# Assessing Quality, Transparency, and Reporting of Individual Studies

**The National Academies of Sciences,**
**Engineering, and Medicine,**
**25 February 2026**

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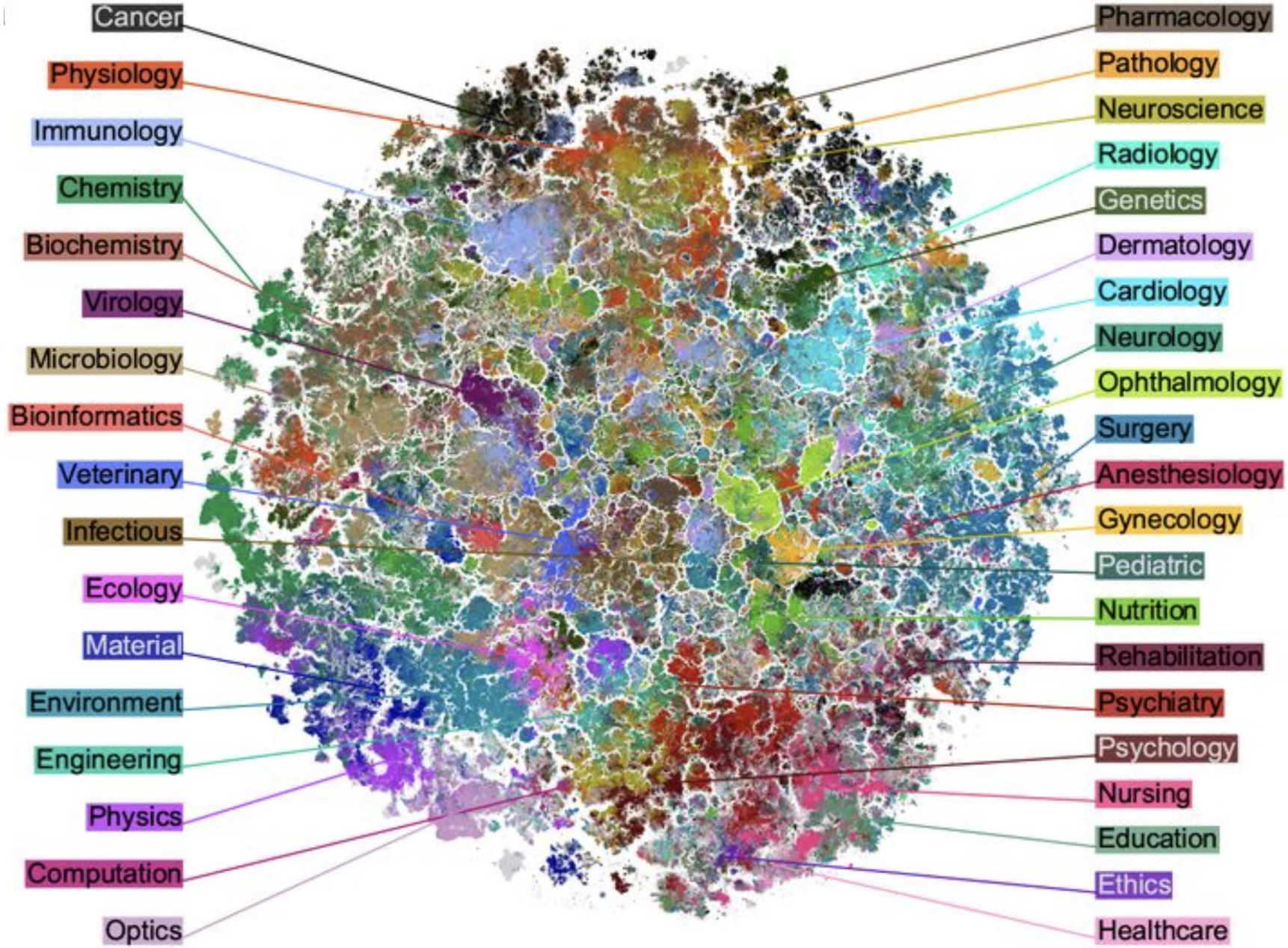
Institute of Health Policy, Management and Evaluation, Dalla Lana School of Public Health, uToronto

# What do we mean by an individual study

- Case-control study as part of a ‘traditional’ review
- Systematic review as part of an umbrella review

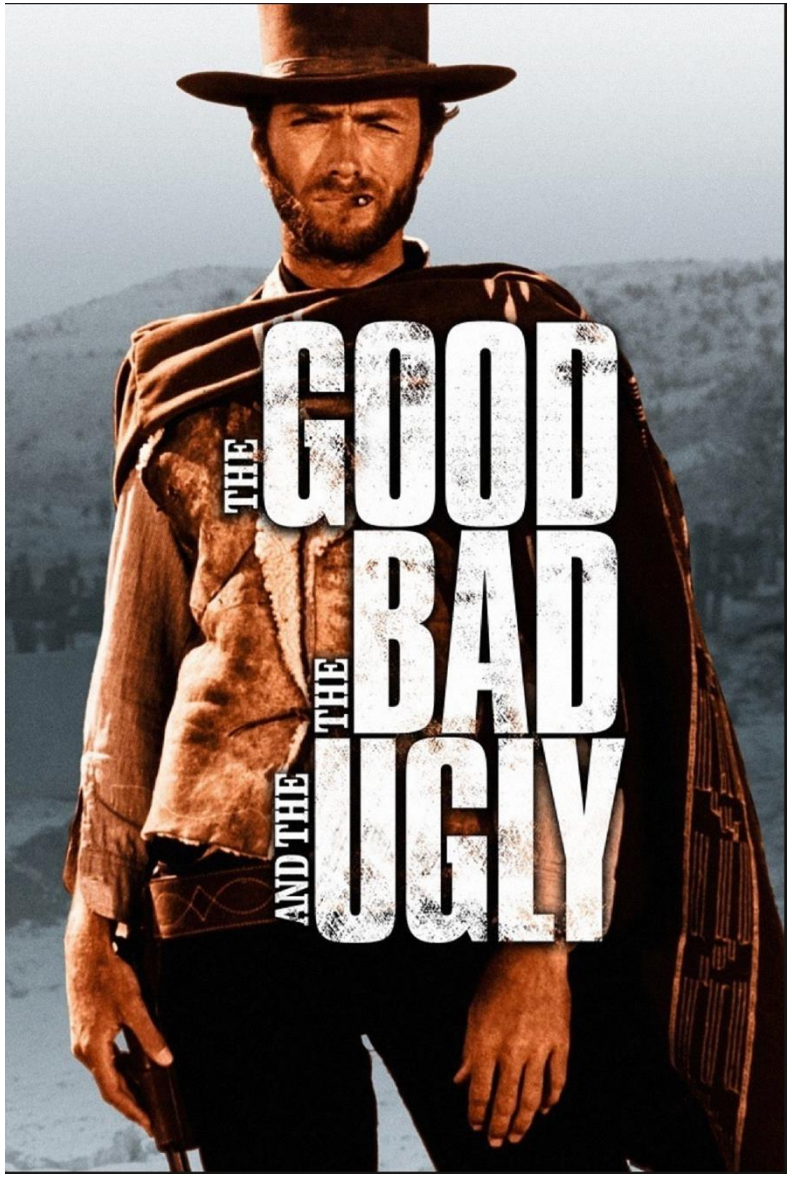
# Methods summary in the 2011 report

- Use **prespecified methods and publicly available protocols** to minimize author bias, document any protocol changes, and make the review process transparent and reproducible
- Recommends comprehensive searching, rigorous screening, and standardized data extraction
- Review teams assess the **quality and risk of bias of individual primary studies**, including attention to funding sources and other design features that may distort results.
- Calls for structured qualitative and quantitative synthesis that explicitly evaluates the **overall strength, limitations, and applicability** of the body of evidence
- Urges sponsors and methodologists to adopt and regularly update SR standards, invest in training, and improve methods and infrastructure (e.g., use of trial registries and other sources of unpublished data) so that systematic reviews provide more reliable, transparent evidence for clinical and policy decisions




**Denominator: 1.5 million publications, annually**

Rita González-Márquez, Luca Schmidt, Benjamin M. Schmidt, Philipp Berens, Dmitry Kobak **doi:** https://doi.org/10.1101/2023.04.10.536208


THE GOOD
THE BAD
AND THE UGLY

# The good (paper)

The NEW ENGLAND JOURNAL of MEDICINE

ORIGINAL ARTICLE

## Dexamethasone in Hospitalized Patients with Covid-19 — Preliminary Report

The RECOVERY Collaborative Group*

ABSTRACT

**BACKGROUND**

Coronavirus disease 2019 (Covid-19) is associated with diffuse lung damage. Glucocorticoids may modulate inflammation-mediated lung injury and thereby reduce progression to respiratory failure and death.

**METHODS**

In this controlled, open-label trial comparing a range of possible treatments in patients who were hospitalized with Covid-19, we randomly assigned patients to receive oral or intravenous dexamethasone (at a dose of 6 mg once daily) for up to 10 days or to receive usual care alone. The primary outcome was 28-day mortality. Here, we report the preliminary results of this comparison.

**RESULTS**

A total of 2104 patients were assigned to receive dexamethasone and 4321 to receive usual care. Overall, 482 patients (22.9%) in the dexamethasone group and 1110 patients (25.7%) in the usual care group died within 28 days after randomization (age-adjusted rate ratio, 0.83; 95% confidence interval [CI], 0.75 to 0.93; P<0.001). The proportional and absolute between-group differences in mortality varied considerably according to the level of respiratory support that the patients were receiving at the time of randomization. In the dexamethasone group, the incidence of death was lower than that in the usual care group among patients receiving invasive mechanical ventilation (29.3% vs. 41.4%; rate ratio, 0.64; 95% CI, 0.51 to 0.81) and among those receiving oxygen without invasive mechanical ventilation (23.3% vs. 26.2%; rate ratio, 0.82; 95% CI, 0.72 to 0.94) but not among those who were receiving no respiratory support at randomization (17.8% vs. 14.0%; rate ratio, 1.19; 95% CI, 0.91 to 1.55).

**CONCLUSIONS**

In patients hospitalized with Covid-19, the use of dexamethasone resulted in lower 28-day mortality among those who were receiving either invasive mechanical ventilation or oxygen alone at randomization but not among those receiving no respiratory support. (Funded by the Medical Research Council and National Institute for Health Research and others; RECOVERY ClinicalTrials.gov number, NCT04381936; ISRCTN number, 50189673.)

The members of the writing committee (Peter Horby, F.R.C.P., Wei Shen Lim, F.R.C.P., Jonathan R. Emberson, Ph.D., Marion Mafham, M.D., Jennifer L. Bell, M.Sc., Louise Linsell, D.Phil., Natalie Staplin, Ph.D., Christopher Brightling, F.Med. Sci., Andrew Ustianowski, Ph.D., Einas Elmahi, M.Phil., Benjamin Prudon, F.R.C.P., Christopher Green, D.Phil., Timothy Felton, Ph.D., David Chadwick, Ph.D., Kanchan Rege, F.R.C.Path., Christopher Fegan, M.D., Lucy C. Chappell, Ph.D., Saul N. Faust, F.R.C.P.C.H., Thomas Jaki, Ph.D., Katie Jeffery, Ph.D., Alan Montgomery, Ph.D., Kathryn Rowan, Ph.D., Edmund Juszczak, M.Sc., J. Kenneth Baillie, M.D., Ph.D., Richard Haynes, D.M., and Martin J. Landray, Ph.D.) assume responsibility for the overall content and integrity of this article.

The affiliations of the members of the writing committee are listed in the Appendix. Address reprint requests to Drs. Horby and Landray at RECOVERY Central Coordinating Office, Richard Doll Bldg., Old Road Campus, Roosevelt Drive, Oxford OX3 7LF, United Kingdom, or at recoverytrial@ndph.ox.ac.uk.

*A complete list of collaborators in the RECOVERY trial is provided in the Supplementary Appendix, available at NEJM.org.

Drs. Horby, Lim, and Emberson and Drs. Haynes and Landray contributed equally to this article.

This article was published on July 17, 2020, at NEJM.org.

DOI: 10.1056/NEJMoa2021436

# The bad (papers) - 1

Goldacre *et al. Trials* (2019) 20:118
https://doi.org/10.1186/s13063-019-3173-2

Trials

RESEARCH Open Access

## COMPare: a prospective cohort study correcting and monitoring 58 misreported trials in real time

Ben Goldacre[1*], Henry Drysdale[1], Aaron Dale[1], Ioan Milosevic[1], Eirion Slade[1], Philip Hartley[1], Cicely Marston[2], Anna Powell-Smith[1], Carl Heneghan[1] and Kamal R. Mahtani[1]

**67** TRIALS CHECKED TO DATE

**9** TRIALS WERE PERFECT

**301** OUTCOMES NOT REPORTED

**357** NEW OUTCOMES SILENTLY ADDED

)n average, each trial reported just 62.0% of its specified outcomes. And on average, each trial ilently added 5.3 new outcomes.

**58** LETTERS SENT

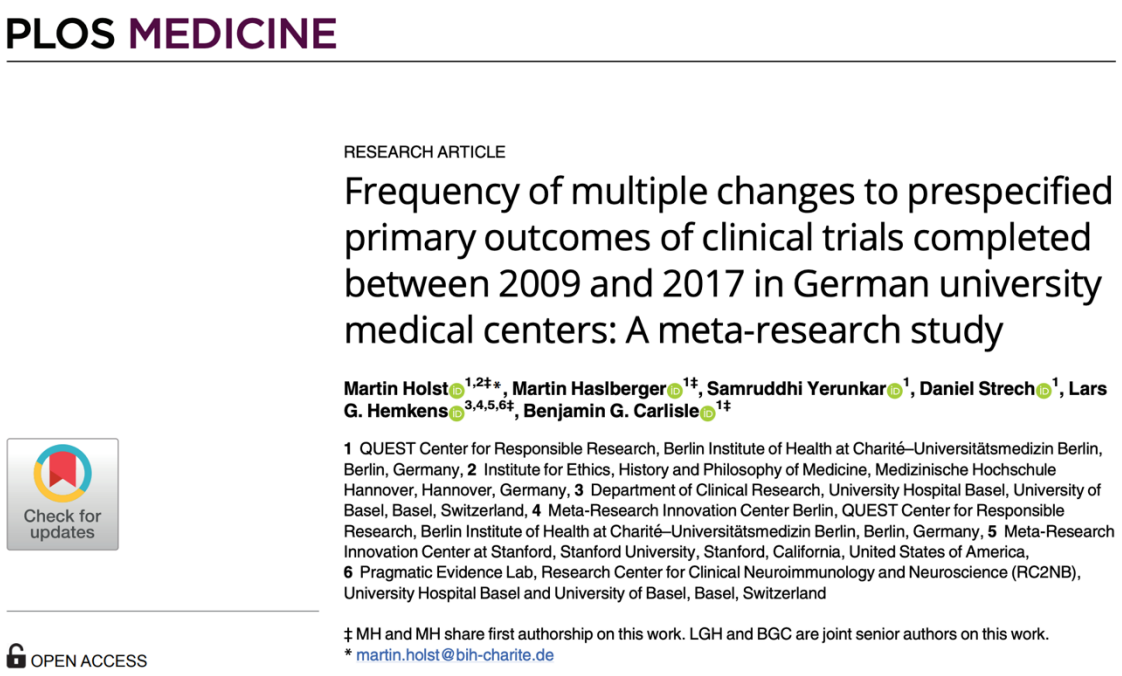
**6** LETTERS PUBLISHED

**31** LETTERS UNPUBLISHED AFTER 4 WEEKS

**16** LETTERS REJECTED BY EDITOR

- 365 'novel' outcomes were reported without declaration
- Only 29 studies had a pre-trial protocol publicly available

# The bad (papers) -2



PLOS MEDICINE

RESEARCH ARTICLE

Frequency of multiple changes to prespecified primary outcomes of clinical trials completed between 2009 and 2017 in German university medical centers: A meta-research study

Martin Holst[1,2‡*], Martin Haslberger[1‡], Samruddhi Yerunkar[1], Daniel Strech[1], Lars G. Hemkens[3,4,5,6‡], Benjamin G. Carlisle[1‡]

1 QUEST Center for Responsible Research, Berlin Institute of Health at Charité–Universitätsmedizin Berlin, Berlin, Germany, 2 Institute for Ethics, History and Philosophy of Medicine, Medizinische Hochschule Hannover, Hannover, Germany, 3 Department of Clinical Research, University Hospital Basel, University of Basel, Basel, Switzerland, 4 Meta-Research Innovation Center Berlin, QUEST Center for Responsible Research, Berlin Institute of Health at Charité–Universitätsmedizin Berlin, Berlin, Germany, 5 Meta-Research Innovation Center at Stanford, Stanford University, Stanford, California, United States of America, 6 Pragmatic Evidence Lab, Research Center for Clinical Neuroimmunology and Neuroscience (RC2NB), University Hospital Basel and University of Basel, Basel, Switzerland

‡ MH and MH share first authorship on this work. LGH and BGC are joint senior authors on this work.
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Check for updates

OPEN ACCESS

"Primary outcomes in publications were different from the latest registry entry version in 41% of trials (120 of the 292 sampled trials; 95% confidence interval (CI) [35%, 47%]), with major changes in 18% (54 of 292; 95% CI [14%, 23%]). Overall, 55% of trials (161 of 292; 95% CI [49%, 61%]) had primary outcome changes at any timepoint over the course of a trial, with 23% of trials (67 of 292; 95% CI [18%, 28%]) having major changes"

# The Ugly

The world this week

**News in focus**

Retractions are skyrocketing as publishers work to remove sham articles from the literature.

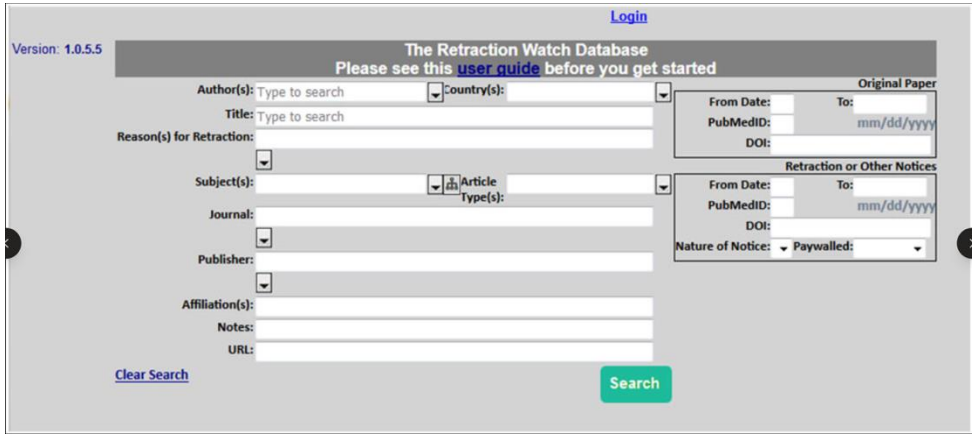
**MORE THAN 10,000 RESEARCH PAPERS WERE RETRACTED IN 2023 — A NEW RECORD**

The number of articles being retracted rose sharply this year. Integrity experts say that this is only the tip of the iceberg.

By Richard Van Noorden

subsidiary of the publisher Wiley (see 'A bumper year for retractions'). So far this

have become notorious for being exploited by scammers to rapidly publish low-quality




- **Retracted papers**
  - Cross check included studies against retraction watch database

**Some paper mill papers; some predatory papers**

- STM Integrity Hub
  - Tools to help identify problem papers
    https://stm-assoc.org/what-we-do/strategic-areas/research-integrity/integrity-hub/

# HOW BIG IS SCIENCE'S FAKE-PAPER PROBLEM?

## Analysis suggests there are hundreds of thousands of bogus 'paper-mill' articles lurking in the literature.

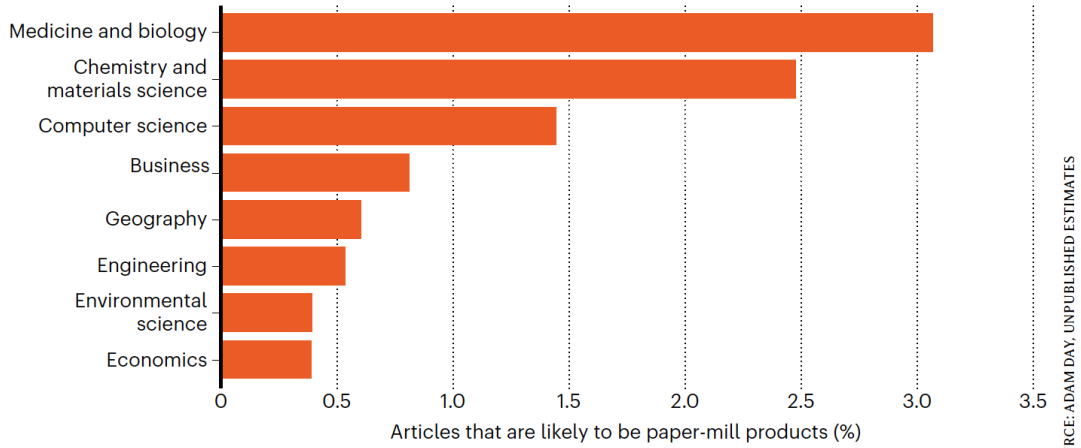
**By Richard Van Noorden**

The scientific literature is polluted with fake manuscripts churned out by paper mills — businesses that sell bogus work and authorships to researchers who need journal publications for their CVs. But just how large is this paper-mill problem?

batches at speed, and they often follow specific templates, with the occasional word or image swapped. Day set his software to analyse the titles and abstracts of more than 48 million papers published since 2000, as listed in OpenAlex, a giant open index of research papers, and to flag manuscripts with text that very closely matched known paper-mill

**SUBJECT BREAKDOWN**

The scientific disciplines with the highest proportions of paper-mill articles are biology and medicine, and chemistry and materials science, the analysis suggests.




Subject fields from analysis of 'concepts' associated with some research articles in OpenAlex database.

SOURCE: ADAM DAY, UNPUBLISHED ESTIMATES

# Trouble finding the included papers

ELSEVIER

Journal of Clinical Epidemiology 166 (2024) 111229

Journal of Clinical Epidemiology

ORIGINAL RESEARCH

## Systematic review search strategies are poorly reported and not reproducible: a cross-sectional metaresearch study

Melissa L. Rethlefsen[a,b,*], Tara J. Brigham[c], Carrie Price[d], David Moher[e], Lex M. Bouter[f,g], Jamie J. Kirkham[h], Sara Schroter[i,j], Maurice P. Zeegers[b,k]

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[b]Department of Epidemiology, Maastricht University, Maastricht, The Netherlands
[c]Library Services-Florida, Mayo Clinic Libraries, Mayo Clinic, 4500 San Pablo Road, Jacksonville, FL 32224, USA
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[h]Centre for Biostatistics, The University of Manchester, Manchester Academic Health Science Centre, Manchester, UK
[i]BMJ, BMA House, Tavistock Square, London WC1H 9JR, UK
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Accepted 27 November 2023; Published online 3 December 2023

**Abstract**

**Objectives:** To determine the reproducibility of biomedical systematic review search strategies.

**Study Design and Setting:** A cross-sectional reproducibility study was conducted on a random sample of 100 systematic reviews indexed in MEDLINE in November 2021. The primary outcome measure is the percentage of systematic reviews for which all database searches can be reproduced, operationalized as fulfilling six key Preferred Reporting Items for Systematic reviews and Meta-Analyses literature search extension (PRISMA-S) reporting guideline items and having all database searches reproduced within 10% of the number of original results. Key reporting guideline items included database name, multi-database searching, full search strategies, limits and restrictions, date(s) of searches, and total records.

**Results:** The 100 systematic review articles contained 453 database searches. Only 22 (4.9%) database searches reported all six PRISMA-S items. Forty-seven (10.4%) database searches could be reproduced within 10% of the number of results from the original search; six searches differed by more than 1,000% between the originally reported number of results and the reproduction. Only one systematic review article provided the necessary search details to be fully reproducible.

**Conclusion:** Systematic review search reporting is poor. To correct this will require a multifaceted response from authors, peer reviewers, journal editors, and database providers. 

- Integrate a librarian as an SRMA team member
- Use PRESS
  - McGowan J, Sampson M, Salzwedel DM, Cogo E, Foerster V, Lefebvre C. PRESS Peer Review of Electronic Search Strategies: 2015 Guideline Statement. J Clin Epidemiol. 2016;75:40–46

# Search preprint servers

- ArXiv existed in 2011
- > 60 preprint servers exist in 2026
- About 2/3 of papers are subsequently published
- Search preprints
  - Lots of knowledge
- There is little data on the prevalence of systematic review teams searching preprints
- There is inconsistent evidence that preprints (compared to their subsequent publication) are of different quality/transparency compared to their peer reviewed published version

# Reproducibility in (psychological) science



RESEARCH ARTICLE SUMMARY

PSYCHOLOGY

## Estimating the reproducibility of psychological science

Open Science Collaboration*

**INTRODUCTION:** Reproducibility is a defining feature of science, but the extent to which it characterizes current research is unknown. Scientific claims should not gain credence because of the status or authority of their originator but by the replicability of their supporting evidence. Even research of exemplary quality may have irreproducible empirical findings because of random or systematic error.

**RATIONALE:** There is concern about the rate and predictors of reproducibility, but limited evidence. Potentially problematic practices include selective reporting, selective analysis, and insufficient specification of the conditions necessary or sufficient to obtain the results. Direct replication is the attempt to recreate the conditions believed sufficient for obtaining a previously observed finding and is the means of establishing reproducibility of a finding with new data. We conducted a large-scale, collaborative effort to obtain an initial estimate of the reproducibility of psychological science.

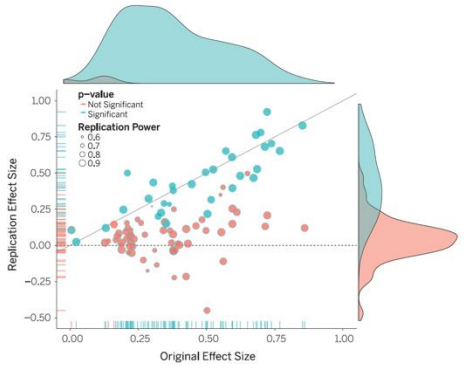
**RESULTS:** We conducted replications of 100 experimental and correlational studies published in three psychology journals using high-powered designs and original materials when available. There is no single standard for evaluating replication success. Here, we evaluated reproducibility using significance and *P* values, effect sizes, subjective assessments of replication teams, and meta-analysis of effect sizes. The mean effect size (r) of the replication effects ($M_r$ = 0.197, SD = 0.257) was half the magnitude of the mean effect size of the original effects ($M_r$ = 0.403, SD = 0.188), representing a substantial decline. Ninety-seven percent of original studies had significant results ($P < .05$). Thirty-six percent of replications had significant results; 47% of original effect sizes were in the 95% confidence interval of the replication effect size; 39% of effects were subjectively rated to have replicated the original result; and if no bias in original results is assumed, combining original and replication results left 68% with statistically significant effects. Correlational tests suggest that replication success was better predicted by the strength of original evidence than by characteristics of the original and replication teams.

**CONCLUSION:** No single indicator sufficiently describes replication success, and the five indicators examined here are not the only ways to evaluate reproducibility. Nonetheless, collectively these results offer a clear conclusion: A large portion of replications produced weaker evidence for the original findings despite using materials provided by the original authors, review in advance for methodological fidelity, and high statistical power to detect the original effect sizes. Moreover, correlational evidence is consistent with the conclusion that variation in the strength of initial evidence (such as original *P* value) was more predictive of replication success than variation in the characteristics of the teams conducting the research (such as experience and expertise). The latter factors certainly can influence replication success, but they did not appear to do so here.

Reproducibility is not well understood because the incentives for individual scientists prioritize novelty over replication. Innovation is the engine of discovery and is vital for a productive, effective scientific enterprise. However, innovative ideas become old news fast. Journal reviewers and editors may dismiss a new test of a published idea as unoriginal. The claim that "we already know this" belies the uncertainty of scientific evidence. Innovation points out paths that are possible; replication points out paths that are likely; progress relies on both. Replication can increase certainty when findings are reproduced and promote innovation when they are not. This project provides accumulating evidence for many findings in psychological research and suggests that there is still more work to do to verify whether we know what we think we know. ■

ON OUR WEB SITE

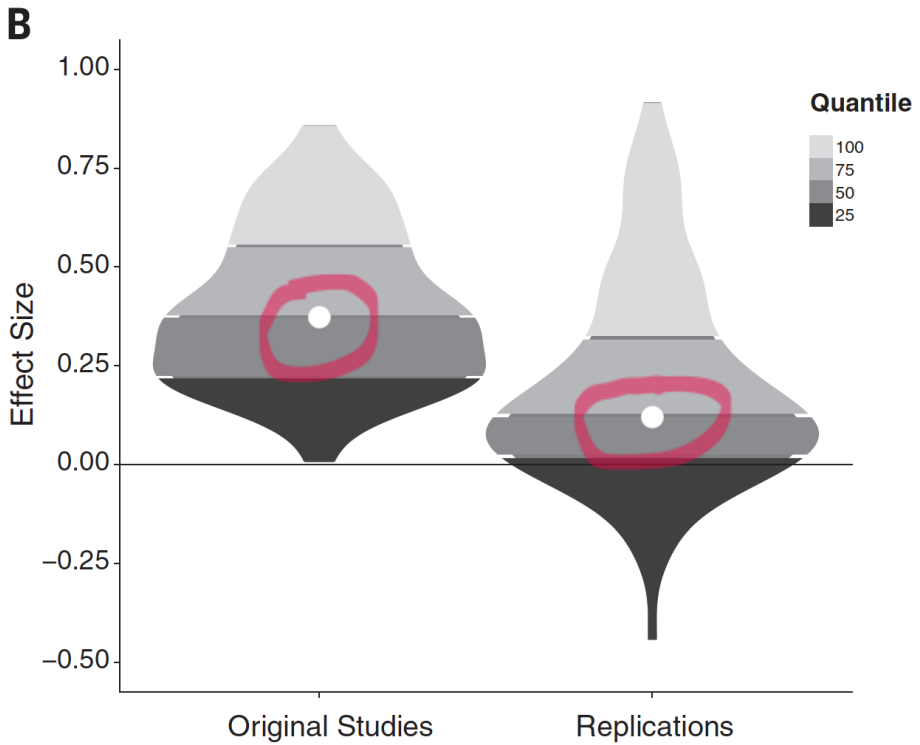
Read the full article at http://dx.doi.org/10.1126/science.aac4716



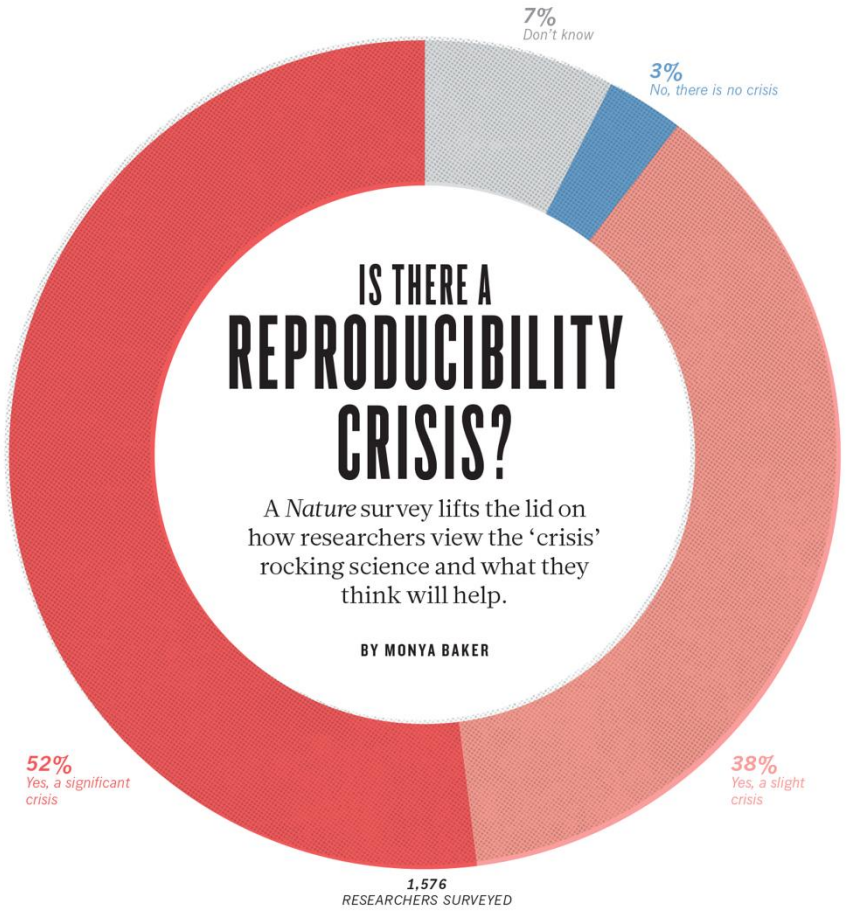

**Original study effect size versus replication effect size (correlation coefficients).** Diagonal line represents replication effect size equal to original effect size. Dotted line represents replication effect size of 0. Points below the dotted line were effects in the opposite direction of the original. Density plots are separated by significant (blue) and nonsignificant (red) effects.

The list of author affiliations is available in the full article online.
*Corresponding author. E-mail: nosek@virginia.edu
Cite this article as Open Science Collaboration, *Science* 349, aac4716 (2015). DOI: 10.1126/science.aac4716

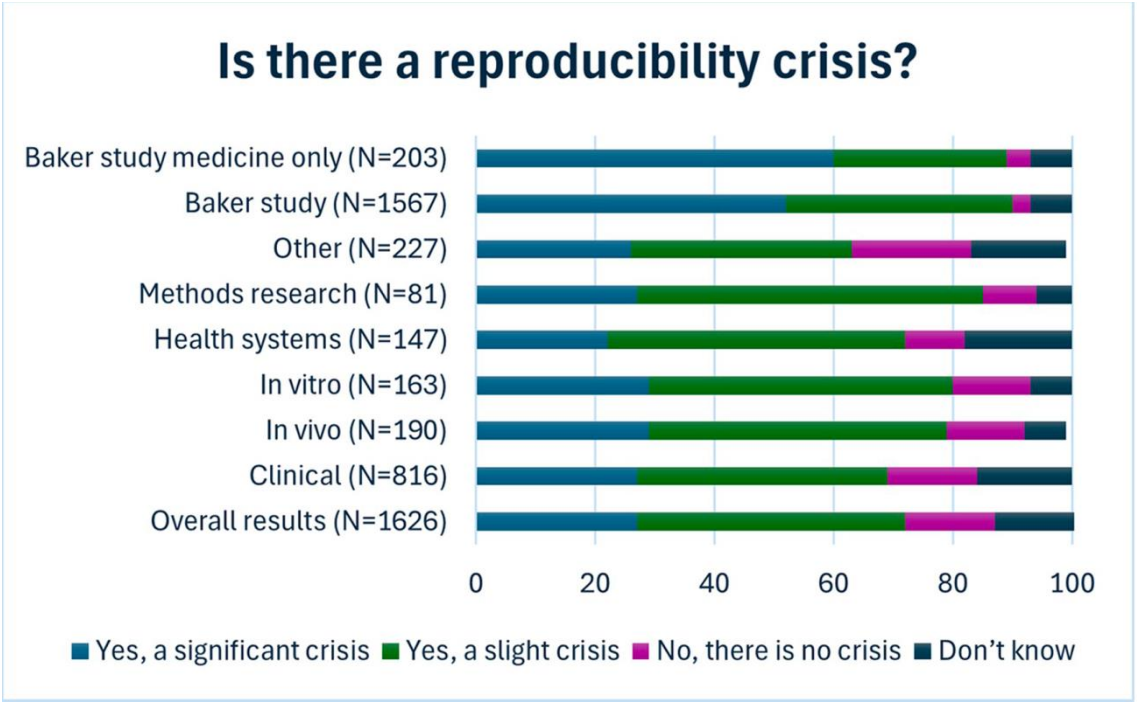


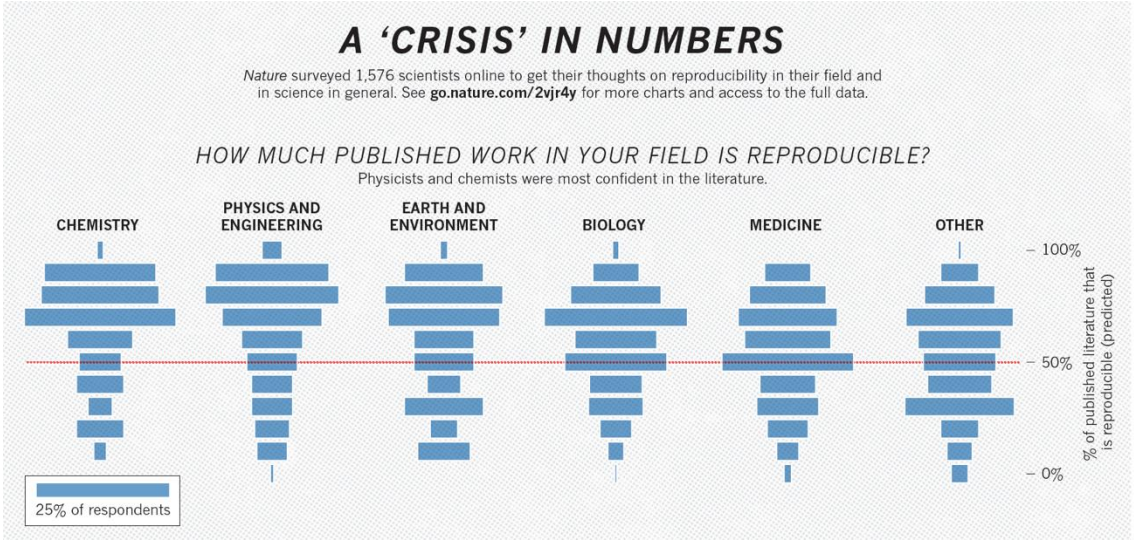



The mean effect size (r) of the replication effects (Mr=0.197, SD= 0.257) was half the magnitude of the mean effect size of the original effects (Mr = 0.403, SD = 0.188)




Baker M. Is there a reproducibility crisis? Nature. 2016; 533:452–454.




Cobey KD, Ebrahimzadeh S, Page MJ, Thibault RT, Nguyen P-Y, Abu-Dalfa F, et al. (2024) Biomedical researchers' perspectives on the reproducibility of research. PLoS Biol 22(11):e3002870

# Why are data important?

## Reproducibility and economic impacts

**$28 billion**

cost of irreproducible biology research to US economy every year

**€10.2 billion**

cost per year to European economy through lack of FAIR data

**75%+ failure rates**

reported by Pharma replicating conclusions of peer-reviewed papers


2. Freedman, L. P., Cockburn, I. M. & Simcoe, T. S. *PLoS Biol.* **13**, e1002165 (2015) http://journals.plos.org/plosbiology/article?id=10.1371/journal.pbio.1002165
3.Publications Office of the European Union. 2019. Cost-benefit analysis for FAIR research data. https://dx.doi.org/10.2777/02999
4. Begley, C. G. & Ellis, L. M. *Nature* **483**, 531–533 (2012), https://doi.org/10.1038/483531a
5. Prinz, F., Schlange, T. & Asadullah, K. *Nature Rev. Drug Discov.* **10**, 712 (2011) https://doi.org/10.1038/nrd3439-c1


SPRINGER NATURE

# CONSIDER VERIFICATION EFFORTS OF STUDIES INCLUDED IN SRMA

FACETS 8: 1–10 (2023) | dx.doi.org/10.1139/facets-2022-0208

FACETS

OPEN ACCESS | Research Article

# Evaluating prospective study registration and result reporting of trials conducted in Canada from 2009 to 2019

Mohsen Alayche[a,b], Kelly D. Cobey[c,d], Jeremy Y. Ng[a], Clare L. Ardern[e,f], Karim M. Khan[g], An-Wen Chan[h,i], Ryan Chow[a,b], Mouayad Masalkhi[j], Ana Patricia Ayala[k], Sanam Ebrahimzadeh[a], Jason Ghossein[b], Ibrahim Alayche[b], Jessie V. Willis[a,b], and David Moher[a,d]

[a]Centre for Journalology, Ottawa Methods Centre, Ottawa Hospital Research Institute, Ottawa, Canada; [b]Faculty of Medicine, University of Ottawa, Ottawa, Canada; [c]University of Ottawa Heart Institute, Ottawa, Canada; [d]School of Epidemiology and Public Health, Faculty of Medicine, University of Ottawa, Ottawa, Canada; [e]Sport and Exercise Medicine Research Centre, La Trobe University, Melbourne, Australia; [f]Department of Family Practice, University of British Columbia, Vancouver, Canada; [g]Department of Family Practice and School of Kinesiology, University of British Columbia, Vancouver, Canada; [h]Department of Medicine, Women's College Research Institute, Toronto, Canada; [i]Institute of Health Policy, Management and Evaluation, University of Toronto, Toronto, Canada; [j]School of Medicine, University College Dublin, Dublin, Ireland; [k]Gerstein Science Information Centre, University of Toronto, Toronto, Canada

## Study registration

**Table 3.** Adherence of Canadian trials to study registration and reporting best practices based on the year of primary completion.

| Year of completion | Number of studies | Prospective registration | Results reported | Findings published* | All three practices* |
|---|---|---|---|---|---|
| 2009 | 65 | 23 (35.38%) | 22 (33.85%) | 24 (36.92%) | 3 (4.62%) |
| 2010 | 216 | 92 (42.59%) | 82 (37.96%) | 120 (55.56%) | 30 (13.89%) |
| 2011 | 399 | 174 (43.61%) | 161 (40.35%) | 210 (52.63%) | 74 (18.55%) |
| 2012 | 554 | 276 (49.82%) | 215 (38.81%) | 304 (54.87%) | 101 (18.23%) |
| 2013 | 681 | 354 (51.98%) | 305 (44.79%) | 386 (56.68%) | 145 (21.29%) |
| 2014 | 736 | 413 (56.11%) | 302 (41.03%) | 438 (59.51%) | 174 (23.64%) |
| 2015 | 787 | 453 (57.56%) | 341 (43.33%) | – | – |
| 2016 | 781 | 472 (60.44%) | 308 (39.44%) | – | – |
| 2017 | 848 | 542 (63.92%) | 347 (40.92%) | – | – |
| 2018 | 834 | 573 (68.71%) | 300 (35.97%) | – | – |
| 2019 | 819 | 595 (72.65%) | 259 (31.62%) | – | – |
| Total | 6720 | 3967 (59.03%) | 2642 (39.32%) | 1482 (55.9%) | 527 (19.88%) |

*Years 2015–2019 were excluded when measuring the "published" variable.

# The era of artificial intelligence

- Are humans the best!

PLOS ONE

RESEARCH ARTICLE

## Error rates of human reviewers during abstract screening in systematic reviews

**Zhen Wang[1,2]*, Tarek Nayfeh[2], Jennifer Tetzlaff[3], Peter O'Blenis[3], Mohammad Hassan Murad[1,2]**

**1** Evidence-based Practice Center, Mayo Clinic, Rochester, Minnesota, United States of America, **2** Robert D. and Patricia E. Kern Center for the Science of Health Care Delivery Mayo Clinic, Rochester, Minnesota, United States of America, **3** Evidence Partners, Ottawa, Ontario, Canada

# The era of artificial intelligence

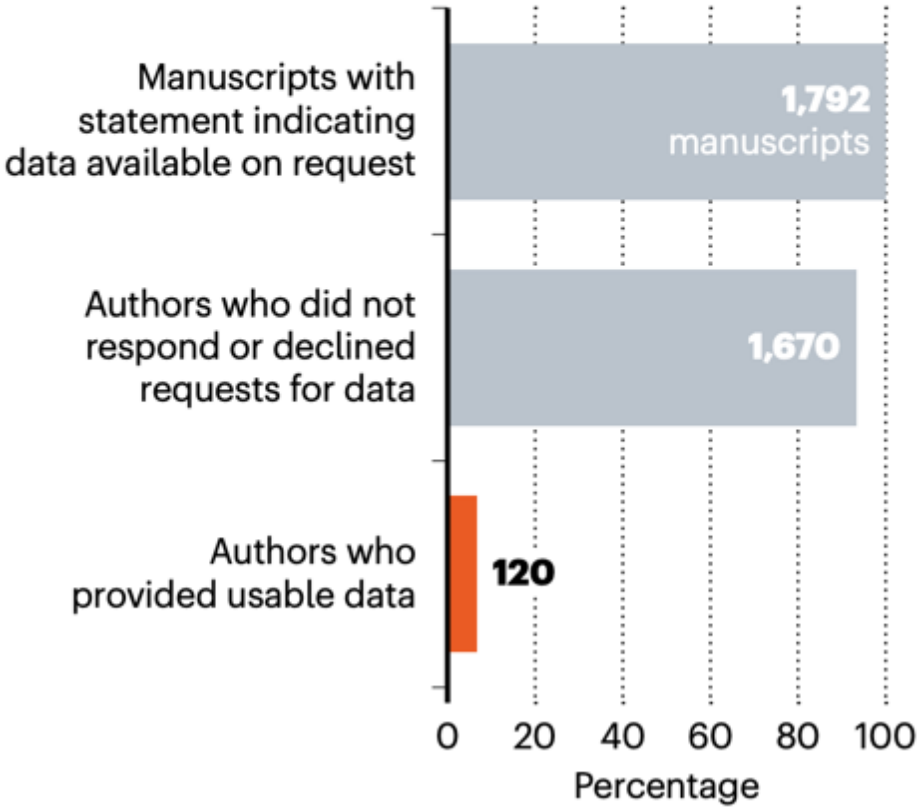
- AI is here to stay and while much of the focus is on ‘single’ categories
  - Screening, risk of bias assessment
- End to End AI is coming and quickly
  - Searching to quantitative analysis
- We need to ensure robust results to have trust
  - Human in the loop
  - Appropriate metrics on using AI in the report of the SRMA

# Any new guidance

- Require sharing of data, code, and materials of papers included in a review’s results and conclusions

## DATA-SHARING BEHAVIOUR

Of almost 1,800 manuscripts for which the authors stated they were willing to share their data, more than 90% of corresponding authors either declined or did not respond to requests for data. Only about 7% of authors actually handed over data.




Is the data, code, and materials of the primary study available

Gabelica M, Bojčić R, Puljak L. Many researchers were not compliant with their published data sharing statement: mixed-methods study. J Clin Epidemiol. 2022 May 30:S0895-4356(22)00141-X. doi: 10.1016/j.jclinepi.2022.05.019. Epub ahead of print. PMID: 35654271

JAMA Network | Open

Original Investigation | Health Informatics

# Patient Perspectives About Decisions to Share Medical Data and Biospecimens for Research

Jihoon Kim, MS; Hyeoneui Kim, RN, PhD; Elizabeth Bell, MPH; Tyler Bath, BS; Paulina Paul, MS; Anh Pham, BS; Xiaoqian Jiang, PhD; Kai Zheng, PhD; Lucila Ohno-Machado, MD, PhD

## Abstract

**IMPORTANCE** Patients increasingly demand transparency in and control of how their medical records and biospecimens are shared for research. How much they are willing to share and what factors influence their sharing preferences remain understudied in real settings.

**OBJECTIVES** To examine whether and how various presentations of consent forms are associated with differences in electronic health record and biospecimen sharing rates and whether these rates vary according to user interface design, data recipients, data and biospecimen items, and patient characteristics.

**DESIGN, SETTING, AND PARTICIPANTS** For this survey study, a data and biospecimen sharing preference survey was conducted at 2 academic hospitals from May 1, 2017, to September 31, 2018, after simple randomization of patients to 1 of 4 options with different layout and formats of indicating sharing preferences: opt-in simple, opt-in detailed, opt-out simple, and opt-out detailed.

**INTERVENTIONS** All participants were presented with a list of data and biospecimen items that could be shared for research within the same health care organization or with other nonprofit or for-profit institutions. Participating patients were randomly asked to select the items that they would share (opt-in) or were asked to select items they would not share (opt-out). Patients in these 2 groups were further randomized to select only among 18 categories vs 59 detailed items (simple vs detailed form layout).

**MAIN OUTCOMES AND MEASURES** The primary end points were the percentages of patients willing to share data and biospecimen categories or items.

**RESULTS** Among 1800 eligible participants, 1246 (69.2%) who completed their data sharing survey were included in the analysis, and 850 of these patients (mean [SD] age, 51.1 [16.7] years; 507 [59.6%] female; 677 [79.6%] white) responded to the satisfaction survey. A total of 46 participants (3.7%) declined sharing with the home institution, 352 (28.3%) with nonprofit institutions, and 590 (47.4%) with for-profit institutions. A total of 836 (67.1%) indicated that they would share all items with researchers from the home institution. When comparing opt-out with opt-in interfaces, all 59 sharing choice variables (100%) were associated with the sharing decision. When comparing simple with detailed forms, only 14 variables (23.7%) were associated with the sharing decision.

### Key Points

**Question** Do patient decisions about sharing their electronic health records and biospecimens for research vary according to health care institution, data or biospecimen item, patient characteristics, data recipient, and format in which consent choices are presented?

**Findings** In this survey study of 1246 patients who completed a data and biospecimen sharing survey after being randomly assigned to 1 of 4 options with different layout and formats of indicating sharing preferences, patient preference for sharing compared with no sharing was significantly higher after controlling for covariates when presented with the opt-out compared with the opt-in format. The form layout (detailed vs simple) was not associated with the sharing decision.

**Meaning** The findings suggest that many patients may be willing to share data and biospecimens for research and that researchers' affiliations, the design of consent forms, and patient age and health literacy are associated with patient sharing decisions.

+ Invited Commentary

+ Supplemental content

SPECIAL ARTICLE

# Clinical Trial Participants' Views of the Risks and Benefits of Data Sharing

Michelle M. Mello, J.D., Ph.D., Van Lieou, B.S., and Steven N. Goodman, M.D., Ph.D.

ABSTRACT

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# Any new guidance

- Require sharing of data, code, and materials of papers included in a review's results and conclusions
  - All reviews (including IPDMA)
    - Data sharing is not "available from the corresponding author upon request"
    - Data sharing in now mandated in many jurisdictions
- Perhaps the single biggest problem when conducting meta-research

# Any new guidance

- Establish standards for AI use in SRMA
- Use reporting guidelines to report research
  - Some journals require this
  - All research performing organizations need to step up to the plate

# Thank you