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# TRAINING PEER REVIEWERS: EVIDENCE-BASED CORE COMPETENCIES

## PEERE CONFERENCE

PRESENTED BY **DAVID MOHER**
SENIOR SCIENTIST

9TH MARCH, 2016; VALENCIA

The Ottawa Hospital RESEARCH INSTITUTE | L'Hôpital d'Ottawa INSTITUT DE RECHERCHE

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## MY DISCLOSURES

- My knowledge is in biomedicine
- Founding editor-in-chief, *Systematic Reviews*
- On the editorial board of several biomedical journals
- Advisory member International Congress on Peer Review and Biomedical Publication
- PLoS ONE's Human Research Advisory Committee
- University of Ottawa Medical Journal Faculty Advisory Board member
- Developing core competencies for editors of biomedical journal
- Trying to develop core competencies for peer reviewers

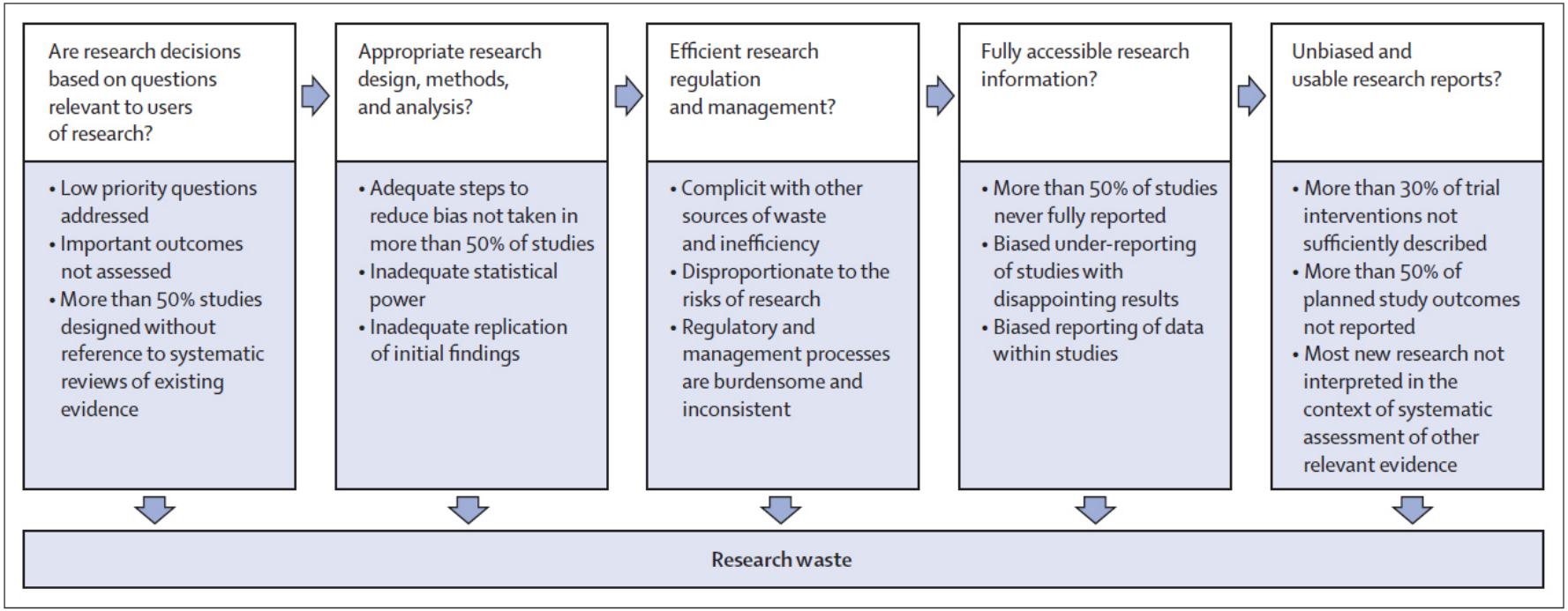
## OUTLINE OF TALK

- Some context of the size of the biomedical literature
- Quality of reporting of biomedical literature
- A program in developing core competencies for editors of biomedical journals
- A framework for developing core competencies for peer reviewers

# CONTEXT

- Massive publications-industrial complex
- About 6,000 publishers
- About 30,000 journals
- Produces about 3 millions manuscripts, annually, of which 50% are published

# THE RESEARCH CONTINUUM



## AUTHORS CANNOT ADEQUATELY DESCRIBE BASIC ESSENTIAL INFORMATION FOR READERS

- 10 essential elements about intervention
  - e.g., drug name, dose, route....
- examined 262 reports of randomized trials from most prominent oncology journals
- overall, only 11% of articles reported all 10 essential items

Duff JM et al. JNCI 2010 102:702-705

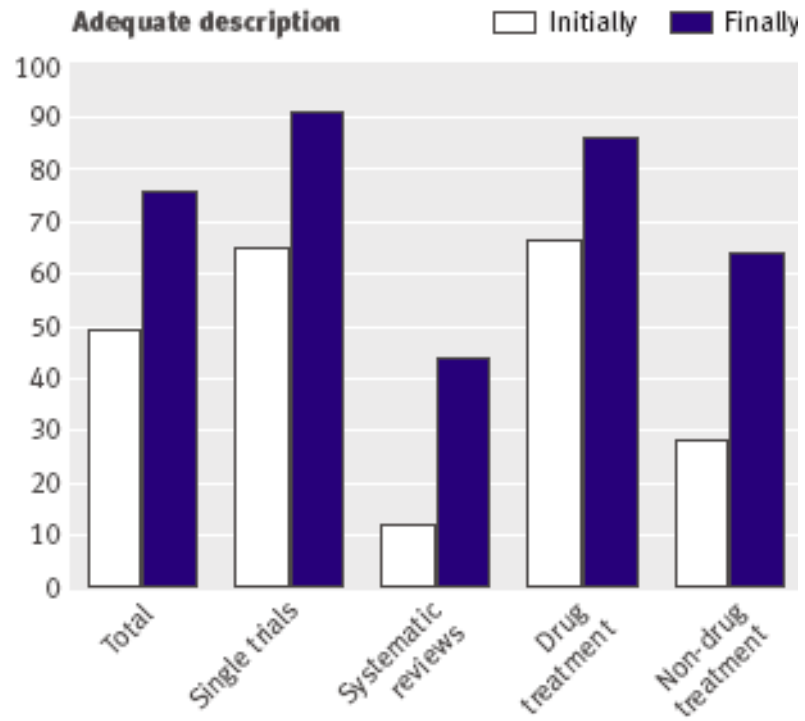
## DELIVERING THE BEST CARE TO PATIENTS

- "Thoughtful consideration of reporting trial-related procedures that could assist with turning "best evidence" to "best Practice" would be worthwhile"
- "Careful and consistent reporting would help to promote safe and effective clinical application of oncology therapeutics ..."

Dancey JNCI 2010; 102:670-671

## REPORTING OF INTERVENTIONS

- 80 consecutive studies
  - Subsequently published in Evidence Based Medicine (Oct 2005 for 12 months
  - 55 RCTs; 25 SRs
- intervention information missing from 41/80
- retrieved through additional methods




g 2 | Percentage of studies with sufficient escription of treatment initially (based only on e published paper) and after supplementary formation was obtained

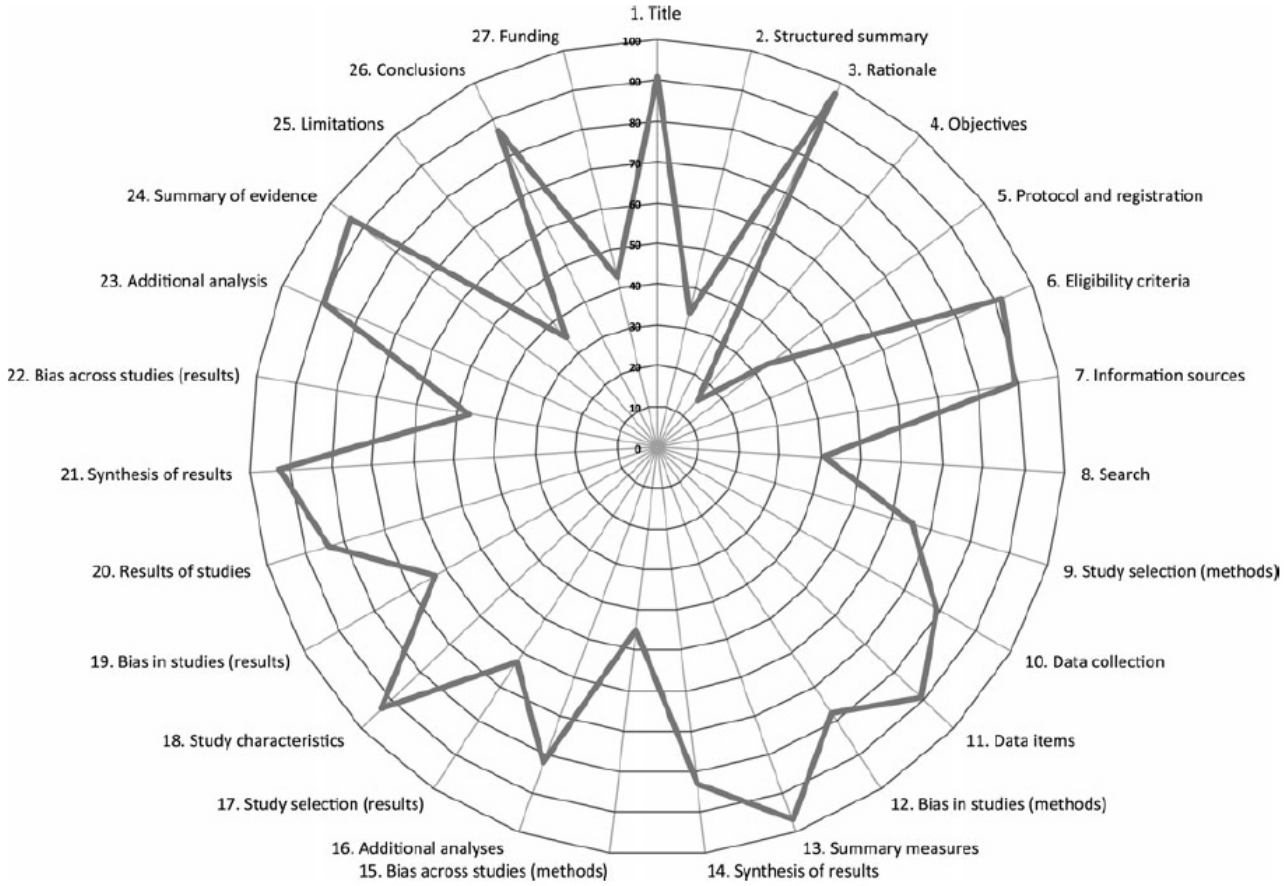



**FIGURE 2**. Star chart depicting proportions of adequately reported PRISMA items. A higher proportion meant that item was better reported.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F1000Research F1000Research 2014, 3:77 Last updated: 05 JAN 2015

SHORT RESEARCH ARTICLE

# Prevalence of primary outcome changes in clinical trials registered on ClinicalTrials.gov: a cross-sectional study [v1; ref status: indexed, http://f1000r.es/34l]

Sreeram Ramagopalan[1], Andrew P. Skingsley[2], Lahiru Handunnetthi[1], Michelle Klingel[2], Daniel Magnus[2], Julia Pakpoor[1], Ben Goldacre[2]

[1]Medical Research Council Functional Genomics Unit and Department of Physiology, Anatomy and Genetics, University of Oxford, Oxford, OX1 3PT, UK
[2]London School of Hygiene and Tropical Medicine, London, WC1E 7HT, UK

v1 **First published:** 26 Mar 2014, **3**:77 (doi: 10.12688/f1000research.3784.1)
**Latest published:** 26 Mar 2014, **3**:77 (doi: 10.12688/f1000research.3784.1)

Open Peer Review

Our analysis showed that 28229 of 89204 (31.7%) registered studies had their primary outcome changed

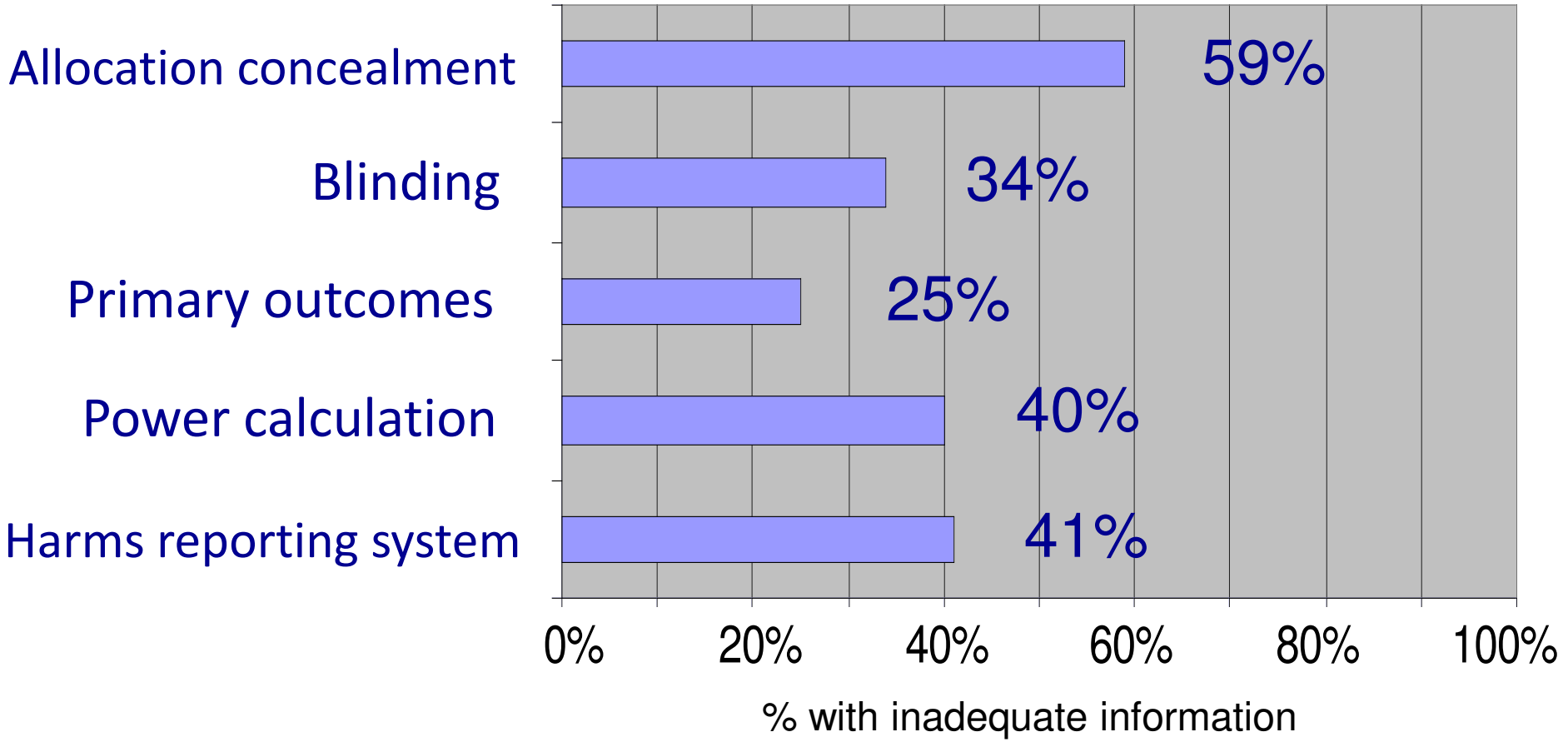
# http://compare-trials.org/

| 67 | 9 | 301 | 357 |
|---|---|---|---|
| TRIALS CHECKED TO DATE | TRIALS WERE PERFECT | OUTCOMES NOT REPORTED | NEW OUTCOMES SILENTLY ADDED |

On average, each trial reported just 62.0% of its specified outcomes. And on average, each trial silently added 5.3 new outcomes.

| 58 | 6 | 31 | 16 |
|---|---|---|---|
| LETTERS SENT | LETTERS PUBLISHED | LETTERS UNPUBLISHED AFTER 4 WEEKS | LETTERS REJECTED BY EDITOR |

# Protocols lack important information




Mhaskar R et al, J Clin Epid 2012; Chan AW et al, BMJ 2008, JAMA 2004; Scharf O, J Clin Oncol 2006; Pildal J, BMJ 2005; Hróbjartsson A et al, J Clin Epid 2009

# Replication

## NIH plans to enhance reproducibility

**Francis S. Collins** and **Lawrence A. Tabak** discuss initiatives that the US National Institutes of Health is exploring to restore the self-correcting nature of preclinical research.

A growing chorus of concern, from scientists and laypeople, contends that the complex system for ensuring the reproducibility of biomedical research is failing and is in need of restructuring[1,2]. As leaders of the US National Institutes of Health (NIH), we share this concern and here explore some of the significant interventions that we are planning.

Science has long been regarded as 'self-correcting', given that it is founded on the replication of earlier work. Over the long term, that principle remains true. In the shorter term, however, the checks and balances that once ensured scientific fidelity have been hobbled. This has compromised the ability of today's researchers to reproduce others' findings.

Let's be clear: with rare exceptions, we have no evidence to suggest that irreproducibility is caused by scientific misconduct. In 2011, the Office of Research Integrity of the US Department of Health and Human Services pursued only 12 such cases[3]. Even if this represents only a fraction of the actual problem, fraudulent papers are vastly ing agencies to establish or enforce policies that insist on data access.

### PRECLINICAL PROBLEMS

Reproducibility is potentially a problem in all scientific disciplines. However, human clinical trials seem to be less at risk because they are already governed by various regulations that stipulate rigorous design and independent oversight — including randomization, blinding, power estimates, pre-registration of outcome measures in standardized, public databases such as ClinicalTrials.gov and oversight by institutional review boards and data safety monitoring boards. Furthermore, the clinical trials community has taken important steps towards adopting standard reporting elements[7].

Preclinical research, especially work that uses animal models[1], seems to be the area that is currently most susceptible to reproducibility issues. Many of these failures have simple and practical explanations: different animal strains, different lab environments or subtle changes in protocol. Some irreproducible reports are probably the result of coincidental findings that happen to reach statistical significance, coupled with publication bias.

# INCOMPLETE REPORTING

## MACLEOD ET AL., 2015

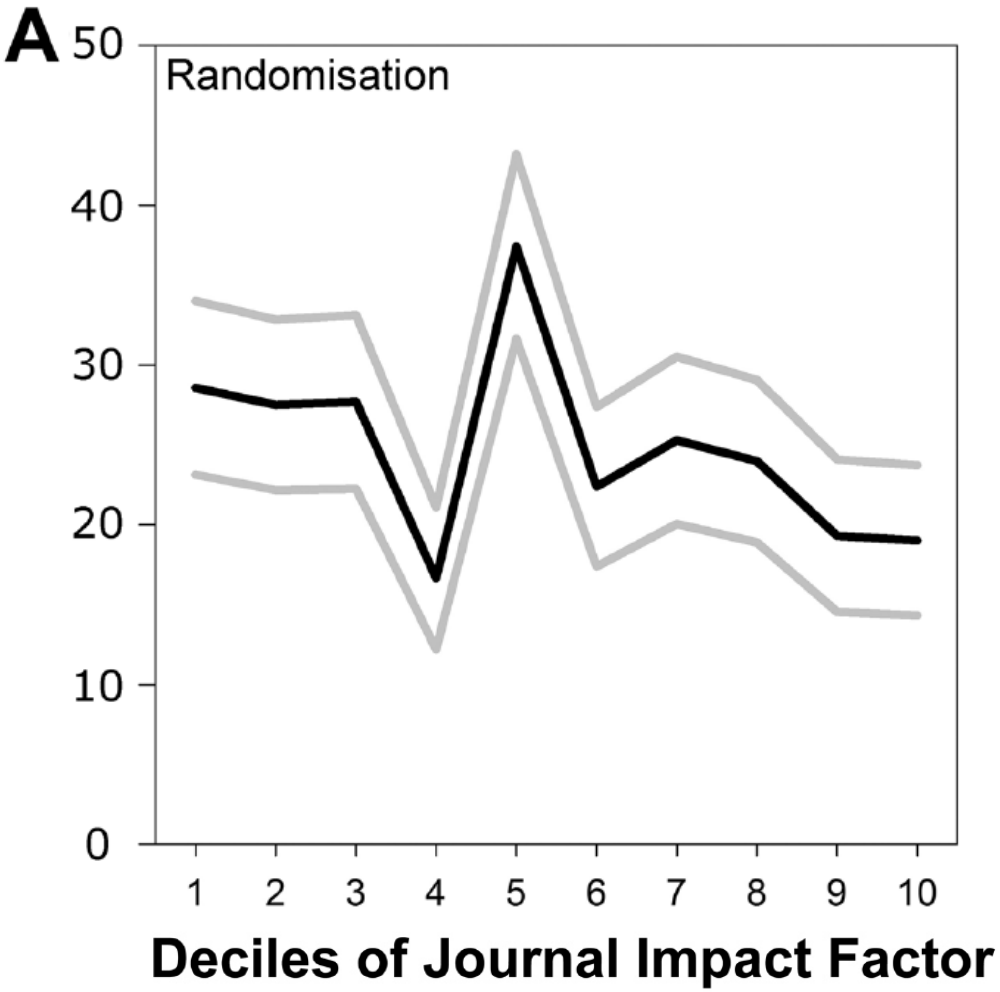



**Fig 4. Prevalence of reporting of (A) randomisation, (B) blinded assessment of outcome, (C) sample size calculations, and (D) conflict of interest reporting by decile of journal impact factor in 2,671 publications describing the efficacy of interventions in animal models of eight different diseases identified in the context of systematic reviews.** Black lines indicate the median value in that decile, and grey lines indicate the 95% confidence limits derived from nonparametric median regression (S4 Data).

ALL HAVE PASSED PEER REVIEW AND EDITORIAL APPROVAL

# EXPENDITURES ON BIOMEDICAL RESEARCH

Clinical Review & Education

Special Communication | SCIENTIFIC DISCOVERY AND THE FUTURE OF MEDICINE

## The Anatomy of Medical Research
## US and International Comparisons

Hamilton Moses III, MD; David H. M. Matheson, JD, MBA; Sarah Cairns-Smith, PhD; Benjamin P. George, MD, MPH; Chase Pallsch, MPhil; E. Ray Dorsey, MD, MBA

**IMPORTANCE** Medical research is a prerequisite of clinical advances, while health service research supports improved delivery, access, and cost. Few previous analyses have compared the United States with other developed countries.

**OBJECTIVES** To quantify total public and private investment and personnel (economic inputs) and to evaluate resulting patents, publications, drug and device approvals, and value created (economic outputs).

**EVIDENCE REVIEW** Publicly available data from 1994 to 2012 were compiled showing trends in US and international research funding, productivity, and disease burden by source and industry type. Patents and publications (1981-2011) were evaluated using citation rates and impact factors.

**FINDINGS** (1) Reduced science investment: Total US funding increased 6% per year (1994-2004), but rate of growth declined to 0.8% per year (2004-2012), reaching $117 billion (4.5%) of total health care expenditures. Private sources increased from 46% (1994) to 58% (2012). Industry reduced early-stage research, favoring medical devices, bioengineered drugs, and late-stage clinical trials, particularly for cancer and rare diseases. National Insitutes of Health allocations correlate imperfectly with disease burden, with cancer and HIV/AIDS receiving disproportionate support. (2) Underfunding of service innovation: Health services research receives $5.0 billion (0.3% of total health care expenditures) or only 1/20th of science funding. Private insurers ranked last (0.04% of revenue) and health systems 19th (0.1% of revenue) among 22 industries in their investment in innovation. An increment of $8 billion to $15 billion yearly would occur if service firms were to reach median research and development funding. (3) Globalization: US government research funding declined from 57% (2004) to 50% (2012) of the global total, as did that of US companies (50% to 41%), with the total US (public plus private) share of global research funding declining from 57% to 44%. Asia, particularly China, tripled investment from $2.6 billion (2004) to $9.7 billion (2012) preferentially for education and personnel. The US share of life science patents declined from 57% (1981) to 51% (2011), as did those considered most valuable, from 73% (1981) to 59% (2011).

**CONCLUSIONS AND RELEVANCE** New investment is required if the clinical value of past scientific discoveries and opportunities to improve care are to be fully realized. Sources could include repatriation of foreign capital, new innovation bonds, administrative savings, patent pools, and public-private risk sharing collaborations. Given international trends, the United States will relinquish its historical international lead in the next decade unless such measures are undertaken.

Editorials pages 143 and 145

Supplemental content at jama.com

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JAMA. 2015;313(2):174-189. doi:10.1001/jama.2014.15939



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## Industry Breakout - Life Sciences

Mon, 12/09/2013 - 6:10am

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**Summary**

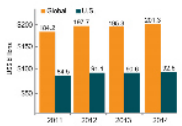
As represented in this Forecast, the life science industry includes biopharmaceuticals, medical instruments and devices, animal/agricultural bioscience and commercial research and testing. However, the industry's R&D spending is driven primarily by the mass and research intensity of the biopharmaceutical sector, which accounts for nearly 85% of all expenditures.

The life science industry's research activities in the United States continue to lead the world, but it is an area that also remains in significant transition. Not only is life science—led by the biopharmaceutical sector—the leading U.S. industry in terms of volume of research, U.S. life science R&D accounts for 46% of the global total—one of the highest shares in any industry.

Still, pressures persist to improve on productivity, product pipelines and ROI in consideration of expiring patents, cost pressures and the rising complexity of innovation in drug development. While primarily affecting the biopharmaceutical sector, the medical device sector is not immune to some of these trends. A new factor complicating the R&D environment for the life science industry is the set of changes in the U.S. healthcare landscape mandated by the Affordable Care Act. While it is hard to predict exactly how this new law will affect life science R&D, these transitions and uncertainties suggest that while the U.S. remains a global leader life science R&D, it is vulnerable, especially as European competitors and new, emerging Asian competitors target life science research for growth.

For the U.S. life science industry, we project a small rebound over 2013 levels (up 2.2%) to R&D spending of about $93 billion in 2014, with the growth coming primarily from smaller biopharmaceutical innovators and medical device manufacturers.

The global expansion of the life science industry has slowed over the last few years, but the industry is forecast to have a stronger recovery (up 3.1%) to more than $201 billion in 2014.



**Regulatory Context Influences U.S. R&D Outlook**

The U.S. life science industry emerged from the combined challenges of the recession and patent expirations with fresh strategies for R&D. Traditional pharmaceutical companies, while still massive and investing significant resources in R&D, continue to struggle with reduced product pipelines and productivity from discovery through development. As these firms rationalize drug development activities, R&D spending often declines and programs are sometimes reduced and refocused. Smaller

The Economist

OCTOBER 19TH–25TH 2013 Economist.com

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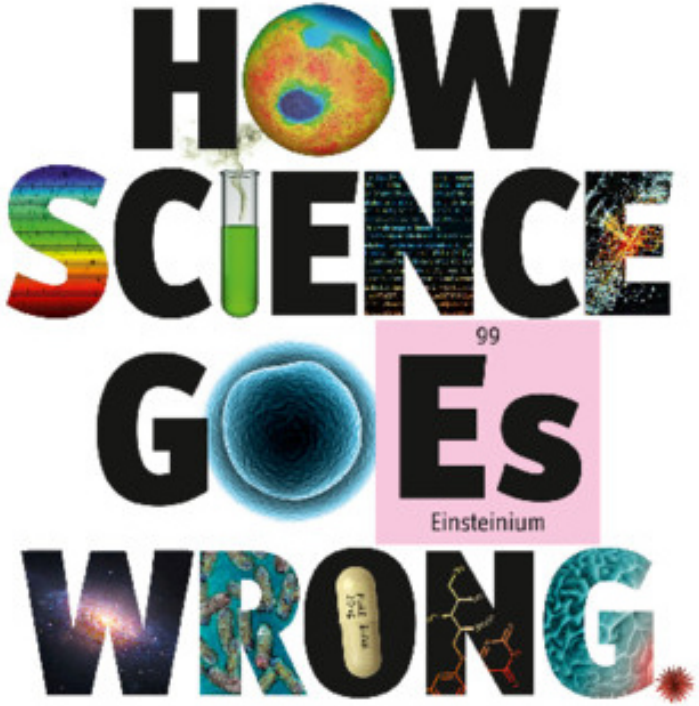
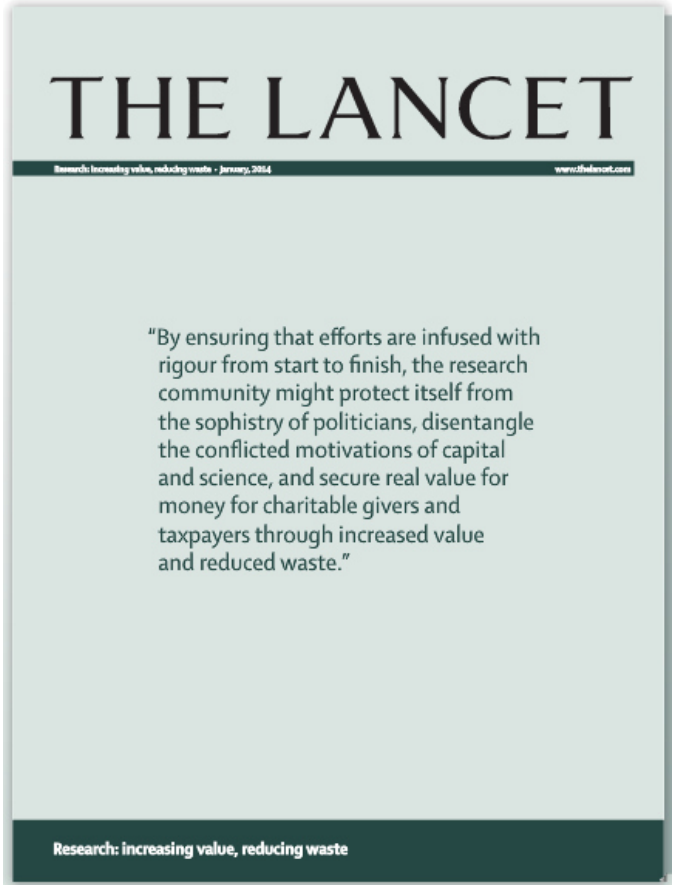
The meaning of Sachin Tendulkar



## LANCET SERIES (2014)
## INCREASING VALUE, REDUCING WASTE

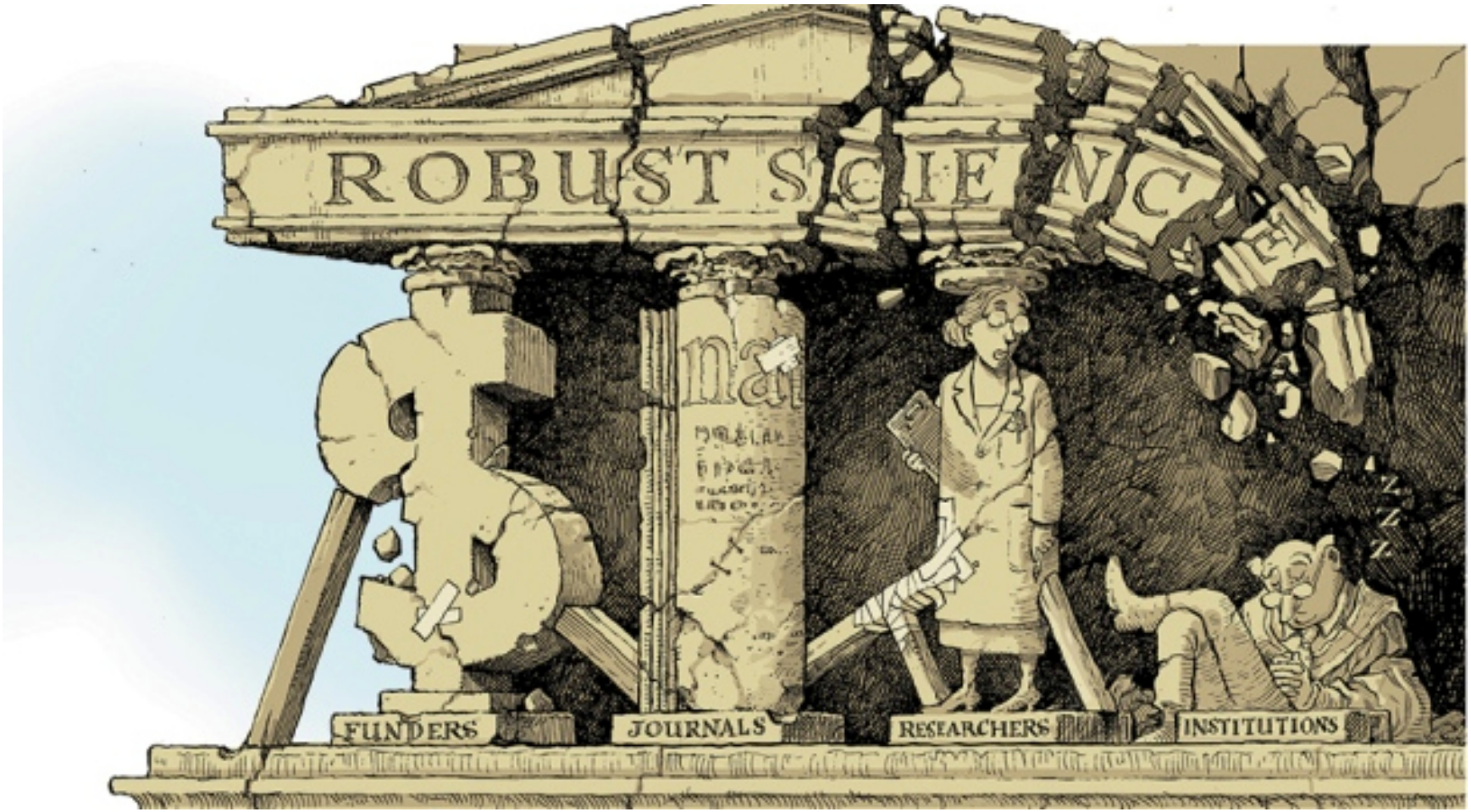
- 7 articles
- 42 authors
- > 50 journal pages
- Several hundred references citing problems (and evidence) in the entire research process
  - From questions asked to how research is reported
- Clinical and preclinical research



# Increasing value, reducing waste

- Series has 17 recommendations
- Targeted:
  - funders, government, journals, academic institutions, regulators, and researchers

# There is good evidence showing that much of this investment is wasted




Begley CG, Buchan AM, Dirnagl U. Robust research: institutions must do their part for reproducibility. Nature 2015 525 (7567): 25-27

## ACADEMIC INSTITUTIONS

- Home to many faculty doing research
- Subsequent generations of researchers
- Subsequent generations of editors and peer reviewers

PLOS | MEDICINE

ESSAY

# Four Proposals to Help Improve the Medical Research Literature

**David Moher[1]*, Douglas G. Altman[2]**

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## Summary Points

- The evidence base underpinning clinical practice is deeply flawed.
- There must be better value gained from resources invested in medical research.
- We make four proposals: (1) introducing publications officers; (2) developing core competencies for editors and peer reviewers, around which (3) training can be tailored; and (4) training authors to write articles fit for purpose.
- All of these ideas need to be piloted and evaluated, and implemented if proven effective.
- We suggest dedicated funding for initiatives aimed at understanding and improving the way that research is conducted and published.
- Academic institutions, funders, publishers, and others should support and implement effective processes to improve the reliability of the medical research literature.

OPEN ACCESS

**Citation:** Moher D, Altman DG (2015) Four Proposals to Help Improve the Medical Research Literature. PLoS Med 12(9): e1001864. doi:10.1371/journal.pmed.1001864

**Published:** September 22, 2015

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# Core competencies for medical journal editors

# Context

- There are substantive and deep problems with published research
  - Clinical
  - Preclinical

- Scientific editors (and ultimately editors-in-chief) are accountable for all published material in their journals
- Readers should expect them to have processes in place to assure the quality of the papers they publish and to strive constantly to improve their journals

- Unlike airline pilots and many other professional groups, however, many medical editors operate their journals largely untrained and certainly uncertified
- This is not the optimal way to instil confidence in readers, provide value for money to funders, or ensure the public can trust the research record

## AVAILABLE RESOURCES

- Some organizations, for example, the World Association of Medical Editors (WAME), provide resources for editors.
- There are some good websites, such as Committee on Publication Ethics (COPE) that provide important information for editors,
- Blogs, such as Journalology (http://journalology.blogspot.ca/).
- Several short courses on being an editor offered by commercial groups (http://www.pspconsulting.org/medical-short.shtm)
- A few large well resourced journals offer in-house training for editors (e.g., BMJ)

## DEVELOPING CORE COMPETENCIES FOR MEDICAL JOURNAL EDITORS

- Environmental scan
- Needs assessment
- Scoping review
- Delphi
- Face to face meeting

- A minimum set of evidence-based core competencies

- Stakeholder engagement
  - WAME
  - CSE
  - COPE
  - EASE
  - BMC
  - Cochrane Collaboration

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Journal of Clinical Epidemiology 68 (2015) 257–265

Journal of Clinical Epidemiology

# A systematic review highlights a knowledge gap regarding the effectiveness of health-related training programs in journalology

James Galipeau[a,*], David Moher[a,b], Craig Campbell[c], Paul Hendry[b], D. William Cameron[a,b], Anita Palepu[d], Paul C. Hébert[e]

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Galipeau *et al. BMC Medicine* (2016) 14:16
DOI 10.1186/s12916-016-0561-2

BMC Medicine

RESEARCH ARTICLE Open Access

# A scoping review of competencies for scientific editors of biomedical journals

James Galipeau[1*], Virginia Barbour[2], Patricia Baskin[3], Sally Bell-Syer[4], Kelly Cobey[1], Miranda Cumpston[5], Jon Deeks[6], Paul Garner[7], Harriet MacLehose[8], Larissa Shamseer[1], Sharon Straus[9], Peter Tugwell[1,10], Elizabeth Wager[11], Margaret Winker[12] and David Moher[1,11]

## Abstract

**Background:** Biomedical journals are the main route for disseminating the results of health-related research. Despite this, their editors operate largely without formal training or certification. To our knowledge, no body of literature systematically identifying core competencies for scientific editors of biomedical journals exists. Therefore, we aimed to conduct a scoping review to determine what is known on the competency requirements for scientific editors of biomedical journals.

## DEVELOPING TRAINING PROGRAMS

- Training programs can then be tailored to ensure all editors meet some basic globally agreed upon standards

- Providing basic comprehensive training, certification, and continuing editor education should be required for all new editors
- Editorial groups, such as the Council of Science Editors, WAME, and other groups invested in the professionalism of editors, such as COPE, would be excellent candidates for helping to provide the training, certification, and continuing education
- Publishers should proudly display such milestones at their journals

## TRAINING MODEL

- Many medical journal editors are physicians and, therefore, familiar with training based on core competencies and being subsequently certified (and licensed) once a certain threshold has been met
- These physicians are also familiar with continuing medical education requirements to maintain licensure in their respective jurisdictions
- This model is in stark contrast to what exists currently for many medical editors

## TRAINING PHYSICIANS

- Residency training is based on an agreed upon set of core competencies
  - CANMEDS – Scholar Role: Key Competencies
    - 4. Critically evaluate the integrity, reliability, and applicability of health-related research and literature
- These competencies are examined
  - Royal college examination
- Licensure
- Continuing Medical Education

# PEER REVIEW – THE EVIDENCE BASE

## CALLAHAM, 2002

**“Effect of Written Feedback by Editors on Quality of Reviews - Two Randomized Trials”**

- Study 1 (n=57 poor-quality reviewers)

  **Conclusions:** Feedback from editors on review quality had no effect on subsequent performance.

- Study 2 (n=127 average reviewers)

  **Conclusions:** Simple written feedback to reviewers seems to be an ineffective educational tool.

Callaham M et al. JAMA 2002 287(21): 2781-2783

## SCHROTER, 2004

**"Effects of training on quality of peer review: randomised controlled trial"**

- *Face to face training (n=204) vs. Self-taught training (n=203) vs. No training (n=202)*
- **Conclusions:** Very short training has only a marginal impact. Cannot recommend use of the interventions that were studied.

Schroter S et al. BMJ 2004 328(7441): 673.

## CALLAHAM, 2007

# "The Relationship of Previous Training and Experience of Journal Peer Reviewers to Subsequent Review Quality"

- 306 experienced reviewers - survey of past training and experiences and assessed quality of 2,856 reviews of 1,484 separate manuscripts over 4 years.
- Only significant predictors of quality:
  - working in a university-operated hospital versus other teaching environment
  - relative youth (under ten years of experience after finishing training)
- No easily identifiable types of formal training or experience that predict reviewer performance.

Callaham ML & Tercier J. PLoS medicine 2007 4(1): e40

## CALLAHAM, 2007

***"Skill in scientific peer review may be as ill defined and hard to impart as is 'common sense.' Without a better understanding of those skills, it seems unlikely journals and editors will be successful in systematically improving their selection of reviewers."***

## SCHROTER, 2008

**What errors do peer reviewers detect, and does training improve their ability to detect them?**

- 607 BMJ peer reviewers randomized to *face-to-face training* vs. *self-taught package* vs. control.
- **Conclusions:**
  - Editors should not assume that reviewers will detect most major errors, particularly those concerned with the context of study.
  - Short training packages have only a slight impact on improving error detection.

Schroter S et al. Journal of the Royal Society of Medicine 2008 101(10): 507-514.

# "EDITORIAL PEER REVIEW FOR IMPROVING THE QUALITY OF REPORTS OF BIOMEDICAL STUDIES"

- Cochrane Review; included 28 studies
- Some evidence to support use of checklists and other standardization media (2 studies).
- No evidence that reviewer training has any effect on the quality of the outcome (1 study).
- Editorial peer review appears to make papers more readable and improve the general quality of reporting (2 studies), but the evidence for this has very limited generalizability.

**Authors' conclusions**

- Little empirical evidence is available to support the use of editorial peer review as a mechanism to ensure quality of biomedical research.

Jefferson T, et al. Cochrane Database Syst Rev. 2007 Apr 18;(2):MR000016

## HOURY, 2012

# "Does mentoring new peer reviewers improve review quality? A randomized trial"

- Mentees at Ann Emerg Med (n=24) received standard written information + mentoring vs. control (n=22) received written informational only
- Paired new reviewers with senior reviewer for first three manuscript reviews
- **Conclusions:** Mentoring did not improve the quality of reviews

Houry D et al. BMC medical education 2012 12(1): 83.

Chauvin *et al. BMC Medicine*
DOI 10.1186/s12916-015-0395-3

BMC Medicine

RESEARCH ARTICLE Open Access

# The most important tasks for peer reviewers evaluating a randomized controlled trial are not congruent with the tasks most often requested by journal editors

Anthony Chauvin[2,3†], Philippe Ravaud[1,2,3], Gabriel Baron[1,3], Caroline Barnes[2,3] and Isabelle Boutron[1,2,3*†]

**Abstract**

**Background:** The peer review process is a cornerstone of biomedical research publications. However, it may fail to allow the publication of high-quality articles. We aimed to identify and sort, according to their importance, all tasks that are expected from peer reviewers when evaluating a manuscript reporting the results of a randomized controlled trial (RCT) and to determine which of these tasks are clearly requested by editors in their recommendations to peer reviewers.

**Methods:** We identified the tasks expected of peer reviewers from 1) a systematic review of the published literature and 2) recommendations to peer reviewers for 171 journals (i.e., 10 journals with the highest impact factor for 14 different medical areas and all journals indexed in PubMed that published more than 15 RCTs over 3 months regardless of the medical area). Participants who had peer-reviewed at least one report of an RCT had to classify the importance of each task relative to other tasks using a Q-sort technique. Finally, we evaluated editors' recommendations to authors to determine which tasks were clearly requested by editors in their recommendations to peer reviewers.

**Results:** The Q-sort survey was completed by 203 participants, 93 (46 %) with clinical expertise, 72 (36 %) with

## WHY SUCH APPARENT 'FAILURE'

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Journal of Clinical Epidemiology 68 (2015) 257–265

Journal of Clinical Epidemiology

# A systematic review highlights a knowledge gap regarding the effectiveness of health-related training programs in journalology

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Accepted 4 September 2014; Published online 7 November 2014

## JOURNALOLOGY SYSTEMATIC REVIEW

**"A systematic review highlights a knowledge gap regarding the effectiveness of health-related training programs in journalology"**

- Searched MEDLINE, Embase, ERIC, PsycINFO, and the Cochrane Library
  - –Comparative studies of formalized training programs in writing for scholarly publication, journal editing, or manuscript peer review.
- 5 studies related to peer review

**Conclusions:**

- Included studies were generally small and inconclusive regarding the effects of training on educational outcomes related to improving the quality of health research.
- Studies were of questionable validity and susceptible to misinterpretation due to risk of bias.
- Review highlights the gaps in our knowledge of how to enhance and ensure the scientific quality of research output for authors, peer reviewers, and journal editors.

Patel *BMC Medicine* 2014, **12**:128
http://www.biomedcentral.com/1741-7015/12/128

BMC Medicine

**OPINION** **Open Access**

# Why training and specialization is needed for peer review: a case study of peer review for randomized controlled trials

Jigisha Patel

**Abstract**

**Background:** The purpose and effectiveness of peer review is currently a subject of hot debate, as is the need for greater openness and transparency in the conduct of clinical trials. Innovations in peer review have focused on the process of peer review rather than its quality.

**Discussion:** The aims of peer review are poorly defined, with no evidence that it works and no established way to provide training. However, despite the lack of evidence for its effectiveness, evidence-based medicine, which directly informs patient care, depends on the system of peer review. The current system applies the same process to all fields of research and all study designs. While the volume of available health related information is vast, there is no consistent means for the lay person to judge its quality or trustworthiness. Some types of research, such as randomized controlled trials, may lend themselves to a more specialized form of peer review where training and ongoing appraisal and revalidation is provided to individuals who peer review randomized controlled trials. Any randomized controlled trial peer reviewed by such a trained peer reviewer could then have a searchable 'quality assurance' symbol attached to the published articles and any published peer reviewer reports, thereby providing some guidance to the lay person seeking to inform themselves about their own health or medical treatment.

**Summary:** Specialization, training and ongoing appraisal and revalidation in peer review, coupled with a quality assurance symbol for the lay person, could address some of the current limitations of peer review for randomized controlled trials.

**Keywords:** Peer review, Evidence based medicine, EBM, Randomized controlled trials, RCT, Clinical training, Medical education, Reporting guidelines, CONSORT

## Background

### A brief history of trial reporting and peer review

'Better have them all removed now.' That was the advice I received in the early 1990s when my pain free unerupted wisdom teeth first came to the notice of a surgeon. He was emphatic that I would suffer complications in the future if I did not have all four teeth removed under a general anesthetic. This seemed drastic to me, but I was given the same advice by two health professionals and it was with trepidation that I questioned their advice. At the time, 'Evidence-Based Medicine' which proposed the use of scientific evidence to inform clinical decision making was still a novel idea [1] and the Cochrane Collaboration [2], aimed at facilitating up-to-date systematic reviews of randomized controlled trials, had recently been founded.

I decided to search for the evidence. My only source of information was a medical library where I could identify and photo-copy relevant looking articles or get copies via an 'inter-library loan'. I did not find any useful information, but I decided against the procedure on the basis that the risk of a general anesthetic and a stay in hospital seemed to me to completely outweigh any benefit of having four perfectly healthy pain-free teeth removed.

A short time later, when I was a junior doctor, a subgroup analysis of the diabetic patients who took part in the original '4S study' [3], reported that simvastatin treatment improved morbidity and mortality in patients with diabetes [4]. At the time, my peers and I took for

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# Training for peer review: why we need it and how to get there

Posted by Biome on 7th October 2014 - 0 Comments

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*In a recent Opinion article in BMC Medicine by BioMed Central's Associate Editorial Director for Research Integrity, Jigisha Patel, the need to train peer reviewers was raised, starting with the peer review of randomized clinical trials. Here David Moher from the Ottawa Hospital Research Institute, Canada, comments on why peer review training is needed, and what is required to bring this about.*

Biomedical journals, whether they are traditional subscription or open access, are important. They are still the most central conduit for dissemination the results of all research. Although when examined more closely, the articles journals publish are problematic – they are often badly reported and often unusable. This is wasteful, reduces scientific and fiscal value, and unethical.

For any journal using best practices there are at least three fundamental steps involved in publishing an article. First, prospective authors must submit a manuscript that is 'fit for purpose' for publication consideration. Ideally the manuscript should be a complete and accurate description of what was planned, any deviations from the proposed plan, and the protocol in sufficient detail to allow interested readers to replicate it, and the results. Second, the submission is typically triaged by the journal editor and if deemed suitable sent for external peer review the results of which help determine the faith of the paper at that journal. Third, often after incorporating reviewers comments the authors send a revised manuscript back to the editor who subsequently makes a final decision about the acceptability of the paper for the journal. Corresponding authors of accepted papers are sent a letter of acceptance.

The second step, above, peer review, has proven problematic. There are short courses on becoming a peer reviewer, such as the Public Knowledge Project, and other resources. However, there is a good deal of evidence indicating that training programs do not appreciably increase the knowledge base and quality of peer reviewers. A Cochrane review of existing evidence indicates that peer review has a very modest effect, if at all, on manuscript quality. Rather than throw the baby out with the bathwater there is an urgent need to step back and develop training based on some agreed upon universal core competencies that all peer reviewers should have and maintain. For example,

Patel J: BMC Medicine 2014 12:128.

http://www.biomedcentral.com/biome/training-for-peer-review-why-we-need-it-and-how-to-get-there/

## FORMAL TRAINING PEER REVIEWERS

- Currently available at your institution?

- Currently available at my institution
  - No specific training in peer review
  - 13-week course in journalology (publication science)

## TRAINING IN PEER REVIEW

- Commercial short courses
  - 2-3 days
- Some online resources
  - PKP (https://pkp.sfu.ca/)
- Journal fellowships
  - CMAJ; Fishbain; BMJ; NEJM

## CORE COMPETENCIES FOR PEER REVIEWERS

- What are they?

ELSEVIER

CrossMark

Journal of Clinical Epidemiology 68 (2015) 257–265

Journal of Clinical Epidemiology

# A systematic review highlights a knowledge gap regarding the effectiveness of health-related training programs in journalology

James Galipeau[a,*], David Moher[a,b], Craig Campbell[c], Paul Hendry[b], D. William Cameron[a,b], Anita Palepu[d], Paul C. Hébert[e]

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Accepted 4 September 2014; Published online 7 November 2014

## FRAMEWORK TO IDENTIFY CORE COMPETENCIES FOR PEER REVIEWERS

- A possible road map?
  - Environmental scan
  - Scoping review
  - Needs assessment
  - Focus interviews
  - Consensus meeting to agree on minimum set of core competencies

## CORE COMPETENCIES FOR PEER REVIEWERS

- Trained as a physician or allied health professional
- Graduate course in journalology (publication science)
- Graduate training in epidemiology
- At least two graduate courses in epidemiology
  - Selective reporting
- At least two graduate courses in biostatistics
- Graduate training in English
- At least two graduate courses in English
- Training in diplomacy/interpersonal relations
- Training in research integrity
- Have an established (or establishing) area of content expertise and/or methods expertise
- Understanding the difference between being an investigator and peer reviewer
- Extensive knowledge of reporting guidelines

## EXTENSIVE KNOWLEDGE OF REPORTING GUIDELINES

- What are reporting guidelines?
  - Checklist
  - Flow diagram
  - Explicit text to guide authors in reporting a specific type of research, developed using explicit methodology

# CONSORT STATEMENT 2010

*Table.* CONSORT 2010 Checklist of Information to Include When Reporting a Randomized Trial*

| Section/Topic | Item Number | Checklist Item | Reported on Page Number |
|---|---|---|---|
| Title and abstract | 1a | Identification as a randomized trial in the title | |
| | 1b | Structured summary of trial design, methods, results, and conclusions (for specific guidance, see CONSORT for abstracts [21, 31]) | |
| Introduction | | | |
| Background and objectives | 2a | Scientific background and explanation of rationale | |
| | 2b | Specific objectives or hypotheses | |
| Methods | | | |
| Trial design | 3a | Description of trial design (such as parallel, factorial), including allocation ratio | |
| | 3b | Important changes to methods after trial commencement (such as eligibility criteria), with reasons | |
| Participants | 4a | Eligibility criteria for participants | |
| | 4b | Settings and locations where the data were collected | |
| Interventions | 5 | The interventions for each group with sufficient details to allow replication, including how and when they were actually administered | |
| Outcomes | 6a | Completely defined prespecified primary and secondary outcome measures, including how and when they were assessed | |
| | 6b | Any changes to trial outcomes after the trial commenced, with reasons | |
| Sample size | 7a | How sample size was determined | |
| | 7b | When applicable, explanation of any interim analyses and stopping guidelines | |
| Randomization | | | |
| Sequence generation | 8a | Method used to generate the random allocation sequence | |
| | 8b | Type of randomization; details of any restriction (such as blocking and block size) | |
| Allocation concealment mechanism | 9 | Mechanism used to implement the random allocation sequence (such as sequentially numbered containers), describing any steps taken to conceal the sequence until interventions were assigned | |
| Implementation | 10 | Who generated the random allocation sequence, who enrolled participants, and who assigned participants to interventions | |
| Blinding | 11a | If done, who was blinded after assignment to interventions (for example, participants, care providers, those assessing outcomes) and how | |
| | 11b | If relevant, description of the similarity of interventions | |
| Statistical methods | 12a | Statistical methods used to compare groups for primary and secondary outcomes | |
| | 12b | Methods for additional analyses, such as subgroup analyses and adjusted analyses | |
| Results | | | |
| Participant flow (a diagram is strongly recommended) | 13a | For each group, the numbers of participants who were randomly assigned, received intended treatment, and were analyzed for the primary outcome | |
| | 13b | For each group, losses and exclusions after randomization, together with reasons | |
| Recruitment | 14a | Dates defining the periods of recruitment and follow-up | |
| | 14b | Why the trial ended or was stopped | |
| Baseline data | 15 | A table showing baseline demographic and clinical characteristics for each group | |
| Numbers analyzed | 16 | For each group, number of participants (denominator) included in each analysis and whether the analysis was by original assigned groups | |
| Outcomes and estimation | 17a | For each primary and secondary outcome, results for each group, and the estimated effect size and its precision (such as 95% confidence interval) | |
| | 17b | For binary outcomes, presentation of both absolute and relative effect sizes is recommended | |
| Ancillary analyses | 18 | Results of any other analyses performed, including subgroup analyses and adjusted analyses, distinguishing prespecified from exploratory | |
| Harms | 19 | All important harms or unintended effects in each group (for specific guidance, see CONSORT for harms [28]) | |
| Discussion | | | |
| Limitations | 20 | Trial limitations; addressing sources of potential bias; imprecision; and, if relevant, multiplicity of analyses | |
| Generalizability | 21 | Generalizability (external validity, applicability) of the trial findings | |
| Interpretation | 22 | Interpretation consistent with results, balancing benefits and harms, and considering other relevant evidence | |
| Other Information | | | |
| Registration | 23 | Registration number and name of trial registry | |
| Protocol | 24 | Where the full trial protocol can be accessed, if available | |
| Funding | 25 | Sources of funding and other support (such as supply of drugs), role of funders | |

Schulz KF, et al. BMJ 2010;340:c332; Moher D, et al. BMJ 2010;340:c869. www.consort-statement.org

## EXTENSIVE KNOWLEDGE OF REPORTING GUIDELINES

- Where can peer reviewers identify reporting guidelines?
- Should editors recommend reporting guidelines a part of the peer review process?
- Are reporting guidelines effective?

## Library for health research reporting

The Library for health research reporting provides an up-to-date collection of guidelines and policy documents related to health research reporting. These are aimed mainly at authors of research articles, journal editors, peer reviewers and reporting guideline developers.

- Search for reporting guidelines
- Reporting guidelines under development
- Translations of reporting guidelines
- Guidance on scientific writing
- Guidance developed by editorial groups

## Reporting guidelines for main study types

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

## EXTENSIVE KNOWLEDGE OF REPORTING GUIDELINES

- Should editors recommend reporting guidelines a part of the peer review process?
- Are reporting guidelines effective?

OPEN ACCESS Freely available online

PLoS one

# Are Peer Reviewers Encouraged to Use Reporting Guidelines? A Survey of 116 Health Research Journals

**Allison Hirst*, Douglas G. Altman**

The EQUATOR Network, Centre for Statistics in Medicine, University of Oxford, Oxford, United Kingdom

## Abstract

***Background:*** Pre-publication peer review of manuscripts should enhance the value of research publications to readers who may wish to utilize findings in clinical care or health policy-making. Much published research across all medical specialties is not useful, may be misleading, wasteful and even harmful. Reporting guidelines are tools that in addition to helping authors prepare better manuscripts may help peer reviewers in assessing them. We examined journals' instructions to peer reviewers to see if and how reviewers are encouraged to use them.

***Methods:*** We surveyed websites of 116 journals from the McMaster list. Main outcomes were 1) identification of online instructions to peer reviewers and 2) presence or absence of key domains within instructions: on journal logistics, reviewer etiquette and addressing manuscript content (11 domains).

***Findings:*** Only 41/116 journals (35%) provided online instructions. All 41 guided reviewers about the logistics of their review processes, 38 (93%) outlined standards of behaviour expected and 39 (95%) contained instruction about evaluating the manuscript content. There was great variation in explicit instruction for reviewers about how to evaluate manuscript content. Almost half of the online instructions 19/41 (46%) mentioned reporting guidelines usually as general statements suggesting they may be useful or asking whether authors had followed them rather than clear instructions about how to use them. All 19 named CONSORT for reporting randomized trials but there was little mention of CONSORT extensions. PRISMA, QUOROM (forerunner of PRISMA), STARD, STROBE and MOOSE were mentioned by several journals. No other reporting guideline was mentioned by more than two journals.

***Conclusions:*** Although almost half of instructions mentioned reporting guidelines, their value in improving research publications is not being fully realised. Journals have a responsibility to support peer reviewers. We make several recommendations including wider reference to the EQUATOR Network online library (www.equator-network.org/).

## EXTENSIVE KNOWLEDGE OF REPORTING GUIDELINES

- Are reporting guidelines effective?

# Consolidated standards of reporting trials (CONSORT) and the completeness of reporting of randomised controlled trials (RCTs) published in medical journals (Review)

Turner L, Shamseer L, Altman DG, Weeks L, Peters J, Kober T, Dias S, Schulz KF, Plint AC, Moher D

THE COCHRANE COLLABORATION®

## USING REPORTING GUIDELINES TO PEER REVIEW

- CONSORT for reporting RCTs
- Interventions
- 5: The interventions for each group with sufficient details to allow replication, including how and when they were actually administered
  - Partial description: signal sampling frame is not reported: every 5 seconds? Every 30 seconds? Every minute? This is relevant since it directly affects precision of the primary outcome measurements.

# CONSORT

- 6a: Completely defined pre-specified primary and secondary outcome measures, including how and when they were assessed
- Outcomes have been indicated; the primary outcome measure is probably difficult to interpret from the clinical point of view, but I reckon this is a common problem in studies on monitoring devices. It is also difficult to judge since the duration of monitoring is extremely variable, ranging from 0.9 hours to 71.4 hours (and data are not presented divided by groups); no explanation for this variability is being given. It is not clear to me what “The burden was [...] extrapolated to 72 hours.” Does this mean that for patients with incomplete duration of monitoring the measured burden was in some way applied to the whole 72h period (e.g. by multiplication)?

BMJ

*BMJ* 2011;343:d6783 doi: 10.1136/bmj.d6783 (Published 22 November 2011)



RESEARCH

# Effect of using reporting guidelines during peer review on quality of final manuscripts submitted to a biomedical journal: masked randomised trial


OPEN ACCESS

E Cobo *senior statistics editor and senior statistical lecturer*[1 2], J Cortés *statistical researcher*[2], J M Ribera *general secretary and chief of clinical haematology department*[1 3 4 5], F Cardellach *general secretary and professor of internal medicine*[1 6], A Selva-O'Callaghan *editorial committee member and senior lecturer in internal medicine*[1 3 7], B Kostov *statistical researcher*[8], L García *statistical researcher*[2], L Cirugeda *statistical researcher*[9], D G Altman *professor of statistics in medicine*[10], J A González *senior statistical lecturer*[2], J A Sànchez *senior statistical lecturer*[2], F Miras *statistical researcher*[2], A Urrutia *editorial committee member and senior lecturer in internal medicine*[1 3 4], V Fonollosa *editorial committee member and professor of internal medicine*[1 3 7], C Rey-Joly *current editor and professor of internal medicine*[1 3 4], M Vilardell *editor in chief and professor of internal medicine*[1 3 7]

## TRAINING PEER REVIEWERS

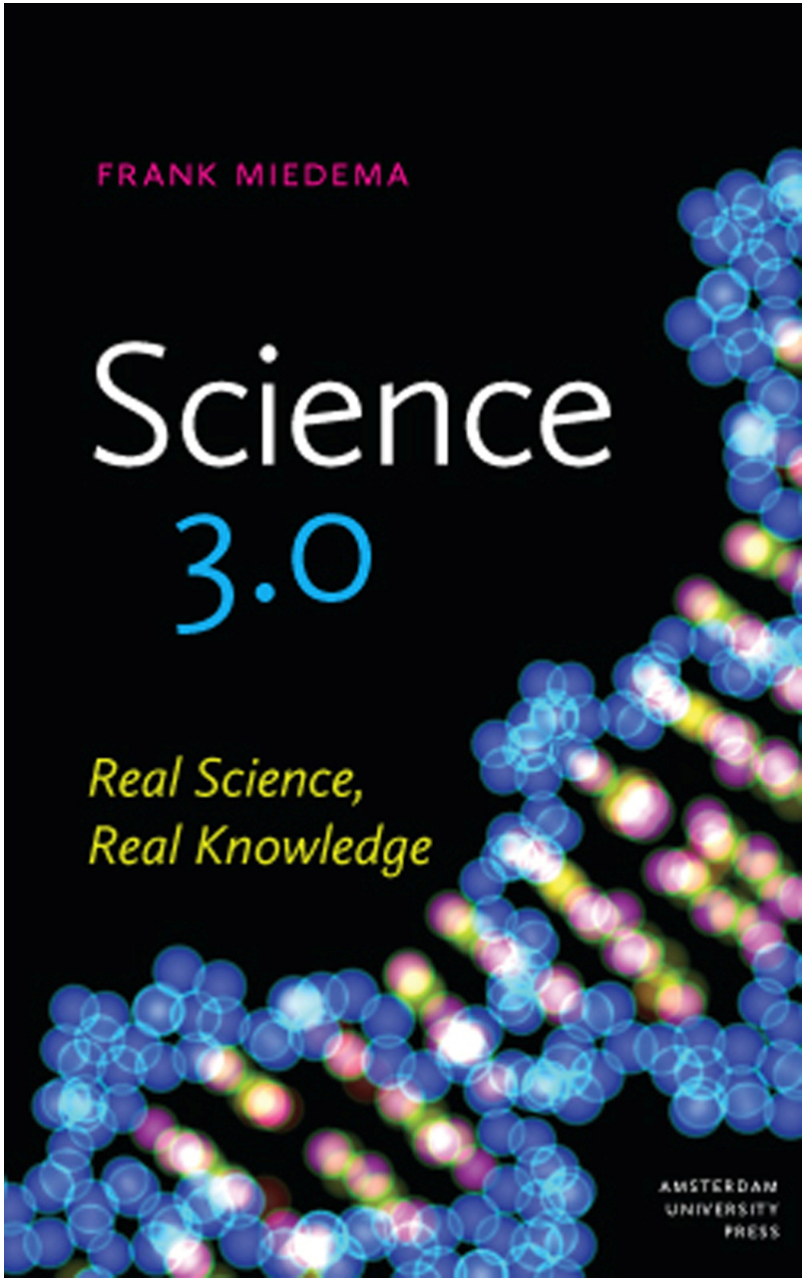
- Must be based on agreed upon core competences
- Must be online
- Must be geared towards adult learning
- Must be self paced

## TRAINING PEER REVIEWERS

- Must be examined and licensed
- Must be part of continuing peer reviewer education

**ART IS I,**
**SCIENCE IS**
**WE**

**(CLAUDE BERNARD, 1865)**



Moher *et al. BMC Medicine* (2015) 13:34
DOI 10.1186/s12916-015-0284-9

BMC Medicine

COMMENTARY Open Access

# The National Institutes of Health and guidance for reporting preclinical research

David Moher[1,2*], Marc Avey[1], Gerd Antes[3] and Douglas G Altman[4,5]

**Abstract**

The quality of reporting clinical and preclinical research is not optimal. Reporting guidelines can help make reports of research more complete and transparent, thus increasing their value and making them more useful to all readers. Getting reporting guidelines into practice is complex and expensive, and involves several stakeholders, including prospective authors, peer reviewers, journal editors, guideline developers, and implementation scientists. Working together will help ensure their maximum uptake and penetration. We are all responsible for helping to ensure that all research is reported so completely that it is of value to everybody.

Please see related article: http://dx.doi.org/10.1186/s12916-015-0266-y

**Keywords:** Implementation, Preclinical research, Quality of reporting, Reporting guidelines

ACRM
AMERICAN CONGRESS OF REHABILITATION MEDICINE

Archives of Physical Medicine and Rehabilitation

journal homepage: www.archives-pmr.org

Archives of Physical Medicine and Rehabilitation 2014;95:415-7

EDITORIAL

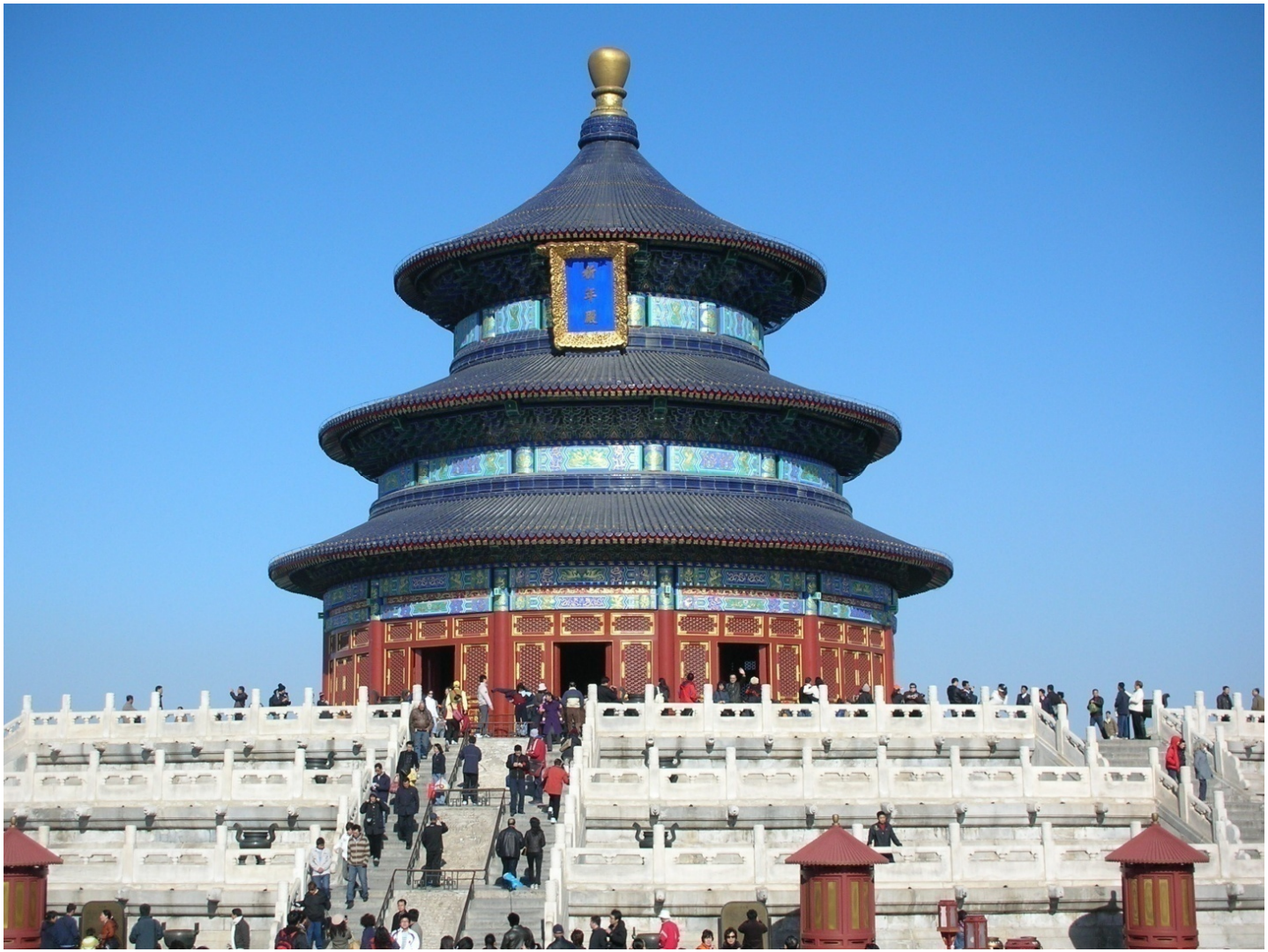
# Elevating the Quality of Disability and Rehabilitation Research: Mandatory Use of the Reporting Guidelines

With the remarkable growth of disability- and rehabilitation-related research in the last decade, it is imperative that we support the highest quality research possible. With cuts in research funding, rehabilitation research is now under a microscope like never before, and it is critical that we put our best foot forward.

To ensure the quality of the disability and rehabilitation research that is published, the 28 rehabilitation journals simultaneously publishing this editorial (see acknowledgments) have agreed to take a more aggressive stance on the use of reporting guidelines.* Research reports must contain sufficient information to allow readers to understand how a study was designed and conducted, including variable definitions, instruments and other measures, and analytical techniques.[1] For review articles, systematic or narrative, readers should be informed of the rationale and details behind the literature search strategy. Too often articles fail to include their standard for inclusion and their criteria for evaluating quality of the improvements in the accuracy and comprehensiveness of reporting. Examples include the following:

(1) CONSORT for randomized controlled trials (www.consort-statement.org);
(2) Strengthening the Reporting of Observational studies in Epidemiology (STROBE) for observational studies (http://strobe-statement.org/);
(3) Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) for systematic reviews and meta-analyses (www.prisma-statement.org/);
(4) Standards for the Reporting of Diagnostic accuracy studies (STARD) for studies of diagnostic accuracy (www.stard-statement.org/); and
(5) Case Reports (CARE) for case reports (www.care-statement.org/).

Chan L, et al. Arch Phys Med Rehabil 2014; 95: 415–17.



# ACADEMIC INSTITUTIONAL INCENTIVES AND REWARDS

- The perverse nature of the incentive-reward system that seems deeply entrenched
- Are incentives and rewards evidence based?
  - publish or perish
- Should we more heavily reward:
  - replication, data sharing, making all research accessible, the importance of good peer reviewing
- Do incentives and rewards need a reboot?

Begley CG et al. Nature . 2015;525:25-27

European Journal of Clinical Investigation

Editorial

# Academic criteria for appointment, promotion and rewards in medical research: where's the evidence?

David Moher[1,2,*], Steven N. Goodman[3] and John P.A. Ioannidis[3]

DOI: 10.1111/eci.12612

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Issue


European Journal of Clinical Investigation

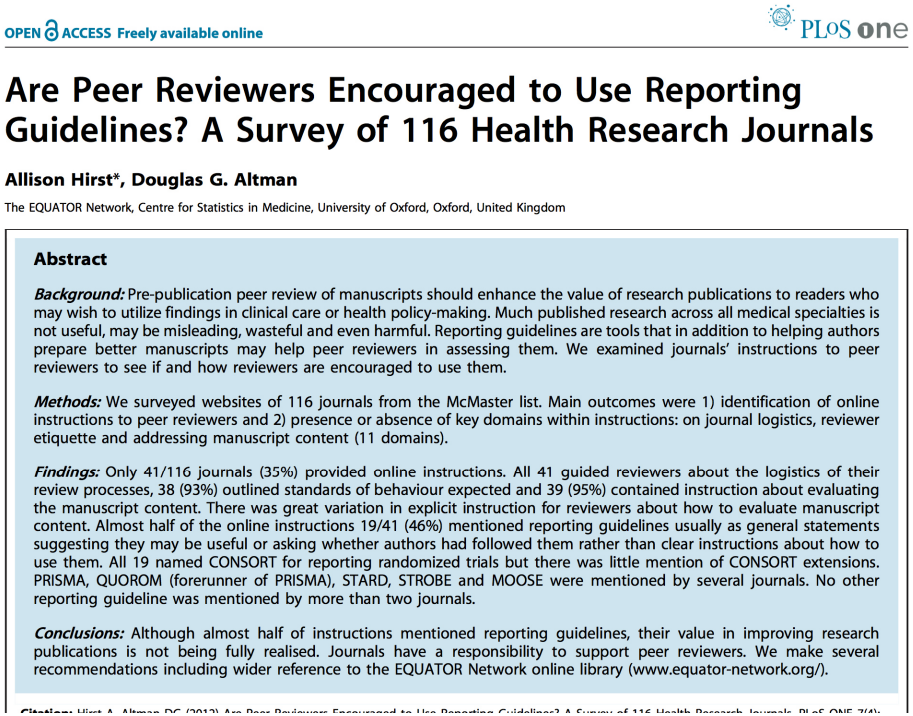
Accepted Article (Accepted, unedited articles published online and citable. The final edited and typeset version of record will appear in future.)

Am score 3

Additional Information (Show All)

# MEASURING SUCCESS

- Attainable increases in research value
  - 10%, annually, over the next decade, in each of the series' 17 recommendations
- Journals' instructions to peer reviewers shows that reference to or recommendations to use reporting guidelines during peer review was rare (19 of 116 journals assessed; 16.4%)
  - Positive incremental change would be observing at least a 10% improvement in guidance to peer reviewers in the 116 journals initially surveyed
- This approach could be used across all key players



OPEN ACCESS Freely available online

PLoS one

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## FROM A DIRECTOR OF PUBLICATIONS

"I have discussed with people across the organization and there is a great deal of interest in supporting the initiative – having handled hundreds of thousands of manuscripts we can attest to the variability in skill, knowledge and understanding of peer reviewers, so anything that could better train them would be invaluable. We would be willing to offer time, expertise and support in pushing the initiative forward. What we are unable to offer, I am afraid to say, is financial assistance."

ARE THERE OPPORTUNITIES TO MOVE THE PEER REVIEW CORE COMPETENCY IS PROGRAM FORWARD COLLABORATIVELY WITH PEERE?

# Thank you ☺