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Trends and Predictors of Biomedical Research Quality: A Meta-Research Study

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3 **Trends and Predictors of Biomedical Research Quality:**
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6 **A Meta-Research Study**
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44 Maryaline Catillon (0000-0002-1360-8133)

45 Ph.D. Program in Health Policy, Harvard University, 14 Story Street, 4th Floor, Cambridge, MA
46 02138

47 mcatillon@g.harvard.edu
48

49 [\(+1\) 857 222 6863](tel:+18572226863)
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ABSTRACT

Objective: To measure the frequency of adequate methods, inadequate methods and poor reporting in published clinical trials and test potential factors associated with adequacy of methods and reporting.

Design: Retrospective analysis of studies included in Cochrane reviews. Time series describe the proportion of studies using adequate methods, inadequate methods and poor reporting. A multinomial logit model tests potential factors associated with methods and reporting, including funding source, first author affiliation, clinical trial registration status, study novelty, team characteristics, technology and geography.

Data: Risk of bias assessment for random sequence generation, allocation concealment, blinding of participants and personnel, blinding of outcome assessment, incomplete outcome data and selective reporting, for each study, mapped to bibliometric and funding data.

Outcomes: Risk of bias on six methodological dimensions, and study-level assessment of adequate methods, inadequate methods or poor reporting.

Results: This study analyzed 20,571 biomedical research articles. 5.7% of studies used adequate methods (N=1,173), 59.3% used inadequate methods (N=12,190) and 35.0% were poorly reported (N=7,208). The proportion of poorly reported studies decreased from 42.5% in 1990 to 30.2% in 2015. The proportion of studies using adequate methods increased from 2.6% in 1990 to 10.3% in 2015. The proportion of studies using inadequate methods increased from 54.9% in 1990 to 59.5% in 2015. Industry funding, top pharmaceutical company affiliation, trial registration, larger authorship teams, international teams, and drug trials were associated with a greater likelihood of using adequate methods. NIH funding and university prestige were not.

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3 **Conclusion:** Even though reporting has improved since 1990, the proportion of studies using
4 inadequate methods is high (59.3%) and increasing, potentially contributing to the
5
6 reproducibility crisis. Stronger incentives for the use of adequate methods are needed.
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13 **STRENGTHS AND LIMITATIONS OF THIS STUDY**

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- 17 • This study combines the full-text and systematic assessment of study methods with
18 bibliometric and funding information in a sample of 20,571 biomedical research articles.
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- 21 • This study analyzes trends in methods and reporting over the past 25 years and identifies
22 factors associated with biomedical research quality including funding source, first author
23 affiliation, clinical trial registration status, study novelty, team characteristics, technology
24 and geography.
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- 27 • This study does not identify causal mechanisms explaining biomedical research quality.
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- 31 • PubMed identifier, full-text and/or funding information were not available for all studies.
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- 35 • Classification of sectors relies on reported affiliation.
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INTRODUCTION

The quality and reliability of biomedical research are of paramount importance to treatment decisions and patient outcomes. Flawed research conclusions can lead to poor treatment and harm patients. As much as 85% of the annual \$265 billion spent on biomedical research may be wasted due to inadequate methods.[1-8]

Previous scientific work aiming to evaluate the reliability of biomedical research has been limited by data and methodological issues. Data challenges include the time and resources necessary to assess methods and reporting, resulting in the use of small selected samples and/or limited information available for each scientific article evaluated in larger samples.[9-27] As a result, it remains unknown what the overall magnitude of waste due to inadequate methods and reporting in biomedical research is and what factors are associated with the use of adequate versus inadequate research methods.

To address these questions, this study combines the full text of studies and systematic assessment of study methods with bibliometric and funding information in a large sample of biomedical research articles included in “gold standard” systematic reviews. The study describes the evolution of adequate research methods and reporting over time. A multinomial logit model tests potential factors associated with methods and reporting, including funding source, first author affiliation, clinical trial registration status, study novelty, team characteristics, technology and geography.

METHODS

Data

Cochrane reviews constitute a valuable data source to assess biomedical research quality as they follow strict methods and precise reporting guidelines as defined in the Cochrane Handbook.[28-

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3 31] The research method dimensions evaluated in Cochrane reviews include random sequence
4 generation, allocation concealment, blinding of participants and personnel, blinding of outcome
5 assessment, incomplete outcome data, and selective reporting (detailed in Supplementary Table
6 A1).
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13 **Sample**

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16 Supplementary Figure A1 summarizes the data flow. All studies assessed for risk of bias after the
17 2011 update of the Risk of Bias Assessment Tool and through October 2017 were considered for
18 inclusion (N=63,748 studies included in 4,195 reviews).
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24 Criteria for study inclusion were: (1) the review included all six assessments (to allow
25 comparison of the overall use of adequate methods, inadequate methods and poor reporting
26 across reviews) (1,988 reviews dropped), (2) the article reporting the study was referenced in
27 PubMed (to allow bibliometric data to enter the analysis)(N=9,201 studies dropped) and (3) the
28 study quality was assessed consistently when assessed multiple times (N=404 studies dropped).
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36 Applying these criteria, the analysis sample for the descriptive statistics and the time-series of
37 methods included 20,571 study publications referenced in PubMed, and consistently assessed for
38 risk of bias on all six dimensions of the Cochrane Risk of Bias Assessment Tool. A full-text PDF
39 was available from the Harvard Library for 11,686 study publications. This subsample was
40 needed to retrieve private funding information from the full-text of the paper and constitutes the
41 analysis sample for regressions including funding information.
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50 **Analysis**

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53 The outcomes were risk of bias on the six assessed methodological dimensions and study-level
54 assessment of adequate methods, inadequate methods or poor reporting. The six methodological
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3 dimensions assessed included (1) random sequence generation, (2) allocation concealment, (3)
4 blinding of participants and personnel, (4) blinding of outcome assessment, (5) incomplete
5 outcome data and (6) selective reporting. The category “Other bias” was not used in this study,
6 as it includes concerns not necessarily about methods or reporting, such as conflicts of interest.
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10 Following guidelines for assessing the quality of evidence,[28] the study-level assessment was
11 “adequate methods” if the study was at low risk of bias on all dimensions assessed. It was
12 “inadequate methods” if the study was at high risk of bias for one or more reasons. It was
13 “poorly reported” if the reviewers did not have enough information to assess whether the
14 methods used were adequate or inadequate (if the study was at “unclear” risk of bias for at least
15 one reason).
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20 Of the studies assessed on all six dimensions, 69.5% matched with a PubMed identifier, which
21 was used to retrieve bibliometric and public funding information.
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26 Sector affiliation with university, government, hospital, non-profit, top pharmaceutical company
27 or other firm, as well as geographic variables were derived from the first author affiliation
28 address. Top 25 Universities were identified using the 2007 Academic Ranking of World
29 Universities in Clinical Medicine and Pharmacy (see supplementary material, Appendix A).
30 Firms were classified as top pharmaceutical companies or other firms using the listing of
31 pharmaceutical companies with a revenue greater than \$10 billion in any year since 2011 (see
32 supplementary material, Appendix B). Technologies were retrieved from the keywords and
33 abstracts of the Cochrane Reviews. Private funding information was retrieved from the full-text
34 PDF of the main reference when available.
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Two analyses were performed. The first reports the time series of the proportion of studies using adequate methods, inadequate methods and poor reporting, for each dimension and in aggregate. The second tests whether adequate methods, inadequate methods and poor reporting are associated with funding source (NIH grant or industry funding), sector affiliation of first author (Top University, Other University, Government, Hospital, Non-Profit, Top Pharmaceutical Company, Other Firm), clinical trial registration status, study novelty (first or subsequent study on a particular research question), team characteristics (number of authors and international collaboration), technology (drug, device, procedure, behavioral intervention or other intervention), and geography of first author (Canada, Europe, UK, USA, or other country). A multinomial logit model using these variables predicted overall adequate methods, inadequate methods and poor reporting, as well as risk of bias along each dimension assessed.

Patient involvement

Patients were not involved in any aspect of the study design, conduct, or in the development of the research question or outcome measures. This study is a meta-research study, based on existing published research. There was no patient recruitment for data collection.

RESULTS

Prevalence of Adequate Methods, Inadequate Methods, and Poor Reporting

Table 1 presents descriptive statistics. Only 5.7% of studies used adequate methods (N=1,173). 59.3% used inadequate methods (N=12,190) and 35.0% were poorly reported (N=7,208).

Figure 1 shows the proportion of studies at low, high or unclear risk of bias for random sequence generation, allocation concealment, blinding of participants and personnel, blinding of outcome assessment, incomplete outcome data and selective reporting, for all studies assessed on all six

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3 dimensions (N=20,571). 38% of trials used inadequate methods for blinding of participants and
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5 personnel. 15 to 20% of trials used inadequate methods for blinding of outcome assessment
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7 (20%), incomplete outcome data (19%) and selective reporting (15%). The proportion of trials
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9 using inadequate methods for random sequence generation and allocation concealment was
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11 lowest (respectively 5% and 7%), but these two dimensions were frequently poorly reported
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13 (respectively 47% and 58% of trials).
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16 17 **Methods and reporting over time**

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20 Figure 2 shows the overall proportion of studies using adequate methods, inadequate methods
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22 and poorly reported methods by year of publication. The proportion of poorly reported studies
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24 decreased from 42.5% in 1990 to 30.2% in 2015. The proportion of studies using adequate
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26 methods increased from 2.6% in 1990 to 10.3% in 2015. The proportion of studies using
27
28 inadequate methods increased from 54.9% in 1990 to 59.5% in 2015.
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32 Reporting improved on all dimensions. The proportion of studies using adequate methods for
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34 random sequence generation, allocation concealment, blinding of outcome assessment,
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36 incomplete outcome data and selective reporting increased. In contrast, the proportion of trials
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38 using inadequate methods for blinding of participants and personnel increased.
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42 Figure A2 (supplementary material) provides graphs similar to figure 2 for all studies assessed
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44 on at least one dimension (N=63,748). Similar patterns suggest that the evolutions observed for
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46 the studies assessed on all dimensions (N=20,571) reflect the evolutions in all studies assessed
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48 on at least one dimension.
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51 52 **Factors associated with methods and reporting**

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3 Figure 3 reports regression results from a multinomial logit model predicting overall quality.
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5 Tables A2 and A3 (Supplementary material) report all regression results.
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8 Public funding was not associated with the overall use of adequate methods. However, NIH
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10 funded studies were less likely to use inadequate methods for random sequence generation
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12 (RR=0.29, $p<0.001$) and allocation concealment (RR=0.51, $p<0.001$). Industry funded studies
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14 were slightly more likely to use adequate methods (RR=0.84, $p<0.05$), because of better blinding
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16 of participants and personnel (RR=0.87, $p<0.05$).
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20 First author affiliation with a top pharmaceutical company was associated with increased use of
21
22 adequate methods (RR=0.43, $p<0.01$). First author affiliation with top universities was not.
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26 Registered trials (RR=0.42, $p<0.001$), larger authorship teams (RR=0.95, $p<0.001$), international
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28 teams (RR=0.51, $p<0.01$) and studies on drugs (RR=0.50, $p<0.001$) were less likely to use
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30 inadequate methods.
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33 **DISCUSSION**

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36 In the context of the “reproducibility crisis”, there are concerns about the quality of biomedical
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38 research. This study assessed whether or not methods and reporting improved over time and
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40 identified the characteristics of better and worse studies.
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44 This study has five main results. First, in a large sample of studies assessed in systematic
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46 reviews, only 5.7% used adequate methods, 59.3% used inadequate methods, and 35.0% were
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48 poorly reported. Since the 1990s, the proportion of poorly reported studies has decreased. In
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50 contrast, the proportion of trials using both adequate and inadequate methods has increased. This
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52 finding is consistent with previous empirical results in small samples,[22] but contrasts with
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3 research in larger samples analyzing each methodological dimension separately to conclude that
4 methods improved over time.[24]
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8 Second, NIH funded studies were not more likely to use adequate methods. This is surprising
9 given the rigorous grant application process, shown to select better scientific proposals,[33] and
10 the public stakes in the reliability of publicly funded research.[34] Notably, the efforts of the
11 NIH to address the reproducibility crisis began just at the end of the study period.[35]
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18 Third, top pharmaceutical company affiliation was significantly associated with better methods.
19 Affiliation with other companies was not. Heterogeneity across firms may explain inconsistency
20 of previous research on the effect of industry funding or affiliation on research methods and
21 outcomes.[27,36]
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28 Fourth, University prestige was not associated with greater use of adequate methods. The current
29 scientific reward system focuses on numbers of publications and citations rather than the
30 assessment of research methods.[37] The resulting incentives affect both scientists and
31 institutions, as through the allocation of grant funding.[38,39] Thus, in a climate of
32 hypercompetition,[40] the careful sharing of materials and methods yields little reward while
33 exposing scientists to better informed scrutiny.
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42 Finally, team size and international collaboration are associated with greater use of adequate
43 methods. Larger teams and international teams produce more frequently cited research, [41,42]
44 and other team characteristics were associated with performance in other settings, opening
45 avenues for future research.[43,44]
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51 **Limitations**

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3 This paper does not identify causal mechanisms explaining biomedical research quality. PubMed
4 identifier, full-text and/or funding information were not available for all studies. Classification of
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6 sectors relies on reported affiliation.
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10 **CONCLUSION**

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13 Even though reporting has improved since 1990, the proportion of studies using inadequate
14 methods is high (59.3%) and increasing, potentially contributing to the reproducibility crisis.
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16 Stronger incentives for the use of adequate methods are needed.
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21 **Contributorship statement**

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24 Maryaline Catillon designed the study, performed the analysis, interpreted the results, wrote the
25 manuscript and approved the final version to be published. Maryaline Catillon accepts full
26 responsibility for the work and the conduct of the study, had access to the data, and controlled
27 the decision to publish.
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52 not necessarily represent the official views of the National Institutes of Health or the NBER.
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Ethical approval

Not applicable. This is a meta-research study.

Data sharing

All data sources necessary to reproduce the analysis are described in the main text or the supplementary material. No additional data available.

What is already known on this subject

Poor reporting and inadequate methods are common in randomized controlled trials.

Reporting has improved since the 1990s.

Previous research has been limited by the use of small selected samples and/or limited information available for each scientific article evaluated in larger samples

What this study adds

This study combines the full-text and systematic assessment of study methods with bibliometric and funding information to analyze trends and predictors of methods and reporting in a sample of 20,571 biomedical research studies.

Only 5.7% of studies used adequate methods, 59.3% used inadequate methods and 35.0% were poorly reported.

Since the 1990s, while the proportion of poorly reported studies decreased, both the proportion of studies using adequate methods and inadequate methods increased.

Industry funding, top pharmaceutical company affiliation, trial registration, larger authorship teams, international teams, and drug trials were associated with a greater likelihood of using adequate methods, but NIH funding and university prestige were not.

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List of Figures and Tables

Table 1: Descriptive statistics

Figure 1: Proportion of studies at low risk, high risk and unclear risk, for each dimension assessed

Figure 2: Evolution of methods and reporting over time

Figure 3: Main regression results predicting relative risk ratios for overall quality

For peer review only

	All	Adequate	Inadequate Methods	Poor Reporting
Sample 1	20,571 (100%)	1,173 (5.7%)	12,190 (59.3%)	7,208 (35.0%)
Sample 2 (with full text)	11,686 (56.8%)	833 (7.1%)	6,783 (58.0%)	4,070 (34.8%)
Funder type				
NIH Grant	2,147 (10.4%)	146 (6.8%)	1,282 (59.7%)	719 (33.5%)
Industry funding	2,783 (13.5%)	283 (10.2%)	1,464 (52.6%)	978 (35.1%)
First Author Affiliation				
Top University	1,063 (5.2%)	51 (4.8%)	601 (56.5%)	411 (38.7%)
Other University	11,120 (54.1%)	677 (6.1%)	6,589 (59.3%)	3,854 (34.7%)
Hospital	4,450 (21.6%)	185 (4.2%)	2,608 (58.6%)	1,657 (37.2%)
Government	1,744 (8.5%)	108 (6.2%)	1,071 (61.4%)	565 (32.4%)
Non-Profit	751 (3.7%)	48 (6.4%)	454 (60.5%)	249 (33.2%)
Top Pharma	239 (1.2%)	26 (10.9%)	115 (48.1%)	98 (41.0%)
Other Firm	195 (1.0%)	13 (6.7%)	115 (59.0%)	67 (34.3%)
Other research institution	200 (1.0%)	18 (9.0%)	120 (60.0%)	62 (31.0%)
Other industry affiliation	570 (2.8%)	44 (7.7%)	287 (50.4%)	239 (41.9%)
Registered studies (NCT)	1,888 (9.2%)	298 (15.8%)	1,011 (53.6%)	579 (30.7%)
Novelty				
First study	2,284 (11.1%)	126 (5.5%)	1,390 (60.9%)	768 (33.6%)
Second study	2,124 (10.3%)	127 (6.0%)	1262 (59.4%)	735 (34.6%)
Team characteristics				
Number of Authors - Avg (Std)	6.15 (3.9)	8.04 (5.5)	5.99 (3.8)	6.13 (6.8)
International	748 (3.64%)	60 (8.02%)	379 (50.67%)	309 (41.31%)
Technology*				
Drug	13,485 (65.6%)	914 (6.8%)	7,306 (54.2%)	5,265 (39.0%)
Device	5,347 (26.0%)	235 (4.4%)	3,366 (63.0%)	1,746 (32.7%)
Procedure	8,710 (42.3%)	460 (5.3%)	4,925 (56.5%)	3,325 (38.2%)
Behavioral	4,543 (22.1%)	122 (2.7%)	3,239 (71.3%)	1,182 (26.0%)
Other	1,199 (5.8%)	78 (6.5%)	819 (68.3%)	302 (25.2%)
Geography**				
Canada	680 (3.3%)	61 (9.0%)	362 (53.2%)	257 (37.8%)
Europe	4,467 (21.7%)	254 (5.7%)	2,693 (60.3%)	1,520 (34.0%)
UK	2,306 (11.2%)	154 (6.7%)	1,399 (60.7%)	753 (32.7%)
USA	4,465 (21.7%)	284 (6.4%)	2,592 (58.1%)	1,589 (35.6%)
Other	4,165 (20.3%)	253 (6.1%)	2,444 (58.7%)	1,468 (35.3%)
Publication Year - Avg (Std)	2001 (10.2)	2005 (8.1)	2001 (10.4)	2001 (9.9)
Study Age at Review - Avg (Std)	13.44 (10.1)	9.81 (8.0)	13.39 (10.3)	14.14 (9.9)

Table 1. Descriptive statistics. Unless otherwise specified, column 1 reports the number of studies and their proportion as of the total number of studies (N=20,571). Columns 2-4 report the number of studies in each category and their proportion as of the number of studies in column 1. For number of authors, publication year and study age at time of review, Table 1 reports the average and standard deviation. *One study can belong to several technology categories. ** For some studies, affiliation address is not provided.

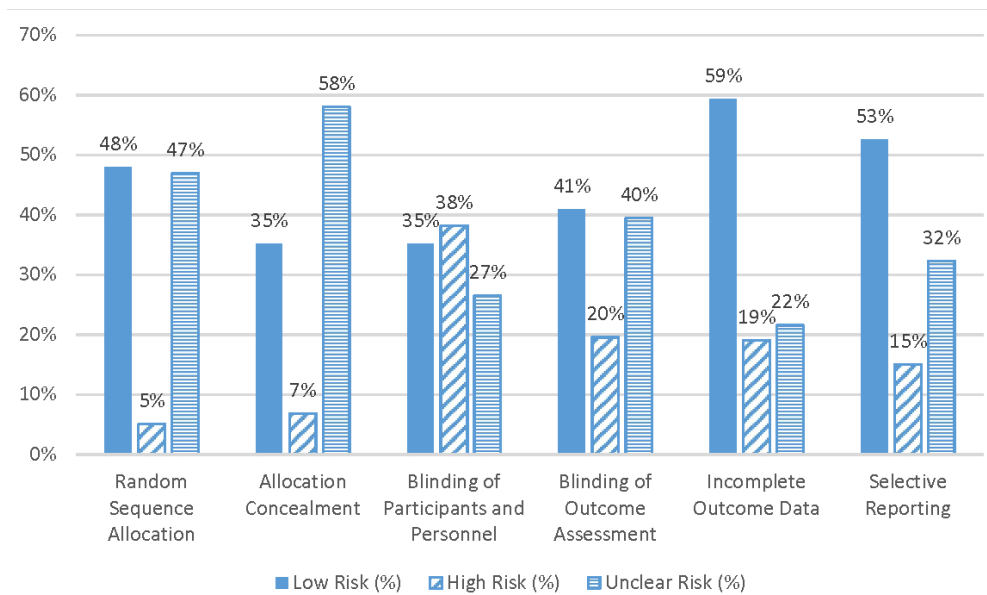


Fig. 1. Proportion of trials at low risk, high risk and unclear risk, for each dimension assessed. An observation is a study assessed on all six dimensions (N=20,571).

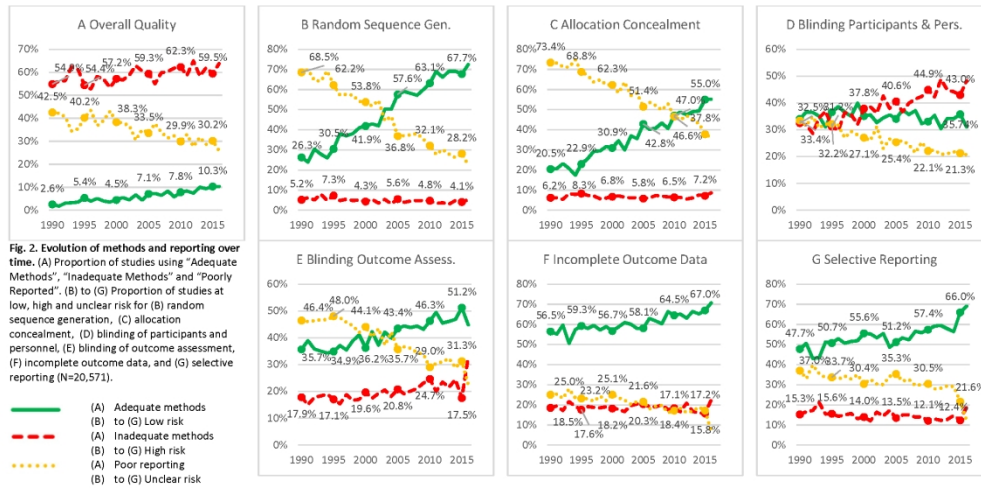


Fig. 2. Evolution of methods and reporting over time.

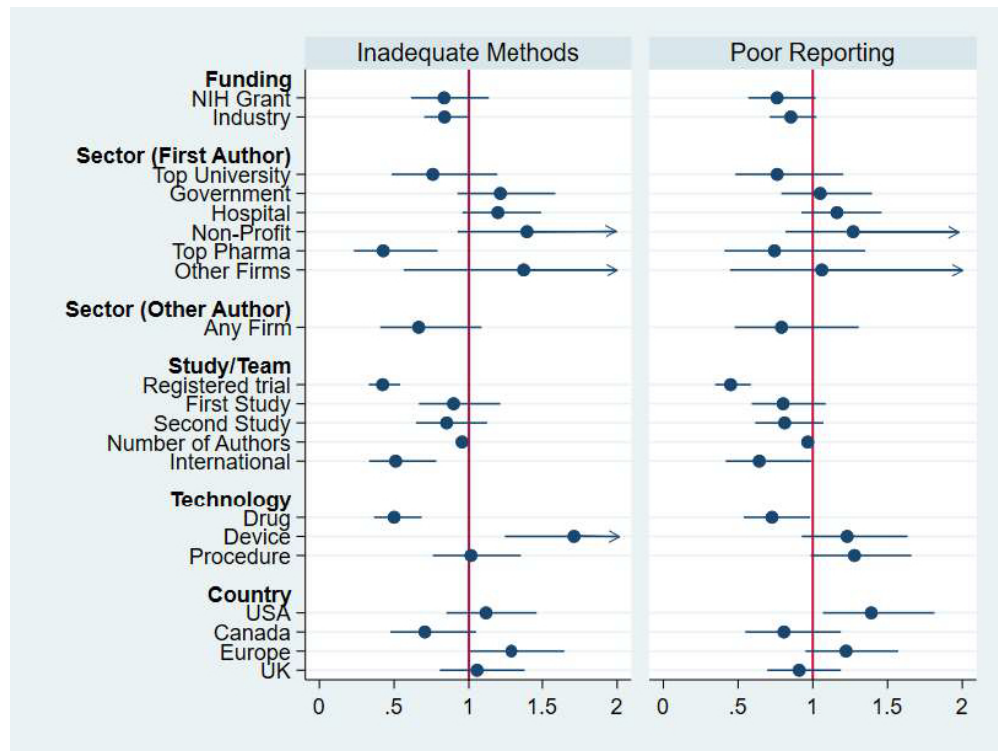


Fig. 3. Main regression results predicting relative risk ratios (RRR) for overall quality. RRR and 95% confidence intervals from estimating the multinomial logit model. An observation is a study (N=11,686). The dependent variable can take three values: adequate methods, inadequate methods and poor reporting. The reference category is adequate methods. Omitted sector category is other university, omitted technology category includes all other interventions, and omitted countries include all other countries. The regression includes topic and year fixed effects.

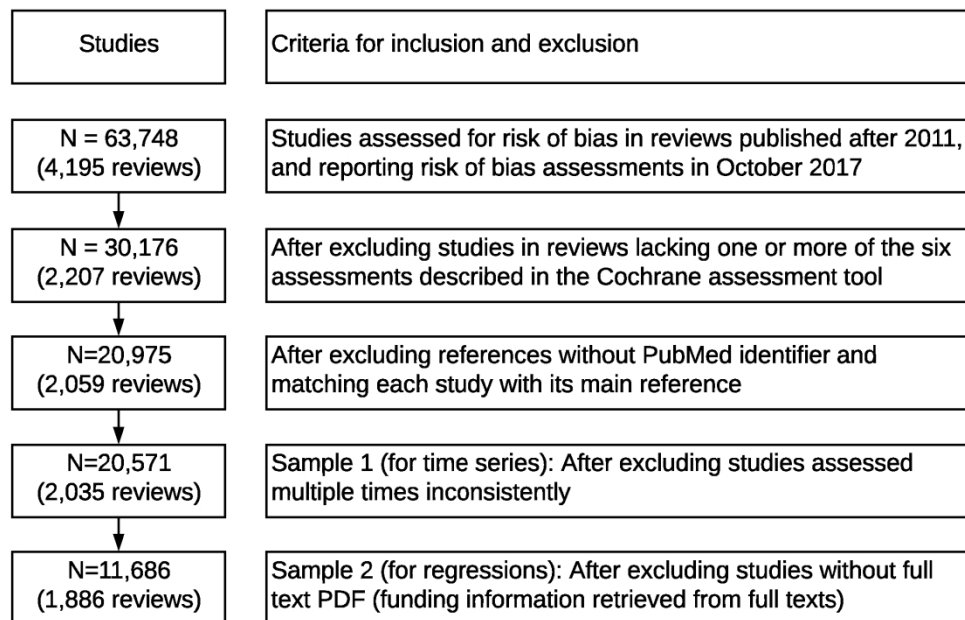


Fig. A1: Data flow and analysis sample

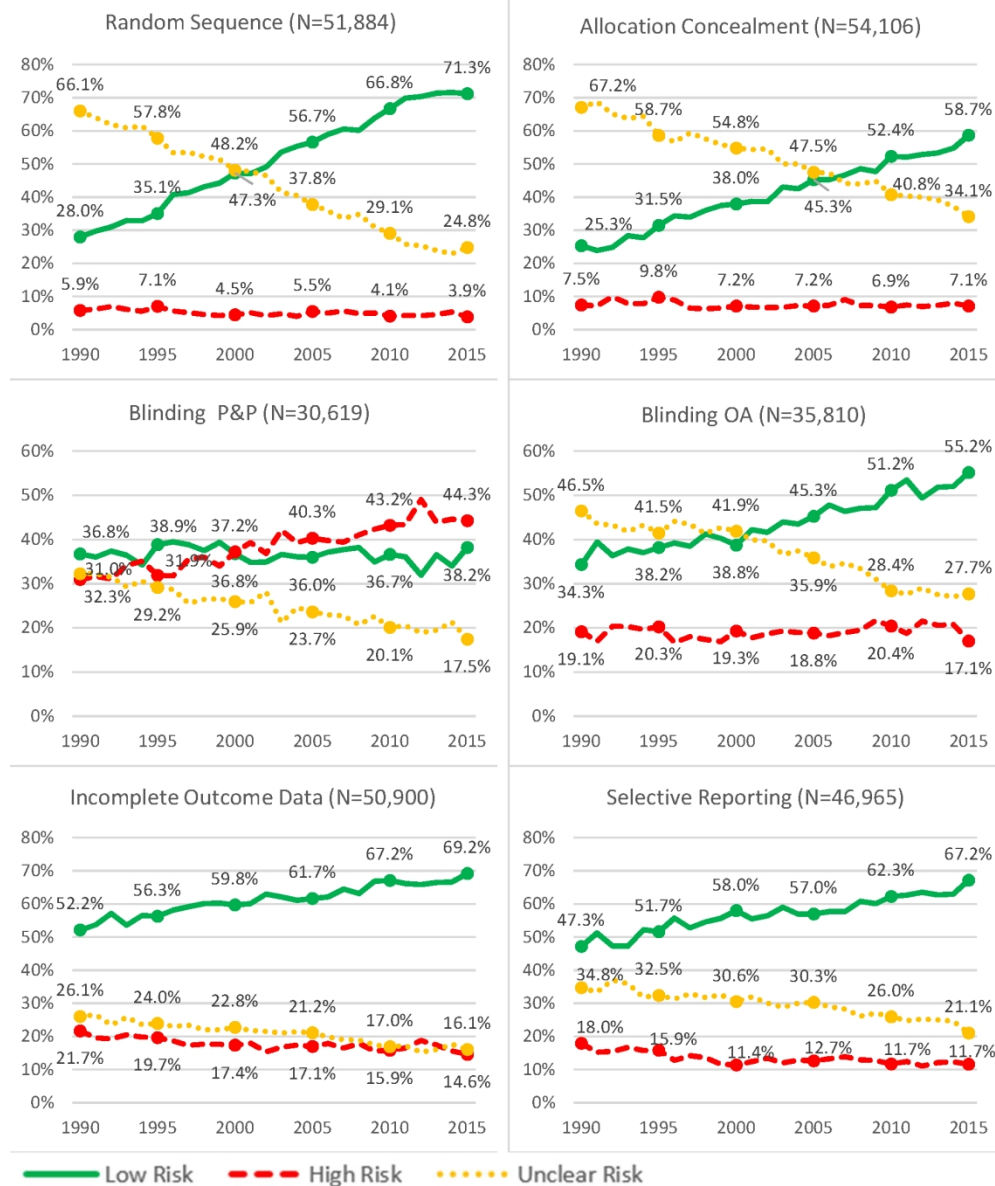


Fig. A2: This figure represents the proportion of studies at "low risk of bias", "high risk of bias", or "unclear risk of bias" for each dimension assessed, by publication year. An observation is a study. On each dimension, all studies assessed are included.

Supplementary Materials, Tables and Figures

Appendix A: List of top 25 universities in clinical medicine and pharmacy

Appendix B: List of top pharmaceutical companies

Table A1: Cochrane Risk of Bias Assessment Tool

Table A2: Main regression results predicting adequate methods, inadequate methods and poor reporting

Table A3: Regression results predicting relative risk ratios for each dimension

Figure A1: Flow diagram

Figure A2: Proportion of studies assessed at low risk of bias, high risk of bias and unclear risk of bias on each criterion, by publication year (including all studies assessed on at least one dimension)

Appendix A: List of top 25 universities in clinical medicine and pharmacy (AWRU, 2007)

- Harvard University
- University of California, San Francisco
- University of Washington
- The Johns Hopkins University
- Columbia University
- University of California, Los Angeles
- The University of Texas Southwestern Medical Center at Dallas
- University of Michigan - Ann Arbor
- Karolinska Institute
- University of Pittsburgh
- Stanford University
- Mayo Medical School
- University of Oxford
- University of Minnesota, Twin Cities
- University of Cambridge
- Yale University
- University College London
- The University of Texas M. D. Anderson Cancer Center
- University of Wisconsin - Madison
- Vanderbilt University
- University of Pennsylvania
- Duke University
- University of California, San Diego
- Tufts University
- The Imperial College of Science, Technology and Medicine

Appendix B: List of top pharmaceutical companies used in this study (by revenue)

- Johnson & Johnson
- Roche
- Pfizer
- Novartis
- Bayer
- Merck & Co
- GlaxoSmithKline
- Sanofi
- Abbvie
- Abbott Laboratories
- Eli Lilly & Co
- Amgen
- Bristol-Myers Squibb
- Gilead Sciences
- AstraZeneca
- Teva Pharmaceutical Industries
- Boehringer Ingelheim
- Merck Group
- Novo Nordisk
- Takeda Pharmaceutical
- Allergan plc
- Shire
- Celgene
- Biogen

Table A1: Cochrane Risk of Bias Assessment Tool

Bias domain	Source of bias	Support for judgement	Review Authors judgement
Selection bias	Random sequence generation	Describe the method used to generate the allocation sequence in sufficient detail to allow an assessment of whether it should produce comparable groups.	Selection bias (biased allocation to intervention) due to inadequate generation of a randomized sequence.
Selection bias	Allocation concealment	Describe the method used to conceal the allocation sequence in sufficient detail to determine whether intervention allocations could have been foreseen before or during enrollment.	Selection bias (biased allocation to interventions) due to inadequate concealment of allocations before assignment.
Performance bias	Blinding of participants and personnel	Describe all measures used, if any, to blind participants and researchers from knowledge of which intervention a participant received. Provide any information relating to whether the intended blinding was effective.	Performance bias due to knowledge of the allocated intervention by participants and personnel during the study.
Detection bias	Blinding of outcome assessment	Describe all measures used, if any, to blind outcome assessment from knowledge of which intervention a participant received. Provide any information relating to whether the intended blinding was effective.	Performance bias due to knowledge of the allocated intervention by outcome assessment.
Attrition bias	Incomplete outcome data	Describe the completeness of outcome data for each main outcome, including attrition and exclusions from the analysis. State whether attritions and exclusions were reported, the numbers in each intervention group (compared with total randomized participants), reasons for attrition or exclusion where reported, and any re-inclusion in the analysis for the review.	Attrition bias due to amount, nature or handling of incomplete outcome data
Reporting bias	Selective reporting	State how selective outcome reporting was examined and what was found.	Reporting bias due to selective outcome reporting.
Other bias	Anything else, pre-specified	State any important concerns about bias not covered in other domains in the tool.	Bias due to problems not covered elsewhere.

Source: Adapted from Higgins et al, 2011

Table A2: Main regression results predicting adequate methods, inadequate methods and poor reporting (Relative Risk Ratios)

	Inadequate Methods	Poor Reporting
Funding		
NIH Grant	0.83	0.76
Industry	0.84*	0.85
Sector (First Author)		
Top University	0.76	0.76
Government	1.21	1.05
Hospital	1.19	1.16
Non-Profit	1.40	1.27
Top Pharma	0.43**	0.74
Other Firms	1.38	1.06
Sector (Other Author)		
Any Firm	0.66	0.79
Study/Team		
Registered trial	0.42***	0.45***
First Study	0.90	0.80
Second Study	0.85	0.81
Number of Authors	0.95***	0.97***
International	0.51**	0.64*
Technology		
Drug	0.50***	0.73*
Device	1.71**	1.23
Procedure	1.01	1.28
Behavioral	2.63***	1.44
Geography		
USA	1.11	1.39*
Canada	0.71	0.81
Europe	1.29*	1.22
UK	1.06	0.91

* p<0.05, ** p<0.01, *** p<0.001

This table presents relative risk ratios and p-values from estimating the multinomial logit model. An observation in this regression is a study (N=11,686). The dependent variable can take three values: adequate methods, inadequate methods and poor reporting. The reference category is adequate methods. Omitted sector category is other university, omitted technology category includes all other interventions, and omitted countries include all other countries. The regression includes topic and year fixed effects.

Table A3: Regression results predicting relative risk ratios for each dimension

	Random Sequence		Allocation Conceal.		Blinding PP		Blinding OA		Incomplete Data		Selective Reporting	
	High	Unclear	High	Unclear	High	Unclear	High	Unclear	High	Unclear	High	Unclear
Funding												
NIH Grant	0.29***	0.90	0.51***	0.93	1.12	1.06	1.01	0.93	1.03	1.04	1.03	0.99
Industry	1.03	1.07	1.18	1.06	0.87*	0.92	0.98	0.98	0.97	0.99	1.06	1.04
Sector (First Author)												
Top University	0.99	0.96	0.91	0.88	0.85	0.83	0.84	0.85	0.90	1.05	1.19	1.08
Government	0.91	1.01	0.85	0.98	1.00	0.96	1.00	0.92	1.29**	1.14	1.15	1.12
Hospital	1.07	1.06	1.05	1.00	1.08	0.96	1.12	1.04	1.05	0.95	0.89	1.03
Non-Profit	1.40	1.05	1.34	0.91	1.08	1.02	1.13	0.99	1.01	1.03	1.03	1.07
Top Pharma	0.49	0.96	0.60	0.83	0.34***	0.73	0.56*	0.74	0.86	0.61	0.70	0.59*
Other Firms	2.19	1.64*	2.01	1.60*	0.64	0.94	0.56	1.41	1.30	1.12	2.16*	1.05
Sector (Other Author)												
Any Firm	0.18**	0.92	0.53	1.04	0.65**	0.94	0.86	1.21	1.39*	1.06	0.94	1.02
Study/Team												
Registered trial	0.31***	0.42***	0.39***	0.41***	0.72***	0.60***	0.58***	0.63***	0.67***	0.71***	0.66***	0.52***
First Study	0.95	0.81**	1.09	0.84*	1.15	1.07	1.02	0.85	0.97	0.90	1.14	1.03
Second Study	1.00	0.83*	1.01	0.80**	1.02	1.03	1.04	1.01	0.87	0.88	1.06	1.01
Number of Authors	0.92***	0.97***	0.93***	0.95***	0.98**	0.96***	0.95***	0.97***	0.98*	0.99	0.99	0.96***
International	0.88	0.79*	0.53*	0.74**	0.79	0.94	0.73*	0.75*	0.91	0.86	0.66*	0.82
Technology												
Drug	0.66*	1.14	0.76	1.11	0.41***	0.48***	0.82	0.87	0.92	0.94	1.00	1.05
Device	1.31	1.02	1.34	1.10	1.52**	0.93	1.27	0.93	0.91	1.02	1.02	0.83
Procedure	0.90	1.21**	0.93	1.22*	0.91	1.24	1.18	1.22	0.85	1.06	1.06	1.13
Behavioral	0.88	1.03	1.21	1.16	2.83***	1.53**	2.09***	1.27	1.34**	1.18	0.89	1.41*
Geography												
USA	1.04	1.15	0.93	1.12	0.73***	0.95	0.81	1.02	1.23*	1.22*	0.96	0.93
Canada	0.55	0.69**	0.69	0.61***	0.75	0.75	0.85	0.66**	0.94	1.09	0.76	0.88
Europe	0.80	1.05	0.79	0.96	1.13	1.05	1.29**	1.09	1.13	0.97	1.01	0.92
UK	0.89	0.89	0.65**	0.67***	1.03	0.87	1.11	0.96	1.04	1.01	1.07	0.86

Regression results predicting relative risk ratio for risk of bias for each dimension (reference category: low risk). *p<0.05, **p<0.01, ***p<0.001

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STROBE Statement—checklist of items that should be included in reports of observational studies

	Item No	Recommendation	Page No
Title and abstract	1	(a) Indicate the study's design with a commonly used term in the title or the abstract	1,2
		(b) Provide in the abstract an informative and balanced summary of what was done and what was found	2
Introduction			
Background/rationale	2	Explain the scientific background and rationale for the investigation being reported	4
Objectives	3	State specific objectives, including any prespecified hypotheses	4
Methods			
Study design	4	Present key elements of study design early in the paper	4
Setting	5	Describe the setting, locations, and relevant dates, including periods of recruitment, exposure, follow-up, and data collection	4,5
Participants	6	(a) <i>Cohort study</i> —Give the eligibility criteria, and the sources and methods of selection of participants. Describe methods of follow-up <i>Case-control study</i> —Give the eligibility criteria, and the sources and methods of case ascertainment and control selection. Give the rationale for the choice of cases and controls <i>Cross-sectional study</i> —Give the eligibility criteria, and the sources and methods of selection of participants	5
		(b) <i>Cohort study</i> —For matched studies, give matching criteria and number of exposed and unexposed <i>Case-control study</i> —For matched studies, give matching criteria and the number of controls per case	N/A
Variables	7	Clearly define all outcomes, exposures, predictors, potential confounders, and effect modifiers. Give diagnostic criteria, if applicable	5,6
Data sources/ measurement	8*	For each variable of interest, give sources of data and details of methods of assessment (measurement). Describe comparability of assessment methods if there is more than one group	6
Bias	9	Describe any efforts to address potential sources of bias	7,8
Study size	10	Explain how the study size was arrived at	5
Quantitative variables	11	Explain how quantitative variables were handled in the analyses. If applicable, describe which groupings were chosen and why	N/A
Statistical methods	12	(a) Describe all statistical methods, including those used to control for confounding	7
		(b) Describe any methods used to examine subgroups and interactions	N/A
		(c) Explain how missing data were addressed	8
		(d) <i>Cohort study</i> —If applicable, explain how loss to follow-up was addressed <i>Case-control study</i> —If applicable, explain how matching of cases and controls was addressed <i>Cross-sectional study</i> —If applicable, describe analytical methods taking account of sampling strategy	N/A
		(e) Describe any sensitivity analyses	N/A

Continued on next page

Results			
Participants	13*	(a) Report numbers of individuals at each stage of study—eg numbers potentially eligible, examined for eligibility, confirmed eligible, included in the study, completing follow-up, and analysed	5
		(b) Give reasons for non-participation at each stage	5
		(c) Consider use of a flow diagram	32
Descriptive data	14*	(a) Give characteristics of study participants (eg demographic, clinical, social) and information on exposures and potential confounders	21
		(b) Indicate number of participants with missing data for each variable of interest	21
		(c) <i>Cohort study</i> —Summarise follow-up time (eg, average and total amount)	N/A
Outcome data	15*	<i>Cohort study</i> —Report numbers of outcome events or summary measures over time	23
		<i>Case-control study</i> —Report numbers in each exposure category, or summary measures of exposure	N/A
		<i>Cross-sectional study</i> —Report numbers of outcome events or summary measures	N/A
Main results	16	(a) Give unadjusted estimates and, if applicable, confounder-adjusted estimates and their precision (eg, 95% confidence interval). Make clear which confounders were adjusted for and why they were included	7,8,9
		(b) Report category boundaries when continuous variables were categorized	N/A
		(c) If relevant, consider translating estimates of relative risk into absolute risk for a meaningful time period	N/A
Other analyses	17	Report other analyses done—eg analyses of subgroups and interactions, and sensitivity analyses	N/A
Discussion			
Key results	18	Summarise key results with reference to study objectives	9,10
Limitations	19	Discuss limitations of the study, taking into account sources of potential bias or imprecision. Discuss both direction and magnitude of any potential bias	10
Interpretation	20	Give a cautious overall interpretation of results considering objectives, limitations, multiplicity of analyses, results from similar studies, and other relevant evidence	9,10
Generalisability	21	Discuss the generalisability (external validity) of the study results	8
Other information			
Funding	22	Give the source of funding and the role of the funders for the present study and, if applicable, for the original study on which the present article is based	11

*Give information separately for cases and controls in case-control studies and, if applicable, for exposed and unexposed groups in cohort and cross-sectional studies.

Note: An Explanation and Elaboration article discusses each checklist item and gives methodological background and published examples of transparent reporting. The STROBE checklist is best used in conjunction with this article (freely available on the Web sites of PLoS Medicine at <http://www.plosmedicine.org/>, Annals of Internal Medicine at <http://www.annals.org/>, and Epidemiology at <http://www.epidem.com/>). Information on the STROBE Initiative is available at www.strobe-statement.org.

BMJ Open

Trends and Predictors of Biomedical Research Quality, 1990-2015: A Meta-Research Study

Journal:	<i>BMJ Open</i>
Manuscript ID	bmjopen-2019-030342.R1
Article Type:	Research
Date Submitted by the Author:	13-May-2019
Complete List of Authors:	Catillon, Maryaline; Harvard University, Ph.D. Program in Health Policy
Primary Subject Heading:	Research methods
Secondary Subject Heading:	Health policy, Health informatics, Health economics
Keywords:	STATISTICS & RESEARCH METHODS, Health informatics < BIOTECHNOLOGY & BIOINFORMATICS, Health policy < HEALTH SERVICES ADMINISTRATION & MANAGEMENT

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21 **Word count: 2855 (main text)**
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44 Maryaline Catillon (0000-0002-1360-8133)

45 Ph.D. Program in Health Policy, Harvard University, 14 Story Street, 4th Floor, Cambridge, MA
46 02138

47 mcatillon@g.harvard.edu
48

49 [\(+1\) 857 222 6863](tel:+18572226863)
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ABSTRACT

Objective: To measure the frequency of adequate methods, inadequate methods and poor reporting in published randomized controlled trials and test potential factors associated with adequacy of methods and reporting.

Design: Retrospective analysis of randomized controlled trials (RCTs) included in Cochrane reviews. Time series describe the proportion of RCTs using adequate methods, inadequate methods and poor reporting. A multinomial logit model tests potential factors associated with methods and reporting, including funding source, first author affiliation, clinical trial registration status, study novelty, team characteristics, technology and geography.

Data: Risk of bias assessments for random sequence generation, allocation concealment, blinding of participants and personnel, blinding of outcome assessment, incomplete outcome data and selective reporting, for each RCT, were mapped to bibliometric and funding data.

Outcomes: Risk of bias on six methodological dimensions, and RCT-level overall assessment of adequate methods, inadequate methods or poor reporting.

Results: This study analyzed 20,571 RCTs. 5.7% of RCTs used adequate methods (N=1,173). 59.3% used inadequate methods (N=12,190) and 35.0% were poorly reported (N=7,208). The proportion of poorly reported RCTs decreased from 42.5% in 1990 to 30.2% in 2015. The proportion of RCTs using adequate methods increased from 2.6% in 1990 to 10.3% in 2015. The proportion of RCTs using inadequate methods increased from 54.9% in 1990 to 59.5% in 2015. Industry funding, top pharmaceutical company affiliation, trial registration, larger authorship teams, international teams, and drug trials were associated with a greater likelihood of using adequate methods. NIH funding and university prestige were not.

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3 **Conclusion:** Even though reporting has improved since 1990, the proportion of RCTs using
4 inadequate methods is high (59.3%) and increasing, potentially slowing progress in medical
5 knowledge and contributing to the reproducibility crisis. Stronger incentives for the use of
6 adequate methods are needed.
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11 12 13 **STRENGTHS AND LIMITATIONS OF THIS STUDY** 14 15

- 16 • This work combines the strengths of expert human assessments with data science
17 techniques to build a comprehensive database on biomedical research quality, including
18 the full-text and systematic assessment of RCT methods with bibliometric and funding
19 information in a sample of 20,571 RCTs.
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- 22 • The study analyzes trends in methods and reporting over 25 years and identifies factors
23 associated with biomedical research quality including funding source, first author
24 affiliation, clinical trial registration status, study novelty, team characteristics, technology
25 and geography.
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- 28 • PubMed identifier, full-text and/or funding information were not available for all RCTs.
29 30.5% of RCTs (unpublished or published in journals not indexed in PubMed) did not
30 have a PubMed identifier. 43.2% of RCTs with PubMed identifier did not have a full-text
31 available from the Harvard Library. 23.6% of included RCTs were reported in articles
32 disclosing NIH or industry funding. Classification of sectors relies on primary reported
33 affiliation.
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35
- 36 • Cochrane reviewers may have been able to obtain more information on more recent
37 RCTs (from authors, registries, or protocols rather than the primary report), suggesting
38 some of the apparent improvement in reporting may reflect an improvement in access to
39 study details.
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- This study does not identify causal mechanisms explaining biomedical research quality.

INTRODUCTION

The quality and reliability of biomedical research are of paramount importance to treatment decisions and patient outcomes. Flawed research conclusions can lead to poor treatment and harm patients. As much as 85% of the annual \$265 billion spent on biomedical research may be wasted due to inadequate methods.[1-8]

Previous scientific work aiming to evaluate the reliability of biomedical research has been limited by data and methodological issues. Data challenges included the time and resources necessary to assess methods and reporting, resulting in the use of small selected samples and/or limited information available for each scientific article evaluated in larger samples.[9-28] As a result, it remains unknown what is the overall magnitude of waste due to inadequate methods and reporting in biomedical research and what factors are associated with the use of adequate versus inadequate research methods.

To address these questions, this study combines the full text of RCTs and full systematic assessment of study methods with bibliometric and funding information in a large sample of RCTs included in “gold standard” systematic reviews. The study describes the evolution of adequate research methods and reporting over time. A multinomial logit model tests potential factors associated with methods and reporting, including funding source, first author affiliation, clinical trial registration status, study novelty, team characteristics, technology and geography.

METHODS

This work combines the strengths of human expert assessments with data science techniques to build a comprehensive database on biomedical research quality, including full-text, systematic

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3 assessment of study methods, bibliometric and funding information in a sample of 20,571 RCTs.
4
5 Python 3.6 and Stata 15 were used to assemble the database and conduct the analysis.
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8 **Data**

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11 Cochrane reviews constitute a valuable data source to assess biomedical research quality as they
12 follow strict methods and precise reporting guidelines defined in the Cochrane Handbook.[29-
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14 30] This study does not involve new assessment of the methods and reporting of included RCTs,
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16 but relies entirely on the assessments available in the Cochrane reviews, which are systematically
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18 performed by two expert reviewers who compare their assessments and reach consensus on the
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20 final assessment.[29] The research method dimensions evaluated in Cochrane reviews include
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22 random sequence generation, allocation concealment, blinding of participants and personnel,
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24 blinding of outcome assessment, incomplete outcome data, and selective reporting (detailed in
25
26 Supplementary Table A1).[31]
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33 The database assembly had seven steps: (1) All included references were extracted from each
34
35 review, including PubMed identifiers. (2) All risk of bias assessments on the six dimensions of
36
37 the 2011 update of the Cochrane Risk of Bias Assessment Tool (see Table A1) were extracted
38
39 from each review. Each assessment included three variables: bias type (e.g., random sequence
40
41 generation), judgement (e.g., low risk) and support for judgement (e.g., computer random
42
43 number generator). (3) Each RCT was matched with its main published reference as identified by
44
45 Cochrane reviewers. (4) PubMed records corresponding to these publications, including
46
47 bibliometric information and first author affiliation, were retrieved using the E-utilities public
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49 API. (5) Affiliation information for other authors (not available from PubMed over the study
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51 period) was retrieved from SCOPUS. (6) Full-text for references with PubMed identifier were
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3 retrieved from the Harvard Library. (7) Industry funding information was extracted from the full-
4 text PDFs.
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7
8 Sector affiliation with university, government, hospital, non-profit, top pharmaceutical company
9 or other firm, as well as geographic variables were derived from the first author affiliation
10 address. Top 25 Universities were identified using the 2007 Academic Ranking of World
11 Universities in Clinical Medicine and Pharmacy (see supplementary material, Appendix A).
12 Firms were classified as top pharmaceutical companies or other firms using the listing of
13 pharmaceutical companies with a revenue greater than \$10 billion in any year since 2011 (see
14 supplementary material, Appendix B). Technologies were retrieved from the keywords and
15 abstracts of the Cochrane Reviews. Private funding information was retrieved from the full-text
16 PDF of the main reference.
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29 30 **Sample**

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32 Figure 1 summarizes the data flow. All RCTs assessed for risk of bias after 2011 (update of the
33 Risk of Bias Assessment Tool) and through October 2017 were considered for inclusion
34 (N=63,748 RCTs included in 4,195 reviews). This list of Cochrane reviews is reported in
35 Appendix C.
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42 Criteria for study inclusion were: (1) the review included all six assessments (to allow
43 comparison of the overall use of adequate methods, inadequate methods and poor reporting
44 across reviews) (1,988 reviews dropped), (2) the article reporting the study was referenced in
45 PubMed (to allow bibliometric data to enter the analysis)(N=9,201 RCTs dropped) and (3)
46 Duplicates were removed. (4) RCTs assessed multiple times with different outcomes (e.g., high
47 risk in one review, unclear risk in another) were dropped. (N=404 RCTs dropped).
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3 Applying these criteria, the analysis sample for the descriptive statistics and the time-series of
4 methods included 20,571 RCTs. A full-text PDF was available from the Harvard Library for
5
6 11,686 RCTs. This subsample was needed to retrieve private funding information from the full-
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8 text of the paper and constitutes the analysis sample for those regressions including funding
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10 information.
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14 15 **Analysis**

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18 The outcomes were risk of bias on the six assessed methodological dimensions and RCT-level
19
20 assessment of adequate methods, inadequate methods or poor reporting. The six methodological
21
22 dimensions assessed included (1) random sequence generation, (2) allocation concealment, (3)
23
24 blinding of participants and personnel, (4) blinding of outcome assessment, (5) incomplete
25
26 outcome data and (6) selective reporting (detailed in Supplementary Table A1). The category
27
28 “Other bias” was not used in this study, as it includes concerns not necessarily about methods or
29
30 reporting, such as conflicts of interest.
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35 Following guidelines for assessing the quality of evidence[31] and previous empirical work [7],
36
37 the RCT-level assessment was “adequate methods” if the study was at low risk of bias on all
38
39 dimensions assessed. It was “inadequate methods” if the study was at high risk of bias for one or
40
41 more reasons. It was “poorly reported” if the reviewers did not have enough information to
42
43 assess whether the methods used were adequate or inadequate (if the study was at “unclear” risk
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45 of bias for at least one reason).
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50 Several reasons support the use of at least one high risk of bias assessment as the definition for
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52 inadequate methods. Some risk of bias domains might translate into more statistical bias than
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54 others, but empirical evidence on the relative importance of the risk of bias domains is limited,
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3 and the effect of several versus one high risk assessment on research outcomes is
4
5 unknown[32,33] The empirical relationship between risk of bias assessments and research
6
7 outcomes (including actual statistical bias) requires further research.
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10 There is also a theoretical reason to use at least one high risk of bias assessment as the definition
11
12 of method inadequacy. Cochrane risk of bias domains can be mapped to important conditions to
13
14 make RCTs valuable. If not truly randomized or if differences between the treatment and control
15
16 group are introduced post-randomization, a RCT may not produce an unbiased estimate of the
17
18 treatment effect.[34] These two conditions imply that one inadequacy in the randomization
19
20 process (non-random sequence generation or inadequate allocation concealment), or one
21
22 difference introduced post randomization between the treatment and control groups (through
23
24 inadequate blinding of participants, personnel, or outcome assessors) or after the trial (due to
25
26 incomplete outcome data or selective reporting) should be the default threshold for assessing
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28 methods adequacy.
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34 Two analyses were performed. The first reports the time series of the proportion of RCTs using
35
36 adequate methods, inadequate methods and poor reporting, for each dimension and in aggregate.
37
38 The second tests whether adequate methods, inadequate methods and poor reporting are
39
40 associated with funding source (NIH grant or industry funding), sector affiliation of first author
41
42 (Top University, Other University, Government, Hospital, Non-Profit, Top Pharmaceutical
43
44 Company, Other Firm), other industry affiliation, clinical trial registration status, study novelty
45
46 (first or subsequent study on a particular research question), team characteristics (number of
47
48 authors and international collaboration), technology (drug, device, surgery, behavioral
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50 intervention or other intervention), and geography of first author (Canada, Europe, UK, USA, or
51
52 other country). A multinomial logit model using these variables predicts overall adequate
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3 methods, inadequate methods and poor reporting, as well as risk of bias along each dimension
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5 assessed.
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8 **Patient involvement**

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11 Patients were not involved in any aspect of the study design, conduct, or in the development of
12
13 the research question or outcome measures. As a meta-research study, based on existing
14
15 published research, there was no patient recruitment for data collection.
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18 **RESULTS**

19 **Prevalence of Adequate Methods, Inadequate Methods, and Poor Reporting**

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21
22 Table 1 presents descriptive statistics. Only 5.7% of RCTs used adequate methods on all six
23
24 dimensions (N=1,173). 59.3% used inadequate methods on at least one dimension (N=12,190)
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26 and 35.0% were poorly reported (N=7,208).
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32 Figure 2 shows the proportion of RCTs at low, high or unclear risk of bias for random sequence
33
34 generation, allocation concealment, blinding of participants and personnel, blinding of outcome
35
36 assessment, incomplete outcome data and selective reporting, for all RCTs assessed on all six
37
38 dimensions (N=20,571). 38% of trials used inadequate methods for blinding of participants and
39
40 personnel. 15 to 20% of trials used inadequate methods for blinding of outcome assessment
41
42 (20%), incomplete outcome data (19%) and selective reporting (15%). The proportion of trials
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44 using inadequate methods for random sequence generation and allocation concealment was
45
46 lowest (respectively 5% and 7%), but these two dimensions were frequently poorly reported
47
48 (respectively 47% and 58% of trials).
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53 **Methods and reporting over time**

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3 Figure 3 shows the overall proportion of RCTs using adequate methods, inadequate methods and
4 poorly reported methods by year of publication. The proportion of poorly reported RCTs
5 decreased, 5 percentage points per decade, from 42.5% in 1990 to 30.2% in 2015. The proportion
6 of RCTs using adequate methods increased linearly, 3 percentage points per decade, from 2.6%
7 in 1990 to 10.3% in 2015. The proportion of RCTs using inadequate methods increased from
8 54.9% in 1990 to 59.5% in 2015.
9

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11
12 Reporting improved on all dimensions. The proportion of RCTs using adequate methods for
13 random sequence generation, allocation concealment, blinding of outcome assessment,
14 incomplete outcome data and selective reporting increased. In contrast, the proportion of trials
15 using inadequate methods for blinding of participants and personnel increased.
16

17
18 Figure 4 provides graphs similar to figure 3 for all RCTs assessed on at least one dimension
19 (N=63,748). Similar patterns suggest that the evolution over time observed for the RCTs
20 assessed on all dimensions (N=20,571) reflects the evolution over time in all RCTs assessed on
21 at least one dimension.
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27 **Factors associated with methods and reporting**

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29 Figure 5 reports regression results from a multinomial logit model predicting overall quality.
30 Tables A2 and A3 (Supplementary material) report all regression results.
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38 Public funding was not associated with the overall use of adequate methods. However, NIH
39 funded RCTs were less likely to use inadequate methods for random sequence generation
40 (RR=0.29, $p<0.001$) and allocation concealment (RR=0.51, $p<0.001$). Industry funded RCTs
41 were slightly more likely to use adequate methods (RR=0.84, $p<0.05$), because of better blinding
42 of participants and personnel (RR=0.87, $p<0.05$).
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3 First author affiliation with a top pharmaceutical company was associated with increased use of
4 adequate methods (RR=0.43, $p<0.01$). First author affiliation with top universities was not.

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8 Registered trials (RR=0.42, $p<0.001$), larger authorship teams (RR=0.95, $p<0.001$), international
9 teams (RR=0.51, $p<0.01$) and RCTs on drugs (RR=0.50, $p<0.001$) were less likely to use
10 inadequate methods. RCTs on medical devices were more likely to use inadequate methods
11 (RR=1.71, $p<0.01$).
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17 18 **DISCUSSION**

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21 In 1951, the first review assessing the quality of clinical trials found that only 27 of 100 were
22 well controlled[35,36]. Since, a steady stream of scholarly work periodically voiced concerns
23 about the quality of medical research[37,38,1-8]. Recent medical reversals[39], and the
24 reproducibility crisis[40], have sharpened focus on medical research quality. Newly available
25 large scale data, and data science techniques provide powerful tools to measure the overall
26 magnitude of the problem, investigate its determinants, and provide an evidence base to inform
27 the design and evaluation of future interventions. This study assessed whether methods and
28 reporting improved over time and identified the characteristics of better and worse RCTs.
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40 This study has six main results. First, in a large sample of RCTs assessed in systematic reviews,
41 only 5.7% used adequate methods, 59.3% used inadequate methods, and 35.0% were poorly
42 reported. Since the 1990s, reporting has improved. But in parallel with this improvement in
43 reporting, the proportion of trials using both adequate and inadequate methods has increased.
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50 The overall proportion of poorly reported trials decreased by about 5 percentage points per
51 decade. This is good news but much remains to be done. At the current rate of improvement, it
52 would take 50 years for 95% of RCTs to be adequately reported. These results are consistent
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3 with previous research finding improvements in reporting in several clinical areas such as
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5 physiotherapy[10], and dentistry[26]. The trends for each dimension assessed separately are also
6
7 very similar to those found in another large sample of RCTs.[25]
8
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10 These improvement in reporting happened over a period of time when the Consolidated
11
12 Standards of Reporting Trials (CONSORT) statement, a minimum set of evidence-based
13
14 reporting recommendations, and other initiatives, such as the EQUATOR Network, developed to
15
16 improve reporting practices.[41-45]. Since the 1990s, the CONSORT statement has been
17
18 endorsed by over 50% of the core clinical journals indexed in PubMed and may improve
19
20 reporting of RCTs they publish.[46] Spurred by the CONSORT statement, the EQUATOR
21
22 (Enhancing the QUALity and Transparency Of health Research) Network, was launched in 2008
23
24 in the UK to improve the reliability of medical publications by promoting transparent and
25
26 accurate reporting of health research.[47] Since, it has developed into a global initiative aiming
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28 to improve research reporting worldwide.[36]
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34 In parallel with this improvement in reporting, the proportion of trials using both adequate and
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36 inadequate methods has increased. The linear increase in the proportion of RCTs using adequate
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38 methods is heartening. However, improvement in the use of adequate methods is even slower
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40 than improvement in reporting. At the current rate of improvement (3 percentage points per
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42 decade), it would take more than a century for half the RCTs to use adequate methods. This
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44 finding is consistent with previous empirical results in small samples,[23] but contrasts with
45
46 research in larger samples analyzing each methodological dimension separately to conclude that
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48 methods improved over time.[25]
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53 Second, NIH funded RCTs were not more likely to use adequate methods. This is surprising
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55 given the rigorous grant application process, shown to select better scientific proposals,[48] and
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3 the public stakes in the reliability of publicly funded research.[49] Notably, the efforts of the
4
5 NIH to address the reproducibility crisis began just at the end of the study period.[50]
6
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8 Third, top pharmaceutical company affiliation was significantly associated with better methods.
9
10 Affiliation with other companies was not. Heterogeneity across firms may explain inconsistency
11
12 of previous research on the effect of industry funding or affiliation on research methods and
13
14 outcomes. [28,51]
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18 Fourth, University prestige was not associated with greater use of adequate methods. The current
19
20 scientific reward system focuses on numbers of publications and citations rather than the
21
22 assessment of research methods.[52] The resulting incentives affect both scientists and
23
24 institutions, as through the allocation of grant funding.[53,54] Thus, in a climate of
25
26 hypercompetition,[55] the use of adequate methods and reporting might yield little reward while
27
28 exposing scientists to better informed scrutiny.
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32 Fifth, team size and international collaboration were associated with greater use of adequate
33
34 methods. Increasing the number of authors by one was associated with a small, but highly
35
36 significant improvement in methods and reporting. Many RCTs are published by large teams so
37
38 it is not surprising that the effect of one additional author was small. But this effect was also
39
40 highly significant, consistent with previous research finding that larger teams and international
41
42 teams produce more frequently cited research.[56,57] Other team characteristics were associated
43
44 with performance in other settings, opening avenues for future research.[58,59]
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49 Finally, RCTs on drugs were more likely to use adequate methods than RCTs on other
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51 interventions, while RCTs on devices were more likely to use inadequate methods. In many
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53 countries, trials on drugs are more tightly regulated than trials on devices. In the US, under the
54
55 Federal Food, Drug, and Cosmetic Act (FDCA, 1938), drugs and devices face different
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premarket review and post-market compliance requirements. The finding is also consistent with specific barriers to the conduct of RCTs on medical devices, in particular for randomization and blinding, and with the lack of scientific advice and regulations for medical device trials [60]. RCTs on drugs were using better methods and reporting than RCTs on other interventions, but much remains to be done. This finding is consistent with previous work showing that even RCTs used in the drug approval process frequently use inadequate methods and reporting.[61]

Future research should carefully evaluate the effect of method adequacy on research outcomes, and identify successful strategies and incentives to accelerate the diffusion of good reporting practices and the adoption of adequate methods. Given the size of the medical research industry and its effect on human lives, successful evidence based policies could have tremendous impact.

Limitations

PubMed identifier, full-text and/or funding information were not available for all RCTs. 30.5% of RCTs (unpublished or published in journals not indexed in PubMed) did not have a PubMed identifier. 43.2% of RCTs with PubMed identifier did not have a full-text available from the Harvard Library. 23.6% of included RCTs were reported in articles disclosing NIH or industry funding. Classification of sectors relies on primary reported affiliation. This paper does not identify causal mechanisms explaining biomedical research quality.

Cochrane reviewers may have been able to obtain more information on more recent RCTs (from authors, registries, or protocols rather than the primary report), suggesting that some of the apparent improvement in reporting may in fact be an improvement in access to study details.

CONCLUSION

1
2
3 Even though reporting has improved since 1990, the proportion of RCTs using inadequate
4 methods is high (59.3%) and increasing, potentially slowing progress in medical knowledge and
5 contributing to the reproducibility crisis. Stronger incentives for the use of adequate methods are
6 needed.
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12 **Contributorship statement**

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16 Maryaline Catillon designed the study, performed the analysis, interpreted the results, wrote the
17 manuscript and approved the final version to be published. Maryaline Catillon accepts full
18 responsibility for the work and the conduct of the study, had access to the data, and controlled
19 the decision to publish.
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27
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49 NBER.
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Competing Interests Statement

Maryaline Catillon has completed the ICMJE uniform disclosure form at www.icmje.org/coi_disclosure.pdf and declares: the author reports grants from the National Institute on Aging of the National Institutes of Health during the conduct of the study.

Ethical approval

Not applicable. This is a meta-research study.

Data sharing

All data sources necessary to reproduce the analysis are described in the main text or the supplementary material. No additional data available.

Licence statement

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Figure 4: Evolution of methods and reporting over time. Proportion of RCTs at low risk, high risk and unclear risk, for each dimension assessed for all RCTs assessed on at least one dimension

Figure 5: Main regression results predicting relative risk ratios for overall quality

	All	Adequate	Inadequate Methods	Poor Reporting
Sample 1	20,571 (100%)	1,173 (5.7%)	12,190 (59.3%)	7,208 (35.0%)
Sample 2 (with full text)	11,686 (56.8%)	833 (7.1%)	6,783 (58.0%)	4,070 (34.8%)
Funder type				
NIH Grant	2,147 (10.4%)	146 (6.8%)	1,282 (59.7%)	719 (33.5%)
Industry funding	2,725 (13.2%)	283 (10.2%)	1,464 (52.6%)	978 (35.1%)
First Author Affiliation				
Top University	1,063 (5.2%)	51 (4.8%)	601 (56.5%)	411 (38.7%)
Other University	11,120 (54.1%)	677 (6.1%)	6,589 (59.3%)	3,854 (34.7%)
Hospital	4,450 (21.6%)	185 (4.2%)	2,608 (58.6%)	1,657 (37.2%)
Government	1,744 (8.5%)	108 (6.2%)	1,071 (61.4%)	565 (32.4%)
Non-Profit	751 (3.7%)	48 (6.4%)	454 (60.5%)	249 (33.2%)
Top Pharma	239 (1.2%)	26 (10.9%)	115 (48.1%)	98 (41.0%)
Other Firm	195 (1.0%)	13 (6.7%)	115 (59.0%)	67 (34.3%)
Other research institution	200 (1.0%)	18 (9.0%)	120 (60.0%)	62 (31.0%)
Other industry affiliation	570 (2.8%)	44 (7.7%)	287 (50.4%)	239 (41.9%)
Registered RCTs (NCT)	1,888 (9.2%)	298 (15.8%)	1,011 (53.6%)	579 (30.7%)
Novelty				
First study	2,284 (11.1%)	126 (5.5%)	1,390 (60.9%)	768 (33.6%)
Second study	2,124 (10.3%)	127 (6.0%)	1262 (59.4%)	735 (34.6%)
Team characteristics				
Number of Authors - Avg (Std)	6.15 (3.9)	8.04 (5.5)	5.99 (3.8)	6.13 (6.8)
International	748 (3.64%)	60 (8.02%)	379 (50.67%)	309 (41.31%)
Technology*				
Drug	13,485 (65.6%)	914 (6.8%)	7,306 (54.2%)	5,265 (39.0%)
Device	5,347 (26.0%)	235 (4.4%)	3,366 (63.0%)	1,746 (32.7%)
Procedure	8,710 (42.3%)	460 (5.3%)	4,925 (56.5%)	3,325 (38.2%)
Behavioral	4,543 (22.1%)	122 (2.7%)	3,239 (71.3%)	1,182 (26.0%)
Other	1,199 (5.8%)	78 (6.5%)	819 (68.3%)	302 (25.2%)
Geography**				
Canada	680 (3.3%)	61 (9.0%)	362 (53.2%)	257 (37.8%)
Europe	4,467 (21.7%)	254 (5.7%)	2,693 (60.3%)	1,520 (34.0%)
UK	2,306 (11.2%)	154 (6.7%)	1,399 (60.7%)	753 (32.7%)
USA	4,465 (21.7%)	284 (6.4%)	2,592 (58.1%)	1,589 (35.6%)
Other	4,165 (20.3%)	253 (6.1%)	2,444 (58.7%)	1,468 (35.3%)
Publication Year - Avg (Std)	2001 (10.2)	2005 (8.1)	2001 (10.4)	2001 (9.9)
Study Age at Review - Avg (Std)	13.44 (10.1)	9.81 (8.0)	13.39 (10.3)	14.14 (9.9)

Table 1. Descriptive statistics. Unless otherwise specified, column 1 reports the number of RCTs and their proportion as of the total number of RCTs (N=20,571). A RCT uses adequate methods if it is at "low risk of bias" on all six dimensions assessed (see Table A1). Methods are inadequate if a RCT is at "high risk of bias" for at least one reason. Methods are poorly reported there is no evidence of methods inadequacy, but at least one assessment is "unclear risk of bias". Columns 2-4 report the number of RCTs in each category and their proportion as of the number of RCTs in column 1. For number of authors, publication year and study age at time of review, Table 1 reports the average and standard deviation. *One RCT can belong to several technology categories. ** For some RCTs, affiliation address is not provided.

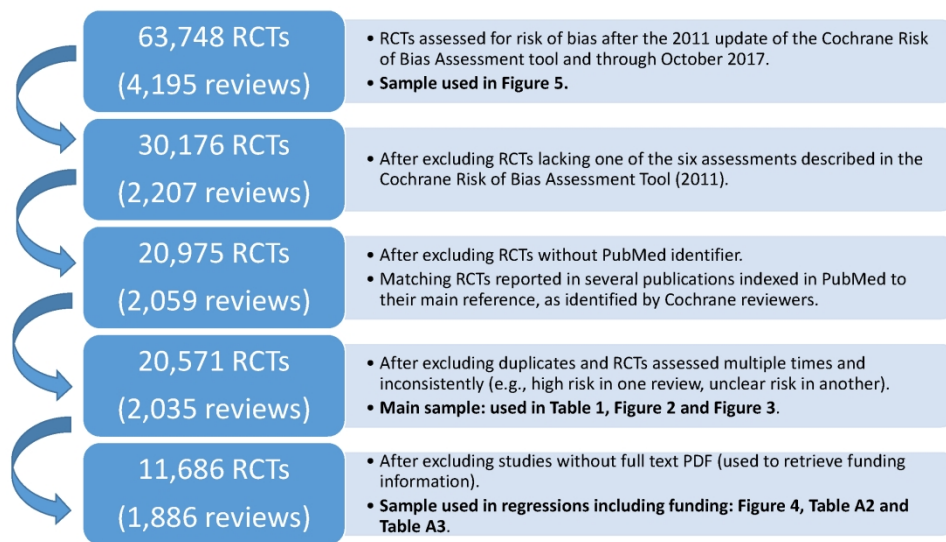


Fig.1. Data Flow

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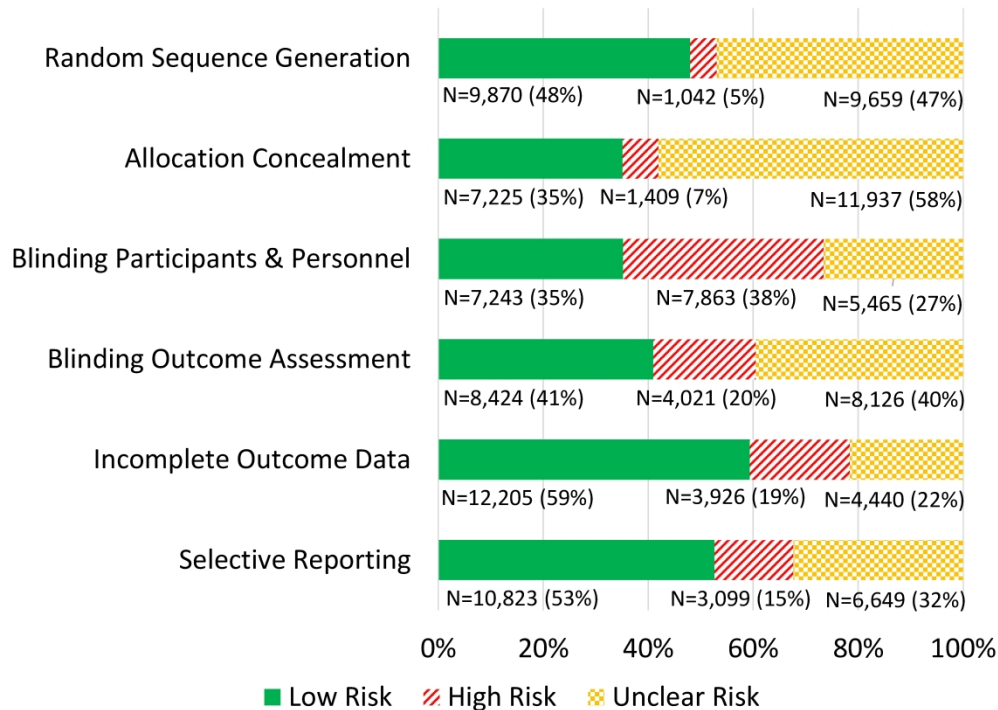


Fig.2. Number and proportion of RCTs at low risk of bias, high risk of bias and unclear risk of bias (N=20,571)

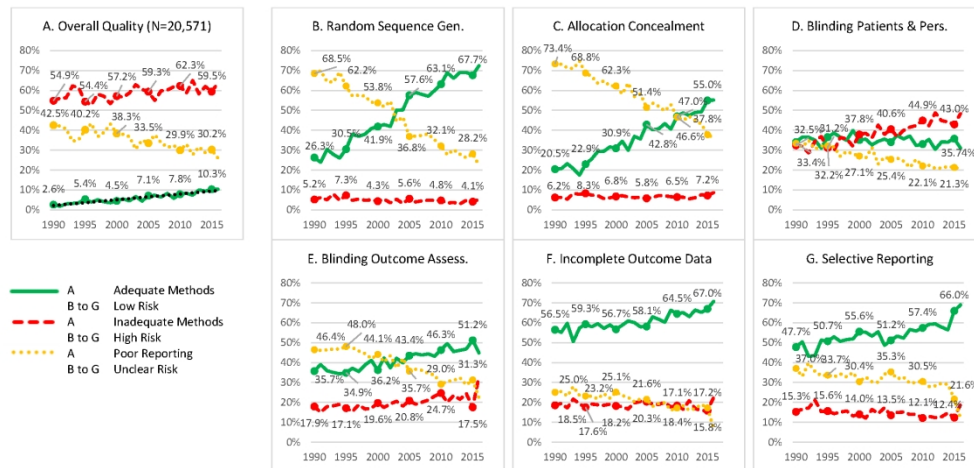


Fig.3. Evolution of methods and reporting over time. A.: Proportion of RCTs using adequate methods, inadequate methods and poorly reported. B. to G.: Proportion of RCTs at low risk of bias, high risk of bias and unclear risk of bias for each dimension assessed. See Table A1 for the definition of each dimension. N=20,571 RCTs. An observation is a RCT assessed on all six dimensions. See Figure 1 for more detailed information about the sample.

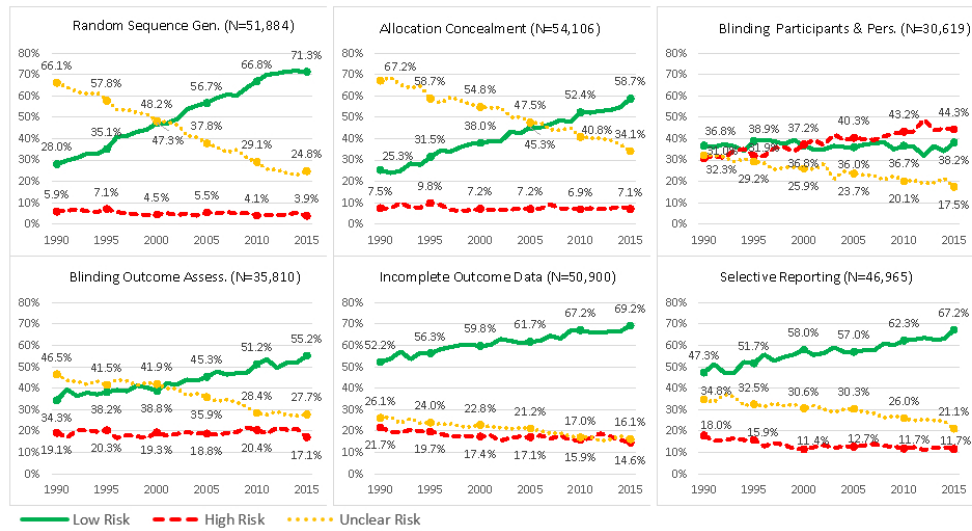


Fig.4. Same figure as Figure 3, but including all RCTs assessed on at least one dimension (as opposed to RCTs assessed on all six dimensions). Evolution of methods and reporting over time. A.: Proportion of RCTs using adequate methods, inadequate methods and poorly reported. B. to G.: Proportion of RCTs at low risk of bias, high risk of bias and unclear risk of bias for each dimension assessed. See Table A1 for the definition of each dimension.

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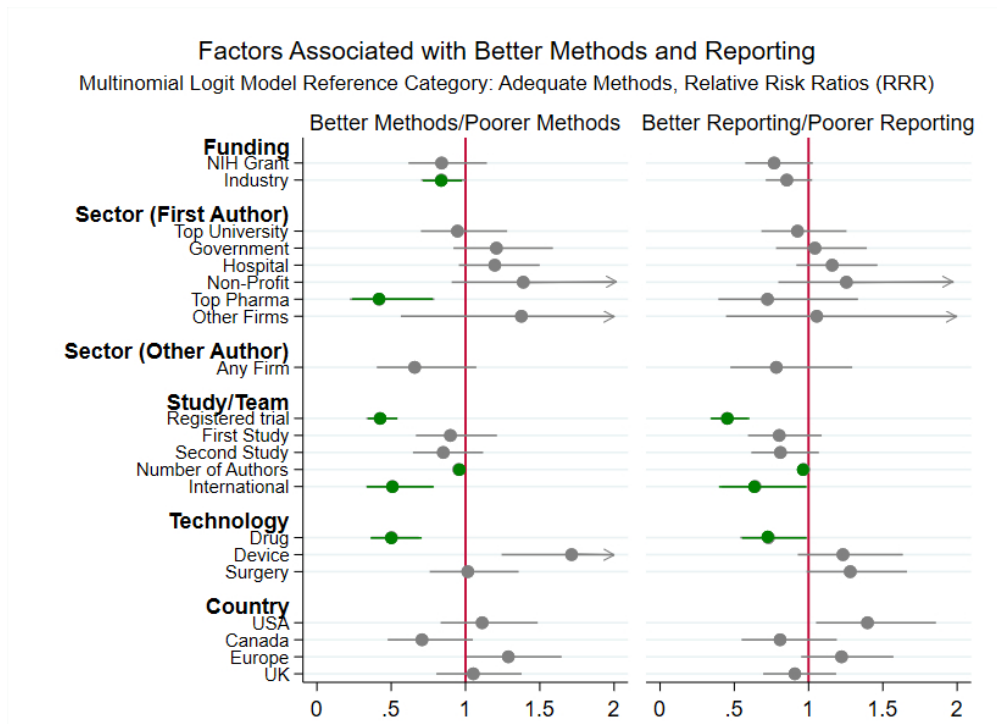


Fig.5. Main regression results (relative risk ratios and 95% confidence intervals) from the multinomial logit model predicting overall RCT quality. The arrow heads on the confidence intervals indicate that the upper bound of the 95% confidence interval is greater than 2. The dependent variable is a categorical variable and can take three values: adequate methods, inadequate methods and poor reporting. Adequate methods is the reference outcome category. The regression sample includes 11,686 RCTs with accessible full-text. See Figure 1 for more detailed information about the sample. The relative risk ratios represent the likelihood of a RCT with specific funding, sector, study/team, technology and country characteristics using inadequate methods (or being poorly reported), as compared to the likelihood of a RCT in a reference group without these characteristics using inadequate methods (or being poorly reported). In the regression, sector, technology and country are categorical variables. The omitted category for sector is other university. The omitted category for technology is other interventions. The omitted category for country is other countries. The regression includes topic and year fixed effects. The regression coefficients are reported in Table A2. Regression results predicting relative risk ratios for high or unclear risk of bias on each dimension assessed (as opposed to overall quality) are reported in Table A3.

289x216mm (72 x 72 DPI)

Supplementary Materials, Tables and Figures

Table A1: Cochrane Risk of Bias Assessment Tool

Table A2: Main regression results predicting adequate methods, inadequate methods and poor reporting

Table A3: Regression results predicting relative risk ratios for each dimension

Appendix A: List of top 25 universities in clinical medicine and pharmacy

Appendix B: List of top pharmaceutical companies

Appendix C: List of included Cochrane reviews

Table A1: Cochrane Risk of Bias Assessment Tool

Bias domain	Source of bias	Support for judgement	Review Authors judgement
Selection bias	Random sequence generation	Describe the method used to generate the allocation sequence in sufficient detail to allow an assessment of whether it should produce comparable groups.	Selection bias (biased allocation to intervention) due to inadequate generation of a randomized sequence.
Selection bias	Allocation concealment	Describe the method used to conceal the allocation sequence in sufficient detail to determine whether intervention allocations could have been foreseen before or during enrollment.	Selection bias (biased allocation to interventions) due to inadequate concealment of allocations before assignment.
Performance bias	Blinding of participants and personnel	Describe all measures used, if any, to blind participants and researchers from knowledge of which intervention a participant received. Provide any information relating to whether the intended blinding was effective.	Performance bias due to knowledge of the allocated intervention by participants and personnel during the study.
Detection bias	Blinding of outcome assessment	Describe all measures used, if any, to blind outcome assessment from knowledge of which intervention a participant received. Provide any information relating to whether the intended blinding was effective.	Performance bias due to knowledge of the allocated intervention by outcome assessment.
Attrition bias	Incomplete outcome data	Describe the completeness of outcome data for each main outcome, including attrition and exclusions from the analysis. State whether attritions and exclusions were reported, the numbers in each intervention group (compared with total randomized participants), reasons for attrition or exclusion where reported, and any re-inclusion in the analysis for the review.	Attrition bias due to amount, nature or handling of incomplete outcome data
Reporting bias	Selective reporting	State how selective outcome reporting was examined and what was found.	Reporting bias due to selective outcome reporting.
Other bias	Anything else, pre-specified	State any important concerns about bias not covered in other domains in the tool.	Bias due to problems not covered elsewhere.

Source: Adapted from Higgins et al, 2011

Table A2: Main regression results predicting adequate methods, inadequate methods and poor reporting (Relative Risk Ratios)

	Inadequate Methods	Poor Reporting
Funding		
NIH Grant	0.83	0.76
Industry	0.84*	0.85
Sector (First Author)		
Top University	0.76	0.76
Government	1.21	1.05
Hospital	1.19	1.16
Non-Profit	1.40	1.27
Top Pharma	0.43**	0.74
Other Firms	1.38	1.06
Sector (Other Author)		
Any Firm	0.66	0.79
Study/Team		
Registered trial	0.42***	0.45***
First Study	0.90	0.80
Second Study	0.85	0.81
Number of Authors	0.95***	0.97***
International	0.51**	0.64*
Technology		
Drug	0.50***	0.73*
Device	1.71**	1.23
Procedure	1.01	1.28
Behavioral	2.63***	1.44
Geography		
USA	1.11	1.39*
Canada	0.71	0.81
Europe	1.29*	1.22
UK	1.06	0.91

* p<0.05, ** p<0.01, *** p<0.001

This table presents main regression results (relative risk ratios and p-values) from estimating the multinomial logit model predicting overall RCT quality. The dependent variable is a categorical variable and can take three values: adequate methods, inadequate methods and poor reporting. Adequate methods is the reference outcome category. The regression sample includes 11,686 RCTs with accessible full-text. See Figure A1 for more detailed information about the sample. The relative risk ratios represent the likelihood of a RCT with specific funding, sector, study/team, technology and country characteristics using inadequate methods (or being poorly reported), as compared to the likelihood of a RCT in a reference group without these characteristics using inadequate methods (or being poorly reported). In the regression, sector, technology and country are categorical variables. The omitted category for sector is other university. The omitted category for technology is other interventions. The omitted category for country is other countries. The regression includes topic and year fixed effects. These results are plotted in Figure 3. Other regression results predicting relative risk ratios for high or unclear risk of bias on each dimension assessed (as opposed to overall quality) are reported in Table A3.

Table A3: Regression results predicting relative risk ratios for each dimension

	Random Sequence		Allocation Conceal.		Blinding PP		Blinding OA		Incomplete Data		Selective Reporting	
	High	Unclear	High	Unclear	High	Unclear	High	Unclear	High	Unclear	High	Unclear
Funding												
NIH Grant	0.29***	0.90	0.51***	0.93	1.12	1.06	1.01	0.93	1.03	1.04	1.03	0.99
Industry	1.03	1.07	1.18	1.06	0.87*	0.92	0.98	0.98	0.97	0.99	1.06	1.04
Sector (First Author)												
Top University	0.99	0.96	0.91	0.88	0.85	0.83	0.84	0.85	0.90	1.05	1.19	1.08
Government	0.91	1.01	0.85	0.98	1.00	0.96	1.00	0.92	1.29**	1.14	1.15	1.12
Hospital	1.07	1.06	1.05	1.00	1.08	0.96	1.12	1.04	1.05	0.95	0.89	1.03
Non-Profit	1.40	1.05	1.34	0.91	1.08	1.02	1.13	0.99	1.01	1.03	1.03	1.07
Top Pharma	0.49	0.96	0.60	0.83	0.34***	0.73	0.56*	0.74	0.86	0.61	0.70	0.59*
Other Firms	2.19	1.64*	2.01	1.60*	0.64	0.94	0.56	1.41	1.30	1.12	2.16*	1.05
Sector (Other Author)												
Any Firm	0.18**	0.92	0.53	1.04	0.65**	0.94	0.86	1.21	1.39*	1.06	0.94	1.02
Study/Team												
Registered trial	0.31***	0.42***	0.39***	0.41***	0.72***	0.60***	0.58***	0.63***	0.67***	0.71***	0.66***	0.52***
First Study	0.95	0.81**	1.09	0.84*	1.15	1.07	1.02	0.85	0.97	0.90	1.14	1.03
Second Study	1.00	0.83*	1.01	0.80**	1.02	1.03	1.04	1.01	0.87	0.88	1.06	1.01
Number of Authors	0.92***	0.97***	0.93***	0.95***	0.98**	0.96***	0.95***	0.97***	0.98*	0.99	0.99	0.96***
International	0.88	0.79*	0.53*	0.74**	0.79	0.94	0.73*	0.75*	0.91	0.86	0.66*	0.82
Technology												
Drug	0.66*	1.14	0.76	1.11	0.41***	0.48***	0.82	0.87	0.92	0.94	1.00	1.05
Device	1.31	1.02	1.34	1.10	1.52**	0.93	1.27	0.93	0.91	1.02	1.02	0.83
Procedure	0.90	1.21**	0.93	1.22*	0.91	1.24	1.18	1.22	0.85	1.06	1.06	1.13
Behavioral	0.88	1.03	1.21	1.16	2.83***	1.53**	2.09***	1.27	1.34**	1.18	0.89	1.41*
Geography												
USA	1.04	1.15	0.93	1.12	0.73***	0.95	0.81	1.02	1.23*	1.22*	0.96	0.93
Canada	0.55	0.69**	0.69	0.61***	0.75	0.75	0.85	0.66**	0.94	1.09	0.76	0.88
Europe	0.80	1.05	0.79	0.96	1.13	1.05	1.29**	1.09	1.13	0.97	1.01	0.92
UK	0.89	0.89	0.65**	0.67***	1.03	0.87	1.11	0.96	1.04	1.01	1.07	0.86

*p<0.05, **p<0.01, ***p<0.001

1 This table presents main regression results (relative risk ratios and p-values) from estimating the multinomial logit model predicting risk of bias for each dimension assessed.
2 The dependent variable is a categorical variable and can take three values: low risk, high risk or unclear risk. Low risk is the reference outcome category. The regression
3 sample includes 11,686 RCTs with accessible full-text. See Figure A1 for more detailed information about the sample. The relative risk ratios represent the likelihood of a RCT
4 with specific funding, sector, study/team, technology and country characteristics being assessed at high risk (or unclear risk) as compared to the likelihood of a RCT in a
5 reference group without these characteristics being assessed at high risk (or unclear risk). In the regression, sector, technology and country are categorical variables. The
6 omitted category for sector is other university. The omitted category for technology is other interventions. The omitted category for country is other countries. The regression
7 includes topic and year fixed effects. Other regression results predicting relative risk ratios for overall quality (as opposed to relative risk ratios for high or unclear risk of bias
8 on each dimension assessed) are reported in Table A2.
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For peer review only

Appendix A: List of top 25 universities in clinical medicine and pharmacy (AWRU, 2007)

- Harvard University
- University of California, San Francisco
- University of Washington
- The Johns Hopkins University
- Columbia University
- University of California, Los Angeles
- The University of Texas Southwestern Medical Center at Dallas
- University of Michigan - Ann Arbor
- Karolinska Institute
- University of Pittsburgh
- Stanford University
- Mayo Medical School
- University of Oxford
- University of Minnesota, Twin Cities
- University of Cambridge
- Yale University
- University College London
- The University of Texas M. D. Anderson Cancer Center
- University of Wisconsin - Madison
- Vanderbilt University
- University of Pennsylvania
- Duke University
- University of California, San Diego
- Tufts University
- The Imperial College of Science, Technology and Medicine

Appendix B: List of top pharmaceutical companies used in this study (by revenue)

- Johnson & Johnson
- Roche
- Pfizer
- Novartis
- Bayer
- Merck & Co
- GlaxoSmithKline
- Sanofi
- Abbvie
- Abbott Laboratories
- Eli Lilly & Co
- Amgen
- Bristol-Myers Squibb
- Gilead Sciences
- AstraZeneca
- Teva Pharmaceutical Industries
- Boehringer Ingelheim
- Merck Group
- Novo Nordisk
- Takeda Pharmaceutical
- Allergan plc
- Shire
- Celgene
- Biogen

Appendix C: List of included Cochrane reviews (DOIs)

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STROBE Statement—checklist of items that should be included in reports of observational studies

	Item No	Recommendation	Page No
Title and abstract	1	(a) Indicate the study's design with a commonly used term in the title or the abstract	1,2
		(b) Provide in the abstract an informative and balanced summary of what was done and what was found	2
Introduction			
Background/rationale	2	Explain the scientific background and rationale for the investigation being reported	4
Objectives	3	State specific objectives, including any prespecified hypotheses	4
Methods			
Study design	4	Present key elements of study design early in the paper	4
Setting	5	Describe the setting, locations, and relevant dates, including periods of recruitment, exposure, follow-up, and data collection	4,5
Participants	6	(a) <i>Cohort study</i> —Give the eligibility criteria, and the sources and methods of selection of participants. Describe methods of follow-up <i>Case-control study</i> —Give the eligibility criteria, and the sources and methods of case ascertainment and control selection. Give the rationale for the choice of cases and controls <i>Cross-sectional study</i> —Give the eligibility criteria, and the sources and methods of selection of participants	5
		(b) <i>Cohort study</i> —For matched studies, give matching criteria and number of exposed and unexposed <i>Case-control study</i> —For matched studies, give matching criteria and the number of controls per case	N/A
Variables	7	Clearly define all outcomes, exposures, predictors, potential confounders, and effect modifiers. Give diagnostic criteria, if applicable	5,6
Data sources/ measurement	8*	For each variable of interest, give sources of data and details of methods of assessment (measurement). Describe comparability of assessment methods if there is more than one group	6
Bias	9	Describe any efforts to address potential sources of bias	7,8
Study size	10	Explain how the study size was arrived at	5
Quantitative variables	11	Explain how quantitative variables were handled in the analyses. If applicable, describe which groupings were chosen and why	N/A
Statistical methods	12	(a) Describe all statistical methods, including those used to control for confounding	7
		(b) Describe any methods used to examine subgroups and interactions	N/A
		(c) Explain how missing data were addressed	8
		(d) <i>Cohort study</i> —If applicable, explain how loss to follow-up was addressed <i>Case-control study</i> —If applicable, explain how matching of cases and controls was addressed <i>Cross-sectional study</i> —If applicable, describe analytical methods taking account of sampling strategy	N/A
		(e) Describe any sensitivity analyses	N/A

Continued on next page

Results			
Participants	13*	(a) Report numbers of individuals at each stage of study—eg numbers potentially eligible, examined for eligibility, confirmed eligible, included in the study, completing follow-up, and analysed	5
		(b) Give reasons for non-participation at each stage	5
		(c) Consider use of a flow diagram	32
Descriptive data	14*	(a) Give characteristics of study participants (eg demographic, clinical, social) and information on exposures and potential confounders	21
		(b) Indicate number of participants with missing data for each variable of interest	21
		(c) <i>Cohort study</i> —Summarise follow-up time (eg, average and total amount)	N/A
Outcome data	15*	<i>Cohort study</i> —Report numbers of outcome events or summary measures over time	23
		<i>Case-control study</i> —Report numbers in each exposure category, or summary measures of exposure	N/A
		<i>Cross-sectional study</i> —Report numbers of outcome events or summary measures	N/A
Main results	16	(a) Give unadjusted estimates and, if applicable, confounder-adjusted estimates and their precision (eg, 95% confidence interval). Make clear which confounders were adjusted for and why they were included	7,8,9
		(b) Report category boundaries when continuous variables were categorized	N/A
		(c) If relevant, consider translating estimates of relative risk into absolute risk for a meaningful time period	N/A
Other analyses	17	Report other analyses done—eg analyses of subgroups and interactions, and sensitivity analyses	N/A
Discussion			
Key results	18	Summarise key results with reference to study objectives	9,10
Limitations	19	Discuss limitations of the study, taking into account sources of potential bias or imprecision. Discuss both direction and magnitude of any potential bias	10
Interpretation	20	Give a cautious overall interpretation of results considering objectives, limitations, multiplicity of analyses, results from similar studies, and other relevant evidence	9,10
Generalisability	21	Discuss the generalisability (external validity) of the study results	8
Other information			
Funding	22	Give the source of funding and the role of the funders for the present study and, if applicable, for the original study on which the present article is based	11

*Give information separately for cases and controls in case-control studies and, if applicable, for exposed and unexposed groups in cohort and cross-sectional studies.

Note: An Explanation and Elaboration article discusses each checklist item and gives methodological background and published examples of transparent reporting. The STROBE checklist is best used in conjunction with this article (freely available on the Web sites of PLoS Medicine at <http://www.plosmedicine.org/>, Annals of Internal Medicine at <http://www.annals.org/>, and Epidemiology at <http://www.epidem.com/>). Information on the STROBE Initiative is available at www.strobe-statement.org.