Πανεπιστήμιο Δυτικής Αττικής
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School of Public Health

ΤΜΗΜΑ ΠΟΛΙΤΙΚΩΝ ΔΗΜΟΣΙΑΣ ΥΓΕΙΑΣ
Public Health Policy Department

Ακεραιότητα στην Επιστημονική Έρευνα (Research Integrity)

Τ.Γκαράνη-Παπαδάτου©
Τμημα Πολιτικών Δημόσιας υγείας
Σχολή Δημόσιας υγείας
Πανεπιστημιο Δυτικής Αττικής

Το σύγχρονο πρόσωπο της επιστημονικής έρευνας

- Διεπιστημονική και πολύπλοκη
- Υψηλά ανταγωνιστική
- Διεθνής και παγκόσμια
- Με ιδιωτική, φιλανθρωπική ή δημόσια χρηματοδότηση
- Συνεργασία με βιομηχανία
- Προκλητική, αμφιλεγόμενη….
- Εξαιρετικά γρήγορη
- **Ευεργετική** …

- Πολύπλοκο περιβάλλον σχέσεων
- Αυξημένη ορατότητα της μη ορθής ερευνητικής πρακτικής
- Online δημοσιεύσεις και υψηλότερο ποσοστο σφαλμάτων
- Whistle-blowing
- Αύξηση συλλογής, χρήσης, επεξεργασίας και μεταβίβασης δεδομένων και βιολογικών

Πως εμφανίζεται η ακεραιότητα στην έρευνα και την επιστημονική πρακτική

- Ως ο απαραβίαστος *κανονιστικός πυρήνας* της επιστημονικής έρευνας
- Ως μια αφηρημένη *αρετή*, συνδεδεμένη με την ηθική ως σύνολο (Beauchamp and Childress)
- Ως η *υποχρέωση* συμμόρφωσης με τα υψηλότερα ηθικά ιδεώδη (Κώδικες Δεοντολογίας)
- Ως η *συνήθεια* (habit) και η *στάση* (attitude) του ερευνητή να διεξάγει έρευνα σύμφωνα με τα αντίστοιχα ηθικά, νομικά και επαγγελματικά πλαίσια,
- Ως η *ευθύνη* των ερευνητών για τη φερεγγυότητα της έρευνας τους (The Singapore Statement on Research Integrity)

Απο μια άλλη οπτική:

Ως η ακεραιότητα του υποκειμένου της έρευνας η οποία πρέπει να προστατεύεται (CIOMS 2002) – physical/mental/bodily integrity

Μη γραμμική εξέλιξη …

- **1830:** Charles Babbage: – “Reflections on the decline of science in England and on some of its causes”
- **1929**: Ludwig Fleck: *Zur Krise der Wirklichkeit*
- **1930:** Julius Moses (1868-1942) : The Lübeck case -1930 (Εμβολιασμός BCG)
- **1931:** German *Richthlinien*
- **1947:** Κώδικας της Νυρεμβέργης (10 βασικές αρχές) – και μεταγενέστερες φάσεις
- **1990:** NIH Guide (1990): Requirements for Programs on the Responsible Conduct of Research in National Research Service

Ludwig Fleck: “Genesis and development
of a scientific fact»

Η ακεραιότητα ως ατομικό ζήτημα

α) η ηθική σύλληψη της ακεραιότητας ως απαραίτητης προϋπόθεσης

(θετική προσέγγιση)…

- για τη δημιουργία και την κατανόηση κανόνων
- για τη δημιουργία εργαλείων μέτρησης και πρόληψης
- για το σχεδιασμό μεθόδων και οδηγιών αντιμετώπισης του φαινομένου

β) η μη ορθή ερευνητική πρακτική (research misconduct)

ως η συμπεριφορά [που παραβιάζει την αρχή (“αρνητική”προσέγγιση)

Η ακεραιότητα ως συστημικό ζήτημα

Robert Merton (1910-2003) : ο ρόλος του συστήματος στην επιστημονική συμπεριφορά και η έννοια της «ανομίας στην επιστήμη»

1947: Mertonian Norms (1942) CUDOS i.e.
Communalism, **U**niversalism, **D**isinterestedness, **O**riginality and **S**kepticism

John Ziman (P, L, A, C, E)

Τα δεδομένα:

- Υπαρξη σημαντικών προκλήσεων στις οποίες έχει να απαντήσει ο σχεδιασμός και η ανάπτυξη της επιστημονικής έρευνας
- Αύξηση περιπτώσεων μη-ορθής διεξαγωγής έρευνας
- Δεκαπλασιασμός αποσύρσεων δημοσιευμένων άρθρων(retraction)
- Ισχυρός ανταγωνισμός

και οι συνέπειες …

- Κρίση αξιοπιστίας
- Απειλή για την οικονομική, πολιτική και κοινωνική υποστήριξη της επιστημονικής έρευνας
- Απειλή για την αυτονομία ερευνητών και ακαδημαϊκών
- Απειλή για τους ίδιους τους συμμετέχοντες
- Ερωτήματα για την τύχη των ίδιων των ερευνητών
- Οικονομικό κόστος πιθανών δικαστικών αγώνων.

Το ευρωπαϊκό θεσμικό πλαίσιο

- ESF (European Science Foundation) και η Ευρωπαϊκή Ομοσπονδία Ακαδημιών της Επιστήμης και Κλασικών Σπουδών (European Federation of Academies of Sciences and Humanities - ALLEA)

  European Code of Conduct for Research Integrity

- Science Europe Working Group on Research Integrity - Task Group «Knowledge Growth»

  Seven reasons to care about integrity in research

- **ENERI** European Network of Research Ethics and Research Integrity

  Godecharle, S., Nemery, B., Dierickx, K. (2013) Guidance on research integrity: no union in Europe. *The Lancet* 381**:** 1097–98.

European Science Foundation (ESF) Report

- τιμιότητα στην επικοινωνία
- φερεγγυότητα στη διενέργεια της έρευνας
- αντικειμενικότητα
- αμεροληψία και ανεξαρτησία
- διαφάνεια και προσβασιμότητα
- καθήκον φροντίδας
- ισότητα στην παροχή βιβλιογραφίας και στην αναγνώριση του έργου των άλλων
- ευθύνη για τους επιστήμονες και τους ερευνητές του μέλλοντος

European Science Foundation 2010:
"Fostering Research Integrity"
Μη ορθή διεξαγωγή της έρευνας
Research misconduct→ FFP

1. **F**abrication: χάλκευση, κατασκευή των δεδομένων της έρευνας
   → δεδομένα εξ ολοκλήρου πλαστά τα οποία παρουσιάζονται ως αληθινά

2. **F**alsification: παραποίηση των αποτελεσμάτων της ερευνητικής διαδικασίας η αλλαγή ή παράλειψη δεδομένων ή αποτελεσμάτων
   → το τελικό ερευνητικό αποτέλεσμα δεν είναι ακριβές

3. **P**lagiarism: λογοκλοπή, αντιγραφή: ιδιοποίηση ιδεών, αποτελεσμάτων ή εκφράσεων άλλου προσώπου χωρίς αναφορά στο όνομα του, συμπεριλαμβανομένων και αυτών που έχουν δοθεί στα πλαίσια εμπιστευτικής ανασκόπησης ερευνητικών προτάσεων ή γραπτών άλλων ερευνητών.

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4. Αμφισβητούμενες ερευνητικές πρακτικές (**Q**uestionable **R**esearch **P**ractices).

Γκρίζα περιοχή πρακτικών οι οποίες δεν αλλοιώνουν ευθέως και το ερευνητικό αποτέλεσμα αλλά συμβάλουν στη δυσφήμιση των ερευνητών και της ερευνητικής κοινότητας, με αρνητικό αντίκτυπο στην εμπιστοσύνη της κοινωνίας στην έρευνα

π.χ. Guest authorship
Gift authorship
'salami slicing' publication
failure to disclose conflicts of interest

Leslie K. John, George Loewenstein, and Drazen Prelec (2012) **Measuring the Prevalence of Questionable Research Practices With Incentives for Truth Telling** Psychological Science 23(5) 524– 532 – Ερευνα σε 2,000 ψυχολόγους

Fanelli 2009:

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

- 1.97% (N = 7, 95%CI: 0.86–4.45) of scientists admitted to have fabricated, falsified or modified data or results at least once..
- up to 33.7% admitted other questionable research practices.
- Paper retractions from the PubMed library due to misconduct

  a frequency of 0.02% (=> 0.02 - 0.2%) fraudulent papers
- 8 of 800 papers submitted to *The Journal of Cell Biology* -→ had digital images that had been improperly manipulated, suggesting a 1% frequency
- Routine data audits (FDA) in 10–20% of studies, and led to 2% of clinical investigators being judged guilty of serious scientific misconduct

Επιστημονική Απάτη

(Scientific Fraud)

διάπραξη με δόλο επιστημονικής απάτης

(π.χ. κατασκευή δεδομένων)

Εμπλοκή ποινικού δικαίου

Ψεύδη δια παραλείψεως; (lying by omission)

συνειδητή απάτη ; (conscious fraud)

PLOS BIOLOGY

PERSPECTIVE

The credibility crisis in research: Can economics tools help?

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Abstract

The issue of nonreplicable evidence has attracted considerable attention across biomedical and other sciences. This concern is accompanied by an increasing interest in reforming research incentives and practices. How to optimally perform these reforms is a scientific problem in itself, and economics has several scientific methods that can help evaluate research reforms. Here, we review these methods and show their potential. Prominent among them are mathematical modeling and laboratory experiments that constitute affordable ways to approximate the effects of policies with wide-ranging implications.

OPEN ACCESS

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Introduction

Serious worries have been voiced concerning a "reproducibility crisis" in many biomedical as well as social sciences; this crisis of confidence is fueled by the observation that numerous established findings may correspond to false positives that cannot be reproduced [1–5]. In response to the aforementioned concerns, several reforms have been put forward in various disciplines, purported to increase reproducibility [6]. Special focus has been placed on reforming researcher incentives [7,8,9], and some specific proposals have attracted considerable attention [10,11,12]. However, the study of behavioral responses to incentives is typically not the main focus of biomedical disciplines.

Behavioral responses to incentives may be evaluated with some modeling approaches followed in economics and related disciplines (e.g., political science). These disciplines have a policy focus, supported by the systematic study of how behavior responds to incentives. Formal economic tools are continually evolving and can be usefully employed for any policy analysis, but as yet they tend to be relatively unknown to the biomedical community. It is important to better understand these tools, especially when so many critical reforms of academic structures and incentives are being proposed. In this paper, our objectives are, first, to illustrate the possible benefits of economic analysis with concrete examples from existing reforms in which this analysis provides new insights and, second, to provide a relatively broad

Οι ειδικές συνέπειες για τη Δημόσια Υγεία

- 1980s Γαλλια: Το σκάνδαλο του αίματος και “the blood research community”

  Peter D. Weinberg et al: Legal, Financial, and Public Health Consequences of HIV Contamination of Blood and Blood Products in the 1980s and 1990s

- UK mad cow disease – σκάνδαλα αμιάντου
- The SUPPORT trial παροχή οξυγόνου στα νεογέννητα και κίνδυνος τύφλωσης – ζητήματα ασφάλειας (safety) και καθήκον φροντίδας

- Κοκκύτης (pertussis) ΗΠΑ, Καναδάς και Ιαπωνία - Δοκιμές σε Ιταλία και Σουηδία

- Andrew Wakefield, The Lancet 1998

  The Vaccine-Autism Connection: a public health crisis caused by unethical medical practices and fraudulent science (2011)45 Annals of Pharmacotherapy

2010: Observations GMC Wakefield Verdict ***Why did the Lancet take so long?***

BMJ 2010; 340 doi: https://doi.org/10.1136/bmj.c644 (Published 02 February 2010) Cite this as: BMJ 2010;340:c644

INFECTION AND IMMUNITY, Oct. 2011, p. 3855–3859 Vol. 79, No. 10
0019-9567/11/$12.00 doi:10.1128/IAI.05661-11

EDITORIAL

Retracted Science and the Retraction Index

«Articles may be retracted when their findings are no longer considered trustworthy due to scientific misconduct or error, they plagiarize previously published work, or they are found to violate ethical guidelines. Using a novel measure that we call the "retraction index," we found that the frequency of retraction varies among journals and shows a strong correlation with the journal impact factor. Although retractions are relatively rare, the retraction process is essential for correcting the literature and maintaining trust in the scientific process.»

Εξέλιξη διεθνούς ενδιαφέροντος

2007: 1ο Παγκόσμιο Συνέδριο για την Ακεραιότητα στην Έρευνα – Λισαβόνα
European Science Foundation (ESF)
Office of Research Integrity – ORI, USA

2010: 2ο Παγκόσμιο Συνέδριο για την Ακεραιότητα στην Έρευνα -Σιγκαπούρη
The Singapore Statement on Research Integrity →

2013: 3ο Παγκόσμιο Συνέδριο για την Ακεραιότητα στην Έρευνα – Μόντρεαλ
The Montreal Statement on Research Integrity

2015: 4ο Παγκόσμιο Συνέδριο για την Ακεραιότητα στην Έρευνα -Ρίο ντε Τζανέιρο

2017: 5ο Παγκόσμιο Συνέδριο για την Ακεραιότητα στην Έρευνα -Amsterdam
Amsterdam Agenda for Promoting Transparency and Accountability

2019: 6ο Παγκόσμιο Συνέδριο για την Ακεραιότητα στην Έρευνα – Hong-Kong
Hong Kong Principles for assessing researchers

2022: 7ο Παγκόσμιο Συνέδριο για την Ακεραιότητα στην Έρευνα –Cape Town

2024: 8ο Παγκόσμιο Συνέδριο για την Ακεραιότητα στην Έρευνα ΑΘΗΝΑ 2-5 Ιουνίου

Cancer Research UK: eight types of relationships between investigators and sponsors that constitute a CoI (industrial conflict of interest?)

- Εργασία, διευθυντική θέση, ηγετική θέση
- Συμβουλευτικός ρόλος -Advisory role (paid or unpaid)
- Κατοχή μετοχών - Stock ownership or options
- Άλλο άμεσο ή έμμεσο οικονομικό συμφέρον - Any other direct or indirect financial interest (e.g., via rewards to inventors)
- Αμοιβές για διαλέξεις , παρουσιάσεις ή εμφανίσεις Honoraria-payments for specific speeches, seminar presentations, or appearances
- Χορηγία έρευνας -Research funding
- Καταθέσεις εμπειρογνωμόνων - Expert testimony
- Άλλες μορφές αμοιβής (ταξίδια, δώρα, πληρωμές εις είδος κλπ) - Other remuneration (trips, gifts, in-kind payments, etc.)

R.B.Ghooi Conflict of interest in clinical research

Perspect Clin Res. 2015 Jan-Mar; 6(1): 10–14.

COPE Committee on Publication Ethics - 1997

Promoting integrity in research and its publication

Βασικές δράσεις

1. Ισχυρισμοί μη ορθής διεξαγωγής της έρευνας
2. Συγγραφή και συμβολή
3. Ενστάσεις και παράπονα
4. Σύγκρουση συμφερόντων
5. Δεδομένα και επαληθευσιμότητα
6. Ηθικός έλεγχος
7. Πνευματική ιδιοκτησία
8. Διαχείριση περιοδικού
9. Αξιολόγηση
10. Συζητήσεις και διορθώσεις μετά τη δημοσίευση

COPE…

- Guidelines for Editors
- Guidelines for Peer Reviewers
- Guidelines for Authors

2014 : Principles of Transparency and Best Practice in Scholarly Publishing **(COPE, http://publicationethics.org/)**

- ✓ Peer review process
- ✓ Governing Body
- ✓ Editorial team/contact information
- ✓ Author fees
- ✓ Copyright
- ✓ Process for identification of and dealing with allegations of research misconduct
- ✓ Ownership and management ……

UNIVERSITY of CALIFORNIA PRESS | Collabra

Vazire, S. (2017). Quality Uncertainty Erodes Trust in Science. *Collabra: Psychology*, 3(1): 1, DOI: https://doi.org/10.1525/collabra.74

PERSPECTIVE/OPINION

Quality Uncertainty Erodes Trust in Science

Simine Vazire

When consumers of science (readers and reviewers) lack relevant details about the study design, data, and analyses, they cannot adequately evaluate the strength of a scientific study. Lack of transparency is common in science, and is encouraged by journals that place more emphasis on the aesthetic appeal of a manuscript than the robustness of its scientific claims. In doing this, journals are implicitly encouraging authors to do whatever it takes to obtain eye-catching results. To achieve this, researchers can use common research practices that beautify results at the expense of the robustness of those results (e.g., p-hacking). The problem is not engaging in these practices, but failing to disclose them. A car whose carburetor is duct-taped to the rest of the car might work perfectly fine, but the buyer has a right to know about the duct-taping. Without high levels of transparency in scientific publications, consumers of scientific manuscripts are in a similar position as buyers of used cars – they cannot reliably tell the difference between lemons and high quality findings. This phenomenon – quality uncertainty – has been shown to erode trust in economic markets, such as the used car market. The same problem threatens to erode trust in science. The solution is to increase transparency and give consumers of scientific research the information they need to accurately evaluate research. Transparency would also encourage researchers to be more careful in how they conduct their studies and write up their results. To make this happen, we must tie journals' reputations to their practices regarding transparency. Reviewers hold a great deal of power to make this happen, by demanding the transparency needed to rigorously evaluate scientific manuscripts. The public expects transparency from science, and appropriately so – we should be held to a higher standard than used car salespeople.

Keywords: transparency; open science; replicability; scientific integrity

In any market, consumers must evaluate the quality of products and decide their willingness to pay based on their evaluation. In science, consumers of new scientific findings must likewise evaluate the strength of the findings and decide their willingness to put stock in them. In both kinds of markets, the inability to make informed and accurate evaluations of quality (i.e., quality uncertainty) leads to a lower and lower willingness to put stock in any product – a lack of trust in the market itself. When there are asymmetries in the information that the seller and the buyer have, the buyers cannot be certain about the quality of the products, leading to quality uncertainty.

In science, quality uncertainty threatens people's ability to have confidence in findings and build on them. Here I argue that the lack of transparency in science has led to quality uncertainty, and that this threatens to erode trust

In his paper, "The Market for "Lemons": Quality Uncertainty and the Market Mechanism" (1970), Nobel-Prize-winning economist George Akerlof illustrates this dynamic with the used car market. In this market, the seller has much more information than the buyer, making the buyer uncertain about the quality of any individual car, and thus unwilling to pay much for used cars. At extreme levels of quality uncertainty, the result is that no one is willing to buy a used car at any price – people lose all trust in the market.

There is a parallel with scientific products. In this case, the product is the manuscript or journal article, the seller is the author, and the buyer can be the journal editor, reviewers, or readers of the article – anyone who is choosing whether or not to buy the findings. The source of quality uncertainty in this market is that the authors know much more about what went into the article than do the

Medicine, Health Care and Philosophy
https://doi.org/10.1007/s11019-018-9865-7

SCIENTIFIC CONTRIBUTION

Criminalization of scientific misconduct

William Bülow[1] · Gert Helgesson[2]

Abstract
This paper discusses the criminalization of scientific misconduct, as discussed and defended in the bioethics literature. In doing so it argues against the claim that fabrication, falsification and plagiarism (FFP) together identify the most serious forms of misconduct, which hence ought to be criminalized, whereas other forms of misconduct should not. Drawing the line strictly at FFP is problematic both in terms of what is included and what is excluded. It is also argued that the criminalization of scientific misconduct, despite its anticipated benefits, is at risk of giving the false impression that dubious practices falling outside the legal regulation "do not count". Some doubts are also raised concerning whether criminalization of the most serious forms of misconduct will lower the burdens for universities or successfully increase research integrity. Rather, with or without criminalization, other measures must be taken and are probably more important in order to foster a more healthy research environment.

Keywords Criminalization · Fabrication · Falsification · Plagiarism · Scientific misconduct

Introduction

Scientific misconduct and fraud is a prevailing problem in science and threatens to undermine integrity, credibility and objectivity in research (Fanelli 2009; Pickett and Roche 2018). It also risks undermining trust, both among researchers and the general public (Shamoo and Resnik 2009; Hansson 2011; Resnik 2014). It is therefore important to consider the possible means of countering fraud and misconduct in research. The perhaps most drastic suggestion is that at least the most serious forms of fraud and misconduct, such as fabrication and falsification, should be criminalized and, when it has occurred, punished (Redman and Caplan 2005, 2015; Sovacool 2005; Bhutta and Crane 2014; Pickett and Roche 2018). By criminalization we here mean the decision of making some action a criminal offense for which one may merit criminal punishment, such as fines, community service or even incarceration.

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The need for criminalization of scientific misconduct has been defended in the bioethics literature (see e.g., Bhutta and Crane 2014; Redman and Caplan 2005, 2015; Sovacool 2005; Pickett and Roche 2018). However, from a philosophical point of view, the decision to criminalize a particular action stands in need of a moral justification. Criminal punishment, such as imprisonment, involves either intentional harm or the intentional deprivation of some good, such as liberty. It also has negative consequences for family members and those socially, economically and emotionally dependent on the person being punished. Granted that there is a *prima facie* duty not to intentionally harm others, a moral justification for criminalizing a certain behavior, and thereby allowing for the imposition of punishment, is therefore required.

Among those who defend the need of criminalizing serious scientific misconduct, the assumption is often made that fabrication, falsification and plagiarism (FFP) are the most serious forms of misconduct (Bhutta and Crane 2014; Sovacool 2005). In line with this assumption, it has been argued that these are the types of misconduct that should be criminalized, whereas other forms of misconduct, such as selective presentation of results, sloppiness and inappropriate use of statistics, are explicitly excluded (Sovacool 2005).

Ελληνική Πρωτοβουλία

EARTHnet

Ethical Aspects in Research and Technology for Human Network

= ελληνική πρωτοβουλία ΕΜΠ

→ ευαισθητοποίηση επιστημονικής κοινότητας

→ δίκτυο επικοινωνίας

→ προώθηση πλαισίου ΕΑ στην Ελλάδα

Γνωστες περιπτωσεις research misconduct

- Hwang Woo-Suk: Evidence of a Pluripotent Human Embryonic Stem Cell Line derived from a Cloned Blastocyst, Science 2004, 2005

- Milena Penkowa (γεν, 1973) νευροεπιστήμη

- P. Macchiarini – Karolinska Institute - μεταμοσχεύσεις τραχείας

- Vuorinen et al : shifts in the Enjoyment of Healthy and Unhealthy Behaviors Affect Short- and Long-Term Postbariatric Weight Loss

  Bariatric Surgical Practice and Patient Care 2017 ;12(1): 35–42

- Herndon JM (2016) Human and Environmental Dangers Posed by Ongoing Global Tropospheric Aerosolized Particulates for Weather Modification.
  Front. Public Health 4:139. doi: 10.3389/fpubh.2016.00139

- Andrew Wakefield, The Lancet 1998

  The Vaccine-Autism Connection: a public health crisis caused by unethical medical practices and fraudulent science (2011)45 Annals of Pharmacotherapy