A Systematic Examination of the Citation of Prior Research in Reports of Randomized, Controlled Trials

Karen A. Robinson, PhD, and Steven N. Goodman, MD, MHS, PhD

Background: A randomized, controlled trial (RCT) should not be started or interpreted without accounting for evidence from preceding RCTs addressing the same question. Research has suggested that evidence from prior trials is often not accounted for in reports of subsequent RCTs.

Objective: To assess the extent to which reports of RCTs cite prior trials studying the same interventions.

Design: Meta-analyses published in 2004 that combined 4 or more trials were identified; within each meta-analysis, the extent to which each trial report cited the trials that preceded it by more than 1 year was assessed.

Measurements: The proportion of prior trials that were cited (prior research citation index), the proportion of the total participants from prior trials that were in the cited trials (sample size citation index), and the absolute number of trials cited were calculated.

Results: 227 meta-analyses were identified, comprising 1523 trials published from 1963 to 2004. The median prior research citation index was 0.21 (95% CI, 0.18 to 0.24), meaning that less than one quarter of relevant reports were cited. The median sample size citation index was 0.21 (95% CI, 0.18 to 0.24), suggesting that larger trials were not selectively cited. Of the 1101 RCTs that had 5 or more prior trials to cite, 254 (23%) cited no prior RCTs and 257 (23%) cited only 1. The median number of prior cited trials was 2, which did not change as the number of citable trials increased. The mean number of preceding trials cited by trials published after 2000 was 2.4, compared with 1.5 for those published before 2000 (P < 0.001).

Limitation: The investigators could not ascertain why prior trials were not cited, and noncited trials may have been taken into account in the trial design and proposal stages.

Conclusion: In reports of RCTs published over 4 decades, fewer than 25% of preceding trials were cited, comprising fewer than 25% of the participants enrolled in all relevant prior trials. A median of 2 trials was cited, regardless of the number of prior trials that had been conducted. Research is needed to explore the explanations for and consequences of this phenomenon. Potential implications include ethically unjustifiable trials, wasted resources, incorrect conclusions, and unnecessary risks for trial participants.

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For author affiliations, see end of text.
RCTs included in 1 forest plot or 1 summary estimate). When multiple meta-analyses were reported in the same review, the analysis with the largest number of RCTs was selected. A database from Web of Science provided the articles referenced by each systematic review, and the articles referenced by those articles. These data were manipulated and analyzed by using Python (Python Software Foundation, Wolfeboro Falls, New Hampshire) and Stata (StataCorp, College Station, Texas).

### Statistical Analysis

#### Prior Research Citation Index and Sample Size Citation Index

For each RCT, the prior research citation index (PRCI) was calculated as the number of cited RCTs divided by the number of RCTs eligible to cite. The number of RCTs eligible to cite, or number of citable trials, was defined as all RCTs in the cohort that were published more than 1 year before the citing RCT. The 1-year interval was used to account for the time during which a report of the citing RCT may be in the publication process; this is the same period that Fergusson and associates used (5). We repeated the analysis with intervals of 2, 5, and 10 years.

We also calculated the sample size citation index (SSCI) to assess the proportion of prior study participants captured in cited research. This was defined as the number of participants in cited RCTs divided by the number of participants in RCTs eligible to cite.

In addition to these indices, we examined the absolute number of cited trials, summarized as means and medians. Because we identified groups of RCTs from within the same meta-analysis, a clustering effect could result in that trials following each other would tend to cite the same literature. We explored and minimized the effect of clustering within meta-analyses in several ways. First, we stratified our analyses by the number of preceding citable trials. That stratification generally used 1 trial per meta-analysis, because trials within a meta-analysis could share the same number of preceding trials only if they were published around the same time. In addition, the PRCI and SSCI were calculated by using the unweighted average of individual trial measures as well as within each cluster (meta-analysis cohort). However, the latter measure turned out not to be useful because the PRCI depended on cluster size, for reasons that are explained in the Results section. Confidence intervals were calculated by using bootstrap techniques (12, 13).

#### Qualitative Analysis of RCTs

We assessed the discussion and introduction sections of a selection of RCTs as Clarke and colleagues did (1–4). We identified the RCTs with the highest and lowest PRCIs. Fifteen of the 377 RCTs in the lowest PRCI quintile and 15 of the 381 RCTs in the highest quintile were randomly selected, and their introduction and discussion sections were reviewed. We assessed whether the article claimed to report the first trial on the subject; whether it referenced a systematic review; whether methods were described to identify prior trials; and whether there was any attempt to incorporate the prior results, quantitatively or qualitatively, with the data from that study.

### Role of the Funding Source

No funding was received for this study.

#### RESULTS

We retrieved 655 citations in our search for meta-analyses. A total of 257 systematic reviews were eligible after abstract and full-text screening. From each of the reviews, we chose 1 meta-analysis with at least 4 RCTs, a group comprising 3256 selected RCTs. When we excluded meta-analyses with RCTs that were not found in Web of Science, 227 meta-analyses remained, comprising 1523 RCTs.

For these 1523 RCTs, the number of citable prior RCTs ranged from 3 to 58. The mean number of citable RCTs was 9.7, of which an average of 1.9 were cited (median, 2; lower and upper deciles, 0 and 4). Of the 1101 RCTs that had 5 or more prior trials to cite (72% of the total), 257 (23%) cited 1 prior trial and 254 (23%) cited none. The proportion of reports of RCTs that cited 0 or 1 prior relevant trial (46%) remained essentially constant as the number of citable trials increased (Table 1).

**Table 1. Number of Reports That Cited 0 or 1 Prior Relevant Trial**

<table>
<thead>
<tr>
<th>Number of Citable Trials</th>
<th>Reports, n</th>
<th>Reports That Cited 0 Trials, n</th>
<th>Reports That Cited 1 Trial, n</th>
<th>Reports That Cited 0 or 1 Trial, n (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>≥3</td>
<td>1523</td>
<td>363</td>
<td>378</td>
<td>741 (49)</td>
</tr>
<tr>
<td>≥5</td>
<td>1101</td>
<td>254</td>
<td>257</td>
<td>511 (46)</td>
</tr>
<tr>
<td>≥10</td>
<td>508</td>
<td>138</td>
<td>123</td>
<td>261 (51)</td>
</tr>
<tr>
<td>≥15</td>
<td>282</td>
<td>79</td>
<td>69</td>
<td>148 (52)</td>
</tr>
</tbody>
</table>

Figure 1 shows the distribution of the number of cited trials according to the number of citable trials. No gradient was observed; the median number of cited preceding trials varied from 1 to 2, with no apparent pattern. This analysis, which minimized any clustering effect, also showed that there was little effect of clustering: Later trials in a meta-analysis on average cited no more preceding research than did earlier trials. Therefore, for ease of interpretation, subsequent summaries are based on per-trial averages.

The surprising constancy of the number of cited trials with increasing number of citable trials meant that the 2 proportional citation measures—the PRCI and SSCI—must be interpreted with care. Across the 1523 RCTs, the median PRCI was 0.21 (95% CI, 0.18 to 0.24; lower and upper deciles, 0 and 0.67). As expected, the PRCI decreased as the number of citable trials increased because the absolute number cited was constant (Figure 2). Thus, the PRCI and SSCI of any collection of trials depend in part on the average number of citable trials within that group.
Allowing for 2 years between the publication of an RCT and its citation in subsequent reports of RCTs did not change the PRCI. However, RCTs cited a lower proportion of older trials than more recent ones. The median PRCI for prior trials published 5 or more years earlier was 0.11 (747 trials; mean PRCI, 0.24), and at 10 years, the proportion of prior trials cited was even lower (311 trials; median PRCI, 0.04; mean PRCI, 0.17). Conversely, we examined whether more recent trials were citing more preceding research than older trials: that is, whether citation practices were improving. A small improvement ($P < 0.001$) was seen in trials published after 2000 (citing mean, 2.4; median, 2) compared with those published earlier (citing mean, 1.5; median, 1) (Table 2). Pediatrics RCTs cited the most prior trials (2.76), whereas immunology RCTs cited the fewest (1.44) (Appendix Table, available at www.annals.org).

We assessed the proportion of participants in cited trials in 1261 RCTs with sample size data. The median SSCI was 0.24 (CI, 0.21 to 0.27; lower and upper deciles, 0 and 0.83); this value is almost the same as the median PRCI (0.21), meaning that larger trials were not selectively cited and information from 76% of participants enrolled in prior RCTs was not acknowledged.

Finally, we did a qualitative assessment of a randomly selected group of 30 RCTs (Table 3). The 15 selected reports of trials in the lowest quintile of PRCI had a mean of 13 prior trials to cite (range, 3 to 41 trials) and none of...
the reports citing any of the prior trials in their cohort (PRCI, 0). The 15 trials in the highest quintile had a mean of 5 prior studies to cite (range, 3 to 9 trials), with a mean number cited of 3.4. None of the 30 reports described a search method for prior trials. Four of the 15 reports in the lowest PRCI quintile claimed to be the first trial assessing that research question. Two of these 4 specifically stated that there were no prior RCTs on the topic, when in fact one had 4 and the other had 8. The other 2 trials, in which 6 and 9 prior trials were uncited, suggested that their trial population was unique. In the highest quintile of PRCI, 1 of the 15 reports claimed to be the first trial (Table 3).

Only 1 of the 30 reports of trials cited an existing systematic review; this report also cited the most prior research. We found no reports that formally incorporated the results of prior trials.

**DISCUSSION**

To our knowledge, this study is the first attempt to systematically assess the citation of prior research in reports of RCTs across the full range of health disciplines and over 4 decades. We found that a median of only 21% of prior research was cited in reports of RCTs that had 3 or more relevant RCTs to reference. Our findings are similar to the proportion of eligible prior trials cited in Fergusson and associates’ cumulative meta-analysis (25%) (5) and a study by Schmidt and Gotzsche (21%) (9). Among RCTs that had 5 or more prior studies to cite, 46% cited none or only 1, and this proportion increased as the potential number of prior trials to cite increased. Remarkably, we found that the median absolute number of trials cited did not vary as the number of citable trials increased. Hence, the more RCT evidence that existed, the more likely that investigators on subsequent trials would ignore it.

In many domains of research, citation accords intellectual credit and perhaps priority of discovery (14), but multiple experiments or claims do not constitute arithmetically more evidential support for a hypothesis. However, every RCT contributes to the cumulative evidence for an intervention’s effect, so each omission contributes to an under-statement of that evidence. Accurate representation of the prior cumulative evidence is necessary both to ethically justify a trial and to make proper inferences. Studying prior research also can lead to designs more likely to fill evidence gaps. Although the presence of a trial citation does not tell us how information from that trial was used, the absence of a citation almost guarantees that it was not.

The findings here show not just that the prior evidence is understated but also that it is barely acknowledged. Our finding of very limited citation is particularly concerning because it indicates that evidence is missing and because selection of the few trials that are cited is likely to have been biased (7, 8, 14–16).

There are several possible explanations for the extreme discrepancy between the evidence as perceived by systematic reviewers and the evidence acknowledged by trial investigators. One is that trial investigators and meta-analysts see the evidential landscape differently from one another. Most trials do not exactly replicate a previous study; typically, the new study is designed somewhat differently from previous ones, making it almost unique from the investigator’s perspective. In contrast, meta-analysts might be more tolerant of modest qualitative dissimilarities among trials, believing that studies of similar interventions across different populations and settings are mutually informative. However, this explanation does not account for the constant average number of citations as the number of citable trials increased.

**Table 3. Summary of Results From Qualitative Review of Selected Randomized, Controlled Trials**

<table>
<thead>
<tr>
<th>Variable</th>
<th>Current Study</th>
<th>Results from Clarke et al*</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Lower Quintile</td>
<td>Upper Quintile</td>
</tr>
<tr>
<td>Claimed to be the first trial assessing the question</td>
<td>4</td>
<td>1</td>
</tr>
<tr>
<td>Actually the first trial to assess the question</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Contained an updated systematic review integrating new results</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Discussed a previous review but did not attempt to integrate new results</td>
<td>0</td>
<td>1</td>
</tr>
<tr>
<td>No apparent systematic attempt to set new results in context of other trials</td>
<td>15</td>
<td>14</td>
</tr>
</tbody>
</table>

PRCI = prior research citation index.
* References 1–4.
The possibility that journal space limitations are causing this lack of citation seems unlikely. We find it implausible that authors are being forced to limit themselves to 2 or fewer of their most critical citations by page or reference list limitations.

We found that a smaller proportion of older articles was cited than those published more recently, suggesting that evidence from older trials tends to be neglected, which has not been reported previously (16, 17). We also found that the few studies that were cited were not the largest ones. This is consistent with prior research on citation bias showing that strength of evidence, whether qualitative or quantitative, did not predict citation (16, 18–23).

When we examined the introduction and discussion sections in the reports of 30 trials in a similar manner to Clarke and colleagues (1–4), we found that reports were not citing systematic reviews instead of individual trials, nor were they integrating their findings with the trials they did cite, and several claimed to be the first trial even when many trials preceded them.

There are many incentives for the patterns seen here. Foremost is the need to claim that a given RCT is the first to address a particular question. If enough particulars about the design are included, every RCT can legitimately claim to be “the first.” This powerful incentive affects both funders and journals. Institutional review boards have neither the capacity nor the charge to second-guess a researcher’s claim that a new RCT is needed. The obvious remedy—requiring a systematic review of relevant literature—is hampered by a lack of necessary skills and resources, the perceived delay it would impose, and the lack of awareness that a problem exists. Even when prior systematic reviews exist, they are often not used (24).

Our methodology has limitations. First, we used meta-analyses to define the citeset of RCTs. We accepted the systematic reviewers’ judgment that the trials were similar enough to justify mathematical pooling, a fairly high bar for similarity for the much lower criterion of citation. When conclusions of systematic reviews vary, it is usually because of differing trial selection criteria (25–27). Thus, the numbers of eligible trials used here could vary, but this variation is small in contrast to the large gaps seen and would not explain the near constancy of the number of studies cited regardless of the number eligible.

In addition, the pool of meta-analyses was limited to 1 year (2004), but the data set included RCTs from many decades. The publication years for the citing RCTs ranged from 1963 to 2004, with more from 1994 to 2004. A small upward time trend in citation was seen in these data, from 1963 to 2004, with more from 1994 to 2004. A decades. The publication years for the citing RCTs ranged year (2004), but the data set included RCTs from many trials preceded them.

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In addition, the pool of meta-analyses was limited to 1 year (2004), but the data set included RCTs from many decades. The publication years for the citing RCTs ranged from 1963 to 2004, with more from 1994 to 2004. A small upward time trend in citation was seen in these data, but we know of no external forces that would have induced citation practices to change substantively since 2004. Repetition of this study with a more recent cohort of meta-analyses is needed to explore current citation practices, although the bulk of the cited RCTs would still extend over the same years that we examined.

We believe that uncited evidence played no role in the inference or in claims about the incremental value of a published study. Studies not cited in a published RCT may have been cited in a funding proposal or institutional review board application. This study does not tell us whether inferences from the published RCTs would have changed materially if the preceding cumulative evidence was examined, or whether the nonciting studies were indeed not justified in light of prior evidence; we can only say that it is impossible for readers to know.

Cumulative meta-analyses have shown repeatedly that randomized experimentation often proceeds beyond the point where key questions have been answered, or where study designs should have been altered (5, 28, 29). Our study confirms that these lessons probably have not been fully absorbed when it comes to the justification or interpretation of a particular RCT.

There are currently no barriers to funding, conducting, or publishing an RCT without proof that the prior literature had been adequately searched and evaluated. Chalmers recently described this situation as “an ongoing scandal in which research funders, academia, researchers, research ethics committees and scientific journals are all complicit” (5), and there have been many calls for this to change (30–34). Requirements to find prior evidence when designing or reporting RCTs have been instituted by some European funding agencies (31); The Lancet (32, 33); and the Centers for Medicare & Medicaid Services, which require that a covered trial not “unjustifiably duplicate existing studies” (34). The CONSORT (Consolidated Standards of Reporting Trials) guidelines require discussion of results in light of preceding trials or a systematic review (35) but do not require a structured search for such trials. Such a policy could be enforced by the International Committee of Medical Journal Editors, just as trial registration has been required (36). Referencing or posting a systematic review could be required as part of the trial registration process. At a minimum, description of the search strategy used to find prior studies should be reported. In the aprotinin example (5), where few of the more than 60 trials cited each other, a simple PubMed search that includes the terms “aprotinin” and “randomized controlled trial” is sufficient to retrieve every RCT studied by Fergusson and associates.

An incomplete picture of preexisting evidence violates the implicit ethical contract with research participants that the information they provide is necessary and will be useful to others. We found that across many health care disciplines and questions, less than 25% of prior RCT research was cited, representing only about 25% of the participants in earlier trials; moreover, the percentage of ignored RCTs increasing as the number of those RCTs increased, and the proportion of trials citing no prior evidence stayed constant as the evidence accumulated. Funders, institutional review boards, and journals could take several judicious steps that would promote better use of prior research and
thereby better satisfy the ethical and scientific requirements for justifiable clinical research.

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Critical revision of the article for important intellectual content: K.A. Robinson, S.N. Goodman.
Final approval of the article: K.A. Robinson, S.N. Goodman.
Statistical expertise: S.N. Goodman.
Administrative, technical, or logistic support: K.A. Robinson.
Collection and assembly of data: K.A. Robinson.

APPENDIX: SEARCH STRATEGY FOR META-ANALYSES

To identify meta-analyses, we searched Web of Science in July 2007 by using the following strategy:

1. TS=meta-analy* OR TS=metanaly*, DocTypes=review OR article, 2004
2. TS=random* OR TS = RCT*
3. #1 AND #2

Search results were downloaded into a reference management software package (ProCite, Thomson Scientific, Stamford, Connecticut) and screened for eligibility by 2 independent reviewers using title and abstract. Citations were excluded from further consideration if they were not a systematic review or meta-analysis, did not report a meta-analysis, were not an original report (overviews, commentaries, and editorials were excluded), did not include RCTs or were not a review of RCTs, did not include humans, did not address a health care question, or did not include a specific meta-analysis that included 3 or more RCTs.

We defined “systematic reviews” as reviews with clear and explicit methods, including details about the search for relevant trials. We included meta-analyses only if the analysis was completed as part of a systematic review (that is, we excluded analyses that pooled studies from 1 center or 1 study group only). Disagreements were resolved by consensus. Full articles were retrieved for all citations deemed eligible and for articles for which it was unclear from the abstract whether a meta-analysis was completed or if it was uncertain if RCTs were included. The same criteria were applied during the screening of the full-text articles to determine eligibility.

Appendix Table. PRCI, by Discipline

<table>
<thead>
<tr>
<th>Discipline</th>
<th>Median PRCI</th>
<th>Mean Trials Cited, n</th>
<th>Median Citable Trials, n</th>
<th>Reports That Cited 0 Trials, n (%)</th>
<th>RCTs With ≥3 Citable Trials, n</th>
<th>Meta-analyses, n</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ophthalmology</td>
<td>0.10</td>
<td>0.50</td>
<td>4</td>
<td>1 (50)</td>
<td>2</td>
<td>1</td>
</tr>
<tr>
<td>Immunology</td>
<td>0.33</td>
<td>1.44</td>
<td>5</td>
<td>3 (33)</td>
<td>9</td>
<td>3</td>
</tr>
<tr>
<td>Pulmonology</td>
<td>0.21</td>
<td>1.48</td>
<td>7</td>
<td>7 (21)</td>
<td>33</td>
<td>5</td>
</tr>
<tr>
<td>Dermatology</td>
<td>0.08</td>
<td>1.56</td>
<td>7.5</td>
<td>7 (44)</td>
<td>16</td>
<td>4</td>
</tr>
<tr>
<td>Dentistry</td>
<td>0.33</td>
<td>1.57</td>
<td>4.5</td>
<td>1 (7)</td>
<td>14</td>
<td>2</td>
</tr>
<tr>
<td>Nephrology</td>
<td>0.14</td>
<td>1.58</td>
<td>8</td>
<td>12 (32)</td>
<td>38</td>
<td>7</td>
</tr>
<tr>
<td>Surgery</td>
<td>0.33</td>
<td>1.58</td>
<td>8</td>
<td>31 (26)</td>
<td>118</td>
<td>15</td>
</tr>
<tr>
<td>Endocrinology</td>
<td>0.15</td>
<td>1.60</td>
<td>8</td>
<td>30 (32)</td>
<td>94</td>
<td>15</td>
</tr>
<tr>
<td>Critical care</td>
<td>0.09</td>
<td>1.64</td>
<td>15</td>
<td>38 (28)</td>
<td>137</td>
<td>7</td>
</tr>
<tr>
<td>Psychiatry</td>
<td>0.14</td>
<td>1.64</td>
<td>7</td>
<td>39 (29)</td>
<td>133</td>
<td>20</td>
</tr>
<tr>
<td>Gynecology and obstetrics</td>
<td>0.35</td>
<td>1.68</td>
<td>4</td>
<td>9 (24)</td>
<td>38</td>
<td>9</td>
</tr>
<tr>
<td>General internal medicine</td>
<td>0.25</td>
<td>1.84</td>
<td>6</td>
<td>67 (30)</td>
<td>227</td>
<td>38</td>
</tr>
<tr>
<td>Oncology</td>
<td>0.33</td>
<td>1.96</td>
<td>6</td>
<td>32 (25)</td>
<td>130</td>
<td>23</td>
</tr>
<tr>
<td>Neurology</td>
<td>0.14</td>
<td>1.98</td>
<td>10</td>
<td>18 (13)</td>
<td>134</td>
<td>12</td>
</tr>
<tr>
<td>Cardiology</td>
<td>0.33</td>
<td>2.08</td>
<td>6</td>
<td>48 (20)</td>
<td>243</td>
<td>45</td>
</tr>
<tr>
<td>Hematology</td>
<td>0.17</td>
<td>2.14</td>
<td>4</td>
<td>1 (14)</td>
<td>7</td>
<td>2</td>
</tr>
<tr>
<td>Gastroenterology</td>
<td>0.33</td>
<td>2.32</td>
<td>6</td>
<td>2 (5)</td>
<td>43</td>
<td>7</td>
</tr>
<tr>
<td>Anesthesiology</td>
<td>0.28</td>
<td>2.53</td>
<td>7</td>
<td>10 (19)</td>
<td>53</td>
<td>5</td>
</tr>
<tr>
<td>Pediatrics</td>
<td>0.38</td>
<td>2.76</td>
<td>7.5</td>
<td>7 (13)</td>
<td>54</td>
<td>7</td>
</tr>
<tr>
<td>Total</td>
<td>0.24</td>
<td>1.78</td>
<td>6.87</td>
<td>1526</td>
<td>227</td>
<td></td>
</tr>
</tbody>
</table>

PRCI = prior research citation index; RCT = randomized, controlled trial.