Editorial

To overcome failure to publish negative findings: The OPEN project

In order to make informed decisions, health care practitioners, public health professionals and policy makers rely on evidence from clinical research. It is therefore important that such evidence is made available in an easily accessible and unbiased way.

Unfortunately, however, a large proportion of research findings from clinical trials, as well as epidemiological studies, are never published in a journal or made available to the public or the research community [1]. And where studies are published, a bias resulting from only selectively reporting outcomes with positive findings from the trials is frequently encountered [2].

This non-availability of findings results mainly from a tendency of authors to submit – and a preference of journals to accept – articles that report findings that are new or are deemed important. The publication of unsuccessful trial results on the other hand is often perceived as not necessary at all, or at least not relevant or helpful to the advancement of scientific research [3]. However, such a perspective overlooks that non-publication or selective publication of results is highly problematic. It may not only lead to the duplication of unsuccessful studies thereby potentially harming future patients, but more importantly also skews the available evidence base for clinical decision-making. Non-publication or selective publication of results of clinical trials therefore comes at significant economic cost and an unnecessary use of limited resources.

Furthermore, failure to fully publish the results of clinical research, which involves patients who have consented to participate, because they are led to believe that such research is necessary for the advancement of medical science, disrespects their personal contribution. It also decreases public trust in clinical research and discourages people from volunteering in clinical trials [4]. Given the risks that research participants may be exposed to during a research trial, it may also be argued that those who are conducting the trial have a moral obligation to use and publish the data they recorded fully and in an unbiased fashion.

To increase the transparency of medical research, a first, important point to consider is the appropriate registration of clinical trials in registers that are openly accessible and available to other scientists, to avoid unnecessary duplication of research and produce an overview of current research efforts. Important steps to produce more comprehensive registers have been undertaken, but so far complete registration of all ongoing medical trials has not yet been achieved [4].

The European Union has recognised the need to further investigate the extent and impact of this problem and to develop a set of recommendations pertaining to the questions of incomplete or selective reporting of trial results and the registration of trials respectively, and has committed funds to two ongoing projects, OPEN and UNCOVER, which are supported by the 7th Framework Programme. These projects use different methodologies but aim to address similar problems, namely the non-publication of clinical research studies.

OPEN is a 24-month project, running from November 2011 to October 2013. It is an interdisciplinary initiative that brings together academics and key stakeholders from across Europe who aim to develop evidence-informed recommendations and strategies which focus on overcoming the failure to publish negative research findings.

On the one hand, OPEN has been conducting a series of systematic reviews to assess the occurrence of non-publication of research findings and the resulting publication bias. These reviews address aspects such as existing terminology to describe problems of publication and related biases, available methods to detect and measure publication bias and the extent – and impact of – the problem of non-publication of research findings. [5]

On the other hand, OPEN has sought to describe current practices by various key groups involved in knowledge generation and translation in order to provide insights on how to avoid or reduce bias due to non-publication of research findings and to identify ways to change this practice. This has been addressed by assessing and evaluating the policies and procedures in place for preventing these biases by the main parties involved in funding, conducting and publishing clinical research. Different work packages of OPEN have surveyed funding agencies, the (pharmaceutical) industry, research ethics committees, research institutions, researchers, trial registers, biomedical journals, regulatory agencies, and benefit assessment agencies.

Findings from all different work packages of OPEN have informed a two day recommendations workshop of OPEN project partners and researchers from the UNCOVER project as well as selected key stakeholders from across the world in May 2013, which aimed at developing and refining a set of targeted recommendations that are designed to specifically consider the roles that the respective stakeholder groups should play in reducing the incomplete registration and publication of research findings.

At the time of writing, OPEN’s final recommendations as well as the evaluation of the project’s concluding workshop are still outstanding. However, preliminary results already suggest a substantial need for more coherent efforts to address the problem of bias due to non-publication of research findings and underline the need to simultaneously engage with a large number of key


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players. We have also found substantial differences in practice between European countries, which not only points to a need for greater homogeneity, but should also be cause for optimism that there is scope for learning from existing policy experience in some member countries.

Contributors

Jasper Littmann contributed to first draft and final edit; Daniel Strech contributed to revision and extension of first draft; Gerd Antes contributed to second revision and extension; Joerg J Meerpohl contributed to substantial revision of first and second draft and extension and final edit.

Competing interest

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References


Jasper Littmann a,b

a Centre for Ethics and Law in the Life Science (CELLS), Institute for History, Ethics and Philosophy of Medicine, Hannover Medical School, Hannover, Carl-Neuberg-Str. 1, 30625 Hannover Germany

b University College London, Division of Medicine, United Kingdom

Gerd Antes

German Cochrane Centre, Institute of Medical Biometry and Medical Informatics, University Medical Center Freiburg, Berliner Allee 29, D-79110 Freiburg, Germany

Daniel Strech

Centre for Ethics and Law in the Life Science (CELLS), Institute for History, Ethics and Philosophy of Medicine, Hannover Medical School, Hannover, Carl-Neuberg-Str. 1, 30625 Hannover Germany

Joerg J. Meerpohl a

German Cochrane Centre, Institute of Medical Biometry and Medical Informatics, University Medical Center Freiburg, Berliner Allee 29, D-79110 Freiburg, Germany

a Corresponding author. Tel.: +49 0761 203 6691; fax: +49 0761 203 6712.

E-mail address: meerpohl@cochrane.de (J.J. Meerpohl)

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