Oredlighet i kliniska studier

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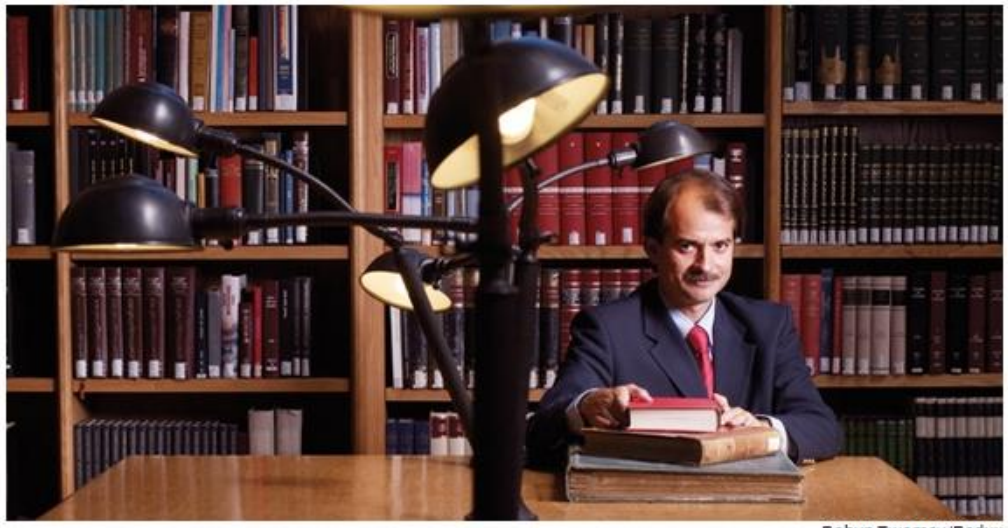
Much of what medical researchers conclude in their studies is misleading, exaggerated, or flat-out wrong. So why are doctors—to a striking extent—still drawing upon misinformation in their everyday practice? Dr. John Ioannidis has spent his career challenging his peers by exposing their bad science.

DAVID H. FREEDMAN | OCT 4 2010, 6:16 PM ET



Robyn Twomey/Redux

IN 2001, RUMORS were circulating in Greek hospitals that surgery residents,

PLoS Medicine 2 (8): e124; 2005

Open access, freely available online

Essay

Why Most Published Research Findings Are False

John P. A. Ioannidis

Summary

There is increasing concern that most current published research findings are false. The probability that a research claim is true may depend on study power and bias, the number of other studies on the same question, and, importantly, the ratio of true to no relationships among the relationships probed in each scientific field. In this framework, a research finding is less likely to be true when the studies conducted in a field are smaller; when effect sizes are smaller; when there is a greater number and lesser preselection of tested relationships; where there is greater flexibility in designs, definitions, outcomes, and analytical modes; when there is greater financial and other interest and prejudice; and when more teams are involved in a scientific field in chase of statistical significance.

factors that influence this problem and some corollaries thereof.

Modeling the Framework for False Positive Findings

Several methodologists have pointed out [9–11] that the high rate of nonreplication (lack of confirmation) of research discoveries is a consequence of the convenient, yet ill-founded strategy of claiming conclusive research findings solely on the basis of a single study assessed by formal statistical significance, typically for a *p*-value less than 0.05. Research is not most appropriately represented and summarized by *p*-values, but, unfortunately, there is a widespread notion that medical research articles

It can be proven that most claimed research

is characteristic of the field and can vary a lot depending on whether the field targets highly likely relationships or searches for only one or a few true relationships among thousands and millions of hypotheses that may be postulated. Let us also consider, for computational simplicity, circumscribed fields where either there is only one true relationship (among many that can be hypothesized) or the power is similar to find any of the several existing true relationships. The pre-study probability of a relationship being true is $R/(R + 1)$. The probability of a study finding a true relationship reflects the power $1 - \beta$ (one minus the Type II error rate). The probability of claiming a relationship when none truly exists reflects the Type I error rate, α. Assuming that c relationships are being probed in the field, the

Scientometrics (2012) 90:891–904
DOI 10.1007/s11192-011-0494-7

Negative results are disappearing from most disciplines

De sannaste resultaten publiceras inte!

Analyserat 4600 uppsatser

Proportionen negativa studier minskade från

30 till 14% mellan åren 1990 och 2007

Abstract Concerns that the growing competition for funding and citations might distort science are frequently discussed, but have not been verified directly. Of the hypothesized problems, perhaps the most worrying is a worsening of positive-outcome bias. A system that disfavours negative results not only distorts the scientific literature directly, but might also discourage high-risk projects and pressure scientists to fabricate and falsify their data.

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PLoS one

How Many Scientists Fabricate and Falsify Research? A Systematic Review and Meta-Analysis of Survey Data

Daniele Fanelli*

INNOGEN and ISSTI-Institute for the Study of Science, Technology & Innovation, The University of Edinburgh, Edinburgh, United Kingdom

Hur många forskare fabricerar och förfalskar resultat i sin forskning

Metaanalys av 23 översikter med enkäter

Ungefär 2 procent medger sig ha endera fabricerat, förfalskat eller på annat sätt ändrat sina resultat minst en gång.
Ungefär 14 % känner en kollega som förfalskat

Vanligare inom medicinsk forskning än inom annan sådan.

Citation: Fanelli D (2009) How Many Scientists Fabricate and Falsify Research? A Systematic Review and Meta-Analysis of Survey Data. PLoS ONE 4(5): e5738. doi:10.1371/journal.pone.0005738

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PLOS | MEDICINE

Essay

Why Growing Retractions Are (Mostly) a Good Sign

Daniele Fanelli[*¤]

Science, Technology and Innovation Studies, The University of Edinburgh, Edinburgh, United Kingdom

Research Integrity Series
This is one article in an occasional *PLOS Medicine* series on research integrity that examines issues affecting the ethics of health research worldwide.

Summary Points

- Corrections to scientific papers have been published for much longer than retractions, and show little sign of a recent increase.
- The number of journals issuing retractions has grown dramatically in recent years, but the number of retractions per retracting-journal has not increased.
- The number of queries and allegations made to the US Office of Research Integrity has grown, but the frequency of its findings of misconduct has not increased.
- Therefore, the rising number of retractions is most likely to be caused by a growing propensity to retract flawed and fraudulent papers, and there is little evidence of an increase in the prevalence of misconduct.
- Statistics on retractions and findings of misconduct are best used to make inferences about weaknesses in the system of scientific self-correction.

Introduction

Retractions of scientific papers have recently been in the spotlight. Unfortunately, the interpretation of statistics about them is often flawed. The realisation that most retractions follow from scientific misconduct [1] seems to have reinforced, in the minds of both scientists and journalists, the idea that data on retractions, and generally data on findings of misconduct, provide information about the prevalence of fraud itself [2]. The recent growth in retractions, for example, is often invoked as evidence that scientific misconduct is increasing [2–4]. Similarly, findings that more papers are retracted by high-ranking journals, in biomedical fields, and in certain countries, and that more men than women are found guilty of misconduct are used to suggest possible risk factors for scientific

tions to previous papers) and retractions as "correction" or "correction, addition" (total $n = 304{,}000$ circa). Retractions can be retrieved from all these "corrections" by selecting those that include the term "retraction" in their title (total $n = 2{,}294$). Notably, most previous studies on retractions have used the PubMed database. Unlike WoS, PubMed has a specific category for retractions. However, PubMed restricts its coverage mostly to biomedical research and only started recording errata in 1987. This limitation may have caused some of the misunderstandings that this essay aims to debunk.

Errata Have Not Increased in Frequency

As observed in previous studies that used PubMed, the number of retractions in the WoS database has grown dramatically over the last 20 years (Figure 1). Although the first retraction recorded in WoS is more recent than that recorded in PubMed (1989 versus 1977), the picture is substantially the same. However, unlike PubMed, the WoS database shows that errata have been published since at least 1901. This should come as no

AAAS project 1999-2016

THE SCIENTIFIC VIRTUES PROJECT

Robert T. Pennock
Professor
Lyman Briggs College
Dept. of Philosophy
Dept. of Computer Science and Engineering
Ecology, Evolutionary Biology and Behavior Program
MICHIGAN STATE UNIVERSITY

Fostering a Culture of Scientific Integrity: Legalistic vs. Scientific Virtue-Based Approaches

6 July 2015 Robert T. Pennock

SCIENTIFIC RESPONSIBILITY, HUMAN RIGHTS AND LAW PROGRAM (/TOPICS/SCIENTIFIC-RESPONSIBILITY-HUMAN-RIGHTS-AND-LAW-PROGRAM)

Robert T. Pennock is Professor of History and Philosophy of Science at Michigan State University, and a Visiting Scholar at the American Association for the Advancement of Science through the end of June 2015.

The research ethics community has come to a consensus that promoting responsible conduct of research (RCR) cannot be done on a piecemeal basis, but will require the cultivation of an ethical scientific *culture* (e.g., Gunsalus 1993, Atlas 2009). One highly-cited paper puts it this way: "[A]ll explanations [of research misconduct] seem to share a common denominator—the failure to foster a culture of integrity" (Titus et. al. 2008, 981-982). Focusing on culture is critical, but ethics and culture interact in complex ways, so fostering an ethical culture is not always straightforward. Science, as C. P. Snow emphasized (1959), has

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Claire Shaw
Guardian Professional, Friday 4 October 2013 11.35 BST

4 OCTOBER 2013 VOL 342 **SCIENCE** www.sciencemag.org
Published by AAAS

Who's Afraid of Peer Review?

A spoof paper concocted by *Science* reveals little or no scrutiny at many open-access journals

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

Sara Schroter[1] • Nick Black[2] • Stephen Evans[2] • Fiona Godlee[1] • Lyda Osorio[2] • Richard Smith[1]

[1] BMJ, BMA House, Tavistock Square, London WC1H 9JR, UK

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Correspondence to: Dr Sara Schroter. E-mail: sschroter@bmj.com

DECLARATIONS

Competing interests FG is the editor of the BMJ, SS is a senior researcher for the BMJ, RS is the former editor of the BMJ and NB, SE, and SS review for the BMJ

Funding This study was funded by the NHS London Regional Office Research & Development Directorate. The views and opinions expressed in this paper do not necessarily reflect those of NHSE (LRO) or the Department of Health

Ethical approval The ethics committee of the London School of Hygiene and Tropical Medicine approved the study

Guarantor SS

Abstract

Objective To analyse data from a trial and report the frequencies with which major and minor errors are detected at a general medical journal, the types of errors missed and the impact of training on error detection.

Design 607 peer reviewers at the BMJ were randomized to two intervention groups receiving different types of training (face-to-face training or a self-taught package) and a control group. Each reviewer was sent the same three test papers over the study period, each of which had nine major and five minor methodological errors inserted.

Setting BMJ peer reviewers.

Main outcome measures The quality of review, assessed using a validated instrument, and the number and type of errors detected before and after training.

Results The number of major errors detected varied over the three papers. The interventions had small effects. At baseline (Paper 1) reviewers found an average of 2.58 of the nine major errors, with no notable difference between the groups. The mean number of errors reported was similar for the second and third papers, 2.71 and 3.0, respectively. Biased randomization was the error detected most frequently in all three papers, with over 60% of reviewers rejecting the papers identifying this error. Reviewers who did not reject the papers found fewer errors and the proportion finding biased randomization was less than 40% for each paper.

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.

Introduction

Peer reviewers are responsible for improving the quality of manuscripts to be published and 'should weed out serious methodological errors'.[1] Despite the use of peer review, errors, inconsistencies and methodological weaknesses are commonly found in published medical research[2–4] and peer review has been criticized as being an ineffective and expensive procedure.[5,6]

Three studies have reported on the rate of detection of errors by reviewers. The first used two fictitious reports submitted to all reviewers of a general medical journal and found that reviewers missed many of the deliberate errors in the manuscripts.[7] A second study introduced 10 major and 13 minor errors in a manuscript and distributed it to 262 reviewers of the *Annals of Emergency Medicine*.[8] Reviewers failed to identify two thirds of the major errors and about 7% recommended

J R Soc Med 101:507; 2008

JAMA 2004

ORIGINAL CONTRIBUTION

Empirical Evidence for Selective Reporting of Outcomes in Randomized Trials

Comparison of Protocols to Published Articles

An-Wen Chan, MD, DPhil
Asbjørn Hróbjartsson, MD, PhD
Mette T. Haahr, BSc
Peter C. Gøtzsche, MD, DrMedSci
Douglas G. Altman, DSc

Context Selective reporting of outcomes within published studies based on the nature or direction of their results has been widely suspected, but direct evidence of such bias is currently limited to case reports.

Objective To study empirically the extent and nature of outcome reporting bias in a cohort of randomized trials.

Design Cohort study using protocols and published reports of randomized trials approved by the Scientific-Ethical Committees for Copenhagen and Frederiksberg, Denmark, in 1994-1995. The number and characteristics of reported and unreported trial outcomes were recorded from protocols, journal articles, and a survey of trialists. An outcome was considered incompletely reported if insufficient data were presented in the published articles for meta-analysis. Odds ratios relating the completeness of outcome reporting to statistical significance were calculated for each trial and then pooled to provide an overall estimate of bias. Protocols

SELECTIVE PUBLICATION OF STUDIES with statistically significant results has received widespread recognition.[1] In contrast, selective reporting of favorable outcomes within published studies has

Author Affiliations: Centre for Statistics in Medicine, Institute of Health Sciences, Oxford, England (Drs Chan and Altman), Nordic Cochrane Centre, Copenhagen, Denmark (Drs Hróbjartsson and Gøtzsche and Ms Haahr), University Health Network, University of Toronto, Toronto, Ontario (Dr Chan).
Corresponding Author: An-Wen Chan, MD, DPhil, Centre for Statistics in Medicine, Institute of Health Sciences, Old Road, Headington, Oxford, England OX3 7LF (anwen.chan@utoronto.ca).

JAMA 2004

ORIGINAL CONTRIBUTION

Empirical Evidence for Selective Reporting of Outcomes in Randomized Trials

Comparison of Protocols to Published Articles

An-Wen Chan, MD, DPhil

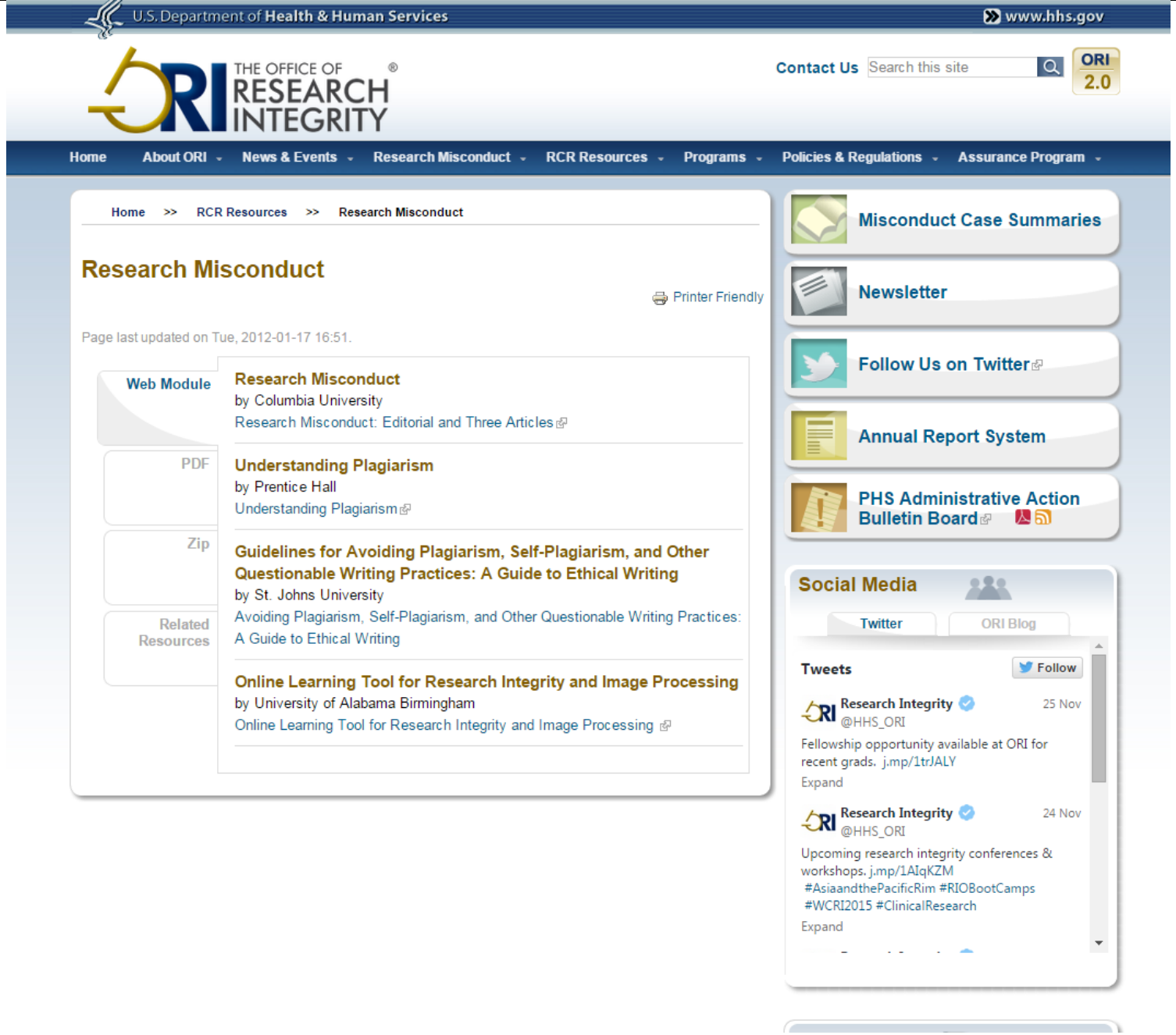
102 trials – 122 papers - 3736 outcome variables

50 % av effect variables and 65 % av harm variables in each paper were not reported

Significant variables were more often reported than non-significant – both for effect ; Odds ratio 2.4 (1.4-4.0) and for harm; Odds ratio 4.7 (1.8-12.0).

In papers based on 62 % of the studied trials at least one of the primary outcome variables were added – or subtracted.

86 % of the authors neglected the existence of modified outcome variables in spite of this being pointed out to them.



http://ori.hhs.gov/research-misconduct-0

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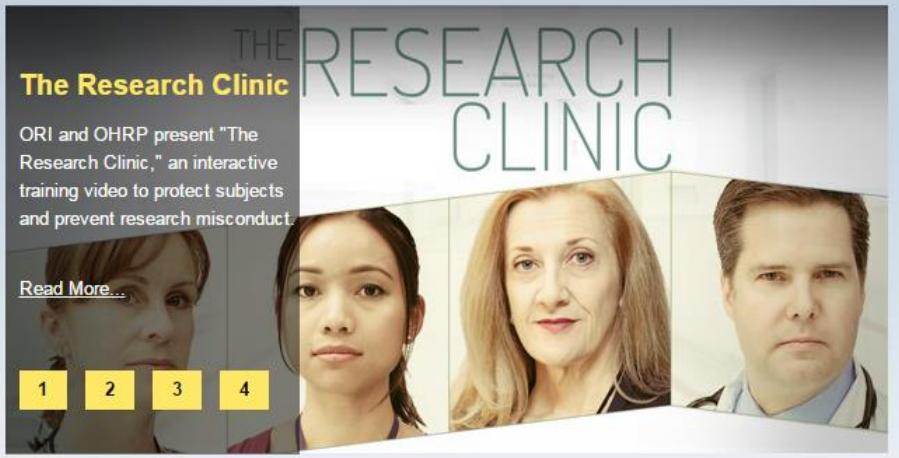

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Nov 20 — Doctoral Forum Available at the 4th WCRI
The organizing committee of the 4th World Conference on Research Integrity is pleased to announce that a Doctoral Forum will be held for the first time! The Forum will provide a unique opportunity for PhD students studying research integrity and/or the responsible conduct of research to get advice and comments from an international panel of specialists. The Doctoral Forum will provide an exciting, friendly and supportive environment for PhD students to share ideas and interact with participants!

Nov 20 — New Research Misconduct Finding: Igor Dzhura
ORI found that Dr. Igor Dzhura engaged in research misconduct by falsifying and fabricating data in research supported by U.S. Public Health Service (PHS) funds.

Oct 29 — New Research Misconduct Finding: Bijan Ahvazi
ORI found that Dr. Bijan Ahvazi engaged in research misconduct by falsifying data in the three published papers.

Oct 06 — Call for Proposals Extended to November 1, 2014
The 4th World Conference on Research Integrity, May 31-June 3, 2015 in Rio de Janeiro, invites proposals for presentations and posters. The conference theme is "Research Rewards and Integrity: Improving Systems to Promote Responsible Research."

Oct 01 — ORI announces postdoctoral fellowship position
A postdoctoral fellowship position is available at ORI. Applicants must earned doctorate within last five years and have experience with quantitative and qualitative research.

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Sweden, rocked by scientific scandals, re-thinking how it investigates misconduct

with one comment

The Swedish government is taking a second look at how it handles misconduct investigations.

According to a spokesperson:

> Yes, we have an national investigation ongoing since last autumn. It will investigate how misconduct is investigated and handled in Sweden…

She also sent us a link to a description of the investigation, in Swedish. The outcome of the investigation is expected in November, 2016.

The inquiry predates the media implosion that's taken place in recent months over the Karolinska Institutet's (KI) investigation of surgeon Paolo Macchiarini, who transplanted tracheas seeded with patients' own stem cells. Read the rest of this entry »

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Written by Alison McCook
February 25th, 2016 at 8:00 am

Posted in misconduct investigations,sweden retractions

Four retractions follow Swedish government findings of negligence, dishonesty

with 2 comments

A Swedish ethical review board has censured two biologists and their employer, Uppsala University, for events related to "extensive image manipulations" in five papers published between 2010 and 2014. The case has led to criticism from an outside expert — who brought the allegations to Uppsala — over the current system in Sweden for handling such investigations.

Four of the papers have been retracted, and the authors have requested a correction in the fifth.

After an eight-month investigation, in September the government-run Expert Group for Scientific Misconduct at the Central Ethical Review Board in Stockholm, Sweden, concluded that Uppsala professor Kenneth Söderhäll — who has published more than 200 papers — and lecturer Irene Söderhäll acted "negligently" and "dishonestly" by Read the rest of this entry »

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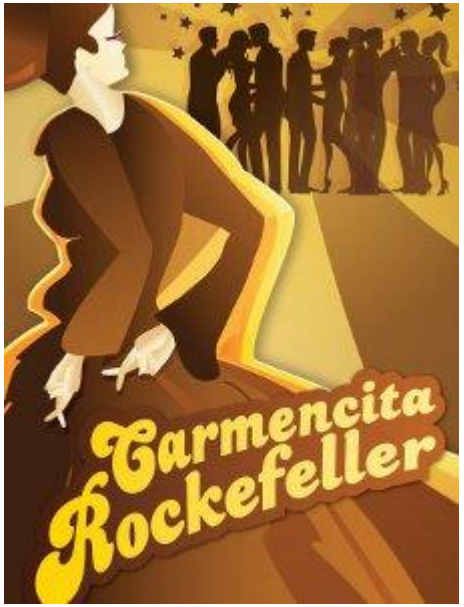
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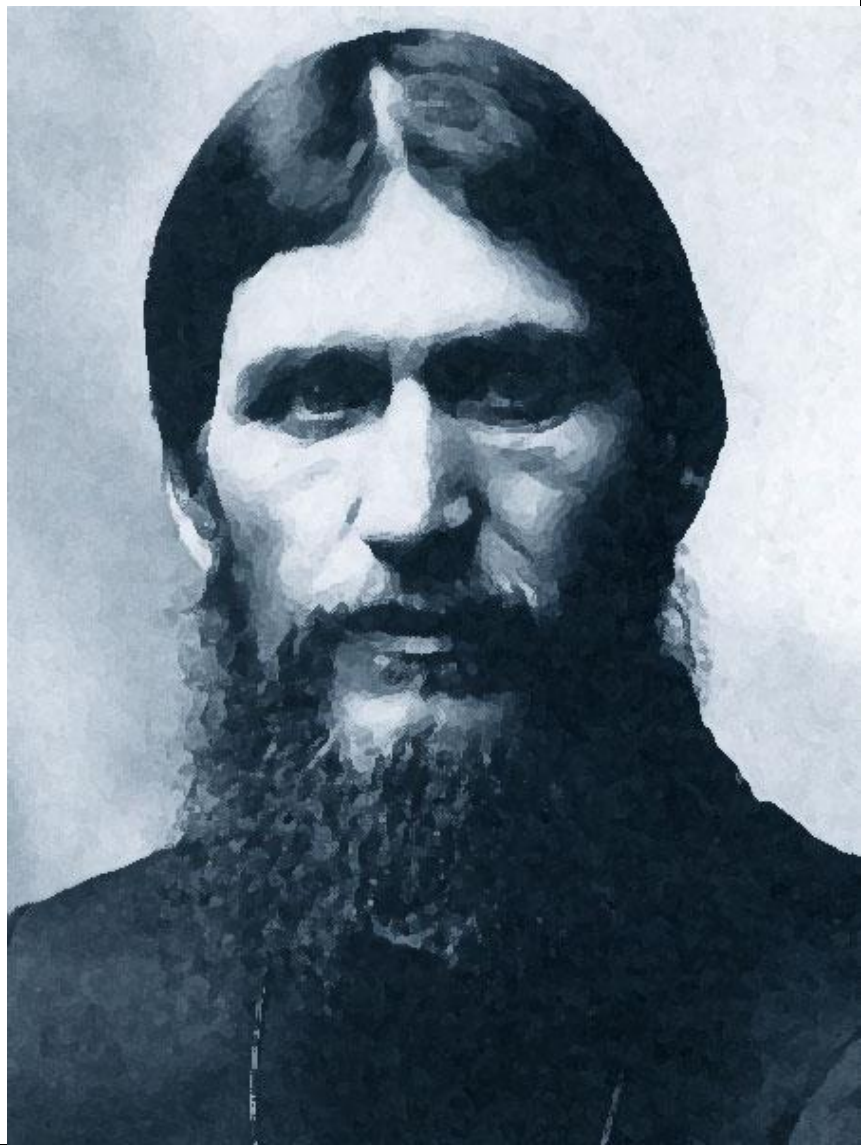


Hur definiera oredlighet i forskning?

Hur definiera forskning?

Centrala etikprövningsnämnden
CENTRAL ETHICAL REVIEW BOARD

2007-10-08

PM

Tillägg 2008-06-01
Se Centrala etikprövningsnämndens skrivelse ”Angående ändringar i lagen (2003:460) om etikprövning av forskning som avser människor (etikprövningslagen) m.m.” (bl.a. ny definition av begreppet forskning, se 2§)

Centrala etikprövningsnämndens praxis när det gäller forskningsbegreppet

Definition av forskningsbegreppet

Etikprövningslagen är tillämplig bara när det är fråga om forskning som avser människor. Om ett projekt inte innefattar forskning är lagen inte tillämplig och en ansökan om godkännande skall då inte prövas. Inte heller något rådgivande yttrande kommer i fråga i dessa fall.

I 2 § etikprövningslagen definieras forskning som ”vetenskapligt experimentellt eller teoretiskt arbete för att inhämta ny kunskap och utvecklingsarbete på vetenskaplig grund”

Definitionen är inte särskilt klargörande och föreslås ändrad i betänkandet SOU 2005:78. Den i betänkandet förslagna definitionen är mera logisk och utarbetad men torde knappast i realiteten underlätta bedömningarna.

Centrala etikprövningsnämnden
CENTRAL ETHICAL REVIEW BOARD

2007-10-08

PM

Tillägg 2008-06-01
Se Centrala etikprövningsnämndens skrivelse "Angående ändringar i lagen (2003:460) om etikprövning av forskning som avser människor (etikprövningslagen) m.m." (bl.a. ny definition av begreppet forskning, se 2§)

Vetenskaplig frågeställning och vetenskapliga metoder

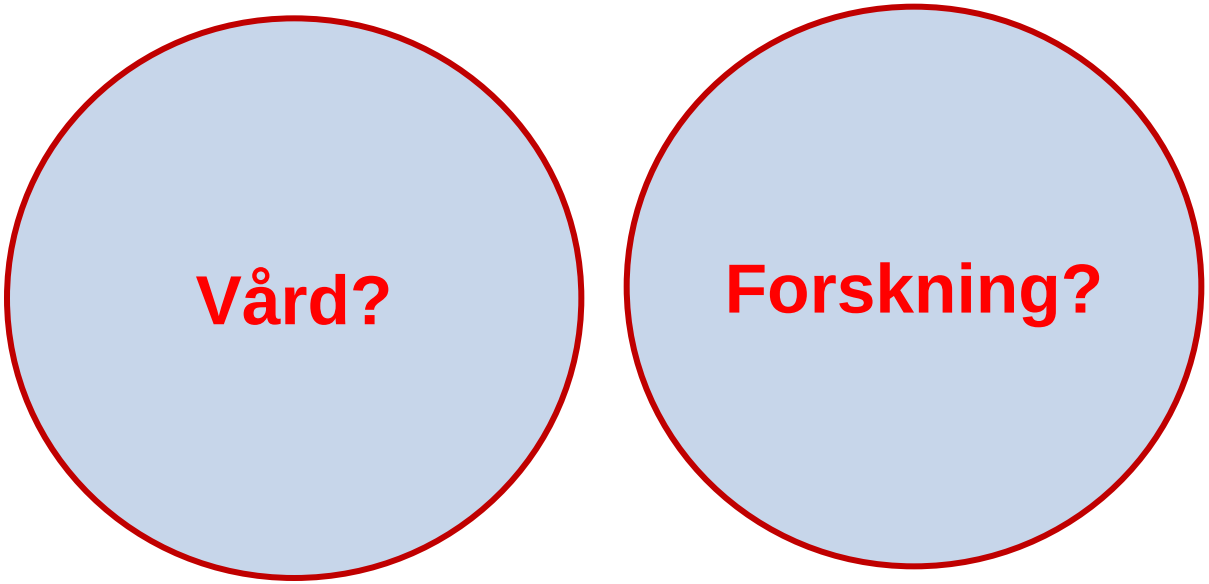
Det finns en rad olika definitioner som är mera upplysande än den som förekommer i etikprövningslagen. Oavsett vilken man vill använda, torde det stå klart att forskning förutsätter att det finns ett vetenskapligt syfte, dvs. en *inomvetenskapligt* relevant frågeställning som man avser att belysa på ett systematiskt sätt eller, om man så vill, med vetenskapliga metoder. Detta är i princip både nödvändiga och tillräckliga krav för att ett projekt skall rubriceras som forskning. Åtminstone i vissa fall krävs dessutom – som strax skall belysas närmare – en avsikt att göra resultaten tillgängliga.

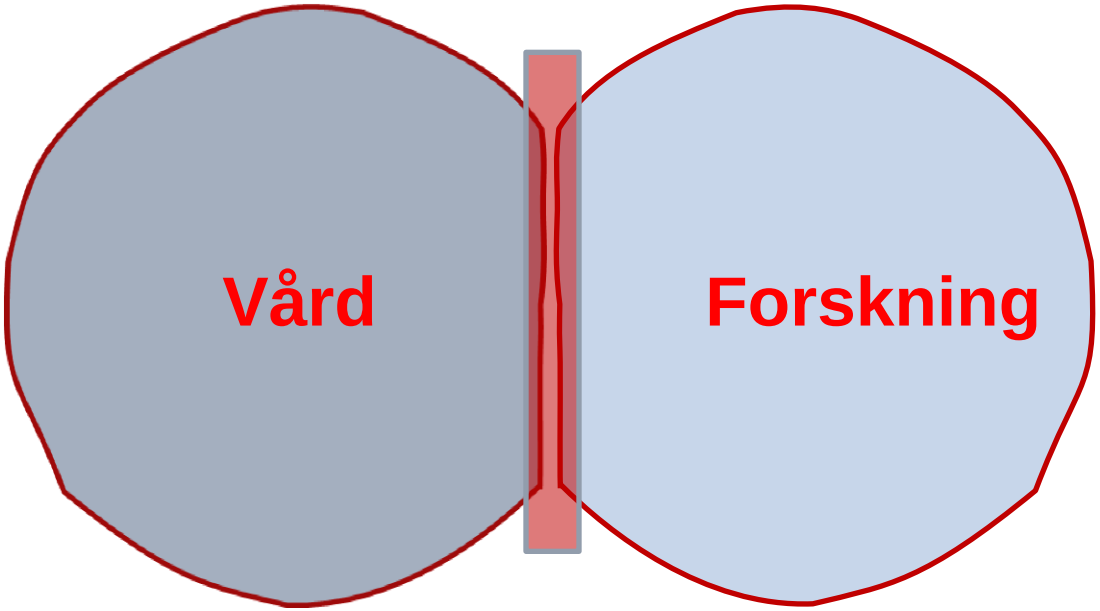
Frågan om det finns en inomvetenskapligt relevant frågeställning som är avsedd att belysas på ett godtagbart sätt är emellertid inte alltid så enkel att besvara. Som förut har sagts är det egentligen inte meningen att nämnderna skall lägga ned stora ansträngningar på att besvara denna fråga, vilken ju i praktiken prövas av många olika organ oberoende av etikprövningen. Resultatet kan bli närmast absurt, om t ex ett visst projekt erhåller forskningsanslag från Vetenskapsrådet under förutsättning att det godkänns vid etikprövningen men etikprövningsnämnden avböjer att göra denna prövning med hänvisning till att nämnden inte anser att projektet utgör forskning.

I Centrala etikprövningsnämndens praxis har utvecklats vissa hjälpregler för bedömningen av om ett projekt skall anses innefatta forskning.

Presumtioner

Centrala etikprövningsnämnden har således i åtskilliga fall framhållit att ett projekt är avsett att läggas till grund för en disputation eller annars ingå som en del i en doktorsavhandling eller att projektet skall utföras av eller under handledning av kvalificerade forskare. Detta bör uppfattas så att nämnden, när det inte finns


Vård?
Forskning?



Gränslandet

vad är vård

vad är forskning

Gränslandet

vad är vård

vad är forskning

”Det finns ett gränsland, men detta gränsland är gemensamt och inte särskiljande.”

Det gemensamma gränslandet

Allt som görs för den enskilde patienten är vård.

Det som görs för att ge kunskap åt nästa patient är forskning.

Att tolka något som vård och inte som forskning tar bort det skydd som etiklagstiftningen ger.

Att tolka något som vård och inte som forskning gör en utsatt patient i realiteten helst skyddslös

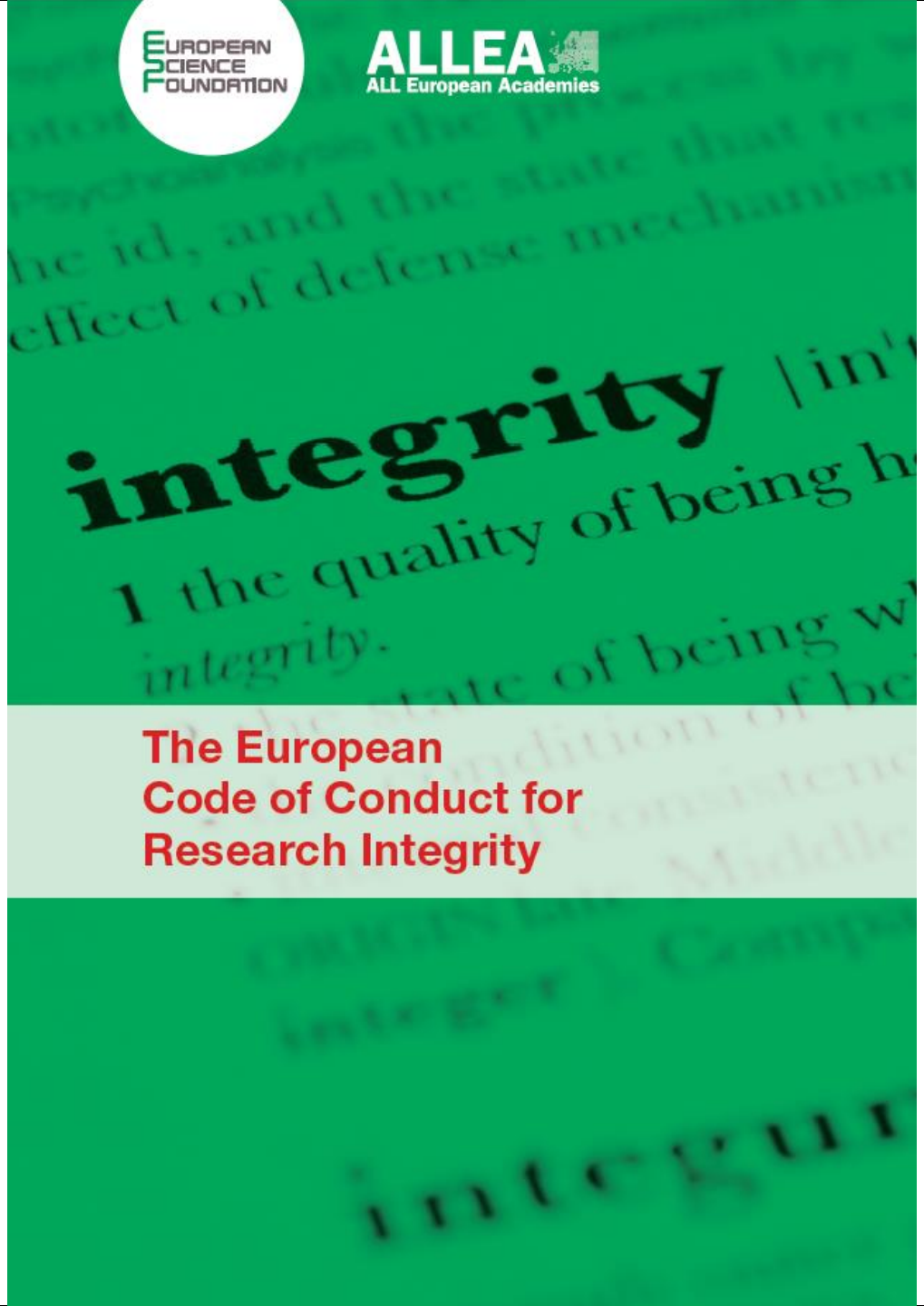
The Belmont Report

Ethical Principles and Guidelines for the Protection of Human Subjects of Research

The National Commission
for the Protection of Human Subjects
of Biomedical and Behavioral
Research

1979

Hur definiera oredlighet?



ESF VR är medlem

ALLEA KVA är medlem

FFP + etik av olika slag

”intentionally, knowlingly or recklessly”

uppsåtligen, medvetet eller med vårdslöshet

Rekommenderad läsning.
Laddas ner från
http://www.scienceeurope.org/downloads

FORTE
FORMAS
VR

Att ha olika definitioner av oredlighet i olika länder är som att ha olika definitioner för doping i ett OS eller VM. Inom Sverige är det som att ha olika definitioner för doping inom olika idrottsklubbar.

Macchiariniskandalen: nio olika universitet

Vem är oredlig?

PLOS ONE

RESEARCH ARTICLE

Misconduct Policies, Academic Culture and Career Stage, Not Gender or Pressures to Publish, Affect Scientific Integrity

Daniele Fanelli[1]*, Rodrigo Costas[2], Vincent Larivière[3]

Bibliographic and personal information were collected on all co-authors of papers that have been retracted or corrected in 2010-2011 (N=611 and N=2226 papers, respectively) and authors of control papers matched by journal and issue (N=1181 and N=4285 papers, respectively), and were analysed with conditional logistic regression.

Case - control på författare

Results, which avoided several limitations of past studies and are robust to different sampling strategies, support the notion that scientific misconduct is more likely in countries that lack research integrity policies, in countries where individual publication performance is rewarded with cash, in cultures and situations were mutual criticism is hampered, and in the earliest phases of a researcher's career. The hypothesis that males might be prone to scientific misconduct was not supported, and the widespread belief that pressures to publish are a major driver of misconduct was largely contradicted: high-impact and productive researchers, and those working in countries in which pressures to publish are believed to be higher, are less-likely to produce retracted papers, and more likely to correct them. Efforts to reduce and prevent misconduct, therefore, might be most effective if focused on promoting research integrity policies, improving mentoring and training, and encouraging transparent communication amongst researchers.

WORLD VIEW *A personal take on events*

UNIV. MICHIGAN PHOTO SERVICES

The road to fraud starts with a single step

The extensive academic fraud of Diederik ga- *psychologist* **Jennifer Crocker** *traces the c*

Fraud happens uncomfortably often — from financier Bernie Madoff to the (now imprisoned) real-estate developer who built the outsized house, recently foreclosed, in my neighbourhood. But it disturbs most when it happens close to our professional home.

Diederik Stapel, a social psychologist and author of many published papers, has resigned his position at Tilburg University in the Netherlands after admitting to fabricating data in his research (see *Nature*

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Nature 479:151, 2011

A HEAVY FOCUS ON **FRAUDSTERS** MAY ALSO CONVENIENTLY **DIVERT OUR** ATTENTION FROM THE FRAUDSTER WITHIN **US ALL.**

Crocker argues that taking questionable research practice seriously at an early stage in a researcher's career is vital, since every minor transgression that goes against the norms of behaviour of the 'good' researcher and is uncorrected, can

Efter Macchiarini

En dystopi

Till sist

Vad kan nu gå fel?

Rätt förhoppning – fel åtgärd

Den mest oredliga forskningen är den som går under radarn!!

Fostering a culture of scientific integrity! Börjar högst upp!

Praktisk - etisk kunskapskropp som processtöd.

Bättre rättsprocess när något redan hänt