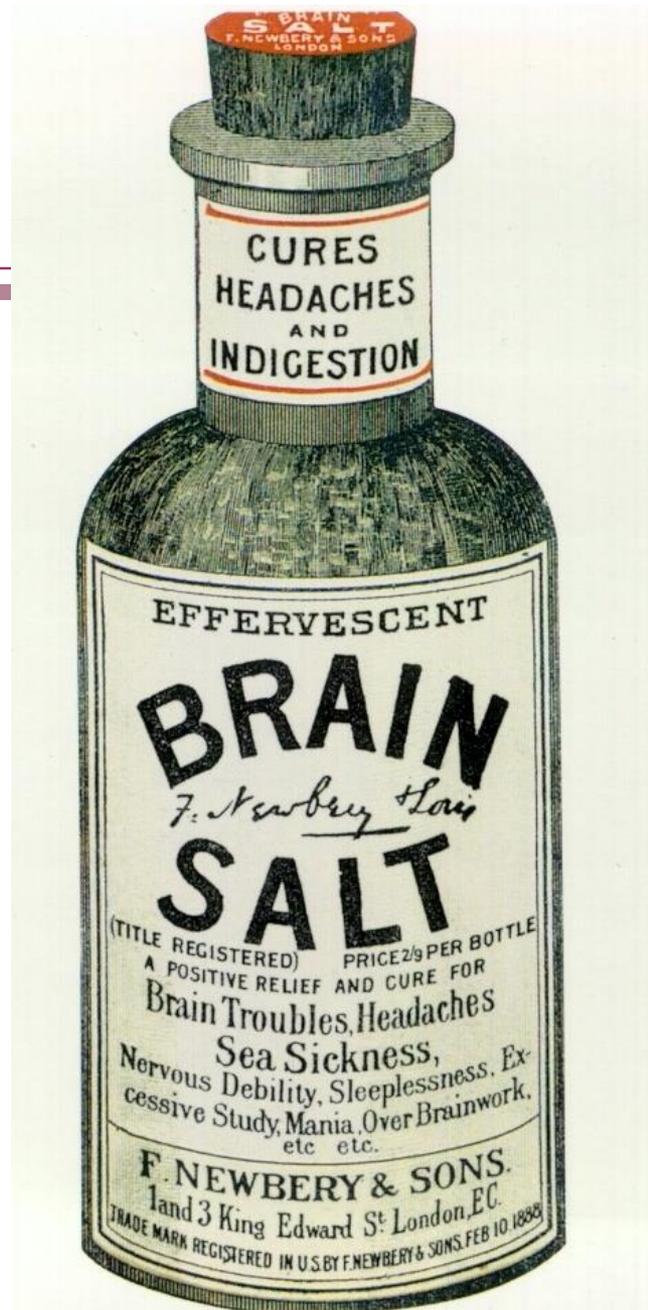

Why published medical research may not be good for your health

Doug Altman

***EQUATOR Network and
Centre for Statistics in Medicine
University of Oxford***







Reliable evidence

Clinical practice and public health policy decisions depend on high-quality information about research findings

- **Research only has value if**
 - Study methods are valid
 - Research findings are published in a usable form

- **We need reliable evidence from research**
 - Good quality research
 - Good reporting of that research

- **This is often not what we get**

Current concerns with the health research literature



- **Poor methodology**
- **Poor reporting**
- **Selective publication**



Special Communications

Statistical Evaluation of Medical Journal Manuscripts

Stanley Schor, PhD, and Irving Karten, MA

JAMA, March 28, 1966

Schor & Karten 1966



“Each communication was subjected to an abbreviated but intensive critical reading by a competent biostatistician with experience in reviewing scientific publications.”

295 articles in 10 top medical journals

149 analytical studies

[146 case descriptions]

Schor & Karten 1966



34% Conclusions drawn about population but no statistical tests applied on the sample

25% Design of study not appropriate for solving problem stated

19% Too much confidence placed on negative results with small-size samples

“Thus, in almost 73% of the reports read (those needing revision and those which should have been rejected), conclusions were drawn when the justification for these conclusions was invalid.”

CORRESPONDENCE

Open Access

An evaluation of the quality of statistical design and analysis of published medical research: results from a systematic survey of general orthopaedic journals

Nick R Parsons^{1*}, Charlotte L Price², Richard Hiskens³, Juul Achten¹ and Matthew L Costa¹

- 39% a different analysis should have been undertaken
- 17% a different analysis could have made a difference to the overall conclusions
- 17% conclusions were not clearly justified by the results

Resu
result
clear
17%

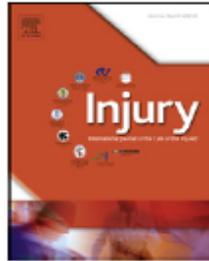
in



Contents lists available at SciVerse ScienceDirect

Injury

journal homepage: www.elsevier.com/locate/injury



Lies, damn lies and statistics: Errors and omission in papers submitted to INJURY 2010–2012

Robin J. Prescott^{a,*}, Ian Civil^b

- 100 successive submitted papers sent for statistical review
 - 47 Inappropriate analysis
 - most common was incorrect analysis of 2x2 tables
 - 22 Inadequate description of some element of the study
 - 26 Additional limitations recommended to be discussed
 - 19 Simple numerical mistakes

“Many of the errors identified are easily avoided”

Erroneous analyses of interactions in neuroscience: a problem of significance

Sander Nieuwenhuis^{1,2}, Birte U Forstmann³ & Eric-Jan Wagenmakers³

Reviewed 513 behavioral, systems and cognitive neuroscience articles in five top-ranking journals (*Science*, *Nature*, *Nature Neuroscience*, *Neuron* and *The Journal of Neuroscience*) in 2009-10

157 (31%) articles had at least one situation in which they compared two effect sizes

78 (50%) used the correct procedure and 79 used the incorrect procedure

“Most of the errors may not have severe implications. In some cases, however, the error may contribute substantially to the article’s main conclusions.”

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New study: Skin cancer protects against heart attack and death

Posted on [September 23, 2013](#) by [Vitamin D Council](#)





Don't laugh, he's going to live longer than you do (Photo: Coloubox)

October 16, 2013
08:00

by KM

Sunbathers live longer

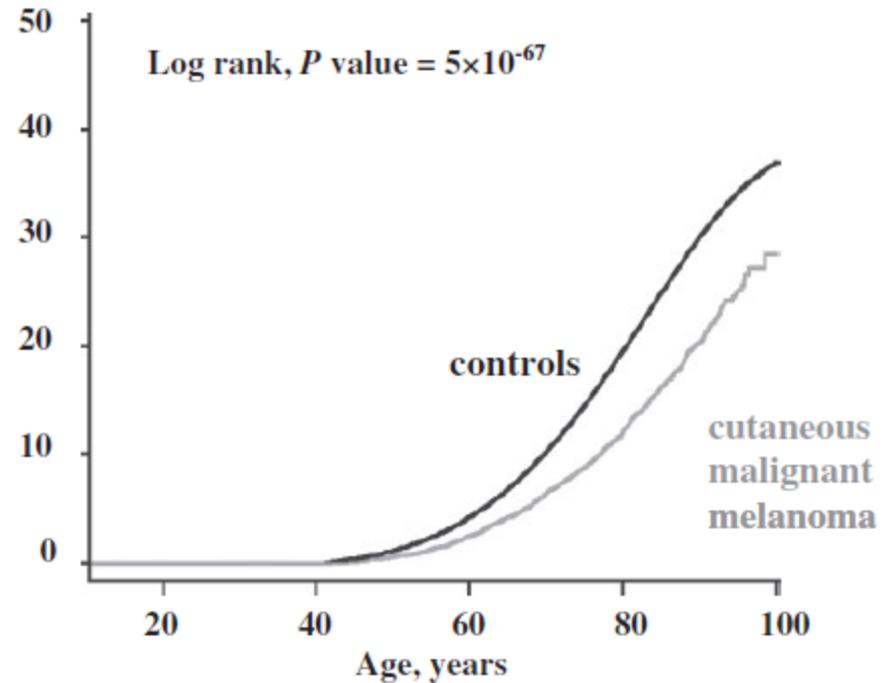
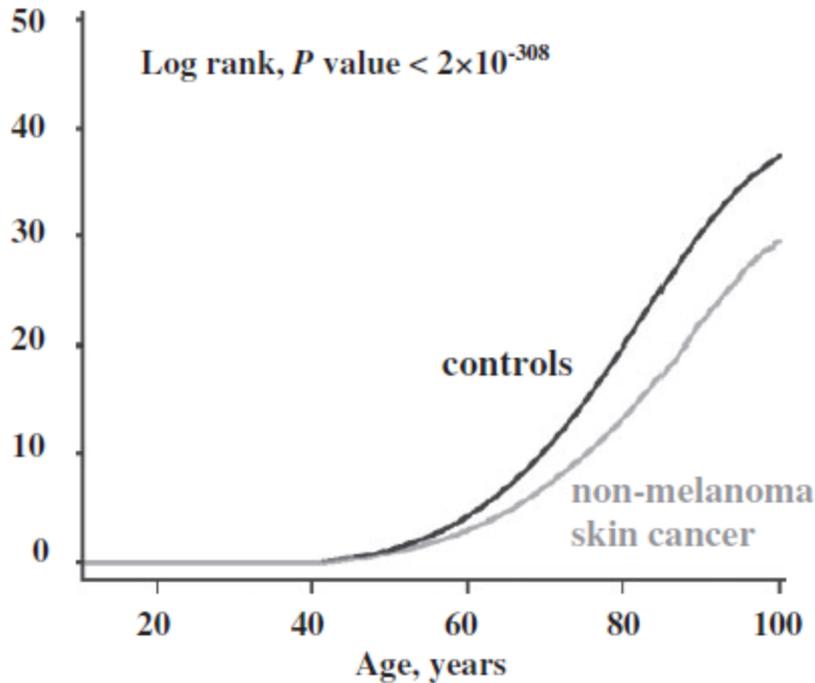
Spending time in the sun can add years to your life, a 20-year study following the health of 4.4 million Danes finds. The team of Danish

Cumulative incidence of MI (%)

[Brøndum-Jacobsen et al, *Int J Epidemiol* 2013]



Myocardial infarction



“Did no alarm bells sound?”

[Lange & Keiding, *IJE* 2014]

Taxonomy of poor reporting



- **Non-reporting (or delayed reporting) of whole studies**
(even when some results have been presented in public)
- **Selective reporting of patient outcomes**
- **Selective reporting of analyses done**
 - e.g. subgroups, alternative analyses
- **Incomplete publication**
 - Omission of crucial aspects of research methods
 - Incomplete results: data cannot be included in meta-analysis
- **Misleading interpretation (spin)**
 - e.g. post hoc change of focus
- **Inconsistencies between sources**
 - e.g. publication vs protocol



Bias from poor reporting

Worst case is when bad reporting practices are related to the actual research findings, to vested interests, or both

- **non-publication**
- **selective publication**

Much empirical evidence shows that such practices are common

P values influence what gets published

PUBLICATION DECISIONS AND THEIR POSSIBLE EFFECTS ON
INFERENCES DRAWN FROM TESTS OF SIGNIFICANCE
—OR VICE VERSA*

THEODORE D. STERLING
University of Cincinnati

AMERICAN STATISTICAL ASSOCIATION JOURNAL, MARCH 1959

In 1959, 97% of 294 studies in 4 major psychology journals had reported statistically significant positive results.

When Sterling repeated the analysis in 1995, nothing had changed

Selective reporting is very common



EUROPEAN JOURNAL OF CANCER 43 (2007) 2559–2579



available at www.sciencedirect.com



journal homepage: www.ejconline.com



Almost all articles on cancer prognostic markers report statistically significant results

Panayiotis A. Kyzas^a, Despina Denaxa-Kyza^a, John P.A. Ioannidis^{a,b,c,}*

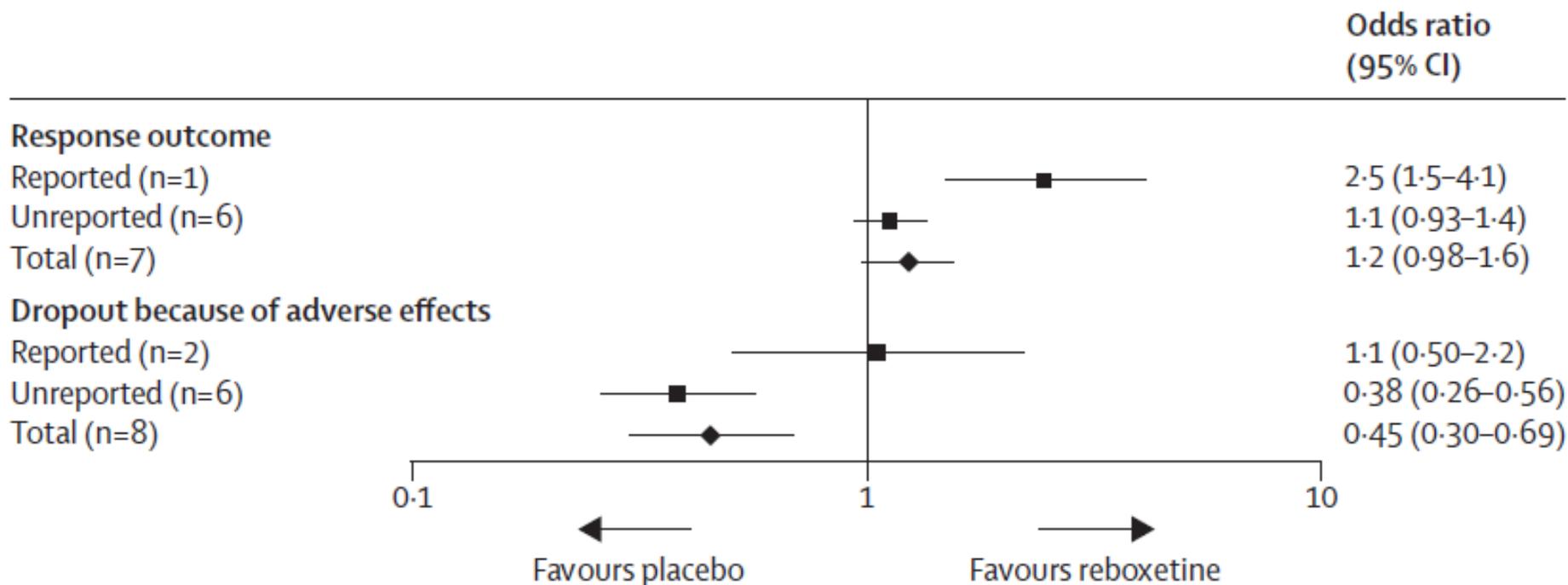


Figure 3: Results of a meta-analysis of reported and unreported randomised trials of reboxetine versus placebo for acute treatment of major depression

Data used to create this figure from Eyding et al.¹⁸

Chan et al, *Lancet* 2014

...and this is where we put the non-significant results.



som^{ee}cards
user card

Consequences of failure to publish



- **Non-publication of research findings always leads to a reduced evidence-base**
- **Main concern is that inadequate publication *distorts* the evidence-base – if choices are driven by results**
- **Even if there is no bias the evidence-base is diminished and thus there is extra (and avoidable) imprecision and clinical uncertainty**

Methodology and reporting are inevitably linked



3 major issues with medical literature:

- **Poor study methods**
- **Incomplete reporting**
 - Methods
- **Selective publication**
 - Whole studies
 - Selective findings

Consequences of inadequate reporting



- **Assessing the reliability of published articles is seriously impeded by inadequate reporting**
 - Clinicians cannot judge whether to use a treatment
 - Data cannot be included in a systematic review
- **Serious consequences for clinical practice, research, policy making, and ultimately for patients**



The resource centre for good reporting of health research studies



Library for health research reporting

The Library contains a comprehensive searchable database of reporting guidelines and also links to other resources relevant to research reporting.



[Search for reporting
guidelines](#)



[Visit the library for
more resources](#)



Key reporting guidelines

CONSORT	Full Record Checklist Flow Diagram
STROBE	Full Record Checklist
PRISMA	Full Record Checklist Flow Diagram
STARD	Full Record Checklist Flow Diagram
COREQ	Full Record
ENTREQ	Full Record
SQUIRE	Full Record Checklist
CARE	Full Record Checklist
SAMPL	Full Record
SPIRIT	Full Record Checklist



Toolkits

The EQUATOR Network works to improve the reliability and value of medical research literature by promoting transparent and accurate reporting of research studies.

Our Toolkits support different user groups, including:

[Authors](#)

Information and resources for authors



EQUATOR highlights

[23/05/2014 - AllTrials video – make clinical trials count](#)

AllTrials.net have produced a new video highlighting the issue of non-publication of clinical trial results. [Read More](#)

[16/04/2014 - The STROBE Statement webinar recording now available](#)

The recording of the EQUATOR – PAHO March 2014 webinar on the STROBE Statement [Read More](#)

[17/03/2014 - Scientific meeting and the EQUATOR Annual Lecture 2014, 16 May 2014, Paris, France](#)

The INSERM-Sorbonne Paris Cite Epidemiology and Statistics Research

News

[Exciting new collaboration between EQUATOR and the Global Health Network](#)

1/07/2014

[EQUATOR is recruiting](#)

2/06/2014

[Journals must adopt high methodological standards](#)

28/05/2014

[Scientific meeting and EQUATOR Annual Lecture 2014](#)

22/05/2014

[researchwaste.net](#)

State of play – 1



- **Not all research is published**
- **Methodological problems are common**
- **Research reports are seriously inadequate**
 - May mask methodological weaknesses
- **Improvement over time is slow**
- **Reporting guidelines exist for most research types**
 - Have been shown to improve reporting
 - No incentives for researchers to adhere

State of play – 2



- **Much waste**
 - Wrong studies done
 - Studies done wrong
- **Much research is unethical**
- **Cannot include results in a SR/MA**

- **Research cannot be replicated**
- **Evidence base is distorted**
 - Reduced
 - Biased

How might research lead to harm?



- **Results are misleading**
 - Flawed design
 - Flawed analysis

- **Study not published**

- **Publication is misleading**
 - Incomplete or incorrect description of methods
 - Selective publication of findings
 - Misinterpreted

“It is the responsibility of everyone involved to ensure that the published record is an unbiased, accurate representation of research.”

[PLoS Medicine Editors 2009]

- **So what should be done?**

Research: increasing value, reducing waste 5

Reducing waste from incomplete or unusable reports of biomedical research

Paul Glasziou, Douglas G Altman, Patrick Bossuyt, Isabelle Boutron, Mike Clarke, Steven Julious, Susan Michie, David Moher, Elizabeth Wager

Recommendations

- Funders and research institutions must **shift research regulations and rewards** to align with better and more complete reporting
- Research funders should take responsibility for **reporting infrastructure** that supports good reporting and archiving
- Funders, institutions, and publishers should improve the capability and capacity of authors and reviewers in **high-quality and complete reporting**

Is medical research good for your health?



- **It should be**
- **Much of it is**
- **But bad science – poor methods and selective reporting – can harm people**
- **We need *reliable* evidence**

