

## Research: increasing value, reducing waste 5



# Reducing waste from incomplete or unusable reports of biomedical research

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Research publication can both communicate and miscommunicate. Unless research is adequately reported, the time and resources invested in the conduct of research is wasted. Reporting guidelines such as CONSORT, STARD, PRISMA, and ARRIVE aim to improve the quality of research reports, but all are much less adopted and adhered to than they should be. Adequate reports of research should clearly describe which questions were addressed and why, what was done, what was shown, and what the findings mean. However, substantial failures occur in each of these elements. For example, studies of published trial reports showed that the poor description of interventions meant that 40–89% were non-replicable; comparisons of protocols with publications showed that most studies had at least one primary outcome changed, introduced, or omitted; and investigators of new trials rarely set their findings in the context of a systematic review, and cited a very small and biased selection of previous relevant trials. Although best documented in reports of controlled trials, inadequate reporting occurs in all types of studies—animal and other preclinical studies, diagnostic studies, epidemiological studies, clinical prediction research, surveys, and qualitative studies. In this report, and in the Series more generally, we point to a waste at all stages in medical research. Although a more nuanced understanding of the complex systems involved in the conduct, writing, and publication of research is desirable, some immediate action can be taken to improve the reporting of research. Evidence for some recommendations is clear: change the current system of research rewards and regulations to encourage better and more complete reporting, and fund the development and maintenance of infrastructure to support better reporting, linkage, and archiving of all elements of research. However, the high amount of waste also warrants future investment in the monitoring of and research into reporting of research, and active implementation of the findings to ensure that research reports better address the needs of the range of research users.

### Introduction

In 2006, Lang and Secic<sup>1</sup> warned that “The problem of poor research documentation and statistical reporting in the biomedical literature is long-standing, worldwide, pervasive, potentially serious, and not at all apparent to many readers”. Bradford Hill<sup>2</sup> suggested that reports of research should answer four questions: what questions were addressed and why, what was done (the materials and methods), what was shown (direction, size, and uncertainty of effects), and what the findings mean (in the context of other research). Answers should be readable, complete, and make allowances for different audiences. However, most research reporting falls far short of these ideals. Carp<sup>3</sup> noted that the methods in 241 reports of functional MRI studies often did not have sufficient detail needed for replication, deficits were common in the reporting of parameters used, data acquisition methods, and preprocessing and analysis methods. More than a third of studies did not describe the number of examinations, examination duration, and the range and distribution of intertrial intervals, and less than half reported the resolution, coverage, and slice order of images. These deficits make interpretation risky, and replication—an essential element of scientific progress—nearly impossible. Such problems occur in all types of research, as documented in a series in the journal *Nature* about the challenges of irreproducible research. The need for replicability underpins *Nature's*

new requirement for inclusion of relevant details about several elements of experimental and analytical design.

Although concern about research fraud and misconduct is appropriate (a pooled estimate of 18 surveys showed that 2% of scientists admitted to having fabricated, falsified, or modified data or results

### Recommendations

- 1 Funders and research institutions must shift research regulations and rewards to align with better and more complete reporting
  - Monitoring—when assessing research (or researchers), funders and research institutions should consider the accessibility of research protocols, study materials, study data, and their use by others
- 2 Research funders should take responsibility for reporting infrastructure that supports good reporting and archiving
  - Monitoring—funders and research institutions should regularly report expenditures for reporting infrastructure and archiving
- 3 Funders, institutions, and publishers should improve the capability and capacity of authors and reviewers in high-quality and complete reporting
  - Monitoring—researchers should use reporting guidelines, registries, archives, etc; and take up training opportunities

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For the reporting policies of **Nature** see <http://www.nature.com/authors/policies/reporting.pdf>

For the series in **Nature** see <http://www.nature.com/nature/focus/reproducibility/index.html>

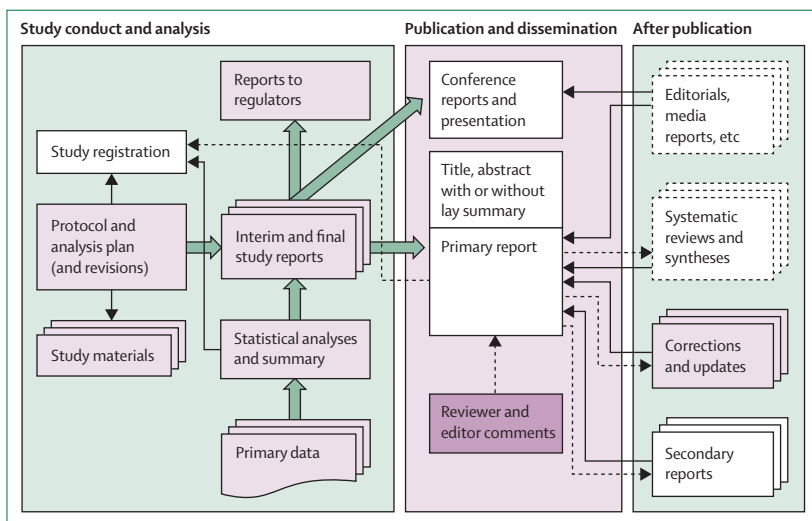
at least once<sup>4</sup>), these issues represent the tip of a much larger iceberg of misrepresentation and waste in research that we have attempted to document and address.<sup>5</sup> Findings from a 2009 article suggested that at least 50% of research reports were sufficiently poor or incompletely as to make them unusable, which represented a waste of tens of billions of pounds.<sup>5</sup> In this Series paper, we extend that analysis with a more detailed breakdown of the problems in reporting of research. Although publication is essential for communication between researchers and others, it can also be a vehicle for miscommunication. The problems in reporting extend beyond missing details—eg, when the protocols and publications of 102 trials were compared, 62% had at least one primary outcome changed, introduced, or omitted.<sup>6</sup>

Discussions of waste in the reporting and usability of research articles commonly focus on peer-reviewed journals, but should look more broadly at the multiple and various forms in which research processes and findings are reported (figure 1). The efficiency of any reporting system depends on the quality of both the individual documents and the linkages between them. The complete documentation of a study includes several elements which often present the same information in different ways (panel 1). For some studies, such as the CRASH trial of corticosteroids after head injury, investigators provide most of these documents in one website. However, a problem that became apparent during the preparation of this review is the dearth of research on the usability of research reports. One (inadequately assessed) format is often assumed to be best, and the various needs of different

research users are disregarded.<sup>7</sup> Across the set of documents problems in reporting can be subdivided into missing or incomplete information (eg, missing details of treatments, outcomes in methods not shown in results, or selective presentation of findings); incorrect or misleading information in reports (eg, misleading figures, incorrect statistical analyses, a change of primary outcome, or spin in conclusions); inconsistent information (eg, differences between report summaries in trial registers *vs* articles in peer-reviewed journals); poorly written text, and poor use of figures and tables; and information presented in obscure or less-than-optimum formats (eg, non-searchable PDF files).

A large systematic review update in 2012 involving 50 studies and reports of more than 16 000 randomised trials that assessed the effect of journal endorsement of the CONSORT checklist showed that, despite improvements in the completeness of reporting for 22 of 25 checklist items, there are still major reporting deficiencies in journal publications.<sup>8</sup> Although the adoption of reporting guidelines such as CONSORT, STARD, and PRISMA has helped to improve the quality of research reports, all guidelines remain much less adhered to than they should be. In the previous paper in this Series, Chen and colleagues<sup>9</sup> examined the large amount of non-publication or delayed publication of research. In the fifth paper of the Series, we document problems in each of Bradford Hill's four areas and examine some options to improve reporting of research.

For the documents from the CRASH trial see <http://www.crash.lshtm.ac.uk/>



**Figure 1: Inefficiency of research reporting due to information being presented in multiple formats, inadequate linkage between information sources, and inaccessibility of documents**

Many documents are unavailable; dark purple boxes indicate those that are rarely available, light purple boxes those that are sometimes available, and white boxes those that are usually publicly available. Block green arrows indicate flow of data, thin lines references or links. Many documents are poorly linked; solid arrow indicates those that are usually linked, and dashed arrow those that are rarely linked.

#### Panel 1: Components of study documentation

- 1 The protocol and related documents, such as details submitted for study registration
- 2 Published and unpublished reports of results, such as the clinical trial and safety reports required by regulatory authorities, conference presentations, journal publications, and result summaries presented to investigators, the public, and patients
- 3 Supplementary materials, such as education materials for patients, clinician training resources, and videos
- 4 The abstract, and other synopses, which will be more widely read than will the full report
- 5 Secondary publications, such as reports of secondary outcomes or subgroup analyses
- 6 Other forms of dissemination of study findings (eg, result summaries on trial registration websites, media releases, and reports)
- 7 The primary data, data manuals, and statistical code for analyses
- 8 Declarations of conflicts of interest, competing interests, contributorships, etc
- 9 Reliable and stable bidirectional linkages between all these elements

	Number and selection of studies	Items absent in reports and proportion of studies that included items
Diagnostic studies <sup>15</sup> (STARD <sup>16</sup> )	90 diagnostic accuracy studies of commercial tests for tuberculosis, malaria, and HIV reported 2004–06 and indexed on PubMed and Embase	STARD items that were reported in less than 25% of studies: methods for calculation and estimates of reproducibility (0%), adverse effects of the diagnostic tests (1%), estimates of diagnostic accuracy between subgroups (10%), distribution of severity of disease or other diagnoses (11%), number of eligible patients who did not participate in the study (14%), blinding of the test readers (16%), description of the team doing the test (17%), and management of indeterminate or outlier results (17%)
Animal studies <sup>17</sup> (ARRIVE <sup>18</sup> )	271 reports of original research on live rats, mice, and non-human primates indexed on Medline and Embase between January, 1999, and March, 2005	Reporting of the hypothesis or objective, and the number and characteristics of the animals used (59%), sample size explained (0%), and reporting of exact numbers of animals in method and result section (46%)
Observational studies <sup>19</sup> (STROBE <sup>20</sup> ; STREGA <sup>21</sup> )	174 observational studies of interventions in five general medical and five epidemiological journals published between January, 2004, and April, 2007	For STROBE: details of selection (10%), and inclusion of confounders (51%)
Clinical prediction research <sup>22</sup> (REMARK <sup>23</sup> tumour markers prognosis; GRIPS <sup>24</sup> genetic risk prediction)	71 publications in six high-impact-factor general medical journals in 2008	Assessment of predictors and outcomes (blinding reported in 22% and 75%), sample size calculation reported (17%), missing data reported (62%), methods used for handling of missing data reported (46%), and reporting of adjusted (20%) and unadjusted (18%) results of the full model with all candidate predictors considered
Surveys <sup>25</sup>	117 studies from the top 15 high-impact-factor journals for health science, public health, general internal medicine, and medical informatics published between January, 2008, and February, 2009	Provision of the survey or core questions (35%), reporting of the psychometric properties of existing instrument (10%), clear description of development process or pretest methods (17%), description of sample representativeness (11%), and reporting of sample size calculation (6%)
Surveys <sup>26</sup>	Publication of 88 novel questionnaires from <i>Journal of the American Medical Association</i> , <i>New England Journal of Medicine</i> , and <i>The Lancet</i> from January, 2000, to May, 2003	Access to the questionnaire from the published report (8%), access after authors were contacted (54%)
Qualitative studies <sup>27</sup>	30 (19 reported) qualitative studies alongside randomised controlled trials of complex health-care intervention	Study context described (27%), sampling method described (37%), method of data collection described (40%), and method of analysis described (43%)

**Table: Examples of inadequate reporting in studies other than randomised controlled trials and systematic reviews**

## What was planned and done: the question and methods

Researchers, clinicians, and other users of research findings often want to apply and act on research that has shown benefit or promise. To do so, they need accurate and adequate descriptions of the study objective, methods, populations, interventions, tests, markers or biomarkers, and context. However, many authors seem unaware of how to achieve these aims.

Several therapeutic assessment studies have shown that key information is often absent from reports. Incomplete reporting means that the apparent methodological quality of published randomised controlled trials might not show the actual quality of the study as assessed from the protocol.<sup>10</sup> Without better reporting, or easy linkage to a publicly accessible protocol, reviewers and readers cannot make an informed judgment about quality and risk of bias.

Adequate information about interventions is available in about 65% of reports of clinical trials, but this proportion is much lower for systematic reviews.<sup>11</sup> The adequacy of details can differ by clinical area and by stringency of the assessment. For example, only three (13%) of 24 reports of back pain trials were considered to supply sufficient information;<sup>12</sup> only 30 (11%) of 262 reports of chemotherapy trials provided all ten items in a treatment checklist;<sup>13</sup> and only 26 (17%) of 150 reports of patient education trials provided all ten items in their intervention checklist.<sup>14</sup> Similarly, when the reporting of control conditions is poor, readers cannot draw correct inferences about the effect of the intervention (table). Particularly if control conditions include, but do not

report, so-called active ingredients, then the effects of the intervention might be masked.<sup>28</sup>

Although most widely documented for randomised trials, inadequate reporting occurs in all types of studies (table), including animal and preclinical studies, diagnostic studies, epidemiological studies, clinical prediction research, surveys, and qualitative studies. For example, investigators of one analysis noted that only 59% of reports of animal studies stated the hypothesis or objective of the study and the number and characteristics of the animals used.<sup>17</sup> A study of 88 published reports of surveys that used novel questionnaires could access only seven (8%) of the questionnaires (four in the article and three online), yet for 54% of reports, the original authors provided the details on request, showing that the problem is partly remediable.<sup>26</sup>

Although inadequate reporting in original publications in peer-reviewed journals is our main concern, it occurs with other types of research communication, such as press releases, conventional mass media, or on the internet. For example, a critical appraisal of press releases issued by 20 academic medical centres showed that 42% of releases did not provide any relevant caveats about the research findings, and 90% of releases for animal or laboratory studies did not contain caveats about extrapolation of results to human beings.<sup>29</sup> For half of articles in newspaper columns, authors regarded the medical advice as inappropriate, with 28% of advice deemed unsafe or dangerous.<sup>30</sup> Results of a study of science information on the internet showed that about a third of the information is inaccurate.<sup>31</sup> This statistic is particularly worrying because of the effect of mass media on health-service use.

## What was shown: reporting of results fully and clearly

### Introduction to the problem

In the results section of a paper, readers expect to find an informative description of what actually happened in the study and the answers to the study questions. The outcomes and analyses presented should correspond with those specified in the study protocol and the statistical analysis plan, if this plan exists, and should match what is stated in the methods section. They should not be presented selectively and should provide adequate data and detail to allow incorporation in future analyses. Unfortunately, study reports are not always helpful in these respects.

### Characteristics of sample

To judge the relevance of research findings in relation to their circumstances, readers need the key summary characteristics of the patients (or animals, cells, etc) that were eligible and actually included in the study. In a review of 141 studies of test accuracy published in 2004, 57 (40%) did not report the age and sex of study participants.<sup>32</sup> Of 271 reports of animal studies in mice, rats, and primates, 71 (26%) did not disclose the sex of the animals and 66 (24%) reported neither the weight nor the age of the animals used.<sup>17</sup> Reported characteristics of participants might differ from the eligibility criteria specified in the protocol.<sup>33</sup>

### Study conduct

Readers wish to see whether the study was completed as planned. Investigators of one review noted that 58 (41%) of 141 studies of test accuracy did not report how many of the eligible study participants actually underwent the test under assessment and did not report the clinical reference standard.<sup>32</sup> For randomised trials, the CONSORT flow diagram provides a valuable way to summarise the flow of participants from enrolment through to allocation, intervention, and inclusion in analyses of data. Data from a review of 469 primary reports of randomised trials showed that 263 (56%) included a CONSORT flow diagram.<sup>34</sup> However, flow diagrams often did not include all the recommended information—eg, only 40% reported the number of patients who actually received the allocated interventions. Similar diagrams are recommended for other study designs, but have not been widely adopted. For studies of biomarkers, the REMARK guidelines suggest inclusion of a study profile that outlines key characteristics of the participants, variables, and outcomes, and details of all analyses done.<sup>35</sup>

### Study results

Information reported in journal articles often does not accurately show what was planned or done. Authors often do not present the analyses and outcomes that were proposed in the original study protocol. This selective reporting has been well documented for randomised

controlled trials.<sup>36</sup> A Californian group assessed efficacy trials from 33 drug applications for new molecular entities approved by the US Food and Drug Administration in 2001 and 2002.<sup>37</sup> Of 128 published papers, 41 primary outcomes from reports of new drug applications were omitted. These omissions tended to lead to more favourable presentations of the drugs in the publications. Similarly, results of an assessment of 164 trials of breast cancer comparing the outcomes set out in the trial registry with those reported in the abstracts and paper showed both under-reporting and spin—33% showed bias in reporting of the primary endpoint and 67% in the reporting of toxic effects.<sup>38</sup>

Although reporting of randomised controlled trials has been assessed most often, other types of research are likely to have similar problems. For example, 135 (45%) of 302 reports for studies of biomarkers in patients with pancreatic ductal adenocarcinoma did not present multivariable analyses, and a further 42 (14%) did not present hazard ratios and confidence intervals.<sup>39</sup> A variable not known at baseline was inappropriately included for 127 (19%) of 682 studies for which survival analysis were reported.<sup>40</sup> Of 39 reports presenting risk prediction models for patients with diabetes, handling of missing data was not reported in 16 (41%).<sup>41</sup>

Information about adverse effects (harms) is especially poorly reported in reports of randomised controlled trials.<sup>42</sup> Chowder and colleagues<sup>43</sup> reviewed 49 randomised controlled trials of highly active antiretroviral therapy. Only 16 of 49 trials (33%) had all adverse events (AEs) reported; for the remainder only some events were reported (eg, the most frequent, those with  $p < 0.05$ , or selected adverse events). The investigators stated that “These facts obstruct our ability to choose [highly active anti-retroviral therapy] based on currently published data”. Reporting of adverse effects is also poor in systematic reviews.<sup>44</sup>

Figures and tables are often incomplete or uninterpretable. 31% of all graphs published in the *Journal of the American Medical Association* in 1999 and 2000 could not be interpreted unambiguously because some features were not self-explanatory.<sup>45</sup>

### Distorted presentations

In an analysis of 72 randomised controlled trials reported in 2006, Boutron and colleagues<sup>46</sup> noted that distorted presentation of results (spin) was common in reports of trials with non-significant differences in primary outcomes. Several reports focused on additional results, such as significant within-group comparisons, comparisons in subgroups, or analyses of secondary outcome measures. Similar issues have been shown in studies of diagnostic test accuracy.<sup>47</sup> Spin might be related to conflicts of interest. Yank and colleagues<sup>48</sup> showed that financial ties to one company did not affect actual results, but did affect favourable conclusions from these results. Other studies have had similar findings.<sup>49,50</sup>

## Results reported in abstracts

Abstracts merit, but rarely get, particularly careful attention. They might be both the most read and cited part of a paper, and the part that is prepared with the least care.<sup>51,52</sup> Reviews of reports of randomised controlled trials and diagnostic accuracy studies with non-significant primary outcomes<sup>47,53</sup> noted that the abstract was particularly prone to spin.

## Options for improvement

### The need for a multistage approach

Improvements in reporting could occur at the presubmission, reviewing, publication, or post-publication stages. Although early correction is likely to be preferable, an expectation that all problems can be identified and fixed at any one stage is unrealistic; therefore, a multistage approach will be needed, including informal and formal presubmission commentary. Additionally, responsible reporting of research should be taught as an essential component of research training.

### Presubmission

Reporting guidelines, including CONSORT, STARD, PRISMA, STROBE, and ARRIVE,<sup>34</sup> were developed to improve transparency (panel 2). These reporting guidelines have been widely disseminated through publications in high-impact-factor journals and endorsements by several editors. Nevertheless, adherence of authors to these reporting guidelines remains low.<sup>8,32</sup>

### Reviewing

Editors and reviewers have an essential part to play, and simple actions can improve the quality of reporting, beginning with checks of standards at the initial submission stage. A systematic review<sup>55</sup> of 32 studies (including only 3 randomised trials) showed some evidence of improvements in reporting with intensive editorial processes, provision of instructions to authors, and structuring of abstracts. Investigators of a subsequent study noted that journals that introduced an active policy to enforce reporting guidelines (defined as “any action to enforce adherence to CONSORT, that is, an email was sent to authors...or changes were made by the assistant editors”) had an improvement in the reporting of abstracts, whereas journals endorsing the guidelines with no enforcement policy did not.<sup>52</sup> Findings of a randomised controlled trial suggested that an additional peer reviewer specifically looking for missing items from reporting guidelines improved the quality of reporting.<sup>56</sup> Hence, although reporting guidelines are important, major improvements need active enforcement.

### Pre-publication

After acceptance, technical editing seems to improve readability and quality of abstracts, and reduce errors in references.<sup>55</sup> Computer-assisted assessment of papers in

## Panel 2: Some examples of initiatives to support better reporting of research

### Reporting guidelines

The EQUATOR network works to improve the reliability and value of publications of medical research through the promotion of transparent and accurate reporting. The website includes a comprehensive searchable database of reporting guidelines (eg, CONSORT, PRISMA, STARD, CARE, SAMPL), instruments for better reporting aimed at different groups, and information about relevant webinars, courses, and events.

For EQUATOR see <http://www.equator-network.org/>

### Study registration

ClinicalTrials.gov, a registry funded by the National Institutes of Health, is a database of publicly and privately supported clinical studies that includes more than 30 000 trials and other studies (roughly half US-based, half non-US-based). It also allows for links to protocols and for reporting of all protocol outcomes, even when details are not included in the published report.

For ClinicalTrials.gov see <http://clinicaltrials.gov>

### Linkage

CrossRef is an independent membership association, founded and directed by publishers, to connect users to primary research content. CrossRef is the official DOI link registration agency for scholarly and professional publications, covering tens of millions of articles and other items from thousands of scholarly and professional publishers. It provides not-for-profit support for permalinks for publications and other research materials.

For CrossRef see <http://www.crossref.org/>

### Archiving

Center for Open Science allows researchers to work with collaborators, organise and archive research materials and data, and later make these publicly available. It allows investigators to create frozen versions to mark the state of a project at a particular point in its history—eg, onset of data collection, at manuscript submission, and final version for publication. Open Science Framework is partly a network of research materials, partly a version-control system, and partly a collaboration software.

For Centre for Open Science see <http://centerforopenscience.org>

### Post-publication commentary

PubMed Commons will provide a long-term website for post-publication commentary and linkages. Anyone who has been an author for any item in PubMed will be able to add comments or links to any record within PubMed, with every comment getting a permalink and stable identifier.

For PubMed Commons see <http://www.ncbi.nlm.nih.gov/pubmedcommons/>

### Monitoring and improvement

Adding Value in Research is an initiative of the UK's National Institute for Health Research (NIHR) that undertakes a range of activities to ensure maximum value from the NIHR's investment. The website includes guidance for applicants to ensure that all primary research is informed by a review of the existing literature, is reported, and is delivered to time and target.

For Adding Value in Research see <http://www.nets.nihr.ac.uk/about/adding-value-in-research/>



the future is likely to enhance the feasibility of routine checks.<sup>57</sup> However, by simply contacting authors, the proportion of trials that had an adequate intervention description increased from 65% to 90%.<sup>11</sup> Provision of better linkage to additional materials (figure 1), including non-standard media such as video (shown by the *Journal of Visualised Experiments*), might improve the completeness and usability of reports. At least two journals (*Addiction* and *Implementation Science*) will not publish intervention studies for which the intervention protocol is not publicly available. More journals should adopt this policy, and make available the option for (linkage to) extended online materials.

### Post-publication

Even when there are good review and publication processes, problems and errors will be detected after publication. Letters, rapid responses, and retractions all serve as post-publication review, but they are underused, poorly managed, and poorly linked—eg, many retracted reports continue to be cited long after retraction.<sup>58</sup> Enhanced post-publication efforts to detect and correct reporting for some publications might also be worthwhile (panel 2).<sup>59</sup> Journals should revise policies that restrict the number and timing of letters and other limitations on feedback.<sup>60</sup>

### What it means: setting results in the context of previous research

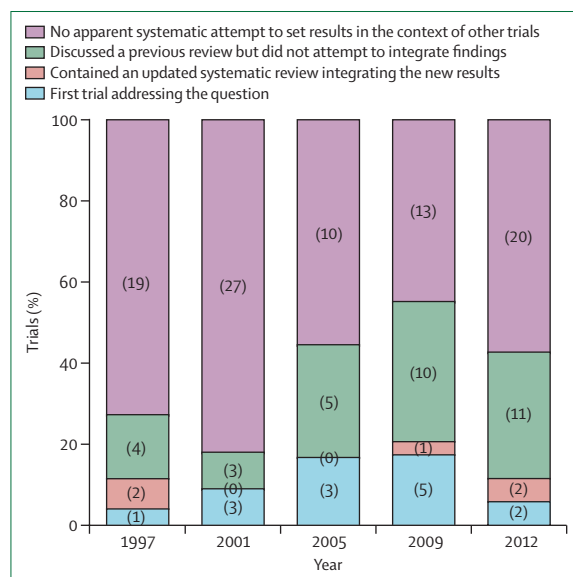
Reports of new research should set the new findings in the context of the body of other relevant research. Although apparently simple, the wide scatter and poor indexing of research makes this process difficult and so it is usually done poorly. For example, of 136 trials of

methods to prevent pain from propofol injections published after January, 2002, 37 (27%) did not cite a systematic review that was published in 2000;<sup>61</sup> and, because most contributors did not use the review to inform study design, 75% of trials were considered inappropriate.<sup>62</sup> More broadly, new reports of trials cite a very small proportion of previous relevant trials. Investigators of one study of 227 meta-analyses reported that later trials cited a median of 21% of citable relevant earlier trials,<sup>63</sup> and, of a subset of the trials in 30 of the meta-analyses, none reported a search strategy for previous trials, and only one of 30 cited an existing systematic review.

Such poor citation of relevant research also seems to be selective. For example, an analysis of 530 randomised clinical trials in hepatobiliary diseases reported in 11 journals between 1985 and 1996, showed that positive (statistically significant) studies were more than twice as likely to be cited than were negative (not statistically significant) ones, compounding the problem of publication bias.<sup>64</sup> Another analysis of 111 trials in rheumatoid arthritis showed that a higher proportion of the positive trials were cited than were the negative trials for the same question.<sup>65</sup> This skewed citation process extends across different study designs and phases. For example, citation of observational studies suggesting (incorrectly) that vitamin E reduced ischaemic heart disease and that  $\beta$ -carotene reduced cancer continued well after clear evidence from large-scale randomised trials had contradicted these findings, with most citing studies not referencing evidence from available randomised trials.<sup>66</sup>

Increased awareness of these issues and of guidelines by major journals seems to have had little effect. A 1999 proposal<sup>67</sup> for structured discussion sections that suggested specific inclusion of a paragraph describing “Strengths and weaknesses in relation to other studies, discussing particularly any differences in results” has been widely cited and suggested as appropriate for genetic, observational, health informatic, and clinical research. However, the proposal was criticised for not going far enough,<sup>68</sup> and some suggested that an earlier proposal to integrate new trial results into a systematic review should be extended to all types of research. This issue led Jefferson<sup>68</sup> to state: “It is no longer acceptable for authors to publish research that may have an impact on people’s lives without attempting to interpret the results within the available body of systematically collected and evaluated knowledge”.

Analysis of trials in five general medical journals every 4 years showed a widespread and continuing failure of reports to integrate existing research with new findings, and only slight improvement in 12 years (figure 2).<sup>69,70</sup> Investigators of only five (4%) of 127 studies that were not the first trial of a new intervention set their results in the context of updated systematic reviews.



**Figure 2: Percentage (and number) of trials that set their results in the context of a systematic review by 4 year intervals**  
Data from references 69 and 70.

Several improvements are needed, both for individual studies and for infrastructure. First, new research reports should set findings in the context of updated systematic reviews. Without this context, readers cannot fully judge the research's relevance, particularly because most single studies will not provide sufficient data to resolve key uncertainties. Although a full review is not always possible, study authors could readily compare their study's estimate and confidence interval with values from previous meta-analyses, and, if appropriate, provide a weighted combination of these. Among high-profile general medical journals, *The Lancet* has been exemplary in asking authors for reports of new research to place their findings in the context of a systematic review of other evidence. In 2010, *The Lancet's* editors reiterated their 2005 requirement and asked that "all research reports—randomised or not—contain a panel in the discussion as outlined above, and put the results into the context of the totality of evidence".<sup>71</sup>

Second, linkage to relevant reviews and studies should be made easier. Even if authors and journals do not set research in context, individuals looking for research should be readily able to identify related reviews or research. The related articles function in PubMed shows the potential of such linkage, but, at present, this function does not specifically find or highlight existing systematic reviews relevant to a research paper, or even indicate that a study in Medline has been included in a systematic review.

Third, the effort required to do systematic reviews should be reduced. The previous two recommendations will not close the current gaps unless the cost of doing systematic reviews is reduced substantially. Through a series of incremental advances, the cost of gene sequencing technology has plummeted over the past two decades; by contrast the cost of preparing systematic reviews has increased. An international sustained effort to improve the efficiency of reviews is needed. This feat is achievable through standardisation, streamlining, and computerisation of the many steps of a systematic review. Although some work to improve software and processes for reviews has occurred, it has been piecemeal and without the global effort that occurred with genetic sequencing.

## Conclusions and recommendations

### Reducing waste in reporting

A precise quantification of the amount of waste in the reporting of research is not possible. However, figure 3 summarises issues that relate to different parts of the standard primary publication. Although flaws are likely to be correlated, the numbers clearly suggest that most publications have elements that are missing, poorly reported, or ambiguous. The options for improvement that we have discussed suggest that most problems are remediable at fairly low cost.

The AllTrials campaign has proposed that "All trials past and present should be registered, and the full

Abstract
<b>Trials:</b> missing effect size and confidence interval (38%); no mention of adverse effects (49%) <sup>72</sup>
Methods
<b>Trials:</b> 40–89% inadequate treatment descriptions <sup>11,13</sup> <b>fMRI studies:</b> 33% missing number of trials and durations <sup>3</sup> <b>Survey questions:</b> 65% missing survey or core questions <sup>25</sup> <b>Figures:</b> 31% graphs ambiguous <sup>45</sup>
Results
<b>Clinical trials:</b> outcomes missing: 50% efficacy and 65% harm outcomes per trial incompletely reported <sup>6</sup> <b>Animal studies:</b> number of animals and raw data missing <sup>17</sup> (54%, 92%); age and weight missing (24%) <b>Diagnostic studies:</b> missing age and sex (40%) <sup>15</sup>
Discussion
<b>Trials:</b> no systematic attempt to set new results in context of previous trials (50%) <sup>69</sup>
Data
<b>Trials:</b> most data never made available; author-held data lost at about 7% per year

**Figure 3: Estimates of the prevalence of some reporting problems (see publication column, figure 1).**

fMRI=functional MRI.

methods and the results reported". A previous article in this Series, Chan and colleagues,<sup>9</sup> described the problems with and need for registration and publication. In this Series paper, we have set out the problems of incomplete and poor reporting from protocol to final paper, and the poor public linkage between the study report elements. All readers have the right to expect that reports of research will be usable and that basic information will be completely and transparently reported, including clear descriptions of any interventions under investigation. Such reports can then be used in different ways by many groups, including clinicians, systematic reviewers, patients, consumers, and policy makers. Anything less than complete, clear, and transparent reporting is questionable science that some regard as unethical.<sup>73</sup>

To improve, this situation needs increased understanding of the complex issues involved in research conduct, reporting, and publication, and extensions of the efforts of organisations such as the EQUATOR network, which developed from the work of the CONSORT group and other reporting guideline development groups. To reduce waste, we have three overarching recommendations based on improvements in incentives, infrastructure, and capacity.

### Recommendation 1

Our first recommendation is that funders and research institutions should shift research rewards and regulations to align with better and more complete reporting. Many of the problems that we describe are attributable to reward and regulation systems being poorly linked to good reporting.<sup>74</sup> Neither the profit motive of commercial research nor the academic reward system of non-commercial research encourage clear, correct, and complete reporting and access to materials, methods,

For AllTrials see <http://www.alltrials.net/>

and data of the research. This situation can be changed. Both regulation of research and research assessment—for individual appointment and promotion, or for institutional funding—should consider the quality of, and access to, wider elements of research shown in figure 1, such as data, materials, and protocol deposition, dissemination, and usage.

Because poor reporting is partly due to fragmentation of responsibility across sectors, solutions might need joint action across sectors. The cross-sectoral support for the AllTrials campaign is encouraging. Another example is the pharmaceutical industry and the academic community jointly promoting better statistical plans and reports of research.<sup>75</sup> Best practice guidelines for reporting of industry-sponsored trials have been endorsed by Statisticians in the Pharmaceutical Industry<sup>76</sup> and The Royal Statistical Society,<sup>77</sup> which stated that “The Royal Statistical Society is committed to transparency in scientific and social research. It considers it to be crucially important that the results of scientific research should be made publicly available and disseminated as widely as is practical in a timely fashion after completion of the scientific investigation provided that there is no conflict with any legislation on confidentiality of data.” Achievement of these laudable ideals is hindered by the current structure of the reward and regulation of research.

Research institutions should consider how best they can join the campaign against wasteful research. Many research institutions already employ grants officers to increase research input, but few employ a publication officer to improve research outputs, including attention to publication ethics and research integrity, use of reporting guidelines, and development of different publication models such as open access. Ethics committees and publication officers could also help to ensure that all research methods and results are completely and transparently reported and published. Research funders provide the resource inputs, but the outputs are managed by journal publishers that have motives similar to other publishers—ie, circulation, sales, reprints, and advertisements. Neither research funders nor publishers are adequately accountable to research users.

### Recommendation 2

Our second recommendation is that research funders should take responsibility for reporting infrastructure that supports good reporting and archiving of research. Good reporting and long-term access to research reports or data, including all elements in figure 1 (protocols, materials, data, etc), needs substantial and sustainable infrastructure such as well indexed long-term digital repositories, report linkage systems, standards and software that support good reporting practice, and funding for collaboration and data sharing. However, such infrastructure is weak and fragmented at present. Although the development and application of reporting

guidelines such as CONSORT and STARD statements has resulted in some progress for the reporting of research findings, substantial gaps remain. Without better reporting infrastructure, progress will continue to be slow. Some immediate low-cost actions could be taken. Funders globally could coordinate efforts to support initiatives aimed at better reporting (panel 2), and make receipt of research funds conditional on registration of proposed and completed medical research in repositories such as ClinicalTrials.gov<sup>78</sup> and PROSPERO,<sup>79,80</sup> which might help to reduce reporting deficiencies. Academic institutions could promote the registration, archiving, and deposition of research reports in online repositories (panel 2). This deposition could both increase access to research results, which are often published behind a reader paywall, and allow more detailed reporting of results than could be published in a journal constrained by paper page limits. However, more substantial and sustainable infrastructure is needed, and it is in research funders’ interests to respond to this need. Use of a small proportion of research funds to enhance infrastructure might be repaid by much larger rewards in research output and effect. Several mechanisms are possible, including direct support for external infrastructure such as registries, provision of internal infrastructure, or dedication of a small proportion of core grant funding to archiving and reporting.

### Recommendation 3

Our third recommendation is that funders, institutions, and publishers should improve the capability and capacity of authors and reviewers to do high-quality and complete reporting. In theory, scientific journal editors and peer reviewers are well placed to help to identify research reports that are not fit for purpose.<sup>54</sup> The irony is that few editors and peer reviewers are adequately trained, and so they might find detection of inadequate reports difficult. Additionally, authors have insufficient training in the range of issues related to reporting of research, such as use of reporting guidelines, publication ethics, and research integrity. Training will therefore need to be given to individuals across a diverse range of roles in the research production process, including authors, editors, and reviewers. Funders interested in value for their research investment should support and monitor such training. Equally, the academic community should integrate the study of research methods, scientific writing, and publishing in their curricula. Publishers could also provide some training to editors, reviewers, and authors, specifically in use of reporting guidelines and provision of better feedback to reviewers. Active implementation of reporting guidelines, such as CONSORT for reporting of randomised trials<sup>81</sup> and STROBE for reporting of observational studies,<sup>20</sup> are another way that journals can help to reduce wasteful reports.<sup>82</sup>

All these efforts will have a greater chance of success if research funders support, and journals more actively



endorse and implement, these initiatives. Failure to do so will send a strong negative signal to the entire research community about the value of these efforts to improve the usefulness of research.

#### Contributors

All authors contributed to the conception of the paper, the search of the published work, and the writing and editing of the report.

#### Conflicts of interest

All authors have been involved in the development and dissemination of reporting guidelines, including CONSORT and for the EQUATOR network. EW is an author of CONSORT for Abstracts and a member of the EQUATOR Network Advisory Group. She is a self-employed consultant and runs workshops for authors, editors, reviewers, and publishers. The others authors declare that they have no conflicts of interests.

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