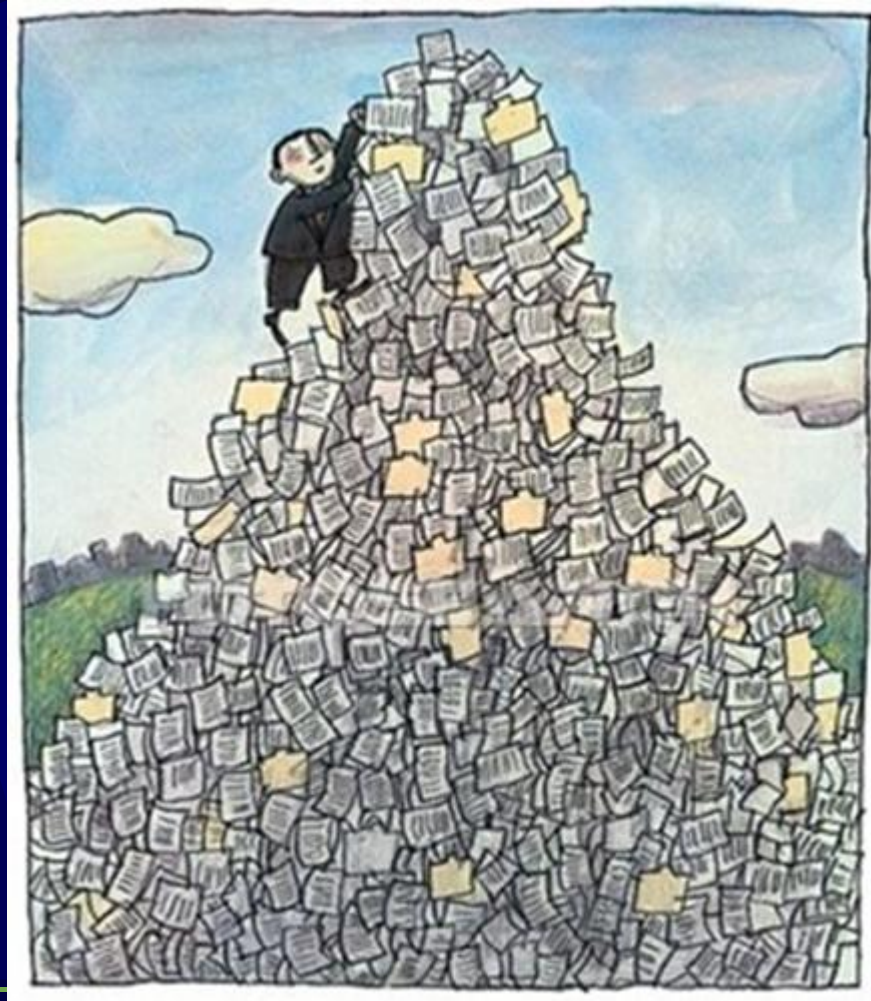
Ethical principles

- Beneficence: promoting good for patients
- Nonmaleficence: avoiding harm
- Justice: fair distribution of limited resources
- Autonomy: person's right to decide
- Fidelity: trustworthiness, honesty

Evidence helps to decide

- What works
- What avoids harm
- What costs are involved
- What people want
- Can promote trust and honesty

Ethics & research



Everyday ethics

- 'A far more dependable safeguard than consent' in research involving humans is 'the presence of an intelligent, informed, conscientious, compassionate, responsible investigator.'

Beecher, H.K. Ethics and clinical research. *New England Journal of Medicine* 1966;274:1354-1360.

Ethics and evidence

- Knowing the question, we go where the evidence leads us.

OR ??

- Knowing the answer, we look for evidence to back up our opinion.

What evidence?

- 20,000—30,000 health and medical journals
- 2,000,000 articles every year

**We critically appraise
the evidence, or...**



- “I look forward to such an organisation of the literary records of medicine that a puzzled worker in any part of the world shall in an hour be able to gain the knowledge pertaining to a subject of the experience of every other person in the world.”
- George Gould, First President of the Medical Libraries Association, USA (May 1898)

**First, what's the
question?**

Falls and hip protectors



- Do they help?
- Where do you look for evidence?

Falls and hip fractures

- 30-60% of older adults fall every year
- About 1% of falls result in hip fracture
- World-wide estimate in 1990: 1.7 million
- Projections for 2050: 6-21 million
- 25% full recovery; 25% die with 1 year; 50% require nursing home care
- Financial cost: US 2001: \$33,000/pt - \$11.5 billion
- Personal cost, physically and quality of life
- Caregiver burden

| Category | Sample Question | Evidence |
|--------------|------------------------------------------------|-------------------------------------------|
| Assessment | How do I best assess mobility of ...? | Prospective cohort study |
| Harm | Do hip protectors cause adverse effects? | Retrospective RCT, cohort or case control |
| Intervention | Do hip protectors prevent hip fractures? | RCT, systematic review |
| Perceptions | How do people feel about using hip protectors? | Observational or qualitative studies |

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KPH website 2010

- 'The Hip Protector of the *New England Journal of Medicine* publication.'
- '...hip fracture risk may be reduced by **84%** if the KPH Hip Protector® is on at the time of the fall.'
- 'If you are concerned by **at least** two of the following risk factors, then it is recommended to wear a KPH Hip Protector®:'

- Concerned about at least two of these:



Ethical responsibilities with evidence

- Thoroughness in searching
- Up-to-date search
- Understand and check the details
- Follow up on suspicions arising from:
 - Different results
 - Inaccuracies
 - Questionable publication ethics
 - Conflicts of interest

Hip protectors: in the beginning

- First major randomised controlled trial (RCT): Lauritzen *et al The Lancet* 1993:
- The relative risk of a hip fracture while wearing a hip protector was 0.44 (95% CI 0.01 to 0.94).
- A large RCT in a prestigious journal showing a striking treatment effect.

Trials published up to 2001

- Large cluster randomised studies
 - Lauritzen *et al* (1993); Ekman *et al* (1997); Kannus *et al* (2000)
- Studies randomised by individual
 - Jantti *et al*, (1998); Chan *et al*, (2000); Harada *et al* (2001); Cameron *et al* (2001)
- Cochrane review (2000)
 - Hip protectors appear to reduce the risk of hip fracture within a selected population at high risk of sustaining a hip fracture.

Parker MJ, Gillespie WJ, Gillespie LD. Hip protectors for preventing hip fractures in older people. *Cochrane Database of Systematic Reviews*

Trials published 2002-2003

- Large cluster randomized study
 - Meyer *et al* (2003)
- Studies randomised by individual
 - Van Schoor *et al* (2003), Birks *et al* (2003), Cameron *et al* (2003)
- Cochrane review (2003)
 - No evidence of effectiveness from studies randomised by individual, but cluster RCTs show an apparent reduction in the incidence of hip fractures.

More evidence 2004-2005

- Birks *et al* (2004)
 - A large community study – no difference
- O'Halloran *et al* (2004)
 - A large cluster randomised study in nursing homes – no difference
- Cochrane review (2005)
 - A marginally statistically significant reduction in hip fractures in frail older people in institutional care.

Cochrane review (2010)

‘Present evidence shows that there is no benefit from hip protectors for the majority of older people living in their own homes. Making hip protectors available to frail older people in nursing care facilities may reduce the risk of fractures.’

‘Poor acceptance and adherence.’

‘It remains unknown ... if these findings apply to all types of hip protectors.’



Which guidance do you follow?



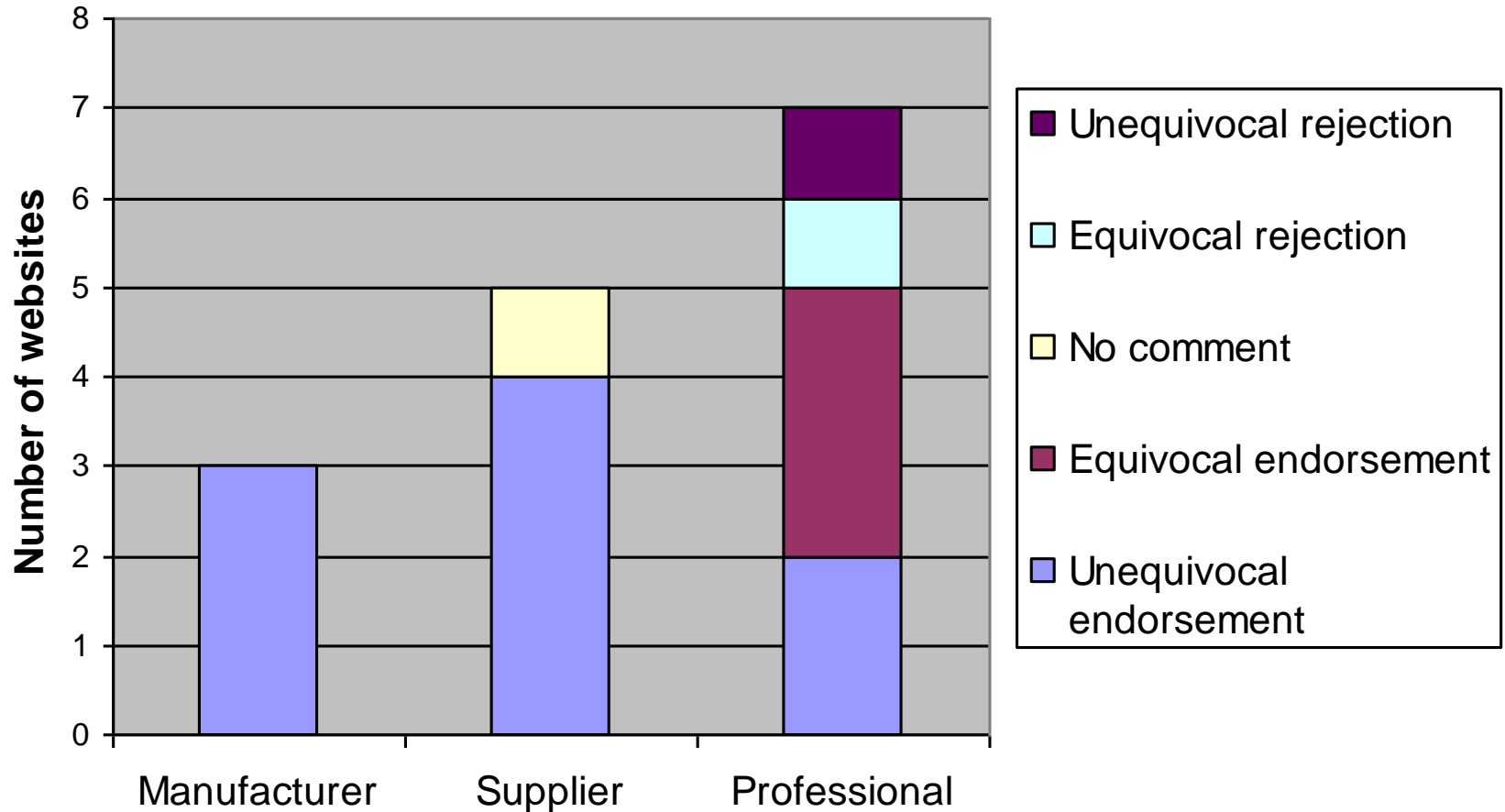
Ethical responsibility to understand the evidence

- Cluster RCT versus individual RCT
- O'Halloran qualitative study
- Different questions require different evidence.

Ethical guidance

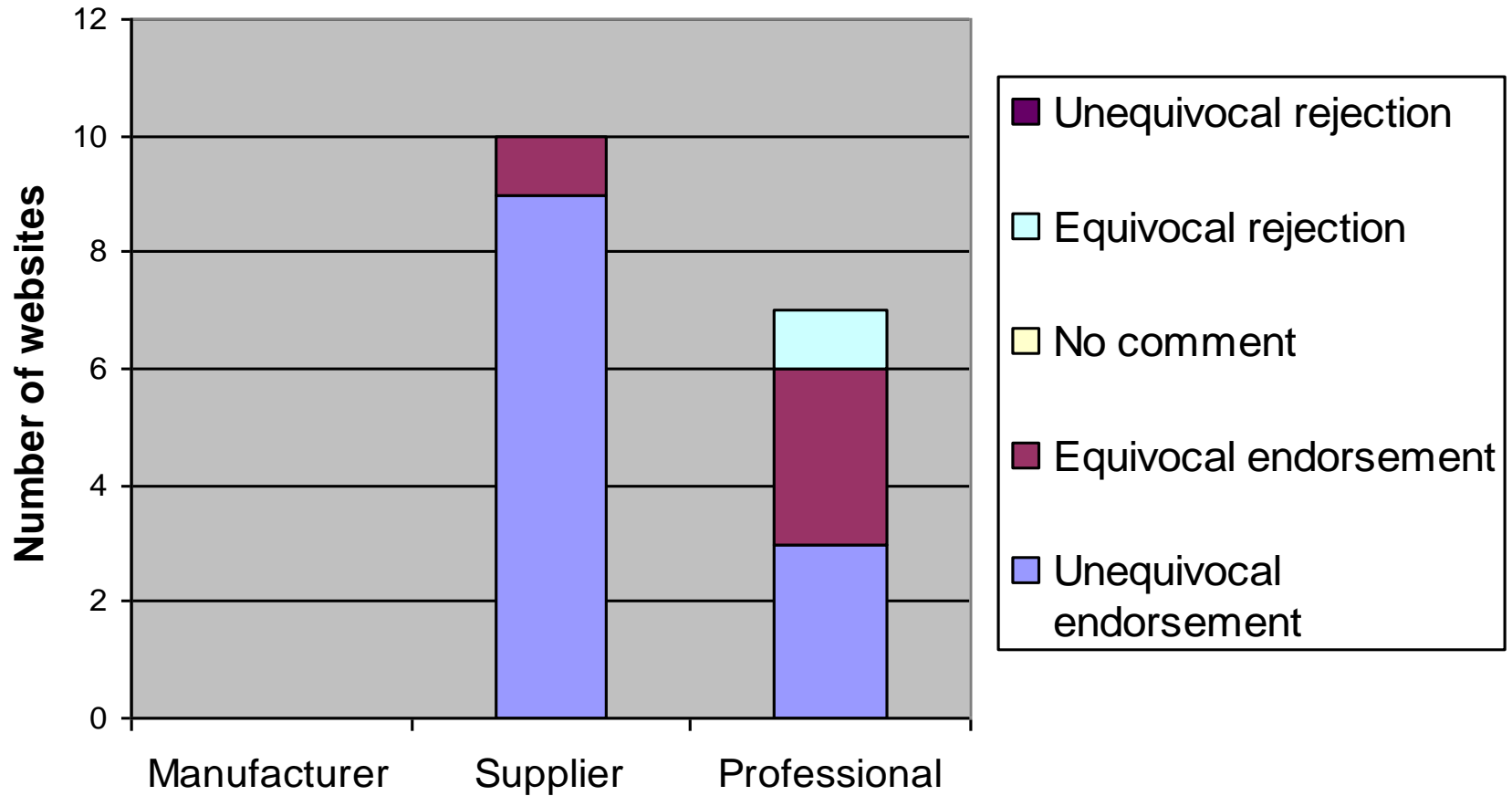
- Promotion of patient/client good
- Avoidance of harm
- Just allocation of resources
- Contribution to informed consent

Levels of endorsement 2006



Overall recommendation re hip protectors by type of website (O'Halloran)

Level of endorsement 2008



Conflict of interest

- Commercial
- Personal
- Ideological

Sloppiness or bias?

- 1996 review article claimed: 'Of those who saw a provider for unconventional therapy, 32% saw a provider for energy healing. This result indicates a greater acquaintance with energy healing modalities such as TT than expected.'
- Original 1993 survey: 1% of all respondents used energy healing, and 32% of those saw a provider.
- Therefore, 0.32% saw a provider for energy healing.
- Authors clarified in 1998 that the most common energy healing therapy involved magnets.

O'Mathúna DP. 2004. In *Commitment and Responsibility in Nursing: A Faith-Based Approach*. Sioux Center, IA: Dordt Press, pp. 147-166.

Misrepresentation of original research

'For example, Therapeutic Touch has been found to be an effective adjunct to medical treatment for decreasing anxiety (Heidt, 1981; Olson, Sneed, Bondonna, Ratliff, & Dias, 1992; Parkes, 1985; Quinn, 1984)...'

Hug Found a failed replication, Quinn, 1989
contradictory Found increased anxiety!
results

- 'Honest errors' indicate 'a lack of a meticulous approach to the preparation of scientific papers for publication. . . . However, such errors are still a cause for concern, because they indicate a lack of discipline that also might reflect the investigator's approach to the research protocol, data management, and laboratory practices in general.'

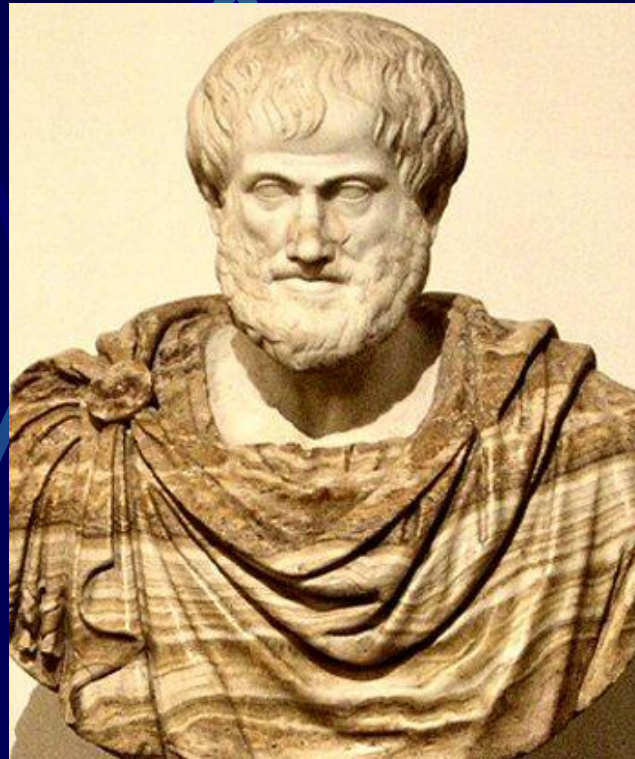
Biebuyck JF. *J Anaesthesiology* 1992;77:1-2x

- ‘During ten years of study of [ethical problems in research] ... thoughtlessness and carelessness, not a willful disregard for patient’s rights, account for most of the cases encountered.’

Beecher, H.K. Ethics and clinical research. *New England Journal of Medicine* 1966;274:1354-1360.

Greek ethics

- Catharcis
- Elenchus



Practically speaking

- Importance of thoroughness, diligence, accuracy, double-checking, updating.
- This takes commitment of time and resources.
- Fraud is rare (we hope!), but happens. Follow up on suspicions.
- Sloppiness is not a good sign.
- The goal of evidence-based practice is an ethical one: improving patient care.

Comments? Questions?

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