

Third Annual Cochrane in Ireland Conference

DCU, February 2007

**“Wound cleansing, pressure ulcers and a
HRB Cochrane Fellowship”**

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Background

“Our understanding of the world around us is constantly being redefined and expanded, and so therefore, it is wiser to be passionate about seeking for truth than knowing it”

(Bryant H Mc Gill)



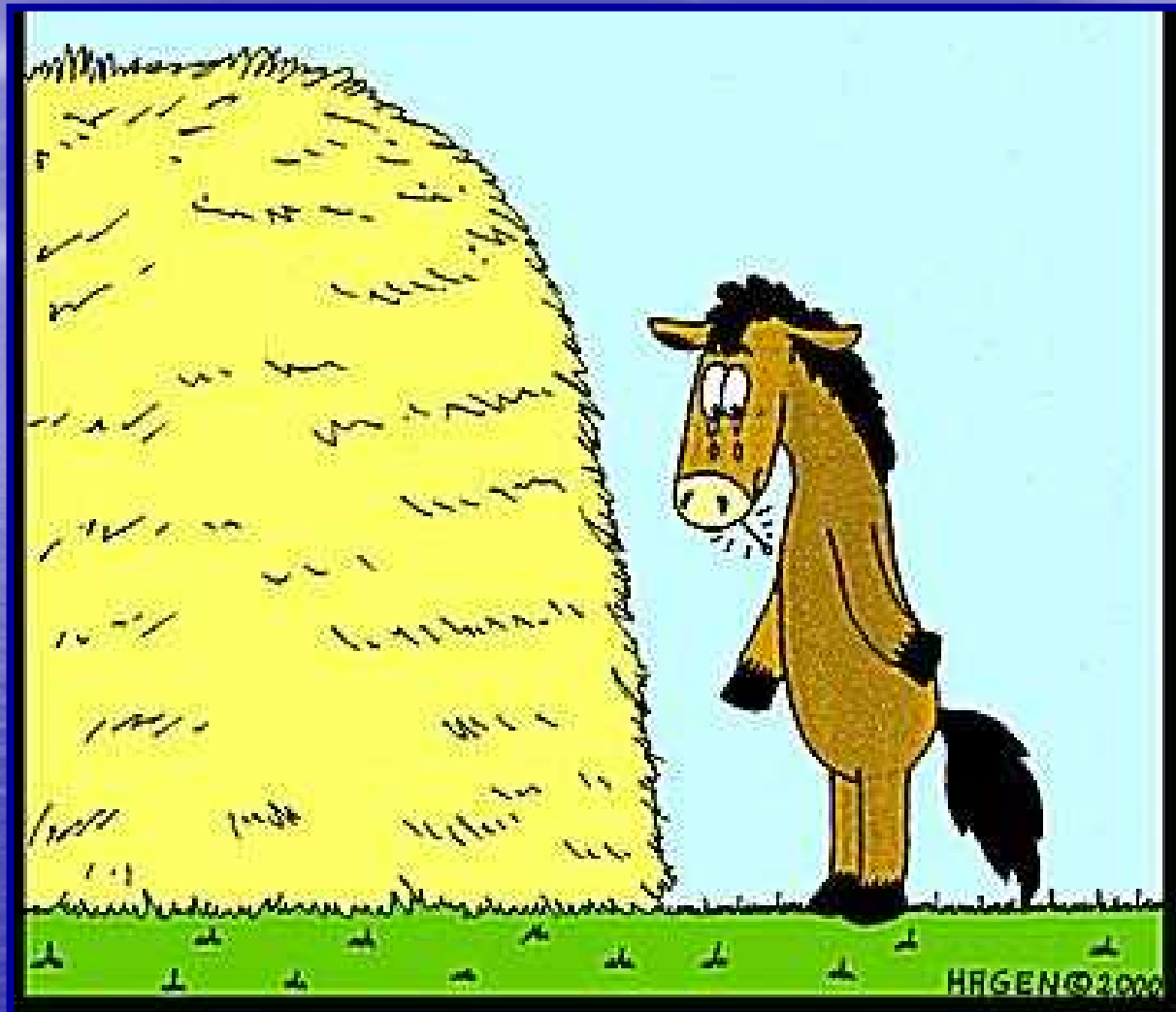


Subscribed journals - the top thirty by article downloads Jan–Nov 2006

British Medical J	15,800	Am J Res
New England J M	10,560	Clinical O
J Biological Chemistry	6,073	J Neurolo
Nursing Standard	4,045	Psychiatr
J Advanced Nursing	2,771	Spine
J Medical Ethics	2,595	Neurosurg
PNAS	2,260	Pediatric
Nature ^a	2,208	Thorax ^a
British J Psychiatry	2,084	Gut
Science Online ^a	2,028	Laryngos
Blood	1,939	J Clinical
The Lancet	1,858	Surgery
JAMA	1,521	J Nursing
J Neuroscience ^a	1,404	British J s
J Immunology	1,250	Nature M
Plastic & Reconstructive Surgery ^a	1,216	Titles man
		Research J

68,000





**Ed was unlucky enough to find
the needle in the haystack!**

Background

*“Those who cannot remember the past are
condemned to repeat it”*

George Santayana (1863–1952)

**Need to know what is already known and not known
about a subject AND what the particular study adds to
the body of knowledge**



Finding the Evidence

Bias

“Something that will cause a consistent deviation from the truth”

(The Cochrane Collaboration, 2002)



Finding the Evidence

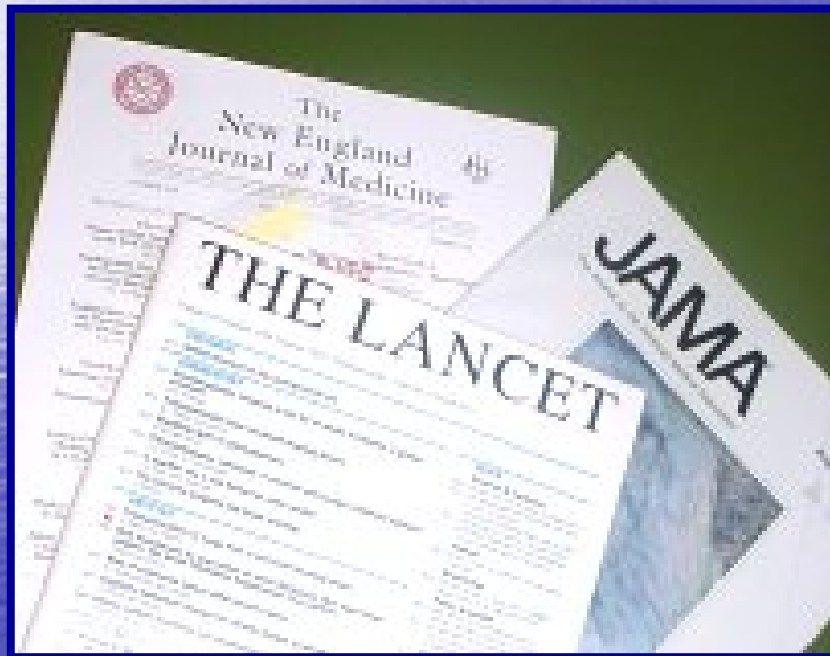
Bias

- Publication bias
- Time lag bias
- Multiple (duplicate) publication bias
- Citation bias
- Language bias
- Outcome reporting bias

Egger et al, (2001)



Finding the Evidence



(Anna Salleh, ABC)

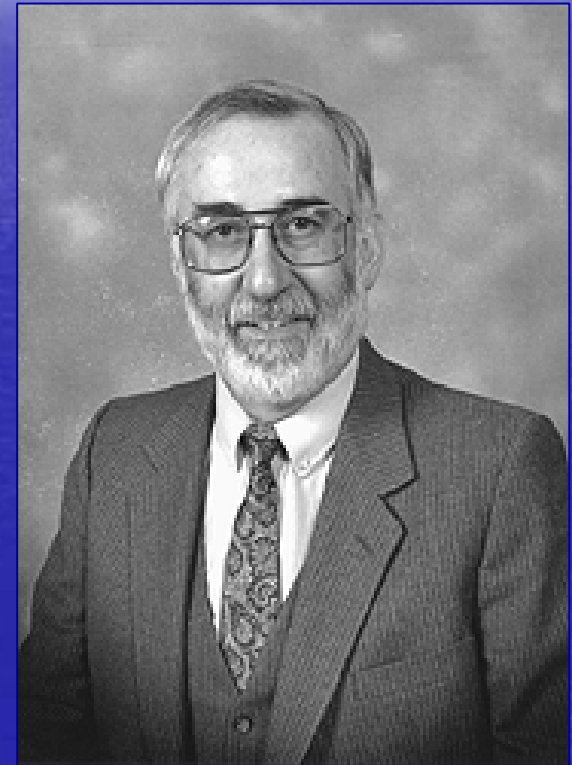
Gatekeepers:

90% of diseases
profiled in medical
journals affect
10% of the world's
population



Finding the Evidence

“Sackett claims that the prestige of experts (including himself) gives their opinions far greater persuasive power than they deserve on scientific grounds alone”



Anna Salleh - ABC Science Online



Finding the Evidence

Time Lag Bias:

- 65 investigators of passive smoking
- 61 studies conducted 1981-1995
- 5 yrs for non statistically significant results
- 3 years for statistically significant results
- In Human studies – a statistically significant result is a predictor of time to publication

Misakian & Bero (1998)



Finding the Evidence

Multiple publication bias:

- Multiple publications from single studies
- Studies with significant results are more likely to lead to multiple publications and presentations
- Combined data from a multicentre trial together with a subset of the same data that had also been reported separately from an individual centre
- Two articles reporting the same trial do not share a single common author

Finding the Evidence

Language Bias:

36 meta-analyses published in leading English language general medical journals from 1991 to 1993, 26 had restricted their search to studies reported in English

Grégoire G, Derderian F, LeLorier J
J Clin Epidemiol 1995;48:159-63.



Finding the Evidence

Outcome reporting bias:

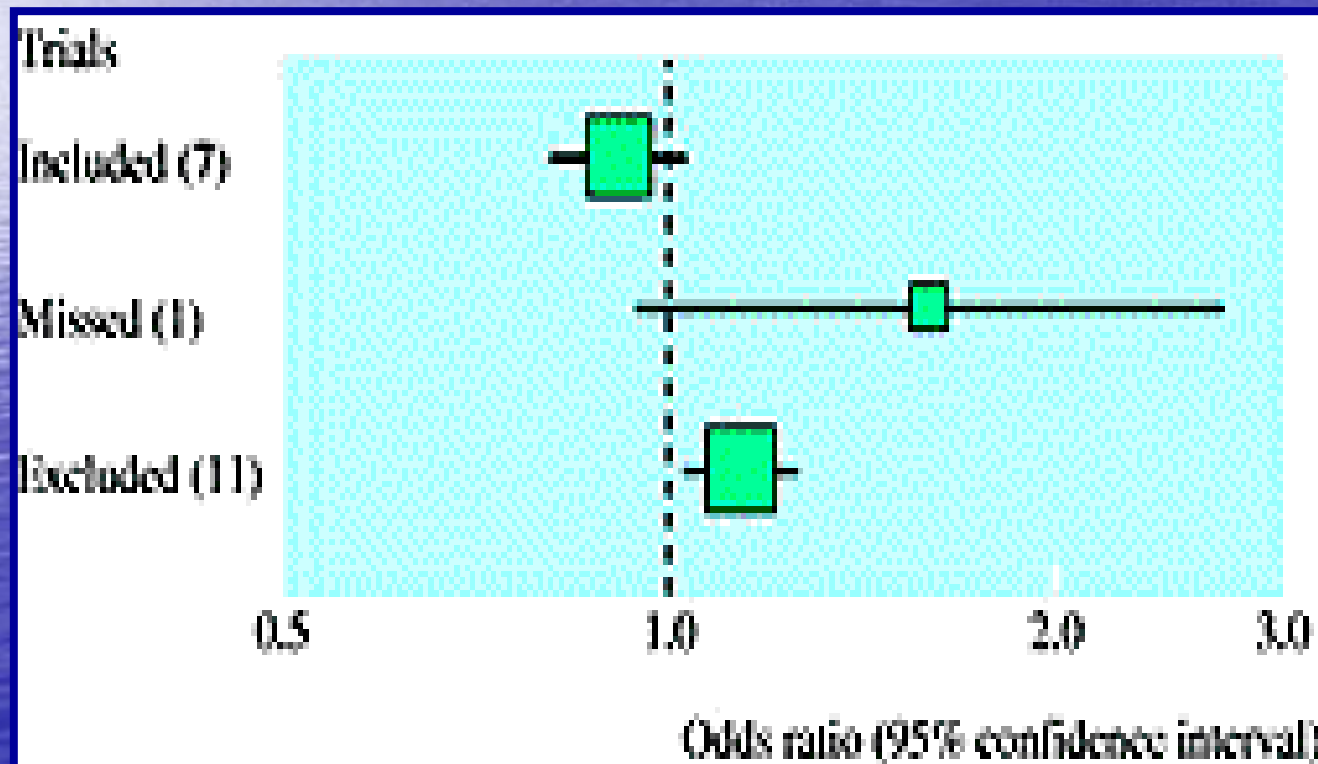
- 519 trials with 553 publications reporting 10,557 outcomes
- 44% of trials have 1 or more unreported outcomes
- Bias towards non statistically significant findings
- Impacts negatively on the ability to critically appraise study quality

(Chan et al, 2005)



Finding the Evidence

Citation Bias:



Rossouw J E,
Lewis B,
Rifkind B M.
N Engl J Med
1990;323:1112-9.





What is it all about?



Wound Cleansing for Pressure Ulcers

Rationale:

- **Decision makers need reliable information**
- **But too much information available**
- **Reviews can be biased**
- **Systematic reviews attempt to minimise bias**
- **May provide new information**

Cochrane Collaboration (2003)



Cochrane Fellowships

The aim of the Cochrane Fellowship scheme is to build capacity in conducting systematic reviews in the health and social care field in Ireland, by freeing up protected time for applicants to conduct a Cochrane systematic review in any topic of their choice



Background



*“To get through
the hardest
journey we need
take only one step
at a time, but we
must keep on
stepping”*



Why Pressure Ulcers?



"Superman" star Christopher Reeve, 52, who went into cardiac arrest at his home in Westchester County, N.Y. after developing a serious systematic infection during treatment for a bedsore

Why Pressure Ulcers?



Why Pressure Ulcers?

**Alzheimer patient's bed sores
extended into bone – inquest told**

The report found the cause of death was sepsis, “probably septicaemia due to pressure sores”.

(Irish Times: 27th January 2005)

Why Pressure Ulcers?

- Prevalence – Ireland 1999 – 12.9%
- Prevalence – Ireland 2002 – 21%
- Prevalence – Ireland 2003 – 12%

(Moore & Pitman, 1999; Jordan O'Brien, 2002;
Moore & Jordan O'Brien 2003)



Why Pressure Ulcers?

- 1:5 hospital patients has a pressure ulcer
- 50% of hospital patients are at risk
- 60% of all pressure ulcers occur in hospital
- An indicator of quality of care
- Recent Court award €70,000 for neglect

(EPUAP, 2003)



Why Pressure Ulcers?

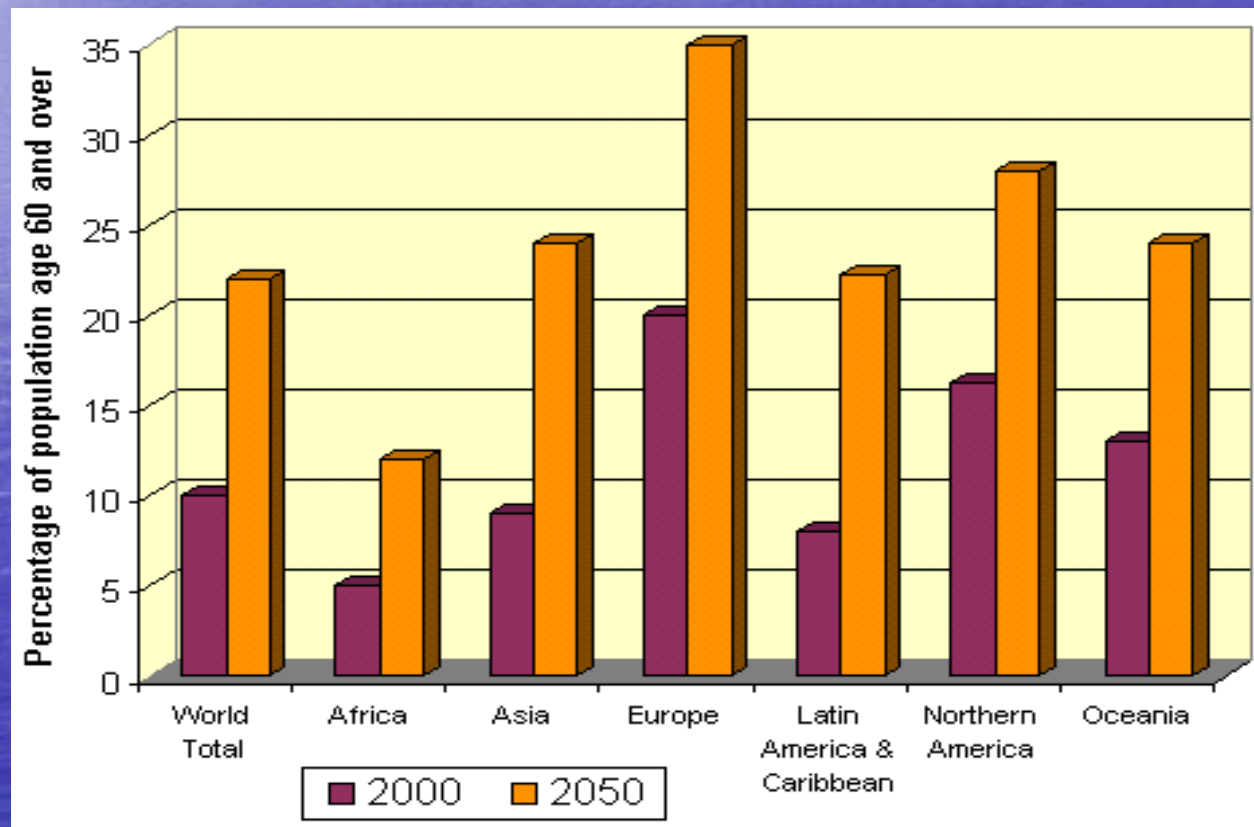
- Incidence – Care of the elderly
3%-23%
- Incidence – USA: 1999-2004
8% - 7%

(NPUAP, 2001; Whittington & Briones, 2004)



Why Pressure Ulcers?

Percentage Increase in Age 60 and Over by Region, 2000-2050



Why Pressure Ulcers?

- Halfens *et al* (2000) OR 2.68, ($p < 0.001$),
- Casimiro *et al* (2002), OR 1.03
- Young *et al* (2002) OR 6.0
- Blaumgarten *et al* (2003) OR 1.3

All linking age with increased risk of pressure ulcer development



Why Pressure Ulcers?

“Pressure ulcers

A key quality indicator”

Dept. of Health U.K. (1993)



Why Pressure Ulcers?

Costs:

- **£1,064 grade 1 pressure ulcer**
- **£10,551 grade 4 pressure ulcer**
- **Annual cost: £1.4 - £2.1 billion - 4% of total health care expenditure**

(Bennett et al, 2004)

Why Pressure Ulcers?

Costs:

- €119,000 to treat one patient with a grade 4 pressure ulcer
- £250,000,000 annually to manage pressure ulcers

(Gethin et al, 2005)



Why Pressure Ulcers?



Hopkins *et al*, (2006)
Fox, (2002)

Endless Pain,
anxiety,
sleeplessness,
worry about
healing restricted
lifestyle

Why Pressure Ulcers?

Policy: Ireland

- **Quality and Fairness, A Health System for You DoHC (2001)**
- **The Value for Money Audit of the Irish Health Care System (2001)**
- **Working Group on Elder Abuse (2002)**



Wound Cleansing for Pressure Ulcers

Background:

- Pressure ulcers a significant health care problem
- Wounds need to be managed successfully
- Cleansing necessary
- Confusion about best practice
- Review of evidence necessary



Wound Cleansing for Pressure Ulcers

Objective:

To assess the effects of wound cleansing solutions and techniques on the healing rates of pressure ulcers



Wound Cleansing for Pressure Ulcers

Type of study:

- RCT's comparing wound cleansing with no wound cleansing
- RCT's comparing different wound cleansing solutions
- RCT's comparing different wound cleansing techniques
- No restrictions regarding year or language of publication



Wound Cleansing for Pressure Ulcers

Type of participants:

Studies involving people of any age, in any health care setting, with existing pressure ulcers (defined as a break in the continuity of the skin caused by pressure with or without shearing/friction forces)



Wound Cleansing for Pressure Ulcers

Type of intervention:

- **Cleansing compared with no cleansing**
- **Comparisons between different cleansing solutions**
- **Comparisons between different cleansing techniques (e.g. irrigation, swabbing, soaking, immersion)**



Wound Cleansing for Pressure Ulcers

Type of outcome measure - primary:

- An objective measure of pressure ulcer healing
- Time to complete healing
- Rate of change in pressure ulcer area or volume
- Proportion of pressure ulcers healed



Wound Cleansing for Pressure Ulcers

Type of outcome measure - secondary:

- Pain, using validated scales where reported
- Ease of use of the method of cleansing
- Secondary outcomes only reported from studies which also report primary outcomes



Wound Cleansing for Pressure Ulcers

Search strategy:

- **Cochrane Central Register of Controlled Trials (CENTRAL)**
- **Specialised Trials Register of the Cochrane Wounds Group (up to August 2005)**
- **Hand search of relevant bibliographies**
- **Contacted experts and researchers in the field**



Inclusion
Criteria applied
3 papers
eligible



Wound Cleansing for Pressure Ulcers

Data Extraction & Analysis:

- 2 authors extracted data independently
- Structured narrative summary initially
- For dichotomous outcomes RR & 95% CI calculated
- For continuous outcomes WMD & 95% CI calculated
- Meta analysis not conducted due to small number of diverse RCT's



Wound Cleansing for Pressure Ulcers

Analysis:

Relative risk is the rate of the event of interest, for example pressure ulcers healed, in the experimental group divided by the rate of this event in the control group. It indicates the chances of pressure ulcer healing for people in the experimental treatment compared to the control group. As, by definition, the risk of an event occurring in the control group is 1 then the relative risk reduction associated with using the experimental treatment is $1-RR$

(CLIB Training 2003)

Wound Cleansing for Pressure Ulcers

Analysis:

The mean difference, called the weighted mean difference, measures the absolute difference between the mean values in the experimental and control groups in a clinical trial. It estimates the amount by which the treatment changes the outcome on average.

Interpretation of the result of this analysis is the same as for relative risk except the point of no effect is 0 rather than 1

(CLIB Training 2003)

Wound Cleansing for Pressure Ulcers

Results:

- No study comparing cleansing with no cleansing
- 2 studies comparing different cleansing solutions
- 1 study comparing different cleansing technique



Study	Bellingeri (2004)	Griffiths (2001)	Burke (1998)
Eligibility Criteria	Described	Described	Described
Random Allocation	Yes	Yes	Yes
Concealed Allocation	No	No	No
Blinded Assessment	No information	Yes	Yes
ITT	No	Yes	Yes

Methodological Quality

Study	Bellingeri (2004)	Griffiths (2001)	Burke (1998)
Setting	Hospital	Community	Hospital
Treatment	Saline solution versus isotonic saline	Water versus Saline	Whirlpool versus no whirlpool
Outcome Measure	PSST	Wound Size	Length X Width
Number	126 patients	8 patients	42 ulcers
Result	$P = 0.025$	NS	NS

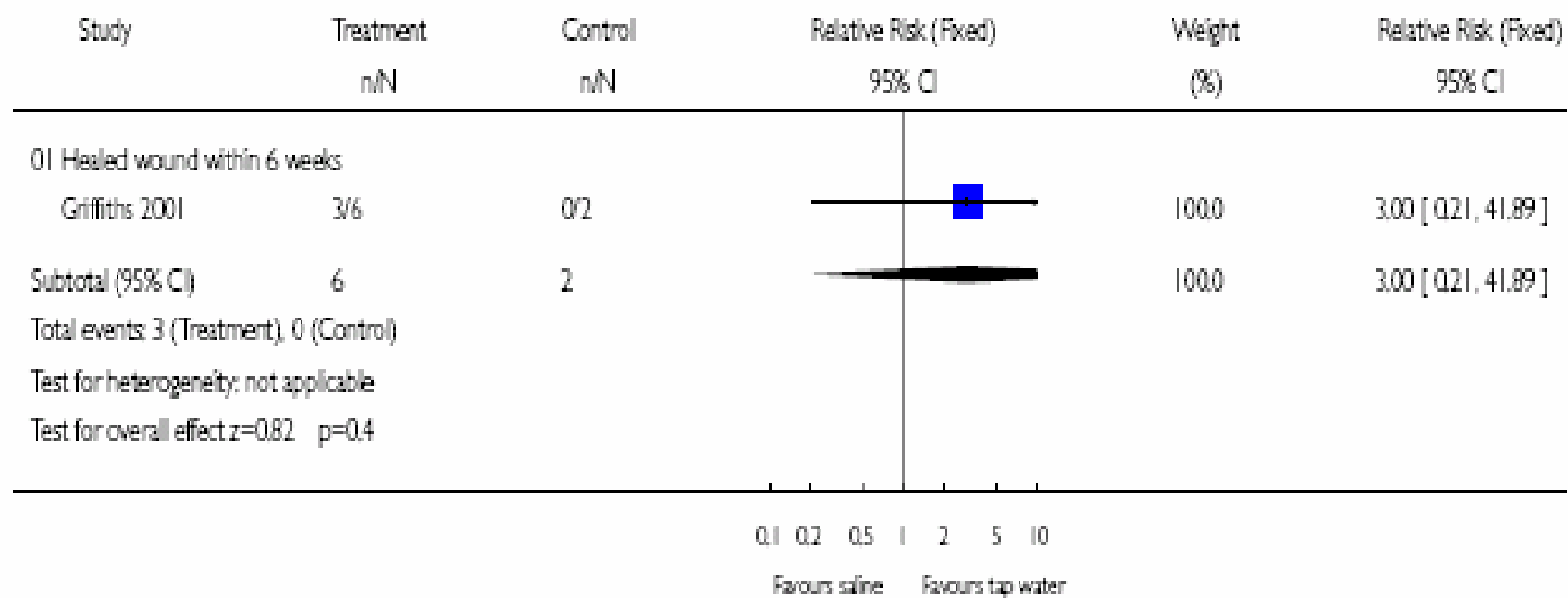
Results

Analysis 02.02. Comparison 02 Different cleansing solutions, Outcome 02 Saline versus tap water

Review: Wound cleansing for pressure ulcers

Comparison: 02 Different cleansing solutions

Outcome: 02 Saline versus tap water

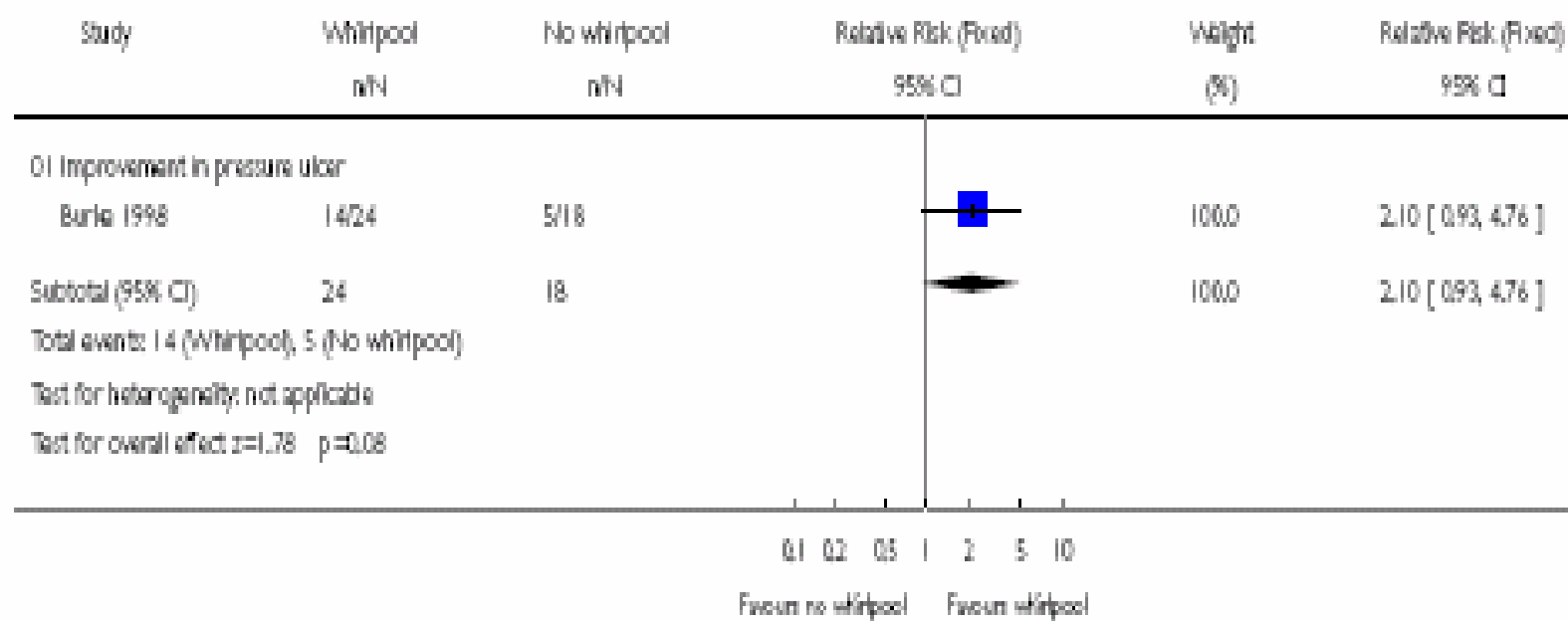


Analysis 03.01. Comparison 03 Different cleansing techniques, Outcome 01 Whirlpool versus no whirlpool

Review: Wound dressing for pressure ulcers

Comparison: 03 Different cleansing techniques

Outcome: 01 Whirlpool versus no whirlpool



Wound Cleansing for Pressure Ulcers

Conclusion:

Overall, there is no good trial evidence to support use of any particular wound cleansing solution or technique for pressure ulcers

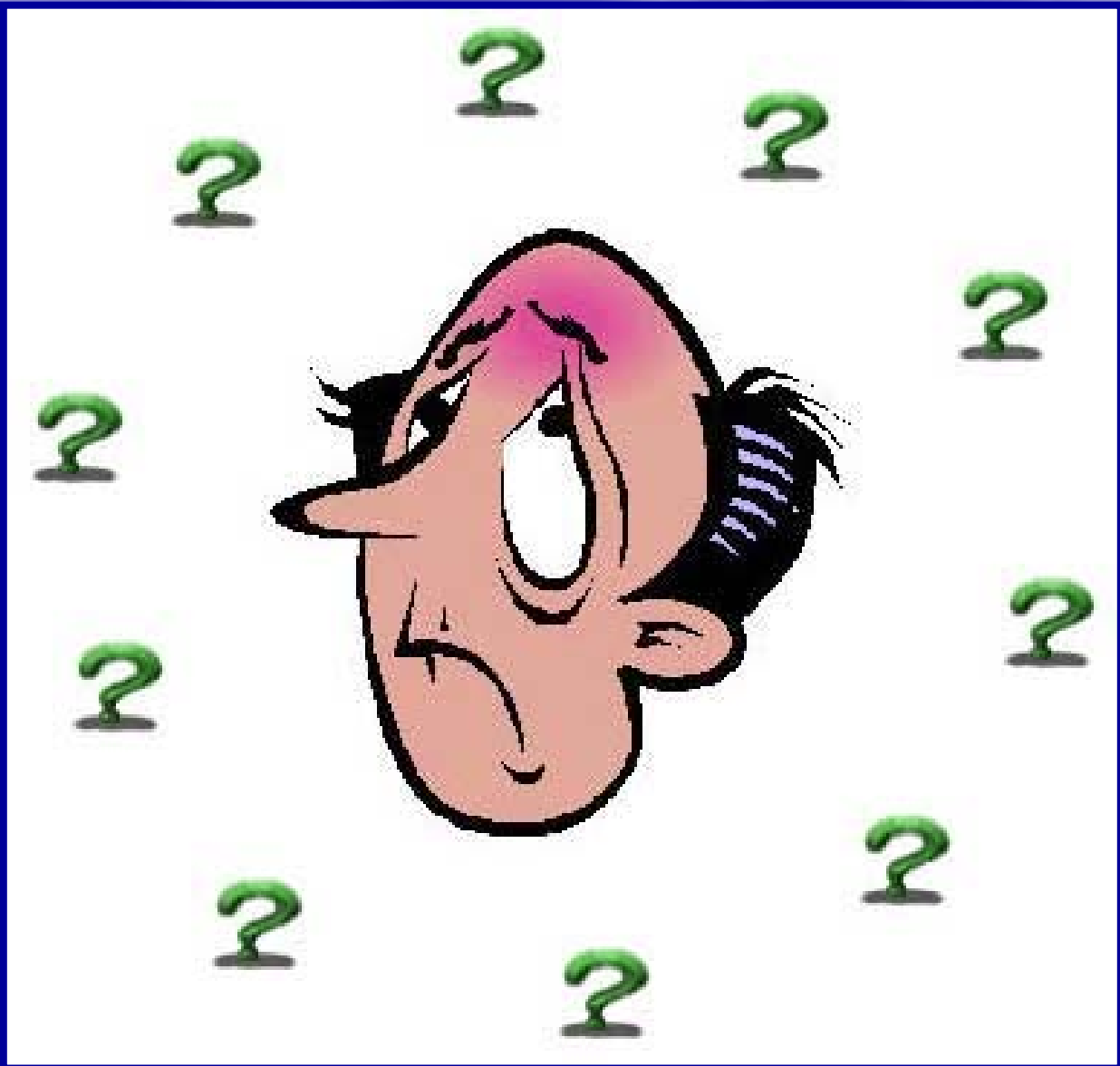




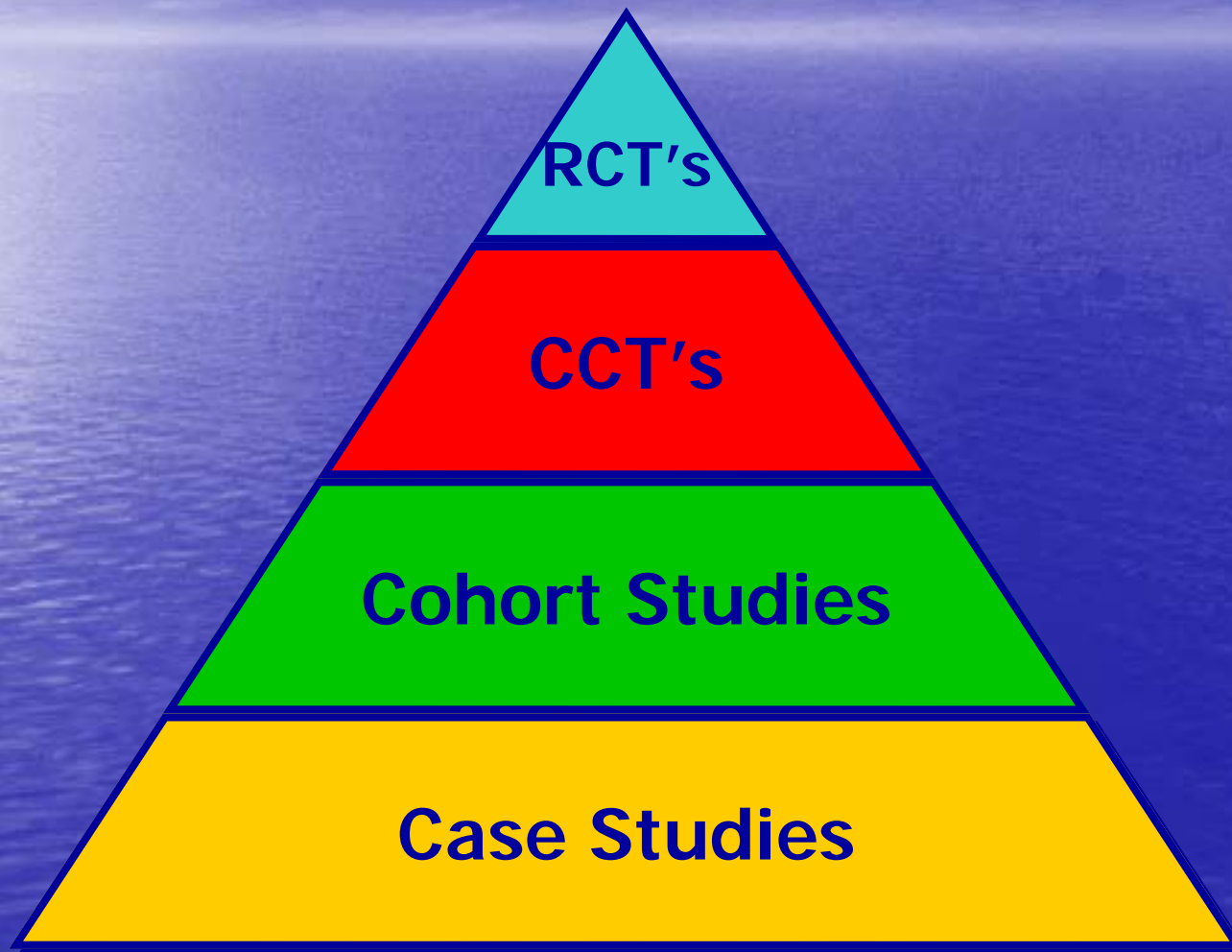
I JUST WANTED
TO SEE WHAT I
COULD SEE...



Why the bear climbed Mount Everest.



Evidence



?

Levels of evidence

- ❖ 1 – evidence from meta-analysis of RCT's or at least one RCT
- ❖ 11 – Evidence from at least one controlled trial without randomisation of at least one other type of quasi-experimental study
- ❖ 111 – Evidence from non-experimental descriptive studies
- ❖ 1V – Evidence from expert committees or reports/clinical experience/respected authorities

Wound Cleansing for Pressure Ulcers

Reflections:

- 19 months work
- Greatest challenge lay in the lack of clarity in publications
- Lack of data a disappointment
- An invaluable (but challenging) learning experience



Wound Cleansing for Pressure Ulcers

And Now?:

- Developed confidence in process
- Undertaking 2 further reviews
- Teaching others to do the same
- Would like to branch out to accuracy of diagnosis



- **Health Research Board, Ireland**
- **Susan O Meara, Sally Bell-Syer**
- **Referees – Jacqui Fletcher, Nerys Woolacot**
- **Coordinating Editor Nicky Cullum**
- **Adrianna Castelli & Ikumi Iwama for translations**
- **Dean & Staff Faculty of Nursing & Midwifery**



Appraising Evidence

“Human beings, who are almost unique in having the ability to learn from the experience of others, are also remarkable for their apparent disinclination to do so”

Douglas Adams (1952-2001)



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