

البحث العلمي المنشور بين الجيد والرديء

سيناء عبد المحسن العقيل
استاذ مشارك بقسم الصيدلة الاكلينيكية
كلية الصيدلة

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Voting

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Peer Review Process



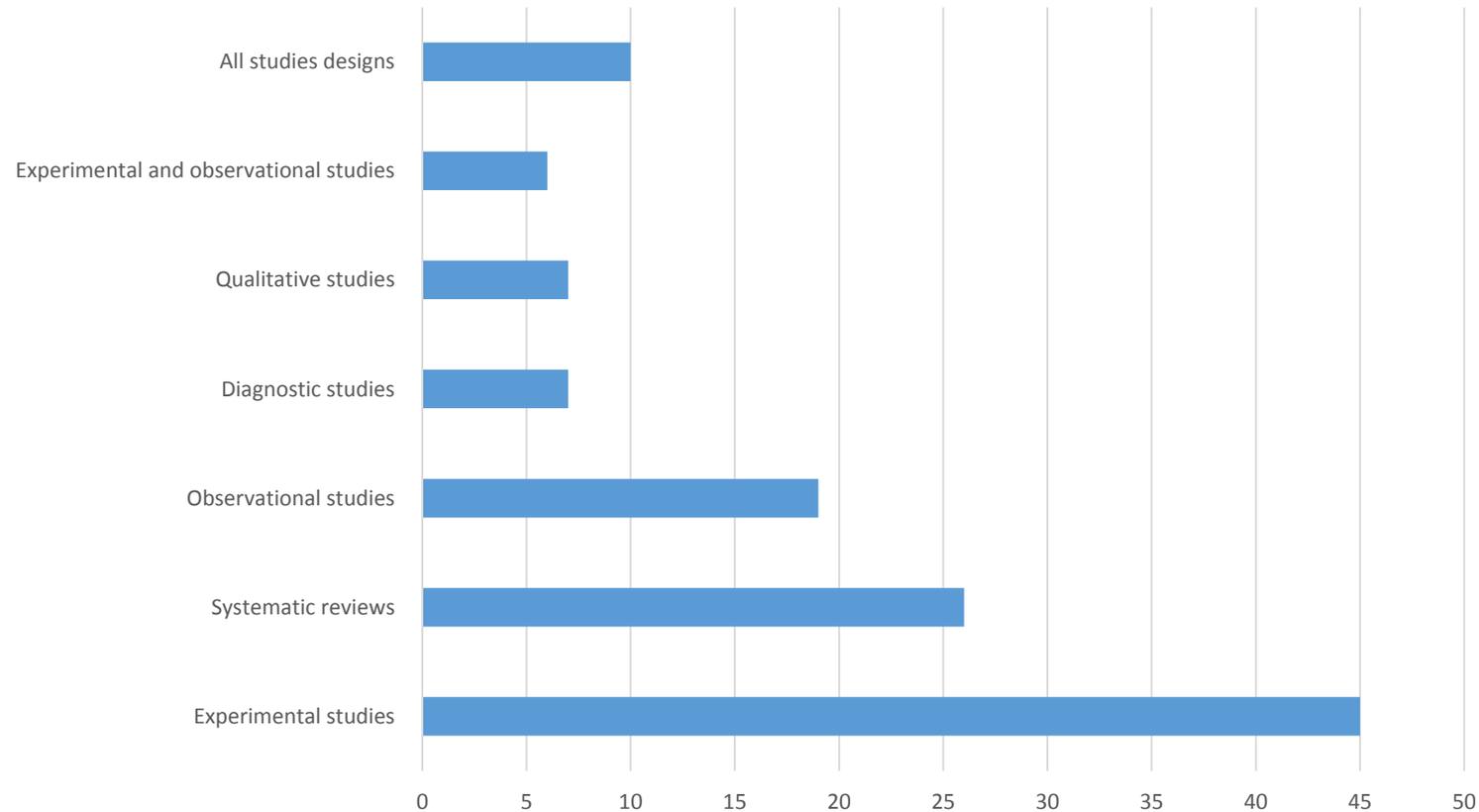
William Whewell, peer-review pioneer
Source: NATURE, VOL 532. 2016



SKEPTICAL HIPPO

Is skeptical.

Critical appraisal tools to evaluate the quality of published research



Source: [BMC Med Res Methodol](https://www.ncbi.nlm.nih.gov/pmc/articles/PMC521688/). 2004; 4: 22.. <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC521688/>

Critical appraisal tools example

NEWCASTLE - OTTAWA QUALITY ASSESSMENT SCALE COHORT STUDIES

Note: A study can be awarded a maximum of one star for each numbered item within the Selection and Outcome categories. A maximum of two stars can be given for Comparability

Selection

- 1) Representativeness of the exposed cohort
 - a) truly representative of the average _____ (describe) in the community
 - b) somewhat representative of the average _____ in the community
 - c) selected group of users eg nurses, volunteers
 - d) no description of the derivation of the cohort
- 2) Selection of the non exposed cohort
 - a) drawn from the same community as the exposed cohort
 - b) drawn from a different source
 - c) no description of the derivation of the non exposed cohort
- 3) Ascertainment of exposure
 - a) secure record (eg surgical records)
 - b) structured interview
 - c) written self report
 - d) no description
- 4) Demonstration that outcome of interest was not present at start of study
 - a) yes
 - b) no

Comparability

- 1) Comparability of cohorts on the basis of the design or analysis
 - a) study controls for _____ (select the most important factor)
 - b) study controls for any additional factor (This criteria could be modified to indicate specific control for a second important factor.)

Outcome

- 1) Assessment of outcome
 - a) independent blind assessment
 - b) record linkage
 - c) self report
 - d) no description
- 2) Was follow-up long enough for outcomes to occur
 - a) yes (select an adequate follow up period for outcome of interest)
 - b) no
- 3) Adequacy of follow up of cohorts
 - a) complete follow up - all subjects accounted for
 - b) subjects lost to follow up unlikely to introduce bias - small number lost - > ____ % (select an adequate %) follow up, or description provided of those lost)
 - c) follow up rate < ____% (select an adequate %) and no description of those lost
 - d) no statement

Critical appraisal tools example

NEWCASTLE - OTTAWA QUALITY ASSESSMENT SCALE CASE CONTROL STUDIES

Note: A study can be awarded a maximum of one star for each numbered item within the Selection and Exposure categories. A maximum of two stars can be given for Comparability.

Selection

- 1) Is the case definition adequate?
 - a) yes, with independent validation
 - b) yes, eg record linkage or based on self reports
 - c) no description
- 2) Representativeness of the cases
 - a) consecutive or obviously representative series of cases
 - b) potential for selection biases or not stated
- 3) Selection of Controls
 - a) community controls
 - b) hospital controls
 - c) no description
- 4) Definition of Controls
 - a) no history of disease (endpoint)
 - b) no description of source

Comparability

- 1) Comparability of cases and controls on the basis of the design or analysis
 - a) study controls for _____ (Select the most important factor.)
 - b) study controls for any additional factor (This criteria could be modified to indicate specific control for a second important factor.)

Exposure

- 1) Ascertainment of exposure
 - a) secure record (eg surgical records)
 - b) structured interview where blind to case/control status
 - c) interview not blinded to case/control status
 - d) written self report or medical record only
 - e) no description
- 2) Same method of ascertainment for cases and controls
 - a) yes
 - b) no
- 3) Non-Response rate
 - a) same rate for both groups
 - b) non respondents described
 - c) rate different and no designation

Critical appraisal tools example

AMSTAR 2: a critical appraisal tool for systematic reviews that include randomised or non-randomised studies of healthcare interventions, or both

| | | |
|---|---|---|
| <p>1. Did the research questions and inclusion criteria for the review include the components of PICO?</p> | | |
| <p>For Yes:</p> <ul style="list-style-type: none"> <input type="checkbox"/> Population <input type="checkbox"/> Intervention <input type="checkbox"/> Comparator group <input type="checkbox"/> Outcome | <p>Optional (recommended)</p> <ul style="list-style-type: none"> <input type="checkbox"/> Timeframe for follow-up | <ul style="list-style-type: none"> <input type="checkbox"/> Yes <input type="checkbox"/> No |
| <p>2. Did the report of the review contain an explicit statement that the review methods were established prior to the conduct of the review and did the report justify any significant deviations from the protocol?</p> | | |
| <p>For Partial Yes: The authors state that they had a written protocol or guide that included ALL the following:</p> <ul style="list-style-type: none"> <input type="checkbox"/> review question(s) <input type="checkbox"/> a search strategy <input type="checkbox"/> inclusion/exclusion criteria <input type="checkbox"/> a risk of bias assessment | <p>For Yes: As for partial yes, plus the protocol should be registered and should also have specified:</p> <ul style="list-style-type: none"> <input type="checkbox"/> a meta-analysis/synthesis plan, if appropriate, <i>and</i> <input type="checkbox"/> a plan for investigating causes of heterogeneity <input type="checkbox"/> justification for any deviations from the protocol | <ul style="list-style-type: none"> <input type="checkbox"/> Yes <input type="checkbox"/> Partial Yes <input type="checkbox"/> No |
| <p>3. Did the review authors explain their selection of the study designs for inclusion in the review?</p> | | |
| <p>For Yes, the review should satisfy ONE of the following:</p> <ul style="list-style-type: none"> <input type="checkbox"/> <i>Explanation for</i> including only RCTs <input type="checkbox"/> OR <i>Explanation for</i> including only NRSI <input type="checkbox"/> OR <i>Explanation for</i> including both RCTs and NRSI | | |
| <p>4. Did the review authors use a comprehensive literature search strategy?</p> | | |
| <p>For Partial Yes (all the following):</p> <ul style="list-style-type: none"> <input type="checkbox"/> searched at least 2 databases (relevant to research question) <input type="checkbox"/> provided key word and/or search strategy <input type="checkbox"/> justified publication restrictions (e.g. language) | <p>For Yes, should also have (all the following):</p> <ul style="list-style-type: none"> <input type="checkbox"/> searched the reference lists / bibliographies of included studies <input type="checkbox"/> searched trial/study registries <input type="checkbox"/> included/consulted content experts in the field <input type="checkbox"/> where relevant, searched for grey literature <input type="checkbox"/> conducted search within 24 months of completion of the review | <ul style="list-style-type: none"> <input type="checkbox"/> Yes <input type="checkbox"/> Partial Yes <input type="checkbox"/> No |
| <p>5. Did the review authors perform study selection in duplicate?</p> | | |
| <p>For Yes, either ONE of the following:</p> <ul style="list-style-type: none"> <input type="checkbox"/> at least two reviewers independently agreed on selection of eligible studies and achieved consensus on which studies to include <input type="checkbox"/> OR two reviewers selected a sample of eligible studies <u>and</u> achieved good agreement (at least 80 percent), with the remainder selected by one reviewer. | | |

NICE National Institute for
Health and Care Excellence





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Enhancing the QUALity and Transparency Of health Research

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Search for reporting guidelines



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Reporting guidelines under development



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Reporting guidelines for main study types

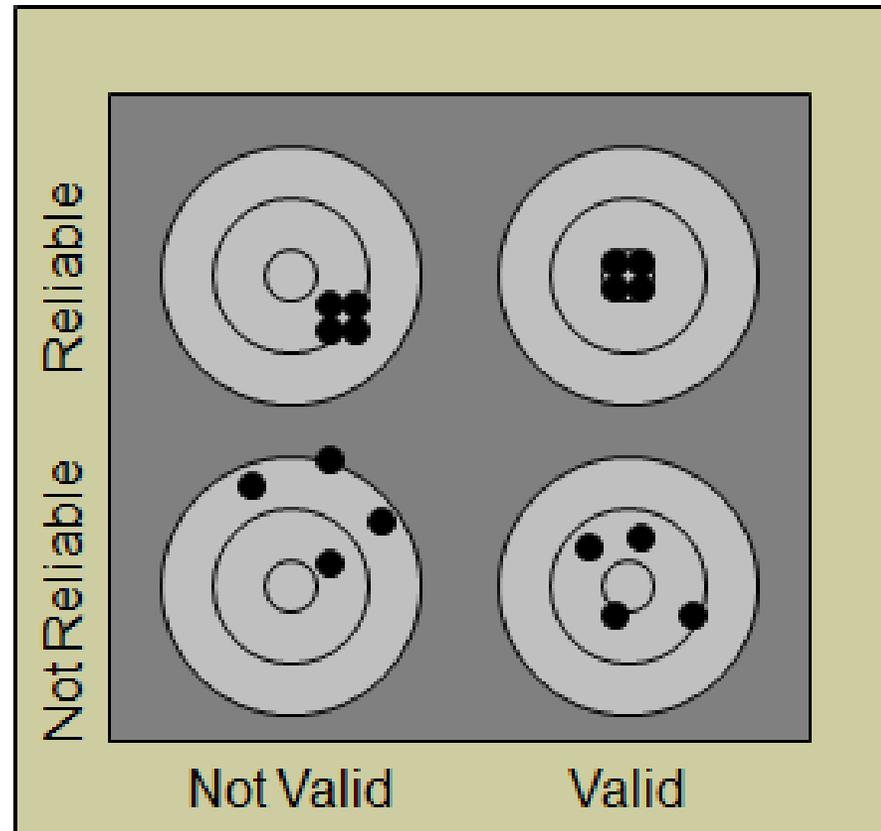
| | | | |
|---|-------------------------|----------------------------|-----------------------|
| Randomised trials | CONSORT | Extensions | Other |
| Observational studies | STROBE | Extensions | Other |
| Systematic reviews | PRISMA | Extensions | Other |
| Case reports | CARE | Extensions | Other |
| Qualitative research | SRQR | COREQ | Other |
| Diagnostic / prognostic studies | STARD | TRIPOD | Other |
| Quality improvement studies | SQUIRE | | Other |
| Economic evaluations | CHEERS | | Other |
| Animal pre-clinical studies | ARRIVE | | Other |
| Study protocols | SPIRIT | PRISMA-P | Other |
| Clinical practice guidelines | AGREE | RIGHT | Other |

Browse reporting guidelines by speciality

The specialities listed below are those for which there are speciality-specific reporting guidelines available. If your speciality is not listed please visit the [main reporting guidelines search page](#).

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Valid and reliable research



Picture Source: <http://businessoverbroadway.com/validity-cem-program>

Threats to validity

Channeling bias

Selection bias

Recruitment/Allocation

Attrition (drop out) bias

Detection bias

Performance bias

Implementation

Reporting bias

Confirmation bias

Publication bias

Analysis/Publication

Research Misconduct

Selection bias: the classic example

630

THE NEW ENGLAND JOURNAL OF MEDICINE

March 12, 1981

COFFEE AND CANCER OF THE PANCREAS

BRIAN MACMAHON, M.D., STELLA YEN, M.D., DIMITRIOS TRICHOPOULOS, M.D., KENNETH WARREN, M.D.,
AND GEORGE NARDI, M.D.

Abstract We questioned 369 patients with histologically proved cancer of the pancreas and 644 control patients about their use of tobacco, alcohol, tea, and coffee. There was a weak positive association between pancreatic cancer and cigarette smoking, but we found no association with use of cigars, pipe tobacco, alcoholic beverages, or tea. A strong association between coffee consumption and pancreatic cancer was evident in both sexes. The association was not affected by controlling for cigarette use. For the sexes combined, there was a significant dose-re-

sponse relation ($P \sim 0.001$); after adjustment for cigarette smoking, the relative risk associated with drinking up to two cups of coffee per day was 1.8 (95 per cent confidence limits, 1.0 to 3.0), and that with three or more cups per day was 2.7 (1.6 to 4.7). This association should be evaluated with other data; if it reflects a causal relation between coffee drinking and pancreatic cancer, coffee use might account for a substantial proportion of the cases of this disease in the United States. (N Engl J Med. 1981; 304:630-3.)

Selection bias: the classic example

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Abstract We questioned 369 patients with histologically proved cancer of the pancreas and 644 control patients about their use of tobacco, alcohol, tea, and coffee. There was a weak positive association between pancreatic cancer and cigarette smoking, but we found no association with use of cigars, pipe tobacco, alcoholic beverages, or tea. A strong association between coffee consumption and pancreatic cancer was evident in both sexes. The association was not affected by controlling for cigarette use. For the sexes combined, there was a significant dose-re-

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OVER the past few decades, cancer of the pancreas has emerged as one of the most important neoplasias in human beings. It now accounts for approximately 20,000 deaths annually in the United States. Causative factors have been sought in several previous studies, but only cigarette smoking has emerged as a consistent, though relatively weak, exogenous risk factor. We report the results of a study that was planned to reevaluate the relation of this disease to smoking and to examine the role of alcohol consumption as a possible confounding variable. Data were also obtained on intake of tea and coffee — factors that have not been adequately investigated in this disease.

METHODS

We conducted a case-control interview study. The cases were patients with histologic diagnoses of cancer of the exocrine pancreas who were in any of 11 large hospitals in the Boston metropolitan area and Rhode Island between October 1974 and August 1979. Patients with tumors of the islet cells, periampullary duodenal mucosa, or ampulla of Vater were not included. We identified 378 patients and interviewed 405 of them. Twenty patients died and 35 were discharged before an interview could be arranged; 78 were too sick to be interviewed, 14 had language difficulties, and 26 refused the interview. Also excluded from the analysis were eight nonwhite patients, four residents of countries other than the United States, eight patients older than 79 years, and 16 patients whose interview information was judged by the interviewer to be of questionable reliability. The analysis is based on data from the remaining 369 patients.

To assemble a control series, the interviewers also attempted to question all other patients who were under the care of the same physician in the same hospital at the time of an interview with a patient with pancreatic cancer. Either before the interview (if the information was known) or afterward, patients with diseases of the pancreas or hepatobiliary tract or diseases known to be associated with smoking or alcohol consumption were excluded. The principal diagnostic categories excluded (in addition to diseases of the biliary tract or pancreas) were cardiovascular disease, diabetes mellitus, respiratory or bladder cancer, and peptic ulcer. From a total of 1118 eligible patients, we interviewed 700, nine died and 131 were discharged before the interview, 179 were too ill, 26 had language problems, and 73 refused. After exclusion of 17 nonwhites, five foreign residents, four persons older than 79 years, and 30 persons

whose interviews were judged to be unreliable, the control series used for the analysis consisted of 644 patients. Minor differences between tables in the stated numbers of cases and controls result from absence of specific items being analyzed in a few questionnaires.

The control series was composed of two principal diagnostic groups: 273 patients with cancer other than cancers of the pancreas and biliary tract, respiratory tract, or bladder and 371 patients with other disorders. Of the control patients with cancer, the tumor was in the breast in 63 patients, colon in 60, rectum in 25, stomach in 24, small intestine in nine, urinary in eight, prostate in eight, and cervix in seven; there were also 16 with melanoma and 13 with lymphoma. No other cancer was found in more than four subjects. Diagnoses in the controls without cancer were of a wide variety, although because of the nature of the practices of many of the physicians who were responsible for patients with cancer of the pancreas, patients with gastroenterologic conditions were probably overrepresented in relation to a general hospital population. The principal diagnoses were hernia in 70 patients; colitis, enteritis, or diverticulitis in 41; bowel obstruction, adhesions, or fistula in 26; gastritis in 17; other gastroenterologic conditions in 47; benign tumors in 29; varicose veins or phlebitis in 21; genitourinary disorders in 20; neurologic disorders in 26; gynecologic disorders in 16; and other conditions in 22.

In the analysis, the patients with pancreatic cancer were compared with the control patients with cancer and independently with the control group without cancer. The findings were quite similar, and only the results with the combined control group are presented here.

Several questions in the interview probed the duration and intensity of smoking of cigarettes, cigars, and pipes. Questions on alcoholic beverages asked about the frequency of use before the onset of illness, the age span over which such use occurred, and the type of beverage used most frequently. The questions on tea and coffee were limited to the number of cups consumed in a typical day before the current illness was evident.

Tests of significance and estimates of adjusted relative risks and their confidence limits were derived with the method of Mantel and Haenszel and its extension.⁵ The data were stratified by age in 10-year groups and by sex where appropriate. All confidence limits are 95 per cent intervals. Most analyses were performed with the calculator programs developed by Rothman and Boice.⁶

RESULTS

Tobacco

There was no difference between cases and controls in the use of cigars or pipe tobacco. Among men, the

To assemble a control series, the interviewers also attempted to question all other patients who were under the care of the same physician in the same hospital at the time of an interview with a patient with pancreatic cancer.

Randomisation

Concealment

Selection bias

Blinding

Detection bias

Performance bias



Time

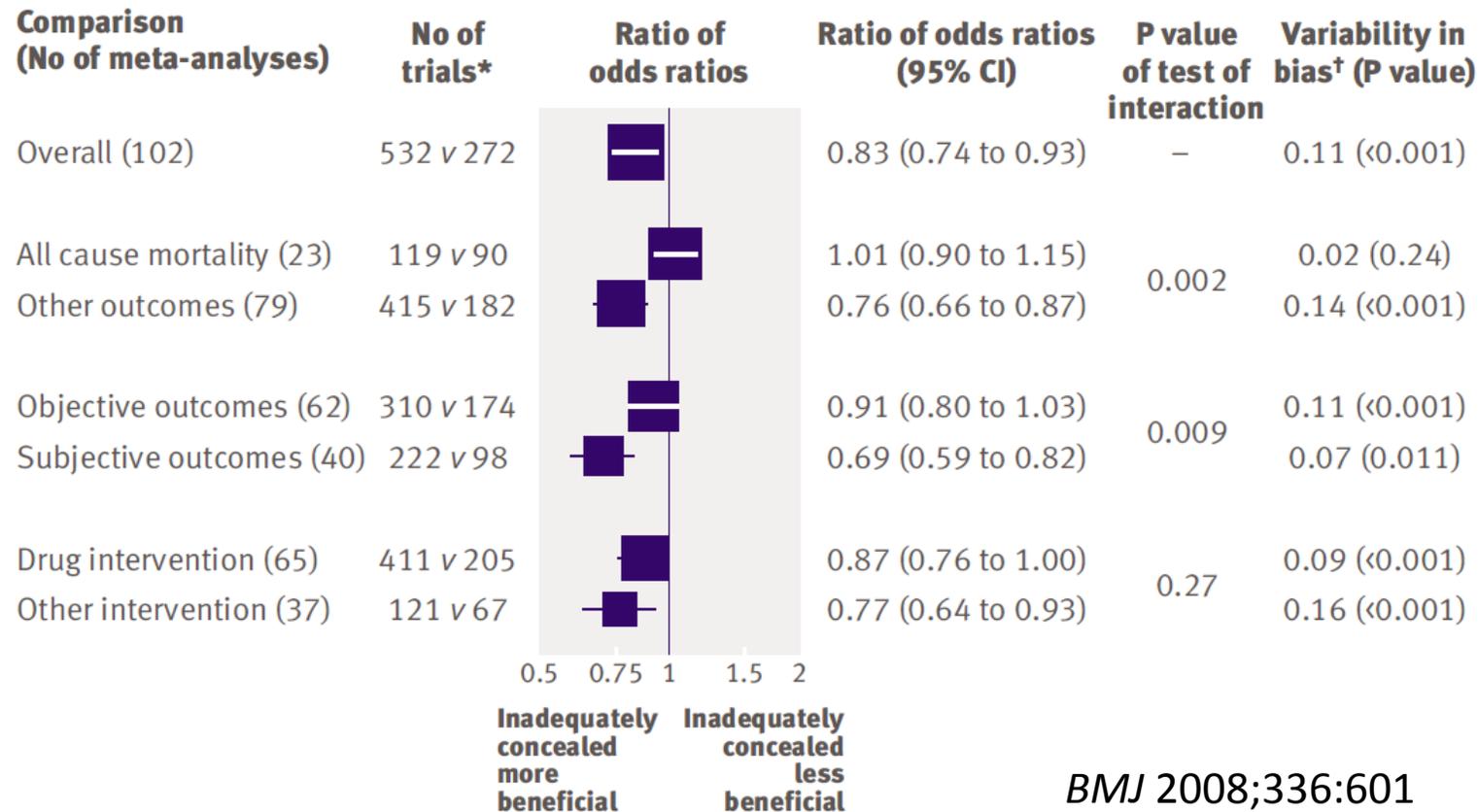
The patient's condition fits the trial, and she has consented. Which treatment pack should I give her?



Yes doctor, your patient is eligible. She will be allocated to treatment pack X32. After the trial we will tell you what treatment X32 was.

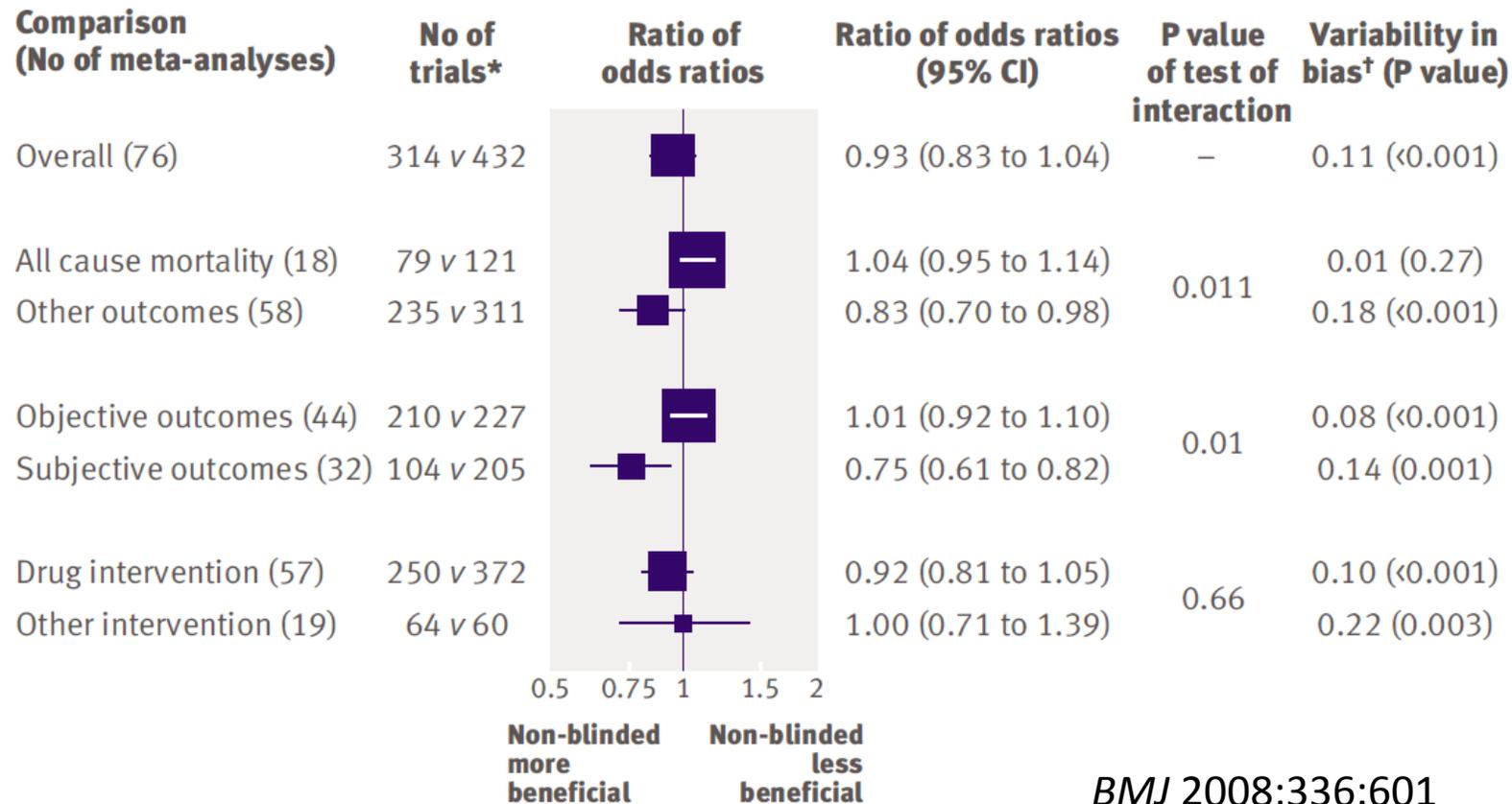


The inadequate or unclear allocation concealment and biased estimates of intervention effects



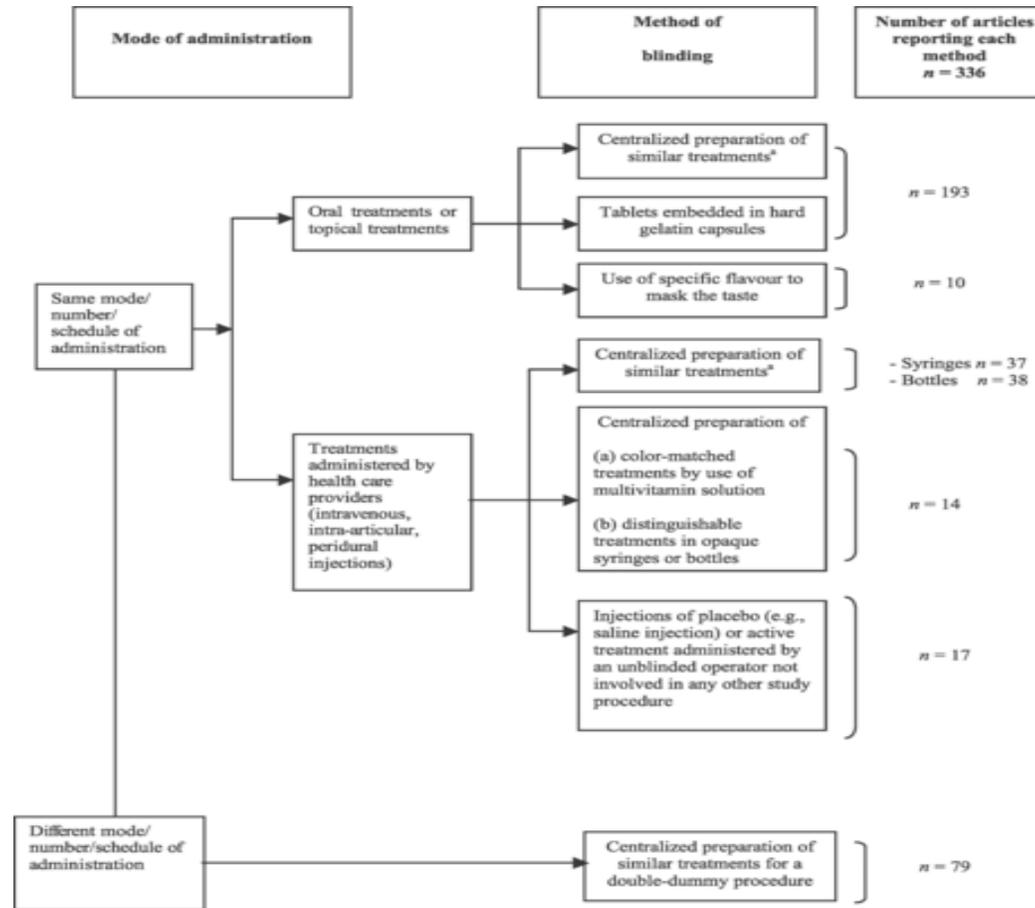
BMJ 2008;336:601

The lack of blinding and biased intervention effects



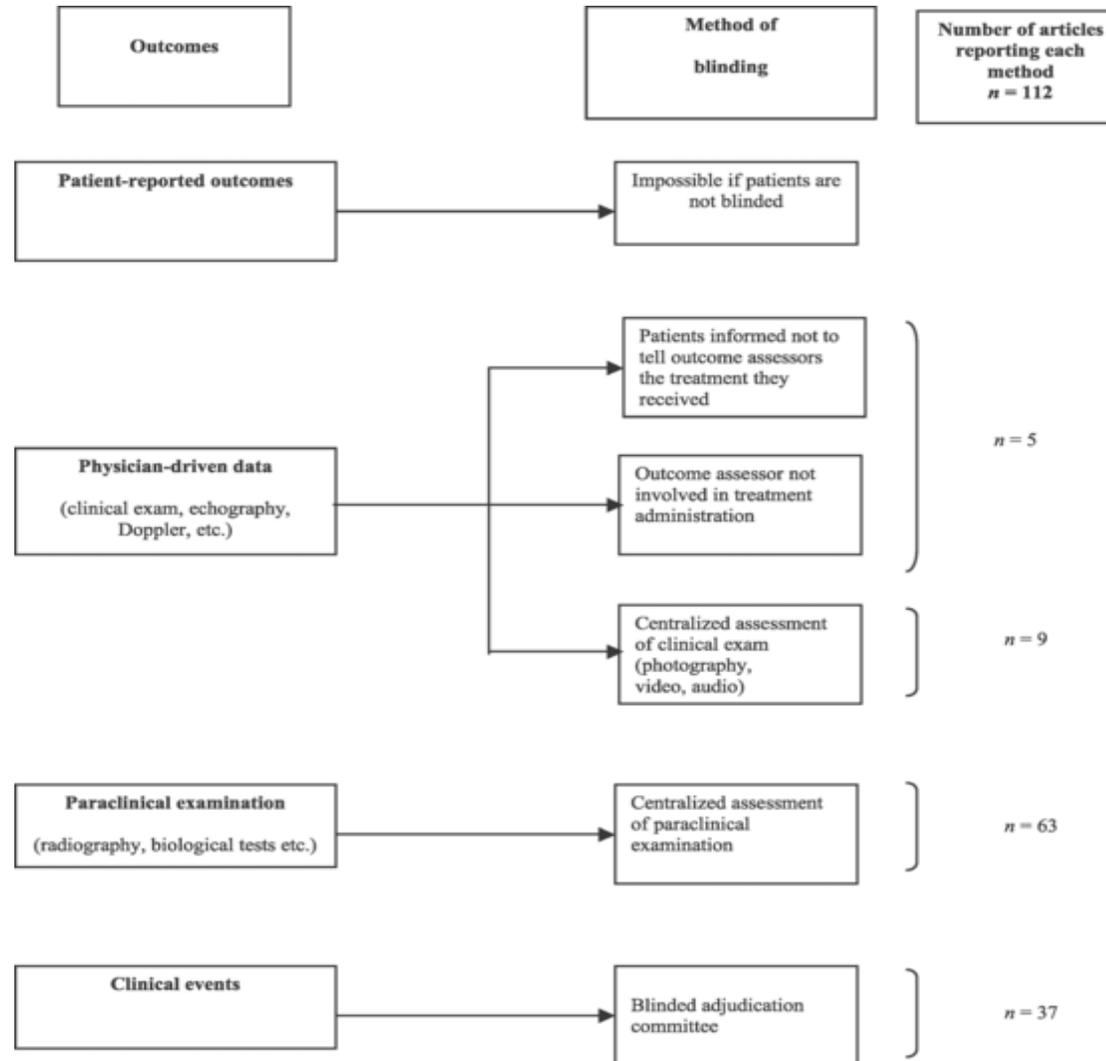
BMJ 2008;336:601

Methods to Establish Blinding in RCTs



*Similar treatments, i.e., same appearance, same package, same label, same instructions

Methods of Blinded Outcome Assessment

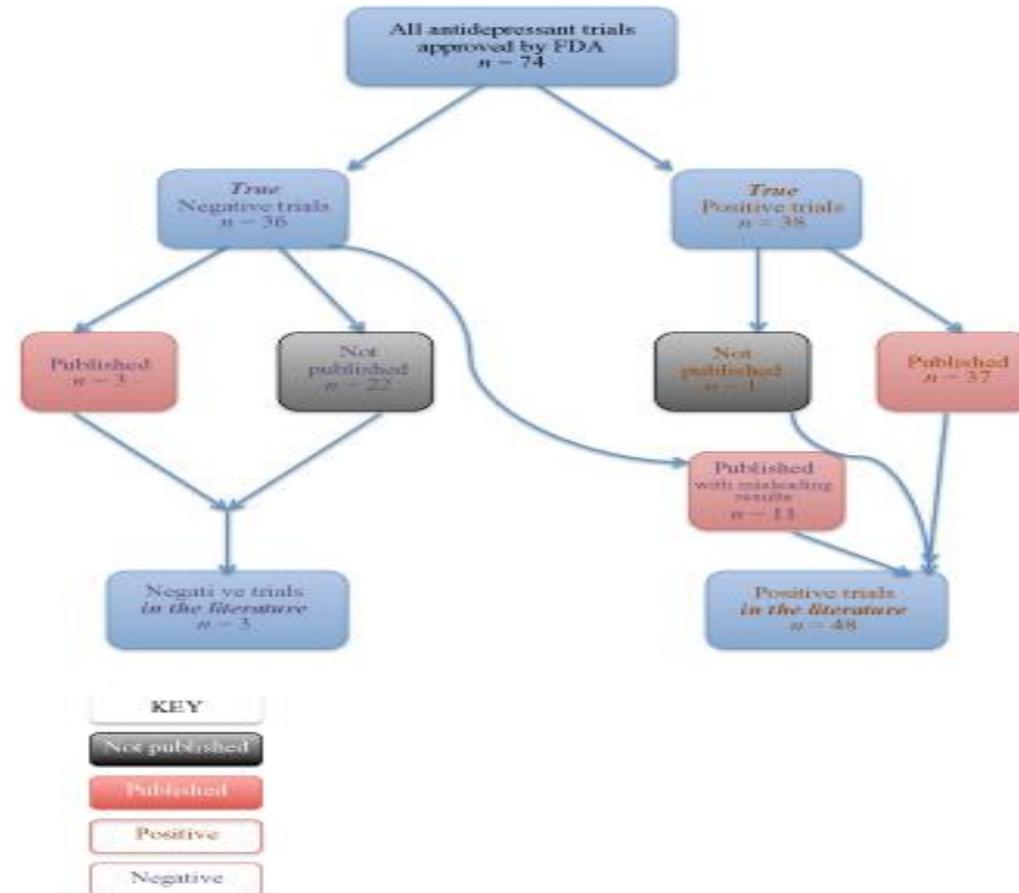


Reporting bias

BMJ Open Feasibility study to examine discrepancy rates in prespecified and reported outcomes in articles submitted to *The BMJ*

Results: In the study period, *The BMJ* received 311 trial manuscripts, 21 of which were subsequently published by the journal. In trials published by *The BMJ*, 27% (89/333) of the prespecified outcomes in the protocol were not reported in the submitted paper and 11% (31/275) of reported outcomes were not prespecified. In the sample

Publication Bias



Publication bias and Selective outcome reporting

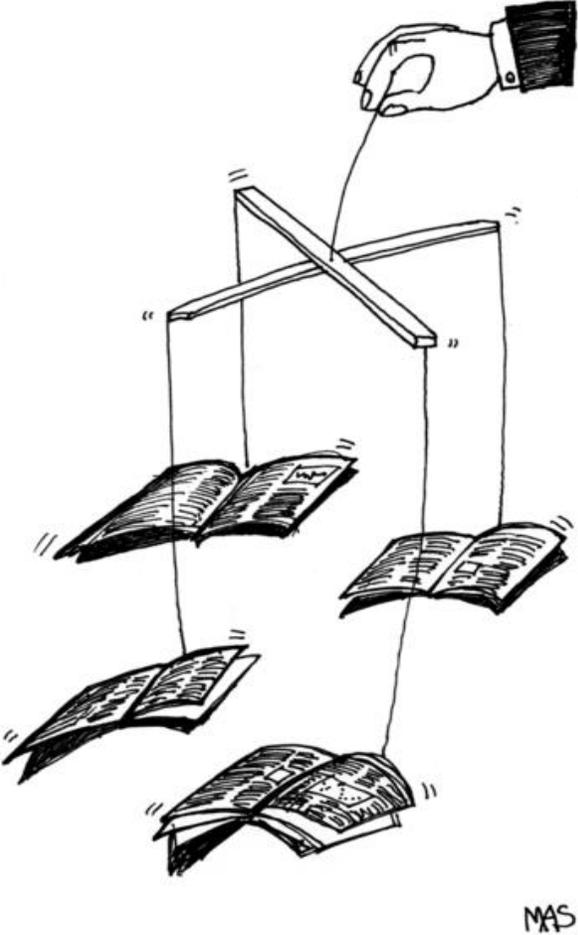
Systematic Review of the Empirical Evidence of Study Publication Bias and Outcome Reporting Bias — An Updated Review

Kerry Dwan*, Carrol Gamble, Paula R. Williamson, Jamie J. Kirkham, for the Reporting Bias Group[†]

Department of Biostatistics, University of Liverpool, Liverpool, England

Methodology/Principal Findings: In this update, we review and summarise the evidence from cohort studies that have assessed study publication bias or outcome reporting bias in randomised controlled trials. Twenty studies were eligible of which four were newly identified in this update. Only two followed the cohort all the way through from protocol approval to information regarding publication of outcomes. Fifteen of the studies investigated study publication bias and five investigated outcome reporting bias. Three studies have found that statistically significant outcomes had a higher odds of being fully reported compared to non-significant outcomes (range of odds ratios: 2.2 to 4.7). In comparing trial publications to protocols, we found that 40–62% of studies had at least one primary outcome that was changed, introduced, or omitted. We decided not to undertake meta-analysis due to the differences between studies.

Medical Journals Are an
Extension of the Marketing Arm
of Pharmaceutical Companies.





The scandal of poor medical research

We need less research, better research, and research done for the right reasons

What, then, should we think about researchers who use the wrong techniques (either wilfully or in ignorance), use the right techniques wrongly, misinterpret their results, report their results selectively, cite the literature selectively, and draw unjustified conclusions? We should be appalled. Yet numerous studies of the medical literature, in both general and specialist journals, have shown that all of the above phenomena are common.¹⁻⁷ This is surely a scandal.

Publication Bias and selective reporting: the Tamiflu Experience



Source: Tamiflu capsules. Photograph: Per Lindgren/REX via The Guardian

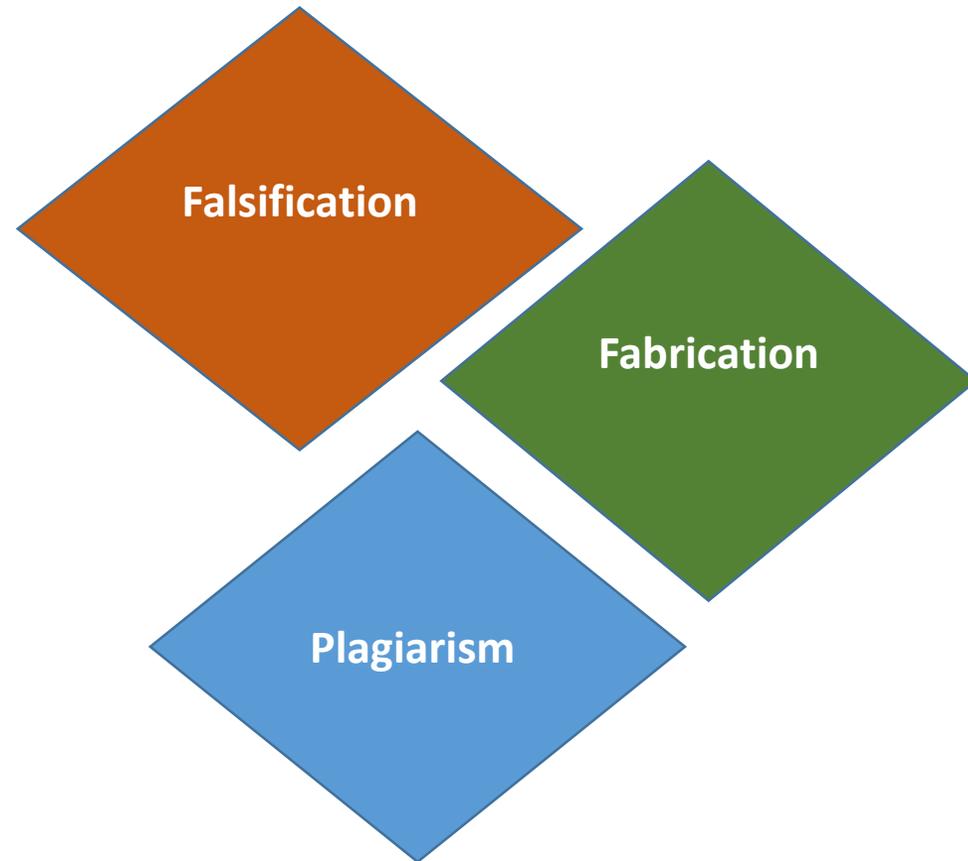


Tom Jefferson

An estimated \$200 billion —85% of global spending on research — is routinely wasted on poorly designed and redundant studies.



Research Misconduct



Research Misconduct



Andrew Wakefield

Early report

Real lymphoid nodular hyperplasia, non-specific colitis, and pervasive developmental disorder in children

J Wakefield, S M Murch, A Anthony, A Linn, S M Duncan, W Smith, W Brown, A P Dhillon, M A Thomson, P Harvey, B Wallis, J J Davis, J A Walker-Smith

Summary

Background We investigated a retrospective series of children with chronic enterocolitis and regressive developmental disorder.

Methods 10 children (mean age 8 years (range 3-15)), 11 boys, were referred to a paediatric gastroenterology unit with a history of normal development followed by loss of acquired skills, including language, together with diarrhea and abdominal pain. Children underwent extensive gastroenterological, neurological, and developmental assessment and tests of developmental status. Measurements were being completed regarding regression (age), autismlike behaviour (ADOS), and limbic-predominant irritative enterocolitis syndrome. Rectal biopsies were done where possible. Immunohistochemical, histological, and microbiological studies were undertaken.

Findings Onset of behavioural symptoms was associated with the parents' acute concerns, usually, and not necessarily, in spite of the 10 children, with some children in one child, and others in two. In the 10 children, the regression was associated with a history of normal development followed by loss of acquired skills, including language, together with diarrhea and abdominal pain. Children underwent extensive gastroenterological, neurological, and developmental assessment and tests of developmental status. Measurements were being completed regarding regression (age), autismlike behaviour (ADOS), and limbic-predominant irritative enterocolitis syndrome. Rectal biopsies were done where possible. Immunohistochemical, histological, and microbiological studies were undertaken.

Conclusions The findings of this study suggest that the children with chronic enterocolitis and regressive developmental disorder have a distinct clinical picture, which is not necessarily associated with the features of regressive autism. The findings also suggest that the children with chronic enterocolitis and regressive developmental disorder have a distinct clinical picture, which is not necessarily associated with the features of regressive autism.

RETRACTED

HOW THE CASE AGAINST THE MMR VACCINE WAS FIXED

In the first part of a special *BMJ* series, **Brian Deer** exposes the bogus data behind claims that launched a worldwide scare over the measles, mumps, and rubella vaccine, and reveals how the appearance of a link with autism was manufactured at a London medical school

When I broke the news to the father of child 11, at first he did not believe me. "Wakefield told us my son was the 11th child they are," he said, going for the first time at the now infamous research paper which linked a supposed new syndrome with the measles, mumps, and rubella (MMR) vaccine. "There's only 12 in this."

The paper was published in the *Lancet* on 28 February 1998. It was retracted on 2 February 2010. Authored by Andrew Wakefield, John Walker-Smith and 11 others from the Royal Free Hospital and School of Medicine, London, it reported on 12 developmentally challenged children, and triggered a decade long public health scare.

"Onset of behavioural symptoms was associated by the parents with measles, mumps, and rubella vaccination in eight of the 12 children," began the paper's "findings." Adopting these claims as fact, its results section added: "In these eight children the average interval from exposure to first behavioural symptoms was 6.3 days (range 1-14)."

Mr 11, an American engineer, looked again at the paper: a five page case series of 11 boys and one girl, aged between 1 and 9 years. Nine children, it said, had diagnoses of "regressive" autism, while all but one were reported with "non-specific colitis." The "new syndrome" brought these together.

Linking brain and bowel diseases, Child 11 was the penultimate case.

Flipping his finger across the paper's tables, over coffee in London, Mr 11 seemed reassured by his assumption of his age and other details. But then he pointed at table 2—headed "seropositive psychiatric diagnoses"—and for a second time objected. "That's not true."

Child 11 was among the eight whose parents apparently blamed MMR. The interval between his vaccination and the first "behavioural symptoms" was reported as 1 week. This symptom was said to have appeared at age 15 months. But his father, whom I had tracked down, said this was wrong.

"From the information you provided me on our son, who I was shocked to hear had been included in their published study," he wrote to me, after we met again in California, "the data clearly appeared to be distorted."

He backed his concerns with medical records, including a Royal Free discharge summary. Although the family lived 5000 miles from the hospital, in February 1997 the boy (then aged 5) had been flown to London and admitted to Wakefield's project, the undisclosed goal of which was to help sue the vaccine's manufacturers.

Wakefield's "syndrome" Unknown to Mr 11, Wakefield was working on a lawsuit, for which he sought a bowel-brain "syndrome" as its centrepiece. Claiming an undisclosed £150 (£180, \$230) an hour through a Norfolk solicitor named Richard Barr, he had been confidentially put on the payroll for two years before the paper was published, eventually grossing him £155,641, plus expenses.

Curiously, however, Wakefield had already identified such a syndrome before the project that would reportedly discover it.

"Children with enterointegrative disorder (an expression he used for bowel inflammation and regressive autism) form part of a new syndrome," he and Barr explained in a confidential grant application to the UK government's Legal Aid Board, "before any of the children were investigated." "Nonetheless the evidence is undeniably in favour of a specific vaccine induced pathology."

The two men also aimed to show a sudden onset "temporal association"—strong evidence to product liability. "We Wakefield feels that if we can show a clear time link between the vaccination and onset of symptoms," Barr told the legal board, "we should be able to dispose of the suggestion that it's simply a chance encounter."

But child 11's case must have proved a disappointment. Records show his behavioural symptoms started too soon. "His developmental milestones were normal until 13 months of age," notes the discharge summary. "In the period 13-18 months he developed slow speech patterns and repetitive hand movements. Over this period his parents remarked on his slow gradual deterioration."

That put the first symptoms two months earlier than reported in the *Lancet*, and a



Research Misconduct



The Results of Investigation into Dr. Yoshitaka Fujii's papers

Toho University Faculty of Medicine announced on March 8, 2012 that 8 manuscripts of Dr. Yoshitaka Fujii had been retracted because of execution of these clinical studies without proper ethical approval. In addition, an article [Appendix 1] entitled "The analysis of 169 randomised controlled trials to test data integrity." was published on-line as a Special Article in Anaesthesia, the Journal of the Association of Anaesthetists of Great Britain and Ireland, on March 8, 2012. Three Editorials

B : Fabricated

Papers which have any discrepancy in numbers of subjects, medication, capability of the method :

171 papers (included 125 papers in RCT, double-blind manner) [Appendix 5]

154 papers out of 193 papers [Appendix 3]

C : Others

Papers with no evidence to prove them fabricated or not fabricated :

38 papers

(No. 1, 2, 3, 4, 5, 6, 7, 8, 13, 15, 17, 18, 23, 24, 25, 26, 32, 33, 34, 44, 45, 46, 68, 70, 71, 75, 92, 93, 94, 96, 97, 113, 122, 123, 139, 141, 152 [Appendix 5])

Research Misconduct



Joachim Boldt



BMJ

BMJ 2013;346:f1738 doi: 10.1136/bmj.f1738 (Published 19 March 2013)

Boldt: the great pretender

The withdrawal of almost 90 fraudulent studies by a German anaesthetist is one of the biggest medical research scandals of recent time. **Jacqui Wise** examines what happened and what lessons have been learnt

Jacqui Wise *freelance journalist*

Editors-in-Chief Statement Regarding IRB Approval of Clinical Trials by Joachim Boldt

February 4, 2011

To our readers:

Landesärztekammer Rheinland-Pfalz ("LÄK-RLP"), the State Medical Association of Rheinland-Pfalz, Germany, today announced the first results of a review of the papers published by Prof Joachim Boldt. The ethics committee of LÄK-RLP serves as the Institutional Review Board (IRB) for clinical research at Klinikum Ludwigshafen, where Professor Boldt's recent research was conducted.

Based on today's announcement, LÄK-RLP has reviewed 74 scientific articles describing clinical trials subject to the requirements of the German Medicinal Act. This includes the article by Professor Boldt recently retracted by *Anaesthesia & Analgesia* and an article submitted by Professor Boldt to *Anaesthesia* but not published. By law these studies required IRB approval. Although

On behalf of our respective journals,

LÄK-
jurisdi
confor
descri
article
not be
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Editor-in-Chief, *Acta Anaesthesiologica Scandinavica*

Steve M. Yentis
Editor-in-Chief, *Anaesthesia*
Argen Schöttler
Editor-in-Chief, *Anästhesiologie und Intensivmedizin*

We, th
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clini
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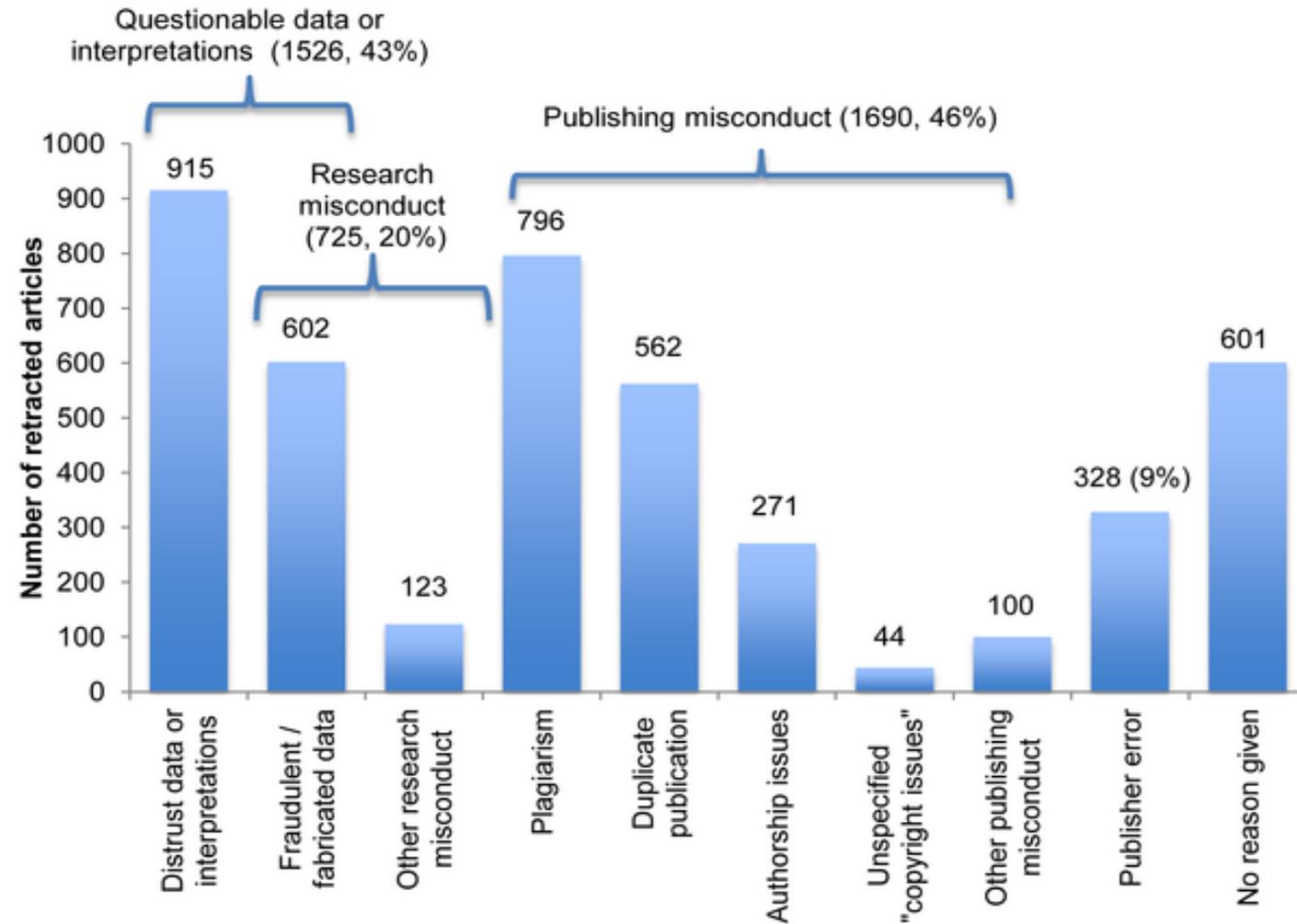


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Justifications for retraction stated in the notices consulted, which accounted for 4,232 retracted articles.



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Grigori Perelman

**A COMPLETE PROOF OF THE POINCARÉ AND
GEOMETRIZATION CONJECTURES – APPLICATION OF THE
HAMILTON-PERELMAN THEORY OF THE RICCI FLOW***

HUAI-DONG CAO[†] AND XI-PING ZHU[‡]

**ERRATUM TO “A COMPLETE PROOF OF THE POINCARÉ AND
GEOMETRIZATION CONJECTURES – APPLICATION OF THE
HAMILTON-PERELMAN THEORY OF THE RICCI FLOW”, ASIAN
J. MATH., VOL. 10, NO. 2, 165–492, 2006***

HUAL-DONG CAO[†] AND XI-PING ZHU[‡]

We would like to thank Bruce Kleiner and John Lott for bringing to our attention the fact that the argument concerning Claim 2 in the proof of Perelman’s singularity structure theorem (i.e., the Step 2 in the proof of Theorem 7.1.1 in our paper, p. 400–402) essentially appeared in the initial version of their notes on Perelman’s first paper posted on the website

<http://www.math.lsa.umich.edu/research/ricciflow/perelman.html>

Hamilton-Perelman's Proof of the Poincaré Conjecture and the Geometrization Conjecture*

Huai-Dong Cao and Xi-Ping Zhu

ABSTRACT. In this paper, we provide an essentially self-contained and detailed account of the fundamental works of Hamilton and the recent breakthrough of Perelman on the Ricci flow and their application to the geometrization of three-manifolds. In particular, we give a detailed exposition of a complete proof of the Poincaré conjecture due to Hamilton and Perelman.

*This is a revised version of the article by the same authors that originally appeared in *Asian J. Math.*, **10(2)** (2006), 165–492.

Self-regulation?



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MEDICINE AND SOCIETY

The Case of Dr. Oz: Ethics, Evidence, and Does Professional Self-Regulation Work?

Jon C. Tilburt, MD, MPH, Megan Allyse, PhD, and Frederic W. Hafferty, PhD

Editor's Note: This article was published on February 1, 2017, and updated on February 13, 2017.

Abstract

Dr. Mehmet Oz is widely known not just as a successful media personality donning the title "America's Doctor," but, we suggest, also as a physician visibly out of step with his profession. A recent, unsuccessful attempt to censure Dr. Oz raises the issue of whether the medical profession can effectively self-regulate at all. It also raises concern that the medical profession's self-regulation might be selectively activated, perhaps only when the subject of professional censure has achieved a level of public visibility. We argue here that the medical profession must look at itself with a healthy dose of self-doubt about whether it has sufficient knowledge of or handle on the less visible Dr. "Ozes" quietly operating under the profession's presumptive endorsement.

Introduction

Dr. Mehmet Oz's surgical credentials including expertise in minimally invasive, heart transplant, and heart valve surgery are impeccable [1]. But when Dr. Oz walks onto the stage of *The Dr. Oz Show*, he's not just a well-trained heart surgeon, he becomes

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