Papers

Identifying outcome reporting bias in randomised trials on PubMed: review of publications and survey of authors

An-Wen Chan, Douglas G Altman

Abstract

Objective To examine the extent and nature of outcome reporting bias in a broad cohort of published randomised trials.
Design Retrospective review of publications and follow up survey of authors.
Cohort All journal articles of randomised trials indexed in PubMed whose primary publication appeared in December 2000.
Main outcome measures Prevalence of incompletely reported outcomes per trial; reasons for not reporting outcomes; association between completeness of reporting and statistical significance.
Results 519 trials with 553 publications and 10 557 outcomes were identified. Survey responders (response rate 69%) provided information on unreported outcomes but were often unreliable—for 32% of those who denied the existence of such outcomes there was evidence to the contrary in their publications. On average, over 20% of the outcomes measured in a parallel group trial were incompletely reported. Within a trial, such outcomes had a higher odds of being statistically non-significant compared with fully reported outcomes (odds ratio 2.0 (95% confidence interval 1.6 to 2.7) for efficacy outcomes; 1.9 (1.1 to 3.5) for harm outcomes). The most commonly reported reasons for omitting efficacy outcomes included space constraints, lack of clinical importance, and lack of statistical significance.
Conclusions Incomplete reporting of outcomes within published articles of randomised trials is common and is associated with statistical non-significance. The medical literature therefore represents a selective and biased subset of study outcomes, and trial protocols should be made publicly available.

Introduction

Researchers have often commented on the existence of unreported study outcomes.[1] [2] Even when outcomes are presented in journal publications, they may be reported with inadequate detail.[3] Outcome reporting bias refers to the selective reporting of some results but not others in trial publications. Direct evidence of such bias has recently been shown in two cohort studies that compared trial publications with the original protocols.[4] [5] However, it is unknown whether selective outcome reporting can be identified when protocols are unavailable.

We used a large representative sample of publications of randomised trials indexed on PubMed to determine the prevalence of incomplete outcome reporting; the reasons for omitting out- comes; and the degree of association between completeness of reporting and statistical significance for trial outcomes.

Methods

Study selection

Using an extended version of Phase 1 from the Cochrane search strategy (see box 1),[6] we identified primary publications of randomised trials published in December 2000 and included in PubMed by August 2002. A primary publication was the first report of final trial results. We excluded studies of cost effective- ness and diagnostic test properties, and those published in languages other than English and French.

We recorded trial characteristics from the primary publica- tions published in December 2000. We identified extra journal publications for these trials through a survey of contact authors, as well as literature searches of PubMed, Embase, the Cochrane Controlled Trials Register, and PsychINFO using investigator names and keywords (final search January 2003). For each trial, we reviewed the primary and any subsequent publications to extract the number and characteristics of reported outcomes (including statistical significance, level of reporting, and specification as primary, secondary, or unspecified according to the text).

Reporting of outcomes

We identified unreported outcomes if they were described in the methods section but not the results section of any publication. Furthermore, using a pre-piloted questionnaire, we asked the contact authors to list any outcomes that were not reported in the published papers and to indicate for each unreported outcome whether it reached statistical significance ($P < 0.05$) in any inter-group comparison; whether it was a primary,

> **Box 1: Modified Cochrane search strategy for identifying randomised trials on PubMed that were published in December 2000**[6]
>
> 1) randomized controlled trial [pt]
> 2) controlled clinical trial [pt]
> 3) randomized controlled trials [mh]
> 4) random allocation [mh]
> 5) double blind method [mh]
> 6) single blind method [mh]
> 7) cross-over studies [mh]
> 8) multicenter study [pt]
> 9) #1 OR #2 OR #3 OR #4 OR #5 OR #6 OR #7 OR #8
> 10) #9 NOT (animal [mh] NOT human [mh])
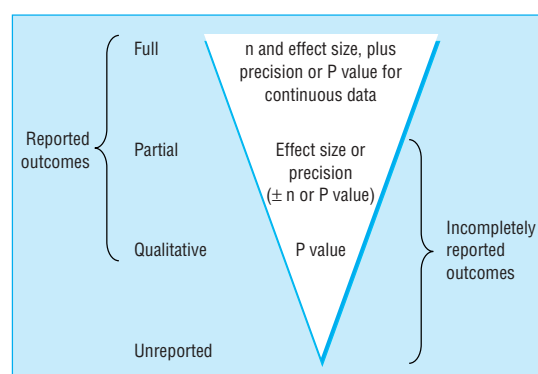> 11) limit 00/12/01 – 00/12/31

Fig 1 Hierarchy of levels of outcome reporting (n=number of participants per group)

secondary, or unspecified outcome according to the protocol; whether it was of little, moderate, or high clinical importance; and the reasons for not reporting it. We sent two reminders via email or post to non-responders.

For each identified outcome, we recorded the level of reporting as one of four levels based on the amount of data presented in any of the journal publications (fig 1). If sufficient data were provided for inclusion in a meta-analysis, we recorded the outcome as fully reported (see box 2). We recorded an outcome as partially reported if the publications provided only some of the data necessary for meta-analysis, and as qualitatively reported if the publications presented only a P value or some indication of the presence or absence of statistical significance. Finally, unreported outcomes were those for which no data were provided in any of the publications despite being identified in the methods section or the authors' responses to our survey.

We used two further terms to describe composite levels of reporting (fig 1). "Reported outcomes" referred to those with some data presented in any of the publications (full, partial, and qualitative). "Incompletely reported outcomes" referred to those

Box 2: Amount of data required in trial publications for outcomes to be classified as fully reported

Unpaired continuous data
- Group numbers *and*
- Size of treatment effect (group means or medians or difference in means or medians) *and*
- Measure of precision or variability (confidence interval, standard deviation, or standard error for means; range for medians) or the precise P value

Unpaired binary data
- Group numbers *and*
- Numbers of events or event rates in each group

Paired continuous data
- Mean difference between groups and a measure of its precision or exact P value *or*
- Raw data for each participant

Paired binary data
- Paired numbers of participants with and without events

Survival data
- Kaplan-Meier curve with numbers of patients at risk over time *or*
- Hazard ratio with a measure of precision

with inadequate data for meta-analysis (partial, qualitative, and unreported).

Statistical analyses

Using Stata 7 (Stata Corporation, College Station, TX, USA), we conducted analyses at the trial level stratified by efficacy and harm outcomes. Primary variables of interest included the proportion of incompletely reported outcomes per trial and the reasons given by authors for not reporting outcomes. We also examined the association between the level of outcome reporting and statistical significance.

For each trial, we created a 2×2 table for the outcomes, relating the level of reporting (full v incomplete) to statistical significance at the $P < 0.05$ level. We calculated odds ratios for each trial and pooled these using a random effects meta-analysis to provide an overall estimate of outcome reporting bias. We excluded trials if entire rows or columns were empty in the 2×2 table, as meaningful odds ratios could not be calculated. If one cell or two diagonal cells were empty we added 0.5 to all four cell frequencies in the table. We conducted sensitivity analyses by excluding trials without survey responses as well as excluding physiological and pharmacokinetic trials. We also assessed the impact of using a different cut-off point for dichotomising the level of reporting (fully or partially reported v qualitatively reported or unreported).

We used exploratory meta-regression to evaluate the effect of 13 factors on the size of bias: trial characteristics (study design, intervention type, sample size, blinding, source of funding, number of centres); journal characteristics (specialty v general medical journal, short v full length publication); and the reporting of important methodological details (power calculation, specification of primary outcomes, description of random sequence generation, allocation concealment, and handling of attrition). Definitions for these characteristics are described in detail elsewhere.[7] We used a restricted maximum likelihood method to estimate residual heterogeneity for the univariate and multivariate backward stepwise regression analyses.[8]

Results

We identified 519 trials with 553 publications and 10 557 outcomes (8325 efficacy and 2232 harm outcomes) (fig 2). Table 1 shows the main trial characteristics. Median sample sizes were 80 (10-90th centile range 25-369) and 15 (8-38) for parallel group and crossover trials respectively. A detailed report of the cohort characteristics has been published separately.[7]

For our survey of contact authors, 69% (356/519) of authors responded to the questionnaire with information. Among the 466 trials with identified funding sources, we obtained lower response rates for those funded solely by industry (65% (108/167)) compared with those with partial industry funding (75% (46/61)), non-industry funding (80% (147/184)), or no funding (100% (54/54)).

Prevalence of incompletely reported outcomes

From publications and survey responses, we identified a median of 11 (10-90th centile range 3-36) efficacy outcomes per trial (n=505) and 4 (1-17) harm outcomes per trial (n=308). Of these trials, 75% (380/505) and 64% (196/308) respectively did not fully report all their efficacy and harm outcomes in any journal publications. The median proportion of incompletely reported efficacy outcomes per trial was 42% (table 2). For harm outcomes, the median proportion per trial was 50%. Of the 232 trials (45%) that defined primary outcomes in their publications, 83 (36%) presented at least one that was incompletely reported.
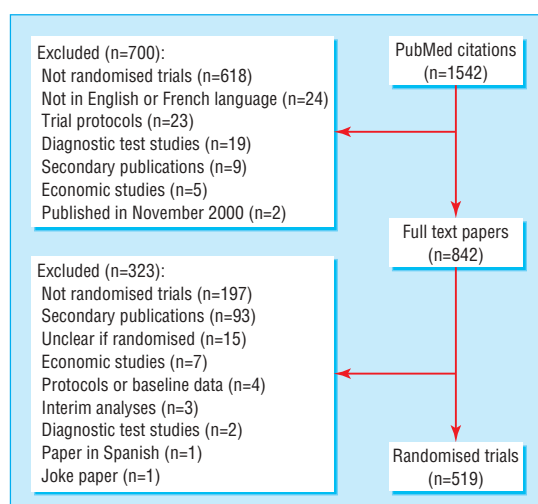
Fig 2 Identification of randomised trials from PubMed citations of studies published in December 2000

Table 1 Overview of characteristics of 519 randomised trials published in December 2000 and cited in PubMed

	No (%) of trials
Study design:	
Parallel group	383 (74)
Crossover	116 (22)
Other*	20 (4)
Intervention:	
Drug	393 (76)
Surgery or procedure	51 (10)
Counselling or lifestyle	55 (11)
Equipment	20 (4)
Study centres:	
Single	376 (72)
Multiple	134 (26)
Unclear	9 (2)
Funding:	
Full industry	167 (32)
Partial industry	61 (12)
Non-industry	184 (35)
None	54 (10)
Unknown	53 (10)
Journal type:	
General†	37 (7)
Specialty	482 (93)

*Split body (n=9), cluster (n=6), factorial (n=4), and "n of 1" (n=1) trials.
†Journals publishing studies from any specialty field.

When we stratified trials by study design, we found that parallel group trials contained much lower percentages of incompletely reported efficacy and harm outcomes than crossover trials (table 2). We found little difference between specialty and general medical journals, but greater deficiencies for reporting of harm outcomes among trials that were solely funded by industry (median 56% per trial) compared with those that were not (27%) (table 2).

Prevalence of unreported outcomes

Among 356 survey responders, 281 stated that there were no unreported outcomes. However, for 32% (90/281) of these responses, we found evidence of outcomes that were mentioned in the methods section but not the results section of individual publications.

From our survey responses alone, we identified 343 unreported outcomes in 71 trials. We identified another 545 unreported outcomes based solely on discrepancies between the methods and results sections of publications for 174 trials. Finally, we identified 27 unreported outcomes based on both survey responses and publications for eight trials.

Using combined data from survey responses and publications, we identified at least one unreported efficacy outcome in 33% (169/505) of trials that measured efficacy data, and 28% (85/308) of trials with unreported harms data. A median of 2 (10-90th centile range 1-7) efficacy and 2 (1-6) harm outcomes were unreported for each of these trials.

Characteristics of unreported outcomes based on survey responses

Fifty three survey responders provided data on the clinical importance of 238 unreported efficacy outcomes (table 3). Of these trials, 26% (14/53) had unreported outcomes that were categorised as having high clinical importance. According to survey responses, the important efficacy outcomes for three of these trials were to be reported in future publications. Sixteen survey responders indicated the clinical importance of 38 unreported harm outcomes, all of which were classified as having low or moderate clinical importance (table 3); 13 authors provided the statistical significance of their unreported harm outcomes, all of which were non-significant.

Fifty four survey responders indicated the specification of their unreported efficacy outcomes as primary, secondary, or neither (table 3). These responders included the authors who provided clinical importance ratings. Primary efficacy outcomes were unreported for 13 trials; according to authors, the primary outcomes for six of these trials were to be reported in future manuscript submissions. Eighteen responders indicated the specification of their unreported harm outcomes: three trials

Table 2 Median proportion of incompletely reported efficacy and harm outcomes per trial, stratified by trial characteristics, among 519 randomised trials published in December 2000 and cited in PubMed

	Efficacy outcomes		Harm outcomes	
		Median % of incompletely reported outcomes per trial*		Median % of incompletely reported outcomes per trial*
Trial characteristic	No of trials		No of trials	
All trials	505	42	308	50
Parallel group trials	375	22	237	25
Crossover trials	110	100	62	82
Other study designs	20	59	9	80
General medical journal	37	40	26	58
Specialty journal	468	43	282	47
Full industry funding†	163	46	133	56
Partial or non-industry funding†	290	42	142	27

*10-90th centile ranges were 0-100% for all median percentages except for efficacy outcomes in crossover trials (48-100%).
†Trials with unknown funding sources were excluded.

Table 3 Randomised trials with at least one unreported outcome for which survey responders provided data on clinical importance and specification

Parameter and survey rating	No (%) of trials among responders*	
	Efficacy outcomes	Harm outcomes
Clinical importance:		
High	14/53 (26)	0
Moderate	26/53 (49)	5/16 (31)
Low	29/53 (55)	13/16 (81)
Specification:		
Primary	13/54 (24)	3/18 (17)
Secondary	28/54 (52)	8/18 (44)
Unspecified	22/54 (41)	8/18 (44)

*Denominator corresponds to number of trials with survey data on clinical importance or specification of unreported outcomes.

(17%) had at least one unreported primary harm outcome listed in the survey responses.

Table 4 shows the reasons given by authors for not reporting outcomes. For efficacy outcomes, the most common reasons were journal space restrictions (47%), lack of clinical importance (37%), and lack of statistical significance (24%). For harm outcomes, the commonest reasons were lack of clinical importance (75%) or of statistical significance (50%)

Association between completeness of reporting and statistical significance

Fig 3 shows the odds ratios for outcome reporting bias in each trial. Statistically significant outcomes had a higher odds of being fully reported than those that were non-significant. The pooled odds ratio for outcome reporting bias in all trials was 2.0 (95% confidence interval 1.6 to 2.7) for efficacy outcomes and 1.9 (1.1 to 3.5) for harms (table 5). Across study designs, the size of bias was similar for efficacy outcomes. We found greater variation between study designs with harm outcomes, although the subset of crossover trials contained few studies.

Sensitivity analyses showed that the overall odds ratios were not greatly affected when we excluded non-responders to our survey or physiological or pharmacokinetic trials (table 5). Dichotomising the level of outcome reporting differently (fully or partially reported v qualitatively reported or unreported) produced greater bias (table 5).

In our exploratory multivariate analysis, sample size and reporting of a power calculation were excluded post hoc based on collinearity with other variables. The final exploratory model revealed that multicentre trials were associated with significantly less bias than were single centre trials (odds ratio 0.44 (95% confidence interval 0.24 to 0.80)), while those that defined primary outcomes in their publications were associated with greater bias than those which did not specify any (1.8 (1.0 to 3.2)).

Table 4 Reasons for omitting one or more outcomes per trial; based on 69 survey responses with unreported efficacy or harm outcomes in randomised trials published in December 2000 and cited in PubMed

Reason*	No (%) of trials	
	Efficacy outcomes (n=59)	Harm outcomes (n=16)
Space constraints:	28 (47)	4 (25)
Journal imposed	11 (19)	1 (6)
Author imposed	21 (36)	3 (19)
Not clinically important	22 (37)	12 (75)
Not statistically significant†	14 (24)	8 (50)
Not yet submitted	13 (22)	1 (6)
Not yet analysed	10 (17)	1 (6)

*Reasons are not mutually exclusive (>1 may have been given per trial).
†P≥0.05 in all inter-group comparisons.

Efficacy outcomes (n=161 trials)

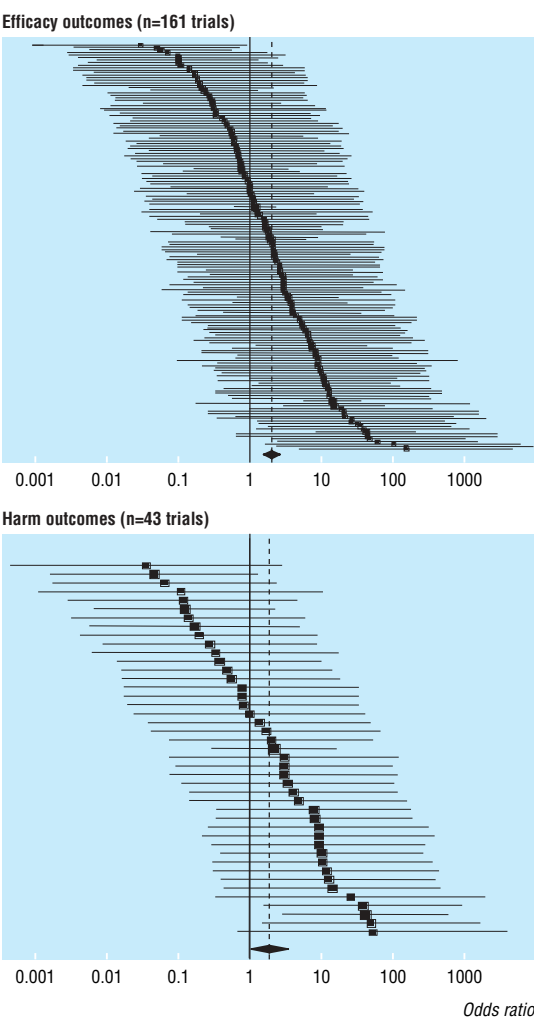**Harm outcomes (n=43 trials)**

Odds ratio

Fig 3 Odds ratios (black squares) with 95% confidence intervals for outcome reporting bias in randomised trials published in December 2000 and cited in PubMed. Size of the square reflects the weight of the trial in calculating the pooled odds ratio (diamond and dotted line)

Discussion

We identified deficiencies in outcome reporting in a large sample of randomised trials that was unrestricted by study location or funding source. Two recent cohort studies compared study protocols with publications to show similar sizes of outcome reporting bias in 102 trials approved by a Danish ethics committee[4] and 48 trials funded by a government research agency.[5] Other evidence of selective outcome reporting is limited to case reports.[9-11]

Contacting authors for information about outcomes

Our survey results indicate that a response rate of almost 70% is achievable when asking authors for unreported outcomes. Overall, a fifth of responders provided us with a list of unreported trial outcomes, many of which were primary outcomes that would not have been identified based on the publications alone. Thus there is potential benefit in reviewers contacting authors for information about study outcomes.

However, we were writing to researchers whose studies were published recently, which is often not the case for systematic reviews. In addition, many authors provided responses that contradicted evidence within their publications. Response rates were

Table 5 Pooled odds ratio for outcome reporting bias (fully reported *v* incompletely reported outcomes) in randomised trials published in December 2000 and cited in PubMed, stratified by study design and sensitivity analyses

Trial population	Efficacy outcomes		Harm outcomes	
	No of trials*	Odds ratio (95% CI)†	No of trials*	Odds ratio (95% CI)†
All trials	161	2.0 (1.6 to 2.7)	43	1.9 (1.1 to 3.5)
Parallel group trials	135	1.9 (1.4 to 2.6)	33	3.1 (1.6 to 5.8)
Crossover trials	22	2.7 (1.4 to 5.3)	9	0.32 (0.10 to 1.1)
Excluding survey non-responders	114	2.1 (1.6 to 2.9)	31	1.4 (0.66 to 3.0)
Excluding physiological or pharmacokinetic trials	148	1.9 (1.4 to 2.5)	38	2.4 (1.3 to 4.4)
Fully or partially reported outcomes *v* qualitatively or unreported outcomes	134	3.2 (2.4 to 4.2)	38	4.2 (2.5 to 7.0)

*Trials excluded if odds ratio could not be calculated because of empty rows or columns in 2×2 table (see methods for details).

†Except for the bottom row, odds ratio >1 signifies that fully reported outcomes have higher odds of being significant ($P<0.05$) than incompletely reported outcomes. In bottom row, odds ratio >1 means that fully or partially reported outcomes have higher odds of being significant ($P<0.05$) than qualitatively or unreported outcomes.

lower for industry funded trials, and it is unclear whether authors would have been willing to provide actual data.

How common are incompletely reported outcomes?

We have shown that trial outcomes are often reported inadequately for inclusion in meta-analysis. Even among primary outcomes, over a third of trials had at least one that was incompletely reported. Publications for crossover trials were particularly deficient, as they often did not provide the necessary paired outcome data.[12] The revised CONSORT statement and its extension for harms recommend full reporting of data for all primary and secondary outcomes.[13] [14]

Why are outcomes unreported?

Unreported outcomes were common, with over a third of trials omitting an average of two or more outcomes each. The decision to omit outcomes from publications seems to be made by investigators based on a combination of journal space restrictions, the importance of the outcome, and the statistical results. However, the omission of outcomes because of space constraints and a lack of clinical importance may well be directly associated with a lack of statistical significance. Outcomes could be deemed post hoc to have little clinical relevance if they fail to show significant findings and may thus be omitted when accommodating space limitations.

Is outcome reporting associated with statistical significance?

On average, the completeness of outcome reporting was biased to favour statistically significant outcomes. The sizes of bias for efficacy and harm outcomes (2.0 and 1.9 respectively) were robust or conservative in various sensitivity analyses, and are similar to those reported in other studies (efficacy odds ratios 2.4 and 2.7).[4] [5] However, we identified fewer unreported outcomes because we did not review trial protocols. Accordingly, we found 44% of trials to have one or more unreported outcomes, compared with 76% and 98% of trials in the earlier studies.[4] [5] We may therefore have underestimated the size of reporting deficiencies in our cohort.

Limitations of study

Response bias was expected in our study, as we relied on self reported data from questionnaires and publications. We observed that for 32% of authors who denied the existence of unreported outcomes there was evidence to the contrary in their publications. In addition, we found lower response rates for trials funded solely by industry. This finding is consistent with previous observations that industry funded researchers may be less willing or able to offer data from their studies.[15–18] Regardless of the funding source, a non-response or inaccurate response may arise from a reluctance to reveal biased practices, and we may

therefore have underestimated the deficiencies in outcome reporting.

Implications for health care and research

Inadequate reporting of outcomes can have a detrimental effect on the critical interpretation of individual trial publications and reviews by limiting the availability of all existing data. Outcome reporting bias acts in addition to and in the same direction as publication bias of entire studies to produce inflated estimates of treatment effect.[19] At its worst, the suppression of non-significant findings could lead to the use of harmful interventions. Perhaps more commonly, a treatment may be considered to be of more value than it merits, depriving patients of more effective or cheaper alternatives.

To limit outcome reporting bias, researchers and journal editors should ensure that complete data are provided for all pre-specified trial outcomes, independent of their results. Discrepancies between outcomes in the methods and results sections of publications should also be addressed during peer review. The increasing use of journal internet sites should help to alleviate concerns over space restrictions.[20]

Given the difficulties in identifying unreported outcomes and in contacting investigators for further information, trials should be registered and protocols should be made available in the public domain before trial completion. At the least, they should be submitted with manuscripts and reviewed when being considered for publication by journals.[21–24] The choice of outcomes and analysis plans would then be transparent, serving as a deterrent to selective reporting.

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What is already known on this topic

Selective reporting of some measured outcomes but not others within published trials has been shown in cohorts restricted by geography and funding source

Outcome reporting bias limits the critical interpretation of individual trials as well as the conclusions of literature reviews

What this study adds

Outcome reporting bias exists in published trials indexed on PubMed

Contacting authors for a list of unreported outcomes has the potential to identify important omissions from publications, although responses are often unreliable

Clinically important trial outcomes are often inadequately reported

Trials should be registered, and protocols should be made publicly available

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University Health Network, Department of Medicine, Suite RFE 3-805, 190 Elizabeth Street, Toronto, ON M5G 2C4, Canada
An-Wen Chan *resident physician*

Cancer Research UK/NHS Centre for Statistics in Medicine, Oxford
Douglas G Altman *director*

Correspondence to: A-W Chan anwen.chan@utoronto.ca