

Journal Watch

Journal Watch is based on the French-language blog Rédaction Médicale et Scientifique, available at <http://www.redactionmedicale.fr>.



Real world data have their reporting guidelines: The RECORD statement

In pricing and reimbursement dossiers, real world data (RWD) are commonly used to complete information from randomised trials. The RWD are routinely collected without specific or a priori research questions developed prior to utilisation for research. Data sources are registries, primary care databases, administrative data, etc. The REporting of studies Conducted using Observational Routinely collected health Data (RECORD) statement was created to assist authors to write papers. RECORD is an extension of the STROBE (STrengthening the Reporting of OBServational studies in Epidemiology) statement, and it has its own website (<http://www.record-statement.org>). It is a result of a collaborative process that involved more than 100 international stakeholders comprising researchers, journal editors and

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consumers of data. The RECORD checklist has 22 items that are described with illustrative examples by Benchimol *et al.* in an article in *PLoS Medicine*.

Reference: Benchimol EI, Smeeth L, Guttman A, Harron K, Moher D, Petersen I, *et al.* The REporting of studies Conducted using Observational Routinely collected health Data (RECORD) Statement. *PLoS Med* 12(10): e1001885.

Scoping reviews: There is a need for a guideline to standardise methods and reporting

A team of Canadian epidemiologists analysed 494 scoping reviews that were disseminated between 1999 and 2014. Scoping reviews are used to identify knowledge gaps, set research agendas and identify implications for decision-making, and their number has steadily increased since 2012. The conduct and reporting of scoping reviews is inconsistent in the literature. Scoping reviews can be seen as a hypothesis-generating exercise, while systematic reviews can be hypothesis-testing. A mean of 118 studies (range 1 to 2600) were included in the 494 scoping reviews. Assessment of scoping reviews was done with the Joanna Briggs Institute methodology guidance: 13% of scoping reviews reported the use of a protocol, 36% used two reviewers for data sharing, 43% used a pre-defined charting form. No guidelines for reporting scoping reviews or studies that assessed the quality of scoping review reporting were identified.

Reference: Tricco AC, Lillie E, Zarin W, O'Brien K, Colquhoun H, Kastner M, *et al.* A scoping review on the conduct and reporting of scoping reviews. *BMC Med Res Methodol*. 2016;16:15

Marketing purposes influence study design for 20% of randomised clinical trials publications in the highest impact general medical journals

Under the leadership of Virginia Barbour, six investigators independently reviewed 194 randomised clinical trials (RCTs) published in 2011 in six journals (*Annals Intern Med*, *BMJ*, *JAMA*, *Lancet*, *NEJM*, *PLoS Medicine*). The investigators defined six indicators of marketing-influenced trials and characterised the reviewed trials as YES/MAYBE/NO suspected marketing trials: 41 trials (21%) were categorised YES, 14 (7%) as MAYBE, and 139 (72%) as NO. All YES and MAYBE trials were funded by the manufacturer compared to 37% of NO

trials ($p < 0.001$). There was no significant difference between groups in the median number of participants screened ($p = 0.49$), but the median number of centres recruiting participants was higher for YES compared with NO trials (171 vs. 13, $p < 0.001$). YES trials were often better reported in terms of blinding, safety outcomes and adverse events than NO trials. YES trials more frequently included speculation that might encourage clinicians to use the intervention outside of the study population compared to NO trials (59% vs. 37%, $p = 0.03$). Two journals (*NEJM* and

Lancet) published 77% (150/194) of the trials. The consensus was that about a fifth of the drug trials published in the highest impact medical journals in 2011 had features that were suggestive of being designed for marketing purposes.

Reference: Barbour V, Burch D, Godlee F, Heneghan C, Lehman R, Perera R, *et al.* Characterisation of trials where marketing purposes have been influential in study design: a descriptive study. *Trials*. 2016;17:31.

Only 29% of completed clinical trials conducted by the faculty at major academic centres were published within two years of completion

Researchers from Yale School of Medicine analysed 4347 interventional trials across 51 US academic centres registered on ClinicalTrials.gov with a primary completion date between October 2007 and September 2010. Among the trials, 1005 (23%) enrolled more than 100 patients, 1216 (28%) were double blind, and 2169 (50%) were phase II to phase IV. Of the 4347 trials, 2458 (56.5%) had been published as of July 2014. The time (months) from primary completion date to publication varied significantly, with 1245 (28.6%) having been published within two years and 952 (21.9%) more than 24 months after the primary completion date. Only 13% (547/4347) reported results on ClinicalTrials.gov. Academic medical centres showed noticeable variation and poor performance in the dissemination of clinical trials results.

Reference: Chen R, Desai NR, Ross JS, Zhang W, Chau KH, Wayda B, *et al*. Publication and reporting of clinical trial results: cross sectional analysis across academic medical centres. *BMJ*. 2016;352:i637.



Randomised clinical trials published in high impact medical journals are less likely than observational studies to be the subject of a journal press release

Researchers from Auckland (NZ) tested whether the design of a clinical study determines the extent of its media coverage, because the latter influences public health beliefs. They compared two study designs: RCTs (n =85) and observational studies (n =86). Observational research is conducted more frequently than RCTs, and can generate hypotheses but not reliably test them. The investigators searched publications in seven high impact journals (*Annals Intern Med*, *BMJ*, *JAMA*, *JAMA intern Med*, *Lancet*, *NEJM*, *PLoS Medicine*) in 2013. They used www.eurakalert.org to collate editorials and press releases that accompanied the publications. They also used *Factiva*, the top 10 USA and UK newspapers, and the top 10 English language news agencies. They observed that

editorials in high impact journals were more commonly written for RCTs than observational research. Journal press releases, which influence the content of news stories, were more common for observational studies than RCTs (50% vs 17%, $P < 0.001$). The conclusion was that study design of clinical studies published in high impact medical journals is not associated with the likelihood or amount of ensuing news coverage.

Reference: Wang MTM, Bolland MJ, Gamble G, Grey A. Media coverage, journal press releases and editorials associated with randomized and observational studies in high-impact medical journals: a cohort study. *PLoS One* 2015;10(12):e0145294



Too many results are irreproducible: strategies to improve reproducibility must be implemented

The report of a meeting held in London with a panel of 80 experts was published at the end of 2015 by the Academy of Medical Sciences, the Biotechnology and Biological Sciences Research Council, the Medical Research Council and the Wellcome Trust. This meeting discussed poor research practices, as described by R Horton in the *Lancet*: "The case against science is straightforward: much of the scientific literature, perhaps half, may simply be untrue. Afflicted by studies with small sample sizes, tiny effects, invalid exploratory analyses, and flagrant conflicts of interest, together

with an obsession for pursuing fashionable trends of dubious importance, science has taken a turn towards darkness." This 80 pages report described six issues: data dredging, omitting null results, unpowered study, errors, underspecified methods, weak experimental design; and seven possible strategies to improve reproducibility: open data, pre-registration, collaboration, automation, open methods, post-publication review, and reporting guidelines. A poster is proposed to researchers with the seven strategies using logos representing the six issues.

Reference:

1. Horton R. Offline: What is medicine's 5 sigma? *Lancet*. 385(9976):1380
2. Reproducibility and reliability of biomedical research: improving research practice. Symposium report: 2015 [cited 2016 Mar 7]. Available from: <http://www.acmedsci.ac.uk/policy/policy-projects/reproducibility-and-reliability-of-biomedical-research/>